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U.S. FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON PATIENT-FOCUSED DRUG DEVELOPMENT FOR
CHRONIC PAIN

FDA White Oak Campus,
10903 New Hampshire Ave.,
Building 31, Room 1503 B & C (Great Room)
Silver Spring, MD 20993

Monday, July 09, 2018

Reported by: Samuel Honig
Capital Reporting Company

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

2 WELCOME

3 MS. CHALASANI: Good morning. Thank you all
4 for being here today. I want to welcome all of you in
5 the room and those of you joining us via webcast to
6 FDA's Patient-Focused Drug Development Meeting for
7 Chronic Pain. I'm Meghana Chalasani from the Office of
8 Strategic Programs within FDA's Center for Drug
9 Evaluation and Research. I will serve as the
10 discussion facilitator today. Theresa Mullin will be
11 providing some opening remarks in a few minutes. But
12 first let me start by asking my colleagues sitting here
13 in the front to state their names and their role within
14 the agency.

15 MS. MULLIN: Good morning. I'm Theresa
16 Mullin. I'm the Associate Director for Strategic
17 Initiatives in the FDA's Center for Drug Evaluation and
18 Research.

19 DR. PAPADOPOULOS: Good morning. I'm Elektra
20 Papadopoulos. I'm the Associate Director for the
21 Clinical Outcome Assessment Staff in the Office of New
22 Drugs here in CDER.

1 DR. HERTZ: Sharon Hertz. I am the director
2 of the Division of Anesthesia, Analgesia and Addiction
3 Products in FDA's Center for Drug Evaluation and
4 Research.

5 MS. TARVER: Hi, I'm Michelle Tarver. I am at
6 the Center for Devices and Radiological Health. And
7 I'm the Director of Patient Science and Engagement.

8 MS. MAYNARD: Good morning. My name is Janet
9 Maynard. I am a Clinical Team Leader in the Division
10 of Anesthesia, Analgesia and Addiction Products.

11 DR. HAGHPANAH: Good morning. My name is
12 Sepideh Haghpanah, I'm a medical officer in the
13 Division of Anesthesia, Analgesia and Addiction
14 Products.

15 DR. WILLET: I'm Gerry Willet, I'm an OBGYN.
16 I'm in the Reproductive, Urology and Bone Division.

17 DR. TAYLOR: My name is Amy Taylor. I'm a
18 pediatrician and I'm a medical officer in the Division
19 of Pediatric and Maternal Health.

20 MS. CHALASANI: Thank you all. And to my
21 right, to your left, we also have Graham Thompson, Lila
22 Lacki (ph) and Shannon Woodward who will be acting as

1 webcast moderators and also our technical gurus, as you
2 can see we're having some difficulties having our
3 slides consistently stay live. So it will be going in
4 and out but we're going to try to make this as
5 efficient as possible and hopefully they will come
6 back. Okay.

7 We have a full agenda for you today. After
8 Theresa's opening remarks we will spend a bit of time
9 providing background on chronic pain. Then we'll move
10 into our discussion with individuals living with
11 chronic pain along with families and advocates. Our
12 two main topics today are symptoms and daily impacts of
13 chronic pain that matter most to patients, followed by
14 perspectives on current approaches to managing your
15 chronic pain.

16 I'll explain the meeting format and the
17 process at the start of those discussions. We have
18 time set aside for open public comment later this
19 afternoon. While the primary discussion is focused
20 with individuals and families, the open public comment
21 will give anyone in the audience the opportunity to
22 provide a comment. To participate in the open public

1 comment session, you will need to sign up at the
2 registration table. Participation is first come first
3 serve. The time allowed for each speaker will be 2
4 minutes.

5 A few logistic and housekeeping points. There
6 is a kiosk where you can get food and beverages, right
7 in that direction. Restrooms are located behind the
8 kiosk. And at any point if you need to get up for any
9 reason, please feel free to do so. We have a dedicated
10 room available if you need to -- if you need space to
11 lie down or relax or stretch. For this break room,
12 please make a left once you exit this room and walk
13 down the hallway. There will be a live stream of the
14 meeting in the break room.

15 We will take an hour lunch break around noon
16 and another 15-minute break around 2:30 p.m. Once
17 again I would like to emphasize that at any point if
18 you need to get up for any reason beyond the lunch hour
19 or the break, please feel free to do so.

20 AUDIENCE MEMBER: (Inaudible).

21 MS. CHALASANI: Sure.

22 AUDIENCE MEMBER: I do realize that

1 (inaudible) pain patients connected, ability for them
2 to speak is hours down the road.

3 MS. CHALASANI: We will actually -- sir, I
4 will be going through the discussion format but we
5 actually will have multiple opportunities to engage
6 with individuals with chronic pain starting around
7 10:35 a.m.

8 AUDIENCE MEMBER: Okay. Thank you.

9 MS. CHALASANI: Thank you for your question.
10 I will ask that at this time you please
11 silence your cell phones. Thank you. This meeting is
12 being transcribed and a live webcast is being recorded,
13 both of which will be archived on our website. As you
14 may have noticed, there are a few media outlets also
15 recording audio and visual. We appreciate that there
16 is a lot of interest in our meeting today. We too
17 believe that this is an important meeting.

18 Please note that if you're asked to
19 participate in an on-camera or off-camera interview,
20 you may accept or decline that invitation at your own
21 discretion. With that I'd like to welcome Theresa for
22 opening remarks.

1 OPENING REMARKS

2 MS. MULLIN: Thanks, Meghana. Good morning
3 and welcome to the great room here at FDA's White Oak
4 Campus. I want to thank you for joining us today for
5 this very important meeting to hear from patients
6 living with chronic pain. For those of you who are
7 living with chronic pain and you're here today in the
8 audience, we're really honored to have you here. We're
9 aware that it takes quite an effort to come here to the
10 White Oak Campus and we're also happy to see so many
11 family members a patient advocates in the audience as
12 well. I understand that we have hundreds more joining
13 us on the webcast today.

14 And we hope that you on the webcast will also
15 be able to share your experiences as fully as you can.
16 This is a what we call a patient-focused drug
17 development meeting and, you know, FDA has a lot of
18 public meetings and we do a lot of consultation of
19 different kinds but I want to tell you that patient-
20 focused drug development meetings, PFDD in short, are
21 special in that these are meetings where we usually
22 have the, you know, "Experts," you know, with MD or

1 Ph.D. or some set of more initials after their name
2 spending all the time talking. This is a meeting where
3 we really only we mainly want to hear from patients and
4 their -- and if they have caretakers who or caregivers
5 who are, have insights about what their loved one is
6 going through then we want to maybe hear from them as
7 well. But we're here to hear about what it's like to
8 live with the disease. We recognize that patients are
9 in a really unique position to tell us about that
10 because they're the ones who are living with that
11 condition and they're the people who are going to be
12 taking the medication and getting any benefit there is
13 to get out of it and suffering from whatever harms
14 there might be exposed to that are often go with
15 medications. There are usually benefits and risks.

16 And we've had about 25 of these meetings so
17 far in different serious disease areas and every time
18 it's been we just hear from patients. And I got to
19 tell you every time we and the people who are
20 experienced reviewers at FDA and her doctors learn
21 something new. We learn stuff we didn't know about
22 that disease even though we have -- some of our staff

1 have treated patients with those diseases, we learn
2 things we didn't know. We get insights about what it
3 is really like to live with the disease and what would
4 really be helpful in a treatment if a new treatment was
5 developed. And these meetings really help inform our
6 drug development and they help inform companies about
7 what they should be trying to develop in new medicines
8 to treat conditions where there really isn't a good
9 alternative today. And frankly that's true for lot of
10 diseases.

11 And similarly, in addition to FDA getting
12 information it helps us in our benefit risk assessments
13 of new drugs. This information, what patients have to
14 tell us are uniquely informing drug companies and
15 device companies in their development of new products
16 because they get to hear what patients really want to
17 see in those treatments and what they want to avoid.

18 Although FDA does not develop new medical
19 products we do oversee and advise drug product sponsors
20 or -- and medical product sponsors in their development
21 programs. We issue written guidance to them about what
22 they ought to be doing in development programs and

1 problems and mistakes to avoid. And we give them
2 feedback and advice when they come in and request
3 meetings on a specific development program.

4 And before a new medical product can be
5 marketed the sponsor has to submit a marketing
6 application that provides all the study data and
7 information to FDA so we can assess whether or not the
8 benefits of that product outweigh its risks. We look
9 forward to incorporating what we learn today in gaining
10 more understanding into what matters to patients when
11 they consider -- we consider the benefit risk -- and
12 risks of a new treatment for chronic pain.

13 Today's meeting focused on chronic pain is an
14 opportunity for us to hear directly from you, to learn
15 about how chronic pain is affecting your life and the
16 aspects of pain that are most bothersome to you and
17 interfere with your ability to live your daily life.
18 We also want to hear how you're managing your pain
19 today and we want to hear what are the benefits you're
20 experiencing and what are the downsides of whatever
21 treatments and modalities you're using and what
22 challenges you may be facing in getting access to

1 medical treatments today.

2 I'd like to note that we also have
3 representation from health professionals, researchers,
4 government partners, industry stakeholders and others
5 here in the room and on the webcast today and I want to
6 thank you all for joining the meeting as well. While
7 FDA plays a critical role in protecting and promoting
8 public health, we just are one part of that system.
9 You all that I -- I've just mentioned the providers and
10 other government researchers and partners in industry
11 represent the other doers and decision makers in this
12 health care ecosystem and we hope that you're also
13 going to gain benefits and insights from what you hear
14 today.

15 I will tell you that as we -- after we posted
16 the announcement of this meeting a number of drug
17 company representatives and staff that I've met over
18 the last couple of months have told me that they're
19 booking rooms in their company to have a whole roomful
20 of people be able to come and hear what you have to say
21 today because they think it's that important to inform
22 their drug development programs going forward. So

1 there are a lot of people who want to hear what you
2 have to say.

3 We also recognize that the impacts of chronic
4 pain and its management have to be considered in the
5 context of the opioid epidemic that's facing America
6 today. While we work to ensure appropriate and
7 rational prescribing of opioids to address that
8 epidemic, FDA is committed to not lose sight of the
9 needs of people living with serious chronic pain.

10 As new policy steps are considered to address
11 the opioid crisis be assured that FDA remains focused
12 on striking the right balance between reducing the rate
13 of new addiction and decreasing exposure to opioids
14 while still enabling appropriate access to patients who
15 need, have a medical need. And this meeting is part of
16 what we're doing to address that today. And again I
17 want to thank you for joining us in this meeting today
18 and now let -- we'll get on with the meeting and I'd
19 like to begin by asking Dr. Haghpanah to come up and do
20 her presentation on the background on chronic pain and
21 treatment options. Thank you.

22 BACKGROUND ON CHRONIC PAIN AND TREATMENT OPTIONS

1 DR. HAGHPANAH: All right. Good morning
2 everyone. My name is Sepideh Haghpanah, I'm a medical
3 officer in the Division of Anesthesia, Analgesia and
4 Addiction Products and I'm going to provide an overview
5 of chronic pain. The outline of this presentation
6 includes definition and epidemiology of chronic pain,
7 types of chronic pain, impacts of chronic pain,
8 evaluation and assessment, treatment options, patient-
9 focused drug development and conclusion.

10 International Association of the Study of Pain
11 defines pain as an unpleasant sensory and emotional
12 experience associated with actual or potential tissue
13 damage or described in terms of such damage. Pain
14 might be acute or chronic. The exact definition of
15 acute versus chronic pain might be different based on
16 the source or the reference that is used. For drug
17 development at FDA acute pain is defined as a type of
18 pain that is self-limited and lasts less than a few
19 weeks such as post-operative pain or pain that is
20 associated with musculoskeletal injury.

21 Chronic pain is defined as a type of pain that
22 persists longer than 1 month beyond the resolution of

1 the underlying consult or pain that persists beyond 3
2 months such as chronic low back pain. Based on a report
3 from Institute of Medicine in 2011 chronic pain affects
4 more than 100 million adults in the United States.
5 Pain contributes greatly to national rates of morbidity
6 mortality and disability. Pain is one of the most
7 frequent reasons for physician visits. Annual economic
8 cost associated with chronic pain is estimated to be
9 \$560 billion to \$635 billion.

10 Pain can be divided based on the origin of the
11 pain, whether it is nociceptive, neuropathic or mixed,
12 nociceptive and neuropathic. Nociceptive pain is due
13 to direct tissue damage and stimulation of nociceptive
14 pain receptors. It can be subdivided into a visceral
15 or nonvisceral pain. Some examples of visceral pain
16 include pancreatitis, pain due to kidney stone or
17 postoperative abdominal pain.

18 Examples of nonvisceral pain include
19 musculoskeletal pain or pain after orthopedic surgery.
20 Neuropathic pain is due to primary damage or
21 dysfunction in the central or peripheral nervous
22 system. Examples of peripheral neuropathic pain

1 include diabetic peripheral neuropathy or post-herpetic
2 neuralgia. Examples of central neuropathic pain
3 include pain after spinal cord injury or pain after
4 stroke. In some cases chronic pain might be due to a
5 combination of both neuropathy and nociceptive pain.
6 Pain is complex. It may or may not be related to a
7 specific disease or injury. Our focus for this meeting
8 today is on chronic pain in general of any type, any
9 etiology, any characteristic or any severity.

10 What are some pain-related characteristics.
11 Pain quality might be described as aching, throbbing,
12 tingling, pinprick, burning or stabbing, where is the
13 location of the pain, is it localized or diffused, is
14 it radiating to any other body parts, what are some
15 temporal aspects of pain, does the pain have a gradual
16 onset or does it happen suddenly, is the pain constant
17 or intermittent, how severe is the pain, is it mild,
18 moderate or severe, what are the trigger factors for
19 the pain, what makes the pain better or worse.

20 All of these pain-related characteristics and
21 the terms mild, moderate or severe are often used both
22 by patients and healthcare providers to describe the

1 pain in different clinical settings. There are also
2 other scales that are used for grading of the pain such
3 as a zero to ten scale. However pain is a subjective
4 experience, it is described differently by each patient
5 and in each clinical condition. Chronic pain can have
6 physical, social, emotional and functional impacts.
7 Chronic pain can cause weakness, sensory changes, gait
8 problem, difficulty with mobility, pain can result in
9 sleep problem, pain can cause emotional stress,
10 anxiety, depression or isolation.

11 As a result of these chronic pain patients may
12 have difficulty maintaining employment or difficulty
13 attending school or other daily activities. Pain can
14 cause withdrawal from family, it can limit social
15 relationships such as interactions with friends or
16 family members. Pain can limit activities of daily
17 living such as bathing, dressing self-care, et cetera.
18 Pain affects many different aspects of patients' lives
19 and we appreciate you providing input on the impact of
20 chronic pain on your daily life.

21 How do we evaluate and assess chronic pain.
22 As we mentioned, pain is a uniquely individual and

1 subjective experience. The tests and imaging studies
2 that we perform provide information about underlying
3 etiologies and comorbid diseases. But these tests do
4 not provide direct assessment of the pain. Different
5 types of tests that might be done are neurologic exam,
6 physical exam, different types of imaging studies,
7 nerve conduction studies, but ultimately patient's
8 input is the key factor in the evaluation and
9 understanding of pain.

10 There are multiple pharmacologic and
11 nonpharmacologic options available for treatment of
12 pain. Pharmacologic treatments include over-the-
13 counter medication such as ibuprofen or acetaminophen.
14 Prescription drugs such as muscle relaxants, opioids,
15 antidepressants, anticonvulsants or topical agents.
16 One of our discussion topics today is about
17 pharmacologic treatment of chronic pain to get your
18 feedback about different options. There are also
19 multiple nonpharmacologic treatment options for chronic
20 pain such as physical therapy, occupational therapy,
21 exercise programs, manipulation et cetera.

22 Cognitive behavioral therapy, stress

1 management, complementary and alternative medicine such
2 as acupuncture, herbal medicine or biofeedback.

3 Vocational rehabilitation and disability management are
4 other important components in treatment of chronic
5 pain. There are also different medical procedures
6 available for chronic pain such as nerve blocks, pain
7 pumps, spinal cord stimulator, peripheral nerve
8 stimulator or different types of surgery.

9 There are multiple options and considerations
10 to determine the optimal treatment for chronic pain in
11 each individual case. Treatment may focus on certain
12 options or utilize a multidisciplinary treatment
13 approach that provides an integrated management plan.
14 Multidisciplinary pain programs provide a collaborative
15 approach that include different treatment options both
16 pharmacologic and nonpharmacologic.

17 The focus of these programs is on individual
18 assessment of each case to provide a comprehensive
19 treatment to control the pain and improve quality of
20 life. In order to achieve optimal result healthcare
21 providers and patients should work together to develop
22 a treatment plan and set goals for each individual

1 patient.

2 What are treatment goals? In most cases of
3 chronic pain we cannot eliminate the pain completely.
4 The goal of chronic pain treatment has evolved from
5 trying to eliminate the pain to decreasing and
6 controlling the pain to improve physical function, to
7 improve social and emotional wellbeing and in general
8 to improve quality of life.

9 What are some potential barriers in treatment
10 of chronic pain? Are the appropriate treatment options
11 available and accessible for the patients? For
12 example, multidisciplinary pain programs may not be
13 available in rural areas or there may be difficulty
14 with availability of some medication. Cost or
15 insurance coverage could be another important limiting
16 factor both for pharmacologic options and
17 nonpharmacological options. Time or duration of
18 therapy may be another barrier in some cases. For
19 example, it may not be feasible for patients to take
20 time off from work or school or from their daily
21 activities to attend multiple therapy sessions.

22 Side effects of the medication are another

1 important barrier in the treatment. Chronic pain
2 patients need to continue medication for a long period
3 of time. It is very important to know if the
4 medication remains effective and well tolerated for
5 long-term use. There are gaps in treatment of chronic
6 pain and we acknowledge that there are state and
7 federal actions that may have impacted some patients.

8 Chronic pain remains an unmet medical need
9 with physical, emotional and social impacts on
10 patient's life. There are numerous important public
11 health issues related to chronic pain but today we will
12 focus on drug development. The purpose of this meeting
13 as patient-focused drug development is to listen to you
14 and obtain information from you as the main source who
15 is suffering from chronic pain.

16 Patients, caregivers and family members,
17 patient advocates are experts in providing the
18 information about the impact of pain on their lives and
19 about available treatments. We want to hear your
20 stories about chronic pain, impact of pain on your
21 function, your treatment goals, treatment barriers that
22 you experience in your daily life with chronic pain.

1 Collecting information from patients'
2 perspectives provides an opportunity for us at the FDA
3 to enhance regulatory decision-making. FDA works with
4 pharmaceutical companies to help them design the
5 clinical trials that will assess the risk and benefits
6 of drugs. These companies perform the studies and
7 submit the information to FDA to support the approval
8 of a new drug, then FDA reviews these application to
9 ensure that the benefits of a drug outweigh its risks,
10 therefore having this kind of meeting is extremely
11 valuable for FDA to understand patients' perspective on
12 chronic pain and the factors that patients consider
13 when selecting a treatment.

14 In conclusion, FDA is aware of the unmet
15 medical needs experienced by patients who have chronic
16 pain, patient-focused drug development is a unique
17 opportunity for the FDA to hear from patients
18 caregivers and family members about the impacts of
19 chronic pain on their lives. We are excited for this
20 opportunity to engage directly with all of you to
21 improve the drug development process for chronic pain.

22 Thank you for being part of this meeting today

1 both in person and remotely on the web to share your
2 experience and perspectives with us. And thank you for
3 your attention during this presentation.

4 OVERVIEW OF DISCUSSION FORMAT

5 MS. CHALASANI: Thank you, Sepideh. I also
6 want to thank all of you for your patience as we're
7 trying to solve the issue that we're having with the
8 slides. We've had 25 meetings to-date as Theresa
9 mentioned but this is still a new technical issue,
10 we've never not had slides. So thank you for your
11 patience.

12 So now we will be starting the patient-focused
13 discussion portion of this meeting. Our goal today is
14 to foster open dialogue on personal experiences and
15 perspectives on chronic pain. Our two main topics for
16 the discussion are symptoms, health effects and daily
17 impacts of chronic pain that matter most to patients and
18 current management approaches for your chronic pain.

19 We will kick off each discussion with a panel
20 of individuals living with chronic pain. We selected
21 panel discussions from the pool of participants who
22 indicated their interest at the time of their meeting

1 registration and submitted summaries that address the
2 discussion questions posted in the Federal Register
3 notice. We identified individuals to reflect a range
4 of experiences with symptoms and treatment approaches.
5 We have four panelists for the first topic and I'll ask
6 our topic one panelist to please come up front at this
7 time. Thank you. After the panel speaks we will
8 broaden the dialogue to include other individuals with
9 chronic pain and family members here in the audience
10 and on the web. The purpose is to build on the
11 experiences shared by the panel. I'll ask a number of
12 follow-up questions inviting participants to raise your
13 hands to speak.

14 My FDA colleagues sitting to my left may also
15 have follow-up questions. We will have staff floating
16 around with microphones, Sarah Edgers (ph) and Puchita
17 Vaidya (ph), and they will come to you with the
18 microphone. So please just raise your hand. When
19 speaking you may remain anonymous or state your first
20 name for the record.

21 For transparency we request that at the time
22 of your comment that you disclose if you are affiliated

1 with an organization that has an interest in issues
2 related to chronic pain or if your travel here today
3 has been funded or if you have significant financial
4 interests in chronic pain medical product development.

5 Please keep your responses focused on the
6 specific question or topic at hand and limit to a
7 minute or so. We have a packed agenda and a full room
8 today, we have a large, large crowd and we're really
9 looking forward to the rich insight and input that
10 you'll be providing us today. So please raise your
11 hand if you have, if you -- to speak, if you have
12 something to add to what has already been said. If you
13 agree with a particular perspective or have had a
14 similar experience please feel free to nod your heads
15 or clap.

16 We will have some polling questions today as
17 well. We ask that only individuals with chronic pain,
18 family members or advocates respond. If you are in the
19 room you will respond using clickers. Most of you
20 should have received a clicker by now but if you have
21 not received a clicker please raise your hand and
22 Shannon will come around and provide you with a

1 clicker. Thanks Shannon. For some questions, for the
2 polling questions you'll have one answer, for others
3 you may have multiple answers. You should feel a
4 little buzz when you click, which means that our system
5 captured your answer. And we'll have a few practice
6 questions in a bit to make sure we're not having any
7 technical difficulties. If your clicker doesn't work
8 please just let us know by raising your hand again and
9 we'll bring you another one. Web participants will
10 also be able to answer the question through the webcast
11 and I'll turn to our webcast moderators from time to
12 time to summarize the results that we're seeing on the
13 web. These polling questions are meant to be a
14 discussion aid for today, they are not a scientific
15 survey. For those of you joining us via webcast, in
16 addition to responding to the polling questions you can
17 also add comments through the web platform, there's a
18 discussion pod. Although we may not be able to read
19 all of the comments out loud today your comments will
20 be incorporated into our summary report.

21 We also have a public docket that will be open
22 until September 10th. I took a look at the docket this

1 morning and we already have 973 comments received from
2 your community and this docket will be open for 2 more
3 months after the meeting and so we're really hoping
4 that you'll add to the dialogue through this docket as
5 well. We encourage you to share your experiences and
6 expand on what we discuss today through this docket.
7 And the docket comments will all be -- we will read all
8 of them and we will include a summary of them in our
9 report as well.

10 Anyone is welcome to comment to the docket and
11 the link is on the slide deck which we will post online
12 and we'll also circulate it via e-mail to you all as
13 well after the meeting. A few ground rules for the
14 discussion today. We are here first and foremost to
15 listen to those with chronic pain and their family
16 members and we will try to accommodate everyone who
17 wants to speak. If we don't get your full thoughts on
18 a topic we encourage you to elaborate in the public
19 docket.

20 We are happy to see participants here today
21 who represent health care provider research and medical
22 product development communities. We believe the input

1 we hear today will be important to you as well, we just
2 ask that you stay in listening mode. Some of you may
3 have requested to participate in the open public
4 comment and we look forward to your input then. During
5 the main focus dialogue we really are here to engage
6 and hear from individuals with chronic pain and their
7 family members.

8 FDA staff is also really here to listen. We
9 know that you may have questions about medical product
10 development, review and policy. If you have specific
11 questions we encourage you to write them down on your
12 evaluation forms which you can find on the tables
13 outside and we will try to get back to you with more
14 information following the meeting.

15 As has been described our discussion today is
16 focused on chronic pain, health effects, daily impacts
17 and management approaches. We understand that there
18 are several important issues to ensuring that
19 individuals with chronic pain get the health care
20 treatment and support that they need. Today we want to
21 focus on the topics that FDA needs most input on so
22 that we can best fulfill our role in the medical

1 product development process and decision-making.

2 Our discussion today may touch upon specific
3 treatments. However the discussion of any specific
4 treatment should be done in a way that helps us
5 understand the broader issues such as what aspects of
6 your chronic pain are being addressed and how
7 meaningful is that to you and your families.

8 The views here expressed here today are
9 personal opinions, they are not just opinions, they are
10 personal stories and everyone has their own story and
11 their own experience and we must respect that today.
12 Respect for one another is paramount. We will have
13 differing views on things today and differing
14 experiences and we will listen to it respectfully. We
15 very much appreciate what complex and personal stories
16 that we are addressing in this public setting and we
17 expect everyone here and on the web to share that same
18 appreciation.

19 Yeah, I think Graham is trying to advance my
20 slides. Thanks Graham. We do want your feedback on
21 the meeting. As I mentioned, we have evaluation forms
22 outside on the tables. What we learn will help us to

1 continue to design and implement patient-focused
2 meetings that are useful to FDA and to individuals and
3 their families. So please fill those out and we'll
4 collect them at the end of the meeting. With that
5 let's begin with a polling question. I'm always very
6 nervous with the first one because technology, you
7 know. Okay, so folks in the room please use your
8 clickers. Where do you live? So if you live within
9 the Washington, D.C. metropolitan area including the
10 Virginia and Maryland suburbs press A. If you live
11 outside of the Washington D.C. metropolitan area please
12 press B. And you'll hear a small buzz, a short buzz if
13 our system captured your response. If your -- if you
14 don't get any buzzing please raise your hands and we'll
15 bring another clicker to you.

16 Yours may -- have another battery, Shannon,
17 Shannon. Can I get a clicker, please? Thank you. I
18 see responses coming. Yes, and folks on the webcast
19 you should have access to these questions as well
20 through your webcast platform and so hopefully we'll
21 see your responses summarized through our webcast
22 moderators in a few moments. Okay. It was working so

1 well. Graham, do you have access to --

2 MR. THOMPSON: Yeah, I do. So we had about 80
3 percent outside the Washington D.C. area, so greatly
4 appreciate you traveling to the meeting. And on the
5 web, as you'd expect, about 90 percent outside the D.C.
6 area.

7 MS. CHALASANI: Okay, thank you, Graham. We
8 have another polling question. We can't see it, so I'm
9 going to read it out loud and just ask me if you need
10 me to repeat any of what the options and so forth are.
11 So the next question is which statement best describes
12 you.

13 MR. THOMPSON: It's back up, Meghana.

14 MS. CHALASANI: Great. Thanks, Graham. A, an
15 individual who experiences chronic pain; B, a family
16 member or caregiver of an individual who experiences
17 chronic pain; C, an advocate for individuals who
18 experience chronic pain.

19 AUDIENCE MEMBER: (inaudible) more than one of
20 those.

21 MS. CHALASANI: Yes, you may be, correct. I
22 think we may have set this to pick one, but there are

1 some others later on where you'll be able to select
2 multiple answers. But thank you so much for
3 highlighting that point. Thank you.

4 Okay, can we get some results, Graham? Okay,
5 now you know what it will look like if we're able to
6 see the slides. Fifty nine percent, sixty percent of
7 you in the room today are an individual who experiences
8 chronic pain, those of you that are responding to the
9 polling questions, sixteen percent a family member or
10 caregiver an individual who experiences chronic pain
11 and twenty five percent an advocate for individuals who
12 experience chronic pain. And as the lady pointed out,
13 we may have some overlap there, so great. Thank you.

14 The next question that we have is what is your
15 or your loved one's age. So those of you that are a
16 family member or a caregiver or an advocate please
17 respond on behalf of an individual with chronic pain
18 for the questions moving forward. So what is your or
19 your loved one's age: A, younger than 18; B, 18 to 29;
20 C, 30 to 39; D, 40 to 49; E, 50 to 59; F, 60 to 69; G,
21 70 or greater? Okay, we have a range of participants
22 in the room here today with 38 percent in the age range

1 of 40 to 49 years old. Great.

2 Could we have our next polling question,
3 Graham. Thank you. Do you or your loved one identify
4 as: A, female; B, male; C other. Anyone having any
5 issues respond with their clickers or I think we have
6 everyone's working, great. Oh, (inaudible).

7 MR. THOMPSON: So we have about 74 percent
8 female and 26 percent male. And on the web very
9 similar, 78 and 22.

10 MS. CHALASANI: Great. And I'll ask the
11 webcast moderator to summarize all of the demographic
12 polling questions in a few minutes for us as well.
13 Thank you.

14 The next question that we have, how long have
15 you or your loved one experienced chronic pain? A,
16 less than 1 year; B, 1 year to 2 years; C, 2 years to 5
17 years; D, 5 years to 10 years; E, more than 10 years;
18 F, I'm not sure. Okay, wow, significant majority of
19 you all have experienced chronic pain for more than 10
20 years in the room today. Thank you.

21 I think we have one more polling question
22 left. It's doing something new now, okay. What type

1 of chronic pain do you or your loved one experience?
2 Here you can check all that apply. A, cancer pain; B,
3 postsurgical or posttraumatic pain; C, neuropathic or
4 nerve pain; D, headache; E, orafacial pain such as
5 mouth, jaws and face; V -- sorry V -- F, visceral organ
6 pain; G, musculoskeletal pain such as arthritis; H, I
7 don't know; I, other.

8 AUDIENCE MEMBER: (Inaudible) all --

9 MS. CHALASANI: All, you can check all that
10 apply. You check all that apply. Graham?

11 MR. THOMPSON: All right. So we had the most
12 common response 71 percent with musculoskeletal pain
13 followed by 63 percent with neuropathic pain and then
14 we had postsurgical, headaches, orofacial and visceral
15 organ pain all at around 25 to 30 percent and then 20
16 percent said other.

17 MS. CHALASANI: Okay, we'll probe into what
18 the other may be later on during the facilitated
19 discussion, that will be interesting for us to hear.
20 We have a range of participants in the room. I do want
21 to turn to our webcast moderators now to perhaps
22 summarize what -- who we have on the web participating.

1 MR. THOMPSON: So for types of chronic pain we
2 have about 80 percent neuropathic and musculoskeletal.
3 About 40 to 45 percent post-surgical and headache. And
4 then about 20 percent for all of the rest. And
5 similarly to those in the room, almost 70 percent of
6 people on the webcast have had chronic pain for more
7 than 10 years.

8 TOPIC 1 PANEL:

9 SYMPTOMS AND DAILY IMPACTS OF CHRONIC PAIN

10 MS. CHALASANI: Okay. Thank you, Graham.
11 With that I'd like to start with our first panel now.
12 If we could have the slide, Graham. Thank you. So as
13 I mentioned previously topic one will really focus on
14 hearing your perspectives on the symptoms and daily
15 impacts of chronic pain that matter most to you. We'll
16 kick start with our panelists. We have three joining
17 us in person. Our fourth panelist, Debbie, was stuck
18 in Beltway traffic for 2-1/2 hours this morning and as
19 individuals with chronic pain you probably understand
20 much better than even I can how difficult that really
21 is, and she was unable to sit any longer and continue
22 the commute in. So I will be reading her remarks on

1 her behalf. But she really does wish that she could
2 have joined us in person here today. With that Amy.

3 MS. PARTRIDGE: Shall I press the red --

4 MS. CHALASANI: Yes, please just press the red
5 button. And then once you're done speaking if you can
6 turn it off, that will help reduce the extra background
7 noise and so forth.

8 MS. PARTRIDGE: (Inaudible).

9 MS. CHALASANI: Yeah, that looks good.

10 MS. PARTRIDGE: Hello everyone, good morning.
11 My name is Amy Partridge. I am an intractable pain
12 patient, I am not an addict. I thought I knew pain.

13 (Applause)

14 MS. PARTRIDGE: I thought I knew pain. I
15 dealt with chronic back pain for decades. Three years
16 ago I learned how bad pain can really be. I also
17 learned how to fight. Starting in 2013 I had a series
18 of spinal surgeries and epidural steroid injections.
19 During the sixth and what would be my final injection
20 in 2015 I knew something was wrong, very wrong. Over
21 the next 6 months as my pain spiraled out of control I
22 saw countless specialists and I fought for a diagnosis.

1 Wow, did I get one, adhesive arachnoiditis.

2 AUDIENCE MEMBER: Right here.

3 MS. PARTRIDGE: As I listened, the doctor
4 explained how scar tissue had grown on the inside of my
5 spinal cord, that scar tissue was and still is
6 strangling the nerves in my spinal cord and has adhered
7 them to the walls of my spinal cord, cementing them
8 there. Adhesive Arachnoiditis is inoperable, permanent
9 and progressive. It has been described as the pain of
10 end-stage bone cancer without the escape of death.
11 Sorry. It is one of the only -- one of only a few
12 conditions referred to as a suicide disease. I went
13 from being a mom, a wife and an executive at the peak
14 of my career to spending nearly every moment in the day
15 bed in my family room. Thank you.

16 I fought my body to allow me to do even a
17 fraction of what I was once able to do. The pain was
18 excruciating and constant and one wrong move and it
19 felt like there was a hatchet in my spine. Pain vary
20 from jellyfish stings to a red hot poker being shoved
21 into my hip. I missed some big events that year,
22 weddings, funerals and countless functions. More

1 difficult were the everyday things that I missed, being
2 able to stand long enough to braid my daughter's hair,
3 sitting long enough to eat Thanksgiving dinner with my
4 family at the dinner table, the simple things that we
5 take for granted. My husband took over, phenomenal
6 man, every household chore, and my mom helped with
7 errands and driving me to appointments. My children
8 had to adapt to having a mom who is mostly bed-bound.
9 Our lives were turned upside down but I fought, I
10 fought my mind to accept that at 38 I was in fact
11 disabled. I fought back tears as I ordered myself a
12 wheelchair, an electric mobility scooter so that I
13 could get out of the house more often only to find that
14 I could really sit long enough to use them.

15 I fought for doctors to acknowledge how much
16 pain I was in. I fought adrenal fatigue, exhaustion
17 and episodes of intense sweating. I fought for a long-
18 term disability. That first year I spent fighting for
19 many things but mostly I fought for treatment. I
20 fought side effects from countless medications and
21 therapies that my doctors prescribed, none worked. I
22 fought to change my diet, and I have a gallon Ziploc

1 bag filled with bottles of supplements that didn't
2 work.

3 The pain was so bad that I actually asked my
4 doctor if they could surgically paralyze me from the
5 waist down. But not even that would rid me of the
6 pain. There was no escape, no way out, just pain. I
7 fought to be seen by one of the only physicians in the
8 world specializing in arachnoiditis, fortunately he
9 agreed to see me.

10 I left my first appointment which was 3,000
11 miles from home with a new sense of hope. These
12 medications worked, and, yes, some of them are pain
13 medications. I returned home only to fight again.
14 This time I fought the pharmacies who flat-out refused
15 to fill my legitimate prescriptions. All medications
16 carry risk. But when you have an incurable condition
17 and spend all day in bed unable to truly live risk is
18 relative.

19 (Applause)

20 MS. PARTRIDGE: Thank you. I then fought the
21 DEA who raided my doctor's office and accused us, his
22 patients, for trafficking drugs. I will never be pain

1 free but with these medications the pain is manageable
2 enough that I can usually leave the house for an hour
3 or two without having to lie down. I still suffer, I
4 will always suffer from debilitating pain that will
5 never go away. I'll never work full time again. And I
6 still have bad days where I miss events but on good
7 days I'm able to live again. But I still fight, I
8 fight the stigma of being a pain patient, a stigma that
9 nearly cost me my life.

10 (Applause)

11 MS. PARTRIDGE: Thank you. The stigma that
12 nearly cost me my life in January when an ER doc was so
13 convinced I was an addict that he missed the
14 perforation in my colon on the CT scan and tried to
15 send me home. I fight for everyone who can't be here
16 today because their medications have been ripped away.
17 I fight for the post-op patients being given Tylenol.
18 Fun fact, NSAIDS have killed more people than
19 prescription pain meds every year.

20 (Applause)

21 MS. PARTRIDGE: I fight for my daughters who
22 may some day new pain medication for the Ehlers-Danlos

1 Syndromes that I passed on to them. I fight for
2 morality.

3 (Applause)

4 MS. PARTRIDGE: Thank you. And compassion and
5 commonsense to be returned to medicine. I fight for
6 politicians to stop practicing medicine. We are not
7 the problem. Thank you all.

8 (Applause)

9 MS. PARTRIDGE: We are not the problem,
10 neither is pain medication, the numbers don't lie. It
11 is illicitly manufactured fentanyl causing this crisis.
12 We must restore access to pain medication for all
13 patients and mandate that these physicians treat our
14 pain and enable them to do so without fear of
15 prosecution.

16 (Applause)

17 MS. PARTRIDGE: Thank you. Our lives
18 literally depend on it and some day yours could too.
19 So members of the FDA, will you stand and fight with
20 me, with us because as Americans we have the
21 fundamental rights of life, liberty and the pursuit of
22 happiness, and the last time I checked those rights

1 don't exist if you have a certain medical condition.

2 AUDIENCE MEMBER: So true.

3 (Applause)

4 MS. PARTRIDGE: Thank you.

5 MS. CHALASANI: Thank you, Amy. Thank you.

6 Next Katie.

7 KATIE: Hello, hi. First of all I just want
8 to say, Amy, like I completely relate, unfortunately,
9 to so much of what you said regarding medications and
10 how we're treated like addicts. I've had a lot of the
11 same experiences, so.

12 My name is Katie, I'm 26 years old, and I have
13 widespread severe chronic pain all over my body. My
14 pain is a result of a laundry list of chronic
15 conditions that has impacted my overall wellbeing in
16 any and every way possible. And most of what I
17 struggle with is like many people with chronic
18 conditions invisible to an outsider.

19 I have a neurological disease in which excess
20 pressure is put on my brain causing nerve, muscle and
21 joint pain in my extremities. In addition I have
22 Ehlers-Danlos Syndromes, a connective tissue disorder

1 which also impacts my joints upon many other bodily
2 functions. It is very under-researched and very
3 misunderstood by the medical community. I have chronic
4 pelvic pain and interstitial cystitis, a very painful
5 bladder condition that basically feels like a 24/7 UTI,
6 8 years. Burning, irritation, frequent infection and
7 generalized pain. And I was diagnosed with Lyme
8 disease officially along with several parasites or co-
9 infections. In late-2016 after many years of valiantly
10 and persistently fighting for answers my pain is not
11 managed by over-the-counter drugs, my pain is not
12 intermittent, my pain has kept me up at night for most
13 of my adult life.

14 And even after finally getting the answers I
15 fought for for so long hoping that it would finally
16 mean relief my pain has been invalidated, my pain has
17 been dismissed and my pain has been willfully ignored.
18 Regardless of the cause --

19 (Applause)

20 KATIE: Regardless of the cause it is there,
21 it is debilitating and it is so all-encompassing that
22 it is very difficult to manage effectively. As a young

1 adult who has spent the majority of my adult life
2 bedridden I would love to be able to have an active and
3 fulfilled life but I can barely drive to my
4 appointments let alone anywhere else without immense
5 dizziness and writhing in pain. I managed to graduate
6 college but often had a very difficult time feeling
7 well enough to attend class. As no one understood what
8 was going on for so many years it became very easy to
9 blame myself for feeling so sick. I also developed
10 severe anxiety. Many of us with chronic pain feel like
11 we could be trying harder. And it's important to
12 remember that no one can make that determination or
13 observation for us.

14 We know how hard we are trying. We may not
15 always look at it but trust that we are internally
16 suffering and that it's not our fault. I have never
17 been able to sustain employment. And without the
18 financial security I need as it's equally as difficult
19 to be granted disability benefits a full life feel
20 unattainable. I have had no choice but to remain
21 dependent and stuck in many ways while my peers are
22 getting married, having kids and pursuing a career.

1 Because of my chronic pain I became both physically and
2 emotionally isolated. Young adults are supposed to be
3 discovering themselves in the world but my chronic pain
4 has not only hindered me physically but in many ways
5 mentally, emotionally, spiritually and psychologically.
6 It has caused me to feel lost.

7 (Applause)

8 KATIE: It has caused me to feel hopeless and
9 defeated. And as I am relatively young acceptance that
10 this will be a lifelong battle is still difficult to
11 register with me. But it has also shown me my
12 strength. And although I feel behind I've actually
13 grown up much faster. My chronic pain has only
14 worsened over time, the impact of our current medical
15 system on the emotional wellbeing of patients creates a
16 grueling cycle. We aren't receiving the proper care we
17 need and have thus become overwhelmed by the pain. The
18 emotional burden thereby creates more physical pain and
19 so on.

20 (Applause)

21 KATIE: They often proceed to handle the issue
22 by sending patients into psychiatric treatment instead

1 of tackling the underlying cause. I went from being
2 able to attend class occasionally to strictly bed bound
3 these past 2-1/2 years. Our system needs to change if
4 patients want to have a full and sustainable life.

5 (Applause)

6 MS. CHALASANI: Thank you, Katie. Thank you.
7 Next, Ten.

8 MS. SYDNOR-CAMPBELL: Good morning. My name
9 is Tien Sydnor-Campbell and I have rheumatoid
10 arthritis, osteoarthritis, osteoporosis, bladah,
11 bladah, bladah (ph). My chronic pain is both nebulous
12 and rebellious. It doesn't have a specific daily
13 routine or even an hourly location. It roams to
14 different parts of my body like a nomad. Let me give
15 you an example. I can start the morning with
16 incredible pain in my feet so much so that I stay in
17 bed for as long as my bladder allows. If I'm lucky the
18 pain won't start wondering yet, if not something like
19 my back or my shoulder or my neck is singing the blues.
20 It ranges in intensity just as much it ranges in
21 location. The only range I don't have is of motion.
22 Of course I have some areas that are more frequently

1 affected. That be my wrists, my neck, low back, my
2 legs. I got bilateral knee replacement so luckily my
3 knees don't affect me as much as they used to. My
4 right foot is currently broken because, well, my feet
5 don't always do what they're told to and I was trying
6 to walk up the steps in my house. I've fallen like
7 four times but this is the first time I broke
8 something. Lucky me. Most significant mobility
9 symptom I experience is that range of motion but it
10 happens in any joint at any time. I can start eating
11 dinner and before I'm done I might not be able to hold
12 the fork because my fingers hurt so bad or my jaw might
13 get that little bit of searing pain that's like an
14 arrow shooting right through the TMJ joint to the other
15 side of my head. So I have to stop eating until
16 something goes away.

17 Chronic pain has completely changed my life
18 and I'm still adjusting to this new existence 8 years
19 into my diagnosis. I was used to doing stuff all the
20 time. Physically I can't do 75 percent of what I used
21 to. I used to be a massage therapist, nowadays I can
22 barely rub lotion on my own hands let alone anyone

1 else. So I bet you're wondering what activities I
2 can't do anymore. I used to be a competitive swimmer,
3 spending hours in the pool was second nature to me.
4 Used to ride my bike 22 miles a day round trip to work,
5 that as a teenager then even as a young adult, as a
6 parent, as a wife. I was still working out. I was
7 still doing this at 40. In fact I completed my first
8 triathlon at the age of 40.

9 One month later, I was so incredibly sick that
10 I could not stand up straight. Three months before I
11 was diagnosed all of that came to a complete stop.
12 Looking back before the diagnosis -- I'd had bad days
13 but I now I was seasick, like really sick. Few
14 hospitalizations and surgeries later I couldn't keep
15 working. Trying to push through the pain only damaged
16 my body further. No sleep because pain, no rest
17 because pain, not staying awake because fatigue and
18 pain. Mind you, this is all while trying to get a diag
19 on the disease under control, to have a fighting chance
20 at some level of normalcy.

21 No more softball with my coworkers, no more
22 dancing with the hubster, no more attending every

1 friend and family gathering, walking and running gone.
2 Putting on my swimsuit was such a painful experience
3 that it left me in tears several times before I had to
4 give it up. I don't even wear pants with zippers
5 anymore because, you know, pained fingers and zippers
6 they are like that kids in that commercial that says
7 "Oh no, oh no, we have a situation."

8 I have been married for over 24 years and yes
9 this has affected my intimacy with my husband too. You
10 name it, it's been affected. Don't forget all the
11 medications that manage this disease, some are just
12 deadly to the libido. I avoid those if at all
13 possible.

14 My chronic pain has evolved over eight years
15 in several ways. It's gone from being an unknown
16 source with debilitating features to a known source
17 with debilitating features. No regular day-to-day
18 activities pre-diagnosis yet. I am hopeful that this
19 will not always be the case. But eight years has
20 taught me not to expect too much from even one good
21 day, let alone a good week. Thank you for listening.

22 (Applause)

1 MS. CHALASANI: Thank you, Tien. I would now
2 like to read Debbie's comments. And I am reading on
3 behalf of Debbie from her perspective. "Hi, I am a 50
4 year old who was diagnosed with CRPS 4 years ago. This
5 condition is extremely painful. Labeled as the most
6 painful condition known to man by the McGill pain
7 index.

8 "My pain is a constant burning sensation, a
9 lot like your -- a lot like you have your shoulder put
10 into ice and you have passed the point where it's cold
11 and now has become very uncomfortable. The point your
12 body has reached the panic mode. You have a need to do
13 something to get away from it. You have no idea how to
14 do it. I live on the edge of that panic every day, all
15 day. Sometimes the pain is just mentally exhausting
16 other times I am in the panic mode. Panic to the point
17 of fast heartbeat, breathing heavy and sweating,
18 looking for anything that gives some kind of relief.

19 Then there is the pressure, tight, hard
20 pressure. Like a tight Spandex band has been wrapped
21 around my upper arm and across my left shoulder and
22 chest; a strange heavy feel to it. Well with this, I

1 have skin sensitivity that creates a shocking sensation
2 when anything touches me; there is an electrical shock
3 similar to being zapped by an outlet. It makes wearing
4 clothing difficult. I look for the lightest weight
5 shirts I can find. I have to use a skin numbing spray
6 before getting dressed to help erase some of this.

7 "But I live in constant fear of anything
8 touching me, like people who are huggers or waitresses
9 who like to pat you on your shoulder. I also have
10 severe muscle spasms that come to me constantly. They
11 are like a wave in an ocean, they start at my neck and
12 roll just like a wave in the water to the end of my
13 shoulder. They then come back and roll again. These
14 spasms are very tiring and painful.

15 "Pain also consumes your thoughts. When I am
16 sitting in a room with family, the family maybe
17 watching TV and enjoying a movie; however, I am
18 thinking about what I can do about my pain. What will
19 make it better? I am thinking, I should get another
20 pillow and put it under my arm. Maybe I should try the
21 heating pad again. I bet my pain rub is wearing off
22 again. My breakthrough meds are not helping me right

1 now, God, why can't I get this to stop for just a few
2 minutes.

3 "A time when I should be creating memories
4 with my loved ones has become out of reach for me. I
5 cannot concentrate on the TV, I can only catch bits and
6 pieces of the movie. Later when they are talking and
7 laughing about what they watched I feel left out even
8 though I was in that room I can tell you very little of
9 what I watched.

10 "People want to know just how bad can this
11 pain really be. This pain has pushed me to my breaking
12 point. One night coming home from an emergency room
13 visit we were driving down Interstate 81, at 65 miles
14 per hour my mind was so overwhelmed with that pain I
15 reached up and tried opening my door so I could jump
16 out of the car. This was not a suicide attempt. It
17 was an overwhelming thought. Maybe if I could just
18 make something else hurt it would take my mind away
19 from the pain I was feeling.

20 "You may think that makes no sense, how was
21 creating more pain going to help. Have you ever bit
22 down on your lip when something hurt really bad? That

1 is your subconscious way of dealing with the pain. If
2 your lip hurts from you biting on it then the other
3 pain just does just does not seem as bad. My pain is
4 so severe my mind thought the only way to cope with the
5 pain was to slam my body on to a hard surface at 65
6 miles per hour. I thank God doors are really hard to
7 open with 65 miles per hour wind pushing on them.
8 Thank God my husband thought fast enough to grab my arm
9 and slam on the brakes.

10 "You see, my pain does not just affect me, it
11 affects my husband, who always has his guard up and
12 ready to help me all the time. My son, who knows how
13 bad the pain can be if I am touched -- if I am touched.
14 He plays bodyguard and protects me from the huggy
15 people and the touchy waitresses.

16 "I always thought if you dealt with the pain
17 long enough you eventually get used to it, the pain
18 gradually becomes less until you no longer pay
19 attention to it. Not with CRPS, every morning when I
20 wake up that is if I was lucky enough to go to sleep,
21 it's like starting all over. My body has found a whole
22 new level of pain it can achieve and wants to push me

1 to the limit."

2 I want to ask everyone to give a round of
3 applause to all of our Topic 1 panelists. Thank you so
4 much.

5 (Applause)

6 LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 1

7 MS. CHALASANI: Thank you, Sarah. So our
8 Topic 1 panelists did a really nice job of setting a
9 foundation for us to build on now. And so, what I'll
10 do is I'll be asking for folks in the audience to
11 really add to what we've heard so far and really build
12 on what we've been talking about so far. So thank you
13 again to our Topic 1 panelists.

14 First, by a show of hands, how many of you
15 heard your or your loved ones' own experiences
16 reflected in what we've heard so far? Okay. For those
17 of you on the webcast, you may not be able to see it
18 but almost all, if not all, of the hands went up from
19 the front of the room where individuals with chronic
20 pain and family members are sitting. Okay. We have a
21 couple more polling questions to help set the context
22 of some of the key characteristics of reflecting the

1 range of experiences that we have in the room today.

2 So Graham, if I could see our first polling
3 question for this topic. And this first question,
4 we'll really be asking, how do your chronic pain
5 symptoms typically manifest? And so, for this question
6 you are allowed to check all that apply. A. I have
7 periods without pain. B. My pain appear suddenly. C,
8 my pain appears subtly. D. My pain is intermittent.
9 E. I always have pain and the intensity changes over
10 time. F. I always have pain and the intensity doesn't
11 change over time. G. My pain worsens over time. H.
12 I don't know. I. My pain manifests in another way.
13 Sorry, am I blocking?

14 And we have this polling question open for the
15 folks on the webcast as well, so please feel free to
16 respond through the webcast platform, thank you. Okay.
17 We have a range of perspectives in the room. We have
18 75 percent of you indicated that your pain -- you
19 always have pain and the intensity changes over time.
20 57 percent indicated that your pain appears suddenly.
21 40 percent for, my pain appears -- sorry, suddenly for
22 57 percent and then 40 percent subtly or one of the

1 other options that I can't see right now. Sorry. I
2 can't memorize all of that that fast. So can we have a
3 summary of what we're seeing on the web, Graham?

4 MR. THOMPSON: The webcast is pretty similar.
5 Of the vast majority of people 83 percent say they
6 always have pain and the intensity changes over time.
7 And about half, 52 percent, says that their pain
8 worsens over time. I also just wanted to add we have
9 about 600 people on the web and almost -- at least 300
10 of them are patients responding to polling questions.
11 So a lot of people listening in.

12 MS. CHALASANI: Okay. Thank you, Graham. So
13 I see 20 percent of you nearly indicated that your pain
14 manifests in another way. So folks that indicated that
15 response would you mind explaining to us how your pain
16 manifests, what that other way maybe. And if you raise
17 your hand we have Conchita (ph) and Sara with
18 microphones.

19 MS. SYDNOR-CAMPBELL: Hello. Hi, I have pain
20 all the time but I have -- which Dr. Lewis explained to
21 me, the best way to explain it is metabolic storage
22 disorder, hypercalcemia from sarcoidosis. So sunlight

1 turns into calcium in my blood system; 20 minutes, I'm
2 in agony; a few hours, my vital organs calcify. So
3 basically I can't go out in the sun, and it's very
4 limiting. I have other problems from sarcoidosis but
5 that's the worst. So one of the things that everyone
6 enjoys, the sun, I cannot enjoy. Not only I cannot
7 enjoy it, it could be fatal to me.

8 MS. CHALASANI: Thank you. Thank you for
9 sharing that. We have -- yes, go on.

10 AUDIENCE MEMBER: Hi, I have a laundry list of
11 conditions, like many of us do. When you have one
12 autoimmune condition you usually have seven. So one of
13 my conditions is Ehlers-Danlos, but it's the pain that
14 has been caused by my conditions has also given me
15 severe PTSD. And I think it's important that we
16 acknowledge that it's not just the physical
17 manifestations of pain but the emotional manifestations
18 of pain. When you go through pain your entire life,
19 when you experience all of this hurt with no sense of
20 relief and no -- no time down, it emotionally drains
21 you. And it comes out as anger, it comes out as
22 anxiety, it comes out as frustration.

1 (Applause)

2 MS. CHALASANI: Thank you, thank you. So I
3 have another quick show of hands questions. So right
4 now sitting here in the room, how many of you are
5 experiencing pain that you would describe as mild?
6 Right now, sitting here in the room right now, how many
7 of you are experiencing pain that you would describe as
8 mild? Okay. For those of you on the web, perhaps 5 to
9 10 hands went up. Okay. How many of you are
10 experiencing pain right now that you would characterize
11 as moderate? Many more hands went up, for folks on the
12 web. And then, how many of you are experiencing pain
13 that you would describe as being severe right now,
14 while you're sitting in this room? And we've had hands
15 go up for this too, from the front of the room as well
16 as the back, for those of you on the web.

17 MS. SYDNOR-CAMPBELL: Can I interrupt and say
18 --

19 MS. CHALASANI: Yes.

20 MS. SYDNOR-CAMPBELL: A lot of times I have
21 pain that's mild in some areas and moderate in others
22 so --

1 MS. CHALASANI: Okay.

2 MS. SYDNOR-CAMPBELL: So I can model moderate
3 depends on the area of the body that we're talking
4 about right now. Head, boom.

5 MS. CHALASANI: Okay, thank you for that
6 comment, Tien. I think we will take one more comment
7 from up here.

8 AUDIENCE MEMBER: And actually this comment is
9 for the group because many of us, you know, polled on
10 this and you can see the -- what the results were but
11 by a show of hands how many of you experience at least
12 half of these at any given time? Yes.

13 MS. CHALASANI: Okay, it has all the hands go
14 up, for those of you on the webcast. Okay, thank you
15 for helping me out. Can we have our next polling
16 question and this will be -- of course, can you just
17 wait for a microphone just so the folks on the webcast
18 can also hear what you're saying.

19 AUDIENCE MEMBER: You asked about the severity
20 of the pain?

21 MS. CHALASANI: Yes.

22 AUDIENCE MEMBER: And what a lot of medical

1 professionals don't realize is when you live with
2 chronic pain you can be in severe pain but physically
3 look okay. You learn to live with a higher level of
4 pain.

5 (Applause)

6 MS. CHALASANI: Yes, I think Katie (ph)
7 mentioned the invisibility and so this is touching upon
8 that. We will take -- how many of you by a show of
9 hands, had -- people have said that you're faking it,
10 right, at any given point? Faking being okay, yes.
11 Okay, okay, okay we'll take one more comment. Sara,
12 there's a woman right behind you. And then we'll take
13 one more here. And then we do have a couple more
14 questions that I think will help put more details
15 around this. Go ahead.

16 AUDIENCE MEMBER: I've had my doctor say that
17 it's amazing that you're sitting here smiling when
18 you're in so much pain. That's how we learn to fake it
19 so we make it. Because people --

20 (Applause)

21 AUDIENCE MEMBER: Thank you. I have lost lots
22 of friends due to the -- my chronic pain because they

1 don't know how to deal with the changed person that
2 I've become.

3 MS. CHALASANI: A lot of head nods, a lot of
4 head nods, so a lot of -- what you're saying is
5 reflecting with others in the audience and I'm sure on
6 the webcast as well. We have one more comment here.

7 AUDIENCE MEMBER: I just want to quickly -- is
8 this on -- I just want to quickly note that, you know,
9 for those of us who are saying mild to moderate pain
10 right now, I think it's important to realize that a lot
11 of that is because we are medicated, you know, that we
12 are being treated. It is not that our pain is not
13 severe --

14 MS. CHALASANI: Sure.

15 AUDIENCE MEMBER: That right now we're
16 medicated.

17 MS. CHALASANI: Okay.

18 AUDIENCE MEMBER: And that's the only reason
19 we can be here.

20 MS. CHALASANI: Okay. Let me ask one more
21 question then on this topic. By a show of hands, how
22 many of you will experience severe pain by the end of

1 the meeting today or at least by the end of the day,
2 when you go to bed tonight because you're sitting here
3 for many hours. Okay. Thank you so much. We
4 understand that this -- this required a lot of effort
5 and time and courage from all of you all to be here
6 today. So, thank you so much for coming here. Could
7 we have the next polling question, Graham? Or I'll
8 read it.

9 MR. THOMPSON: It's up right now so you can
10 read it.

11 MS. CHALASANI: Okay. Until the slide comes
12 back. Okay. So the question is, over the course of a
13 typical day how much time do you spend in pain? You
14 can't laugh yet. Wait, wait, wait -- wait for this. A.
15 Several minutes. Now, you're supposed to laugh. B.
16 Less than four hours. C. Between 4 to 12 hours. D.
17 More than 12 but less than 24 hours. E. All day, 24
18 hours. Please use the clickers to respond. Yes.
19 Thank you. And the folks on the webcast are also
20 responding to this. Okay. Please just wait for the
21 microphone, just so that the folks on the web can also
22 hear what folks are saying.

1 AUDIENCE MEMBER: If you are well managed with
2 a pain doctor those numbers can vary greatly.

3 MS. CHALASANI: And even in the room right now
4 we're seeing a range of experiences as far as how much
5 time you spend in pain in a given day. Though, a
6 majority, 70 percent of you indicated that you're in
7 pain all day, 24 hours. So with this polling question
8 and the previous one we're seeing some characteristics
9 of how you experience your chronic pain. What I'd be
10 interested in hearing from you is, what characteristics
11 of your pain are most bothersome to you? For example,
12 in addition to frequency and severity, we heard a lot
13 about unpredictability in the comments that we've
14 received, for example. Can a couple of you speak to
15 the unpredictability or some of the other bothersome
16 aspects of your chronic pain? Yes, there.

17 AUDIENCE MEMBER: I would just like to say
18 first of all that little scale with the smiley face. I
19 hate that. And I tell the doctor you have a glass of
20 water and it's half full. I have a 5 gallon bucket and
21 it's running over the top. It's -- I have adhesive
22 arachnoiditis, by the way. But it's just stupid and

1 the degree of pain that AA patient suffers. Well, we'll
2 die without care and the most irritating thing for me
3 is no doctor knows what we are and how to treat us and
4 -- or will treat us. And so, it's impossible to get
5 diagnosed and to find care. And they just got rid of
6 the only doctor in the United States that is doing
7 research in our -- our disease. The only doctor in the
8 world.

9 (Applause)

10 MS. CHALASANI: Thank you, thank you. So
11 quickly again, what are some of the other bothersome
12 aspects of your chronic pain? We'll start here and
13 then work our way across to folks across the room.
14 Just hold it.

15 AUDIENCE MEMBER: Is it working? One thing I
16 would say is with the -- you know pain comes on --
17 comes on suddenly, when you can't predict what it's
18 going to do. And with the restrictions that have come
19 into play with the rapidly acting medications, and
20 which, you know, need to be -- you know, need to be
21 used, you know, carefully. Of course like the, even
22 the breakthrough meds or just the -- even the turf type

1 medications, there are people just like with cancer
2 that you know, even if they don't have cancer that, you
3 know I mean, it can basically ruin your whole day. And
4 what would be something that's not that bad just you
5 know spirals into -- you know, you have something that,
6 you know, just beats it -- you know, keeps on beating
7 into itself, but if it was stopped earlier, it would --
8 had been a, you know, a non-issue and I think that's --

9 MS. CHALASANI: That's really important point,
10 thank you.

11 AUDIENCE MEMBER: Thank you.

12 MS. CHALASANI: Sara. Okay. We'll alternate
13 from this side to that side. Okay.

14 AUDIENCE MEMBER: Hello. My name is Lynn and
15 I'm one of the original research patients for 28 years
16 for CRPS and RSD. And recently, I discovered I had
17 adhesive arachnoiditis. And only one man in America
18 would treat me. Because I went and I looked. Because
19 we stopped doing the research. You want to know about
20 the pain? For 28 years, I was deeper undercover than
21 Deep Throat because if I admitted how sick I was, even
22 though I went to work, I wouldn't be able to get a job

1 because the discrimination against a contractor with
2 chronic pain. I wouldn't be able to buy the meds that
3 brought me enough relief, so that I could do my job.
4 And every day the prayer was, I could just continue to
5 work so I wouldn't be a burden on my family.

6 It was hard to wear clothes. I had to dress
7 for success. Try finding a business suit that looks
8 good when clothing hurts, okay, because appearance was
9 so important.

10 MS. CHALASANI: We've heard from several
11 participants as clothing as a trigger, perhaps. I'm
12 not sure if that's the most appropriate word. But kind
13 of increases the intensity or the severity or that
14 causes you to have a flare up, for example. Correct.
15 And I'm seeing a lot of head nods. Can others speak to
16 perhaps other triggers or other things during your day
17 that may cause an increase in severity? Okay, sure.

18 AUDIENCE MEMBER: Going back to the slide that
19 deals with, you know, how --

20 MS. CHALASANI: How much time --

21 AUDIENCE MEMBER: -- how much time you spend
22 in pain, one of the aspects that doesn't get talked

1 about with pain but contributes a lot to stigma is that
2 people lose contact with the normal life continuum of
3 benchmarks. That is for young people they enter
4 employment, if you have chronic pain you don't enter
5 employment. You can barely get through high school and
6 college. If you are getting married or your friends
7 are getting married you're not getting married because
8 you can't keep relationships long enough.

9 If other people are having babies you're not -
10 - you're not building a family. And so as time goes on
11 chronic pain pulls you away from the contacts in your
12 daily life. It contributes to isolation. It
13 contributes to the notion that you are malingering,
14 that you are not worthy of the care that you need
15 because you're not contributing. And so, when we look
16 at the social and cultural aspects of chronic pain we
17 have to pay attention to that. It's very important.

18 MS. CHALASANI: Yes, yes, thank you so much
19 for that comment. Thank you. Someone this side.

20 AUDIENCE MEMBER: Hi. I have a 16-year old
21 son and mine is the predictability that he was feeling
22 it's predictable that I'm going to be in bed 80 percent

1 of every single day. And he's -- was filling out his
2 first application to get his first job and he didn't
3 put me down as a contact, an emergency contact.
4 Because he knows I can't be there for him. And that's
5 the part is he knows, he asks, "Mom can we go for my
6 driver's license? Do you think you'll be okay that
7 day? What time is your best time? When can we go?
8 What -- how many hours you think you'll be out of bed
9 that day?" That's my problem is that he knows, 80
10 percent of the day. And all I think we have here is
11 the only solution for Arachnoiditis is just palliative
12 care and that's all we want; to have a life. Just give
13 me my life back that I lost so I can build memories and
14 that's all I want.

15 (Applause)

16 MS. CHALASANI: Thank you so much for sharing
17 that, thank you. We'll take a couple more comments
18 before the next question and just to let you know, the
19 next question is really going to proffer (ph) on the
20 daily impacts of living with chronic pain. So we'll
21 have a little -- we'll hear more about the emotional,
22 as well as some of the other impacts as well. So,

1 Amanda.

2 AMANDA: Hi. I just wanted to say I have
3 Cauda Equina Syndrome, Chronic Cauda Equina Syndrome
4 which is kind of like adhesive arachnoiditis, but from
5 a different etiology. I also represent Cauda Equina
6 Syndrome Foundation. Just for us to say that, that's
7 about 2,000 members with Cauda Equina Syndrome. I
8 wanted to say that one of my triggers for onset of pain
9 is estrogen spikes. So I cannot have children because
10 I have to remain on birth control plus my medications
11 can cause birth defects. And I can't imagine my life
12 without those medications to get through a pregnancy.
13 I'm 35. When I got injured I was 28 and we were
14 trying. And I -- I can't -- I can't babysit my nephew.
15 I -- my friends have children, I can't walk around and
16 hold them because I'm scared I'm going to fall carrying
17 them, because I don't know when I'm going to get
18 something stabbing me in the leg that's not actually
19 there.

20 And I have just randomly fallen. What if I
21 was holding my child -- my child or my friend's child?
22 I've dislocated a shoulder, I've broken my wrist, you

1 know, I've gotten hurt from falling. What if I did
2 that with my own child? What if they're running out in
3 traffic and I can't chase them? So that's what chronic
4 pain took from me.

5 MS. CHALASANI: Thank you. Thank you so much
6 for sharing that, Amanda. We have one comment.

7 STELLA: Hi. My name is Stella. And I won't
8 go through all the list of my ailments like we all have
9 but when you -- your original question was, what other
10 pain do you have? When my doctor retired, who took
11 care of me for 30 years. He retired, and I honestly
12 think he retired very, very quickly and I think it was
13 because of this opioid crisis. And he might have been
14 prescribing more than what the FDA or whoever is in
15 charge of the -- CDC whatever.

16 Anyway I had to find another doctor. Nobody
17 will take over another doctor's prescription. I went
18 to a pain management doctor who said, "Well, I'm going
19 to start weaning you down because they're on my back.
20 I got to fill out a lot of paperwork." Your -- and I'm
21 not even close to the level, there's a number 90,
22 whatever it is. I'm not near that. I am maintained on

1 a normal nice dose, I guess, whatever -- however you
2 want to say it. But this doctor said, "Well, if you
3 don't like the way I'm weaning you, go find another
4 doctor." So I go find another doctor and he says --
5 "Oh, I" -- you know, my doctor's gone. What do I do?
6 Cold turkey. Put me -- what am I supposed to do? And
7 every single new doctor I went to said, "We will not do
8 this because of the paperwork the FDA and the CDC makes
9 us fill out." We are not -- DEA -- whoever it is. But
10 I have doctors telling me, "I don't want to do it
11 because of the paperwork." I also have cancer, it's a
12 chronic cancer. My oncologist says, "Your pain isn't
13 coming from your cancer, so I'm not going to prescribe
14 it because of the paperwork I have to fill out
15 involved." This is disgusting, it's so disgusting.

16 MS. CHALASANI: Thank you for sharing that
17 really important perspective. And in the afternoon
18 we'll really be probing and hearing more about some of
19 the challenges and barriers that you have in accessing
20 your preferred or optimal therapy. Specifically, what
21 may have changed over the past few years as well. But
22 want to turn to the webcast really quickly and just see

1 what's happening on the web. And see if we can get a
2 summary.

3 DR. HERTZ: So we have a couple of folks that
4 shared a lot of things similar to the room, we have a
5 lot of claps for you guys. People have shared a lot of
6 their triggers with pain, which included things such as
7 showers, noise, car rides, standing for long periods,
8 cold weather and sometimes even stress. A lot of folks
9 has all -- have also echoed the mental impacts of
10 chronic pain, issues with depression and anxiety. And
11 people have also highlighted multiple ways their pain
12 manifests. So one person states, "I have arthritis but
13 I also have muscle spasms." Thank you.

14 MS. CHALASANI: Thank you, Shannon. And I do
15 want to take a quick moment to look at my FDA panelists
16 here and see if anyone has any follow-up questions
17 before we move on to the next, the next polling
18 question. Okay. Sharon?

19 DR. HERTZ: Sure, I am sorry. Hi, once again
20 Sharon Hertz. And I'm the director of the review
21 division that reviews new drug applications for
22 analgesics including opioids and also is responsible

1 for overseeing some of the post marketing information
2 that we get about opioids. And what I would like to
3 hear about -- not even necessarily right now but some
4 of the comments about access, and I believe we will get
5 into that more. I think we need to hear more about,
6 not just from you, but from others that you might know
7 and any consequences from that. So there's today but
8 also you can write in to the docket. And it's very
9 powerful to have the written statements on the docket.

10 So I just want to encourage everybody that if
11 they want to emphasize anything they've had the
12 opportunity to say, or if they haven't had an
13 opportunity to have the microphone. We're going to
14 read all of those comments because it's that important.
15 So I just wanted to make that comment.

16 MS. CHALASANI: Thank you so much, Sharon.
17 Graham could we have the next polling question, please.

18 MR. THOMPSON: Okay.

19 MS. CHALASANI: So the question is, what are
20 the most bothersome impacts of your chronic pain on
21 your daily life? And we've touched upon some of these
22 already. We are going to ask you to please choose up

1 to three impacts. And we did question it so that --
2 that was intentional, we do want to really find out
3 what those most bothersome impacts are. It's all of
4 the above -- okay, okay, okay, all of the above. Okay.
5 It will only -- actually the system will actually only
6 capture three as well, even if you were to select all
7 of them. But we have it noted, all of them, all of
8 them. And I will read them out loud to you, since --
9 okay, we have we -- okay, sorry just if you could wait
10 for a microphone to come to you just so that folks on
11 the web can also.

12 But before we start going into the comments, I
13 do want to read the options so folks can respond first.
14 A. Ability to participate in or perform activities such
15 as work, sports or social activities, driving, making
16 or keeping plans for activities. B. Ability to fall
17 asleep or stay asleep. C. Ability to concentrate or
18 stay focused. D. Ability to care for self, family and
19 others. E. Impacts on relationships. F. Stigma or
20 embarrassment. G. Social discrimination. H.
21 Emotional impacts such as mood, fear, hopelessness.
22 And I. Other impacts not mentioned.

1 AUDIENCE MEMBER: You're missing one very
2 important one. Just to live. Meghan (ph) and I, our
3 disorder is triggered by food, by eating. I have a
4 mitochondrial disorder and that causes a functional
5 motility disorder in my gut. So my gut doesn't work.
6 So my ability to eat. You have to eat to live. I am on
7 IVs that sustain my life. And the IV goes into my
8 heart. And I just had a bacterial infection of my
9 bloodstream and it's life threatening. So it's very
10 tricky -- very tricky and challenging. When something
11 as simple as just taking a bite of food causes extreme
12 severe pain.

13 MS. CHALASANI: Thank you. Thank you for
14 sharing that. Graham, would it be possible for you to
15 summarize what we're seeing in the room, followed by
16 the webcast for this polling question please.

17 MR. THOMPSON: So for the room we have about
18 70 percent of responses on ability to participate in or
19 perform activities, you know, such as work, social
20 activities things like that. For D. 47 percent said,
21 ability to care for self and family. You can -- this
22 one's come back here.

1 MS. CHALASANI: Great. I'll take over from
2 here then for the end person. 33 percent for the
3 emotional impact such as mood, fear, and hopelessness.
4 And then a range, across the board for the other
5 impacts including other impacts not mentioned. So we
6 will come back to that and hear a little bit more. And
7 what do we see on the web, Graham?

8 MR. THOMPSON: Some similarities and some
9 differences. 93 percent said ability to participate in
10 or perform activities. But then it was followed by
11 ability to fall asleep and stay asleep, with almost 55
12 percent. And 50 percent on emotional impacts such as
13 mood, fear, hopelessness. And 50 percent as well on
14 ability to care for self and family.

15 MS. CHALASANI: Okay. Thank you. Before we
16 start taking comments, I do want to tee up the phone
17 line so we can take a couple of callers before we break
18 for lunch. That's always a fun activity, there's a
19 operator that will start speaking from the -- from the
20 ceiling.

21 So 69 percent of you indicated the ability to
22 participate in or perform activities as being a

1 bothersome impact, or not being able to. One thing
2 that we read in comments is that even -- it's not
3 necessarily the physical ability to participate that's
4 impacted but it's just the fear and the anxiety that
5 you're going to experience chronic pain that you don't
6 -- you don't even have the -- you don't even try to do
7 some of the activities and so forth. I'm seeing head
8 nods. Does that resonate? No, not necessarily with
9 everyone? Could we get a microphone? Thanks.

10 MS. SYDNOR-CAMPBELL: Okay. So every summer I
11 test myself to see how long I can stay out in the sun.
12 And of course I end up very, very sick. So it's --
13 sorry.

14 MS. CHALASANI: If you just hold up the mic
15 up, sorry, a little bit closer.

16 MS. SYDNOR-CAMPBELL: I am sorry. The
17 question is the impact is, I'm almost convinced that I
18 don't have this. And then I test myself again every
19 summer. Because who is allergic to the sun, nobody.
20 And then I get sick again. And it goes on, and on, and
21 on. So, like food, how do you avoid the sun and who
22 wants to be with somebody who can't go out in the sun?

1 Nobody. So there are limitations that are so limiting.
2 There's no options at all.

3 And by the way with the doctor, I'm a 93 year
4 old man, away from being cut from the only medication
5 that allows me to stay focused while I detox the
6 calcium out of my body. Without those medications that
7 it, it's done. Nobody will take me as a patient. And
8 I'm in New York City, the doctors outnumber us and
9 nobody will take me.

10 MS. CHALASANI: Thank you for sharing. Thank
11 you. Sara I think --

12 AUDIENCE MEMBER: Hello everyone, I'm a
13 caretaker, my daughter has sickle cell disease. So
14 some people -- it hasn't been an onset for her, she's
15 had it since birth. And we go back and forth about
16 "Why don't you get your driver's permit." Well, she
17 has anxiety, she could have a sickle cell pain crisis
18 any time. So you know for the normal things she hasn't
19 experienced family, and a boyfriend. Because, what if
20 we go out and I have a pain crisis while we go out
21 dancing. So, but one of the things I also wanted to
22 say is, you all are not addicts, you are not standing

1 in a corner scratching and digging, you don't have --
2 you don't have, you know, tracks up and down your arm.
3 You are real people with real symptoms. And as a
4 caregiver of someone who has had sickle cell disease
5 her whole life I think I know better what she needs if
6 she's in pain or not, rarely, and how extreme it is.
7 And when we go to the hospital with our loved one and
8 we tell you they need this, they need that because they
9 can't speak, because they are in so much pain, listen
10 to us.

11 And something as simple as, today it's going
12 to rain, tomorrow it's going to be 90 degrees, the next
13 day it's going to be 50 degrees will send my daughter
14 into a pain crisis. So every day, we don't know is
15 this is going to be the day, is -- am I going to get a
16 phone call while I'm at work. I used to work in
17 Washington and we lived in Baltimore. So which train
18 can I jump on in case she has a pain crisis? So
19 please, when they tell you they are in pain, when their
20 caregiver says they're in pain, hear them, listen.

21 And can we please have some fast-acting
22 medicine. The only pain medicine if she doesn't take

1 oxycodone, tramadol and naproxen at home is morphine.
2 And I have to go through 4 phone calls before I can get
3 through to someone to tell me, it's okay to bring her
4 to the emergency room to get morphine. And it takes
5 five doses for her sickle cell pain crisis to get to a
6 level where she can speak to me. So if you guys can
7 come up with something better, please do it.

8 MS. CHALASANI: Thank you for sharing your
9 comment, thank you so much. A couple more comments on
10 the ability to participate and perform activities or
11 your limitations in regards to that. Maybe one more
12 from right here.

13 JOE: First of all I want to thank you guys
14 for being here and holding this. I am really grateful,
15 you know. And I think everybody in this room is very
16 grateful for you holding this meeting. I also have
17 adhesive arachnoiditis. One thing I want to say how
18 they say like, now pain doesn't matter. If I wouldn't
19 have complained about the pain, I had a staph infection
20 up in my sinus cavity, and I --I wouldn't be here right
21 now if I didn't keep complaining, you know.

22 But another thing that I wanted to ask you

1 guys please, if you could do some thing about, if a
2 person has cancer they might give a medication now,
3 okay. Where I live even that's becoming rare, all
4 right. And if you could live with a lifelong disease
5 you can't get pain care now. I mean that's terrible.
6 When did we become so, you know, just ignoring people's
7 pain and suffering. That -- that's really sad, you
8 know. I think we can do better, you know. If -- and
9 with -- if this is a drug development thing we would
10 all love it if there was a drug where we didn't need to
11 take opiates, you know.

12 But for some people they -- it works for them,
13 you know, and it helps them. My pain, it wakes me up
14 in the morning, you know. And I also, when I was first
15 diagnosed, I couldn't even find a doctor. And if
16 you're poor, good luck finding pain care, okay. And
17 now we're treated like criminals. So and it -- it has
18 to change, you know. And you guys could do a lot for
19 that you know, so thank --

20 MS. CHALASANI: Thank you, Joe. Thank you so
21 much for that comment. Okay sorry, if you could just
22 wait for a microphone just so that folks in the webcast

1 can also hear what we're saying in the room. Thank
2 you. I think we have one comment. Go ahead.

3 AUDIENCE MEMBER: When you talk about does my
4 wife keep herself from doing the things she wants to do
5 because of a fear of the pain? That happens sometimes
6 but more often than not every time she has a good day
7 she tries to push it because she's trying to prove that
8 she's a person. Because she's gotten to the point of
9 not seeing herself as a person because she can't do the
10 things she wants to do.

11 I actually at times have to kind of yell at
12 her and say, you can't do that today because it's going
13 to cost you five days. Even just traveling here, she
14 was laid out in the back of our -- as laid down, the
15 whole way here, I drove everywhere. And just being in
16 the back of the car and getting bounced a little bit
17 while she's laying down. She's -- she was able to sit
18 for 15 minutes, the rest of the time she's been laying
19 down over here, sitting down over here, standing over
20 here, walking around trying to do something to
21 alleviate the pain. She -- the only reason we're here
22 because -- with the pain that she had today, is because

1 I knew that mentally she would never survive this, if
2 she was -- if she was able to -- if she wasn't able to
3 sit here and at least have some comment to say
4 something about how she was feeling.

5 I have to make choices every day about what
6 she can do and can't do because she can't always trust
7 her own judgment because she's trying to be a person
8 again.

9 MS. CHALASANI: Thank you. We really, really
10 appreciate all of you, all being here today. I think
11 you raised a really interesting point of, what does a
12 good day look like. Could we have other folks comment
13 on what a good day may look like versus a bad day or a
14 typical day for that matter? Maybe a comment right
15 here.

16 JENNIFER: Okay. My name is Jennifer and I
17 came from Ohio. I wanted to say that a good day -- I
18 don't remember a good day. I'm sure most of the
19 patients in here, you have them every now and then,
20 they come to you on a whim, they come to you when they
21 choose. But I don't know that there's any way to
22 properly describe what it's like to be 47 years old and

1 not be able to participate in life the way other 47
2 year olds can participate.

3 And I really think that it's important for the
4 FDA to hear -- I know that the whole general purpose of
5 today's thing was about drug development and from that
6 perspective. But I think everybody in this room has
7 been affected by what's been going on across the
8 country. And truly, I think, before we look at drug
9 development and treatment options, there's this looming
10 question this -- that's out there about having
11 accessibility to care in the first place.

12 And right now, the number of certified pain
13 physicians in the United States is pitifully, pitifully
14 low. And unfortunately, there's -- you mean there's
15 100 million of us. You put that slide up earlier --
16 there's not near enough to treat. You can't focus on
17 drug developments and things to treat patients if
18 there's nobody who's going to write a script, or who's
19 going to see us, or maintain our -- coordinate our
20 care.

21 MS. CHALASANI: Thank you, thank you. You
22 raise a really -- a really important point. And we do

1 want to hear all of your experiences with everything
2 that you're using to manage your chronic pain. And we
3 really will elicit some of those perspectives more in
4 the afternoon and really hear from all of you so that
5 it can inform our work and those of other federal
6 efforts as well. I see a comment all the way in the
7 back.

8 AUDIENCE MEMBER: So about two years ago I
9 used to work at the NIHO as a post doc doing research
10 in biochemistry. And back then a good day would be a
11 day that I could work a full 12 hours, the same as my
12 peers. But I would be home the whole next day and I
13 couldn't go back to work probably that day maybe the
14 day after. And so a good day was struggling for about
15 a year just to be able to keep up with my fellow peers.
16 Then about two years ago my ankle gave out. I tore all
17 the ligaments. Since then the last two years I have
18 had three different surgeries for both my ankles and my
19 knee. A good day is to be able to stand here covered
20 in orthopedic braces and that's the only way I can
21 actually stand, I can actually move.

22 A good day is to be able to have a

1 conversation. You can actually think for five minutes
2 to just talk about what the weather is like outside is
3 it sunny, is it cold. I don't know because I can't
4 stand up for maybe 10 minutes in the heat. And that's
5 a good day.

6 MS. CHALASANI: Thank you. Thank you so much
7 for sharing that. I do want to go to the web really
8 quickly to see what folks on the webcast are saying.
9 Shannon or Leila would you mind summarizing some of the
10 web comments for us.

11 LEILA: Sure. So lots of the same things that
12 we have been hearing in the room. One comment said that
13 everyone has a list of what they would like to be able
14 to do and a good day means we can pick one thing we
15 lost and have that back for one day. I think that's a
16 powerful sentiment. People on the web mentions wanting
17 to be a whole person again and regain that sense of
18 normal -- normalcy that people with chronic pain
19 desire.

20 MS. CHALASANI: Okay, thank you, Leila. And
21 for those of you on the web there were a lot of folks
22 in the room nodding -- nodding their heads. So your

1 comments really resonated with them as well.

2 Graham, do we have any phone callers? Okay
3 should I just speak to the operator then. Okay.

4 Operator, can we have our first caller please.

5 OPERATOR: Thank you. Our first question
6 comes from Susan, your line is open. Susan, your line
7 open, please go ahead with your question or comment.

8 MS. CHALASANI: Susan.

9 OPERATOR: We'll go to our next question. Our
10 next question or comment comes from Andrea, your line
11 is open.

12 ANDREA: Good morning. Thank you so much for
13 having this meeting and listening to us. I have been
14 suffering for over 25 years from several painful
15 diseases. And I was managed on medications, on opioid
16 medication and I did have some -- some kind of a normal
17 life. But now because our government is targeting our
18 doctors and our medicines and pretty much calling us
19 addicts and treating us like addicts, now my doctor is
20 forcing everybody to drastically taper my medication
21 and all his patients' medication because of pressure
22 from the government.

1 So now I am basically bedridden and homebound
2 and I have no life anymore. And there's so many people
3 out there, every day, I hear the same thing, and we're
4 losing hope, and there's so many people committing
5 suicide because of this.

6 (Applause)

7 ANDREA: And we just want our life back. We
8 are not addicts. We need non-medication (ph) to
9 survive and that's all we're asking for. We just want
10 our voices to be heard and our life to have meaning, so
11 we can have -- enjoy our family, and enjoy some type of
12 life without being in excruciating pain. Thank you so
13 much.

14 MS. CHALASANI: Thank you so much. Thank you
15 for calling in and sharing your perspectives. Thank
16 you. Okay. A couple more have folks in the audience.
17 I know ma'am, you had raised your hand several times.

18 AUDIENCE MEMBER: Thank you. Today, I'm here
19 as a patient. I'm fortunate that my pain is now
20 managed through spinal cord stimulation. But I
21 remember when I was there -- and disclosure, I do work
22 for a spinal cord stimulator, a medical device company,

1 Nuvecetra. But when I was in the throes of it, a good
2 day was, with a fistful of medication, maybe I was
3 functional just getting around. A bad day, it hurt to
4 breathe. And one of the things that I wanted to
5 address on the -- answers were the -- it was on
6 question A. Could you put that up again? Or -- and
7 the answer was an overwhelming on A. One thing that I
8 think hasn't addressed and I would like to see if
9 anybody else experienced this that I had two options.
10 I was either in such excruciating pain that I couldn't
11 participate in anything. Or if I took enough
12 medication I could participate but I was in such a fog
13 I really wasn't there any way. Anybody else
14 experienced that? Thank you. So, no fog? Okay, so I
15 saw some hands and there are others that didn't so
16 you're fortunate.

17 MS. CHALASANI: Thank you. Thank you so much.
18 We'll take a couple of comments. Kristen (ph)?

19 AUDIENCE MEMBER: Thank you. I will say to
20 start with that I'm here wearing two hats. I'm the
21 wife, 45 years, of a severe chronic pain patient; who
22 would be here today except that he's experiencing

1 severe muscle spasms in his back and so he had to stay
2 at the hotel. So, I'm responding on his behalf.

3 I am also the leader and founder -- co-leader
4 and co-founder of a very small advocacy group called
5 Families for Intractable Pain Relief. We are not a
6 registered nonprofit. We have no money. So I am not
7 obligated to anybody for anything. My husband
8 experiences what he would describe as several
9 distinctly different kinds of pain. He has had pain
10 since he was a child and he is 68 years old.

11 His most debilitating pain is a constant 10,
12 on a scale of 1 to 10, very severe headache that feels
13 as though his skull is being crushed. It is as though
14 someone made a mold of his whole head, made it about a
15 quarter of an inch too small and then forced his head
16 into it anyway. His high dose of opioid pain
17 medications controls that headache very well. But
18 without it he would be bed-bound once again. And he
19 says it's just unbelievable how severe this crushing
20 headache pain is.

21 We attended European FDD (ph) for fibromyalgia
22 in 2014 and he stood up and told you at that time that

1 since he went on high dose opioids in 2010 he has had
2 the best quality of life of his entire adult life. So
3 far we have continued to be able to obtain medication
4 he needs. But over the last year there have been many
5 points in time when we were not sure that would be the
6 case.

7 And if his pain medication goes away and is no
8 longer available his quality of life is finished. It's
9 very important. We need to deal with this opioid
10 supposed crisis that is really a crisis of fentanyl and
11 heroin. My husband has seen the same doctor as Amy and
12 Gary and Lynn and Joe and many other people in this
13 room and without that doctor I'm not sure my husband
14 will even still be here. Thank you so much for having
15 this meeting.

16 MS. CHALASANI: Thank you, Kristen. Thank you
17 for sharing. If folks are okay with going a little bit
18 into lunch, maybe 5 to 10 minutes, we can take a few
19 more comments on this topic. Does that sound okay to
20 folks? Cutting short a little -- cutting lunch a
21 little short. Okay. We have several folks here.
22 Okay.

1 MS. ROBERT: Hello. I am Shiny Robert and I
2 appreciate all of you all coming and for our patient
3 panel speaking. I have hypermobile EDS and I am with
4 the Ehlers-Danlos Society. So thank you for all of us
5 EDS-ers (ph) who made it to this meeting because I know
6 that is a channel. If you are on our message board you
7 know me better as Slap a Smile On, no matter what your
8 condition is that's another one of our tricks that we
9 do so that people don't know how much pain that we are
10 in.

11 In addressing your question about being able
12 to predict when we're going to be in pain or what
13 triggers. Ehlers-Danlos Syndrome are one -- are
14 somewhat unique in the medical world in that they cause
15 both chronic pain and acute pain. And so we know that
16 we're going to be in pain on any day or night that
17 we're living. However, certain activities will cause
18 acute injuries or acute pain. We can't always predict
19 that. I might be able to give my son a high five one
20 day and be fine. I may, another day, give my daughter
21 a hug and have my rib go out of place. I may wake up
22 one day all put together and I may wake up another day

1 and my hip joint is out, it's dislocated. And my
2 husband needs to help me put it in before he goes to
3 work. And so some things we can predict some things we
4 can't.

5 Some things are consistent triggers. Some
6 things we can do fine on one day like reaching for a
7 glass and other days the shoulder dislocates. And yet,
8 we wake up each day and we try the best that we can
9 using as many pain management tools as we have
10 available to us.

11 MS. CHALASANI: Thank you. Thank you so much
12 for sharing that, thank you. We will take one more
13 comment from here.

14 AUDIENCE MEMBER: I also have Ehlers-Danlos
15 and a Chiari malformation.

16 MS. CHALASANI: Sorry just hold that a little
17 bit closer.

18 AUDIENCE MEMBER: Sorry. I think one thing
19 that's really upsetting is what Amy said trying to be a
20 mom. I've always been a disabled mom. My sons only
21 know me as a disabled mom. I passed this on to my son.
22 He also deals with chronic pain. He has a Chiari

1 malformation. And what are we sending -- what message
2 are we sending to our children when we are fighting for
3 pain control and can't get it. Our doctors are looking
4 at us saying, "I don't want to risk going to jail, so I
5 want to reduce your dose." What does that say to my
6 son? What hope does he have? And there are many
7 Ehlers-Danlos children. And I just --

8 MS. CHALASANI: Thank you. Thank you so much
9 for sharing that. Thank you. And we have one more
10 comment from back here in the middle.

11 AUDIENCE MEMBER: Thank you. I'm representing
12 friends and family who have been dealing with pain who
13 can't come because of their pain. And when you ask
14 about a good day I know people who a good day means
15 they leave a room in their house that they live in
16 because they can't go anywhere else because they're in
17 so much pain and they're not being treated for it.
18 They've been convinced there's nothing out there.
19 We've heard from people in New York City who can't get
20 treatment.

21 People in rural areas are desperate. They
22 have no one. And when they're told there's no one they

1 can't go anywhere when it's 4 and 5 or even 2 hours
2 because they can't make the car trip. So they suffer
3 in a single room alone from every one. And when you
4 ask the question of how many years people are in pain.
5 Imagine that for 3 years, 5 years, 10 years, 15 or more
6 years.

7 When a good day means you go from one room in
8 your house to another and maybe you can talk with
9 friends or family, maybe not. It's really important to
10 understand those of us here are here either as
11 advocates or people who are already medicated and are
12 benefiting from that at the moment.

13 But those who have medicine are terrified.
14 It's going to be taken away at the next pharmacy visit,
15 at the next doctor's visit, at any possible moment.
16 That they go to their doctor's office and it's
17 shuttered. So there's that panic that's there. And
18 the people who have pain and aren't treated, you can't
19 get treated for anxiety if you have anxiety due to your
20 pain condition or due to just being terrified at the
21 climate that chronic pain patients are in right now.
22 And it's just really important for people to understand

1 that and glad for you to listen, but what is the
2 actionable event that's going to come out of this that
3 will help pain patients because we need more than
4 listening, we need action, we need it now with people
5 dying, people terrified and people being tortured by
6 their life. Thank you.

7 MS. CHALASANI: Thank you. Thank you for
8 sharing that. And you used the phrase climate and I
9 think we're going to use most of the time this
10 afternoon to really learn from you a little bit more
11 about your experiences or a lot more about your
12 experiences in the current climate to use your phrase
13 and really probe a little bit into the nuances. We
14 heard of things such as pain contracts, the scheduling
15 burden and many other really important issues that we
16 do want to hear about. I do want to take a look at my
17 FDA panel and see if they have any more questions for
18 this morning aspect, we do have one. Amy, go ahead.

19 MS. TAYLOR: Hello, I'm Amy Taylor and as I
20 said at the beginning, I'm with the division of
21 Pediatric and Maternal Health. And I realize that the
22 question where it was asked whether you or your family

1 member is under 18, that was zero in the room, but I
2 would suspect there are some people on the web and I
3 have heard that there are some people who have had
4 their pain from the time as a child up into adulthood.
5 So we would be interested in hearing about the same
6 questions, but from the perspective of children under
7 18. So either into the docket or if you have some
8 comments here, both on topic one and topic two, so that
9 we have a better understanding as we're developing
10 treatments for pediatric patients.

11 MS. CHALASANI: Thank you, Amy. Are there are
12 a couple of folks really quickly that could speak to
13 the pediatric perspective, but I'll really ask that you
14 elaborate about this experience in the public docket
15 because I know -- okay, yes. Let's definitely.

16 AUDIENCE MEMBER: I'm actually 25 now, but
17 I've had sickle cell my whole life and just as a kid
18 being able to play with your sibling or your other
19 friends in the neighborhood such as playing in the
20 snow, can't do it. Just being able to live, period.
21 As a child it's hard to deal with not being able to
22 fully explain your condition to your friends to make

1 them understand that it's not that I don't want to do
2 it, but the result of doing it as my mom said, laying
3 in the bed and having to take morphine five doses
4 before out of the plane, I can't even tell my mom
5 everything that's going on. Then going home after and
6 the next two or three days on pain meds. And basically
7 just lying in my bed, sleep and then as an adult you
8 have your cycle and that increases the pain because
9 you're losing blood and the more blood you lose, of
10 course a crisis comes. So now birth control and using
11 birth control of course gaining weight with that and
12 being able to figure out a diet around it is a
13 challenge.

14 MS. CHALASANI: Thank you. Thank you so much
15 for sharing your experiences with us.

16 AUDIENCE MEMBER: Meghana, may be one more
17 perspective on the pediatric perspective perhaps. If
18 we could do just one more and then we will really have
19 to break for lunch so that -- okay. Okay.

20 AUDIENCE MEMBER: I'm 43 years old today.

21 AUDIENCE MEMBER: Happy birthday.

22 AUDIENCE MEMBER: Happy birthday.

1 AUDIENCE MEMBER: Thank you. And I've been in
2 chronic pain for my entire life. So I've never known a
3 day without pain myself. But your question didn't ask
4 for more than one perspective. I also have a daughter
5 who has chronic pain, she is 6 years old now, so I also
6 represent her. And she has a lot of challenges with
7 her friendships and her life. She is on the swim team,
8 but she misses days every week for doing that and her
9 coaches don't understand and it's hard to explain to
10 them and there aren't any treatments for her. I can't
11 give her opioids and no doctor would ever do that, I
12 can't give her any medications really because she's 6
13 years old and there aren't any medications for her.
14 There aren't physical therapists who really know what
15 to do for her. There's nothing to do to treat her pain
16 at all. There're no treatments for her. There're no
17 doctors that have anything, any idea what to do for
18 her. So I've a daughter that is very sick and there's
19 nothing to do for her, she is in pain all the time and
20 that's her life.

21 MS. CHALASANI: Thank you for sharing that.
22 Folks on the web, just really quickly, are we hearing

1 anything regarding the pediatric perspective perhaps or
2 the young adult, adolescent perspective?

3 MS. WOODWARD: Hello Meghana. Yes, we
4 definitely are, we're encouraging all of them to submit
5 their comments to the docket. For example, some
6 individuals who may have chronic pancreatitis as
7 children, a variety of different conditions.

8 AUDIENCE MEMBER: Okay. Thank you. Leila.

9 MS. CHALASANI: Sure, and I think, sorry,
10 there is one comment and then we'll wrap. Thank you.

11 MS. FARRELL: Hi. I'll try to be fast. My
12 name is Marianne Farrell (ph). I'm here for myself,
13 suffering chronic pain after 34 years from two car
14 accidents. I'm here representing my support group,
15 Chronic Pain Support Group, for the American Chronic
16 Pain Association which I ask all of the people in the
17 panel up here, go online and find the American Chronic
18 Pain Association. We are trying to help people like
19 all of us here with pain. My life has been turned
20 upside down by chronic pain. I've been in a
21 Psychiatric Unit of a hospital for two weeks because of
22 suicidal thoughts because of my pain. I had to give up

1 my profession which was a music teacher. So it effects
2 not just me, the people in my support group, it effects
3 my families, my children, I hear all of you, I feel for
4 you, I may be one of the older people here. It's been a
5 lifelong struggle. Nobody ever heard of fibromyalgia
6 when I was found and diagnosed with it. So I want to
7 thank you for having this meeting, thank you for
8 listening to me and I appreciate everybody coming.

9 MS. CHALASANI: Thank you, ma'am. Thank you.
10 It's 12:10, so I'll just do another quick look at my
11 FDA colleagues for follow-up questions and if not I
12 think we will go ahead and take a full hour break, one
13 hour lunch break and we'll try to make up the time in
14 the afternoon. I do want to put another reminder up
15 for the public docket, please expand on what we've
16 discussed so far already today, give us more details,
17 your experiences that you shared already have provided
18 us already such rich detail, but please elaborate on
19 the docket and encourage others from your support
20 groups, for example, to submit comments as well.

21 I also do want to just touch upon one thing,
22 topics that we're talking about today are sensitive and

1 one of the topics that we heard about and may talk
2 about this afternoon is self-harm or suicide ideation.
3 We want to remind you to seek any help if you need it.
4 We've the information for the national suicide
5 prevention hotline on our slide, which will come up
6 shortly and so we just wanted to put that out there.

7 With that we'll take a break for lunch and,
8 yes, feel free to put the clickers on the chairs and so
9 forth and we'll just make sure everyone has a clicker
10 again in the afternoon. Thank you all. If you
11 preordered lunch, you'll just be able to exchange your
12 ticket for your bag lunch outside. There's indoor
13 seating and outdoor seating for lunch and you're
14 welcome to bring your food into the room as well if
15 you'd like. And if you have any questions, please feel
16 free to find myself, Sarah or Puchita.

17 LUNCH

18 AFTERNOON WELCOME

19 MS. CHALASANI: If I could ask that all of you
20 please take your seats. Thank you. Thank you. So
21 we'll now be kicking off our topic two discussion and
22 similar to how we had our topic one, we'll be kicking

1 it off with comments from a panel of individuals living
2 with chronic pain and then we'll go back into that
3 large facilitated dialogue format and then ask for
4 folks in the audience and on the web to add to the
5 questions that we're asking. Topic two, we'll really
6 focus on management approaches to chronic pain.

7 So we'll be asking all of you to share what
8 you're currently doing to help manage your pain, how
9 well your chronic pain is managed, what are some of the
10 most significant downsides to your current treatments
11 and how those downsides may affect your daily life and
12 then we'll be spending a significant amount of time
13 hearing from all of you about the challenges or
14 barriers to accessing or using medical treatments for
15 chronic pain that you've encountered or you will
16 encounter and we spoke to some of this already in the
17 morning and so we're going to ask that you share some
18 more experiences. And we'll wrap up with the specific
19 things that you may look for in an ideal treatment for
20 your chronic pain.

21 I do want to make a couple of housekeeping
22 announcements before we get started. One is we have a

1 somewhat of a fix for our technical issue that we were
2 having. We were able to get an in room projector. The
3 pro is this should work and be consistent, the con is
4 we won't be able to see it on the side screens or for
5 our panelists up here, you won't be able to see it on
6 the televisions, but this should work.

7 The second announcement that I'd like to make
8 is, we're aware that some pamphlets and information may
9 have been provided outside. I do want to let you know
10 that we do ask that it does not happen, patient focused
11 drug development meetings and FDA public meetings and
12 that information is not FDA sponsored or FDA endorsed.
13 With that I would like to ask our topic two panelists
14 to speak about their perspectives and first we have
15 Lindsay.

16 TOPIC 2 PANEL:

17 PATIENTS' PERSPECTIVES ON TREATMENTS FOR CHRONIC PAIN

18 MS. LINDSAY: No pressure, right, after lunch,
19 it's great. As you said, my name is Lindsay and I am
20 33 years old. And basically every day the back of my
21 head feels like its burning. In 2012 I was involved in
22 a car accident and left with chronic head pain and a

1 mild traumatic brain injury. Since that time I've gone
2 on to have two additional concussions. They always
3 forget to tell you that after you have one, it's very
4 easy to get more. So a lot of my treatments are
5 weighing the side effects of medicines versus the
6 effects of having multiple brain injuries. I just feel
7 like in my journey as so many others here, when I
8 started, I kind of started on all the normal drugs they
9 do.

10 The anticonvulsants, the depression
11 medications and those things and I found that they
12 either did not work or they left me with such harsh
13 side effects like just feeling sedated, weight gain,
14 not being able to concentrate at all, that I had to
15 stop them. In 2014 my pain decided to increase and
16 there're a lot of reasons behind that, but one of them
17 as just my brain was under strain for a couple of years
18 with chronic pain. In 2015 I had a procedure called
19 radiofrequency ablation and was left with life changing
20 complications from that. So I don't want to debunk the
21 myth that these things are not without risk and side
22 effects because everything that we try to do in chronic

1 pain, we are managing those two together.

2 I also want to mention that it is not one size
3 fits all. Yes. As a young woman who is athletic, I do
4 not process medications the same way as someone else
5 does. If I get four hours of relief, I'm extremely
6 excited. I do not ever get six hours of relief. So
7 for me, the reason why I'm kind of able to sit here
8 today and talk to you is through ketamine.

9 I have ketamine infusions every eight weeks at
10 my pain specialist and I spend two days four hours each
11 infusion having ketamine. The idea behind it is that
12 the ketamine resets the NMDA receptors in your brain.
13 For me I decided to do this after that procedure had
14 gone wrong. I had tried facet injections, I had tried
15 trigger point injections, I had tried increased opioids
16 and none of it really worked. I like faced this really
17 daunting reality that I either had to figure something
18 out like ketamine and literally throw a Hail Mary or I
19 was going to be spending my life on my mother's couch.

20 I decided to try ketamine and for me it is
21 what kind of keeps me going each and every day. I'm at
22 a clinic where they've been doing it for probably 10

1 years and I know that there're also a lot of chronic
2 pain patients who are also doing this throughout the
3 country as well. Let me see what else I've got here.

4 I have also been kind of affected by kind of
5 the stigma that's kind of going on right now in chronic
6 pain. I can tell you that after the procedure went
7 wrong, there's a lot of blaming and there wasn't anyone
8 sitting there and saying, how can we help her, how can
9 we make her get better. Another thing we've got to
10 really talk about is what chronic pain does over time
11 and the fact that something that can be kind of mild
12 for somebody else can have months and months of impact
13 on each and every one of us.

14 Last year, I live in Atlanta, and I was in
15 Atlanta traffic and somebody just plowed into me, back
16 of my car. And so my pain went up, obviously I got
17 another concussion and in those moments my pain
18 physician at the time decided that he wanted me to go
19 back on high dose morphine for weeks and I said, no,
20 please say I'm not against opioids at all, I do take
21 one every day and it starts with an N and it's very
22 helpful for managing the day to day chronic pain. But

1 for me it really was that morphine affected my judgment
2 and it made me feel numb. I was really surprised to
3 find out that when I decided to push back instead of
4 then dealing with the situation, I was discharged.

5 I want to say that for me, it was actually a
6 really good thing because I now have a fantastic pain
7 specialist who I think cares and is trying a lot of
8 just different things and my quality of life has gone
9 up significantly. One of the things that I kind of
10 stand out about is that I'm able to hold down a full
11 time job as a marketing manager and I realize that that
12 is not the reality of most people here. I don't even
13 want to think about what my life would be like without
14 having ketamine infusions. Also because I do have the
15 full time job, I have the premium health insurance.

16 So I can afford a lot of the drugs or have
17 access to a lot of the drugs that many of you do not
18 have access to. I can also afford things like
19 acupuncture, chiropractor, physical therapy,
20 occupational therapy, speech therapy, you name it and
21 those are things that are off limits for a lot of
22 people. I think that if the FDA, you're going to walk

1 away from this and me and like, what can we do short
2 term and long term. I think short term one thing that
3 you can really do is to look at the drugs that are
4 already out and see if they could have a use again
5 instead of having to spend millions and billions of
6 dollars creating new drugs, looking at things like
7 ketamine that have been around for so long, but maybe
8 Big Pharma doesn't want to do clinical trials on them
9 because it's a generic drug and they can't make up the
10 money that they spent on the type of exploration.

11 Something else I would say is that I really
12 like to see the government agencies to talk to one
13 another. I think that there's a lack of communication
14 that has definitely impacted me as well and to stop and
15 say, if this was my daughter, if this was my spouse, if
16 this was my child, maybe it is worth extending and
17 working together as agencies to come together to have
18 an overall good thing. And then just moving forward
19 with a lot of these things, to take into effect the
20 fact that a lot of the drugs that are put out have such
21 harsh side effects that you can't function.

22 And so there needs to be more of a discourse

1 and more research done on medications and drugs that do
2 not affect people in that way and allow them to work
3 and allow them to do things like I did last week which
4 is to run the Peachtree Road Race which is 6.2 miles
5 and then go a few days later to go surprise my sister
6 on her 30th birthday. Those are things for me that
7 were not a reality even three days ago, three years
8 ago, sorry.

9 MS. CHALASANI: Thank you, Lindsay. Thank
10 you. Next we have Lou.

11 MR. MAZAWAY: Yeah, thanks Meghana and thanks
12 Lindsay. Thanks everyone. Oh, sorry. Yeah, thanks
13 everyone here for all the stories and you know, makes
14 you -- I always say to my senior people I have chronic
15 pain, 15 years, so it's like -- you know, over almost a
16 quarter of my life. And it's definitely a challenge,
17 you know, I'm always in some pain, and I'm going to
18 talk about how the medication helps me, you know,
19 manage the pain and I'm fortunate like Lindsay to have
20 a full-time job, but it is -- it's a real -- hearing
21 the stories, I always say that it has always -- folks
22 that you have to admire for what they deal with and so

1 many of them are here today and I'm sure online as
2 well, and so I appreciate everything you all do and are
3 going through. So peripheral neuropathy is a kind of
4 an odd -- it's a neurological condition, there are 100-
5 plus causes of it.

6 Mine is autoimmune which is like 7 out of
7 100,000 and usually when it's autoimmune, the symptoms
8 are worse, the pain is worse, the walking, disability,
9 the balance, all those things. So I have all those.
10 And it's -- so in my case it's a protein in the blood.
11 You know, there are hundreds of those and this one is
12 being overproduced and destroying the myelin that
13 surrounds the nerves in the peripheral nervous system.
14 So my feet especially and hands a little bit, only a
15 little fortunately. So when it started, you know, I
16 was a bit of a jogger, I was never great actually, but
17 I would go out and run a couple of miles. And so one
18 day I started running, we were on vacation, and then
19 Tuckett (ph) and all of a sudden I fell, and all of a
20 sudden I realized I wouldn't be able to jog anymore
21 without falling.

22 So fortunately I got a diagnosis very quickly,

1 you know, having the right neurologist or whoever the
2 medical specialty is, me, it makes all the difference
3 in the world. And so I was diagnosed at an early point
4 with this anti-MAG neuropathy. And initially the pain
5 was modest, and it was mainly later in the day, but
6 within about 6 months, it was constant. And still
7 better in the first half of the day. You know, the
8 morning is definitely more manageable, and then as the
9 day goes on, it's, you know, much more painful. My
10 drug treatment has always focused on an anticonvulsant
11 called -- initially it was called Neurontin, and then
12 when I went off patent or generic, it has become known
13 as gabapentin is the name, and it's actually one of the
14 top 10 most prescribed medications.

15 It's very common for folks with peripheral
16 neuropathy and I've always had fortunately good medical
17 coverage like Lindsay at my job and so I was able -- I
18 noticed sometimes they would put the dollar value of
19 the prescription and I know that the Neurontin was like
20 seven times more expensive than gabapentin. So
21 initially I've had to increase the dosage over these
22 years, so initially I was taking like 600 milligrams a

1 day and now to get through I'm taking 1,500 milligrams
2 a day. You know, and I try very hard to manage with
3 that and not increase it although I know some PN
4 patients take as much as 3,300 milligrams a day.

5 And I've had very few side effects from my
6 drug which is always obviously an issue, but so many
7 people say it makes them dizzy, it makes them sleepy.
8 I did put on a few pounds, I blamed that on the, you
9 know, but it may or may not be that, but -- and it's
10 had no effect on my appetite or fortunately my ability
11 to sleep which is another big issue for a lot of folks
12 with neuropathy.

13 I do know, you know, in terms of the
14 management that if I miss a dose, like I get busy at
15 work and I kind of -- I keep the pills -- they're
16 always right there, but even then you sometimes forget
17 to take your dose every 4 hours. And within an hour or
18 two, I will all of a sudden feel much more pain than I
19 did before and obviously you kind of hit yourself on
20 that, you know, how could I forget that. But -- and
21 I've tried other treatments, I tried acupuncture, that
22 didn't really do anything. Other folks have different

1 experience I guess. I exercise regularly because it
2 helps maintain, you know, the muscles that you still
3 need to use to get around and I get regular massage
4 which feels great, and it helps, you know, manage I
5 think, you know, relaxes your muscles, and you feel
6 more -- less tense generally.

7 So how has it affected my life? Well, day to
8 day, I mean I go to the work in the morning most days.
9 It's great. As the day goes on, really by 3:00, 4:00
10 o'clock, I really get -- start to feel fatigued and
11 even if I remembered my medicine, you know, it's still
12 more painful and by the time the evening rolls around,
13 it's, you know, considerably more painful. And so, you
14 know, what I do is I plan everything I do around am I
15 going to be able to stand or walk to the -- where the
16 activity is; is there parking? So many things, you
17 know, I need to think about than most folks that don't
18 have condition like this don't need to think about and
19 that's, you know, that's just the way it is. And still
20 the pain is always there to some degree.

21 And you know, in my nearly 15 years with
22 neuropathy, there really haven't come any new

1 treatments. There are some new medications, you know,
2 LYRICA, things like that that are being touted for my -
3 - for neuropathy, but my neurologist who's one of the
4 gurus up at Johns Hopkins, which is another advantage
5 of living near a place like that, says, you know, if
6 this is the gabapentin that's working, it's milder,
7 just stick with that and don't rock the boat is his
8 advice.

9 So I welcome the FDA's efforts to evaluate and
10 approve better treatment options for PN patients. If
11 you want to learn more about PM (ph) -- PN, tomorrow's
12 post, I mean a support group in D.C. and two of our
13 members Lin (ph) and Robert Mogley (ph), are having an
14 article published in tomorrow's health section which is
15 the first, we've been pushing on this for years, and we
16 -- in the support group until finally they are getting
17 it published. So I think you might -- interested in
18 reading their story. And in my other hat, I'm the
19 president of the Foundation for Peripheral Neuropathy,
20 which is a small nonprofit dedicated to peripheral
21 neuropathy. We have a small staff in Chicago and the
22 great website and for information about neuropathy, how

1 to help yourself, medication, support groups, doctors
2 and the like. So if you know anyone that has
3 peripheral neuropathy, I recommend that to you. And
4 thanks all for listening and being here today.

5 (Applause)

6 MS. CHALASANI: Thank you, Lou. Thank you.

7 AUDIENCE MEMBER: Yeah. Thanks.

8 MS. CHALASANI: Next we have Rose.

9 MS. BIGGAM: Hello, I'm Rose Biggam (ph) and
10 I'm here from the Seattle area where I worked at
11 Microsoft for a little over 23 years before becoming
12 disabled due to chronic pain. Full disclosure, I'm a
13 member of the Alliance for the Treatment of Intractable
14 Pain which is a advocacy group that has no money of any
15 kind, accept no donations. We are self-funded and
16 therefore broke always. And I am brought to you today
17 by the wonders of Prednisone, so that's how I managed
18 to get here from Seattle. Prior to my disability, I
19 had something like seven major surgeries over many
20 years, and each time I was prescribed opioid
21 medications for post-op pain relief, and they worked.
22 I recovered, I stopped taking the pain meds when my

1 pain decreased, just like 99 percent of people
2 routinely do.

3 (Applause)

4 MS. BIGGAM: In 2006 I suddenly experienced
5 crippling low back pain which failed to respond to
6 treatment of any kind, and eventually led to diagnosis
7 of Ankylosing spondylitis, fibromyalgia and Crohn's
8 disease. Up until then, I had been pretty athletic. I
9 was a college scholarship athlete. I like 10:00 this
10 morning did triathlons, did kickboxing, lifted weights,
11 whitewater rafting, hiking, camping. In Seattle we do
12 everything outdoors. And little by little, I had to
13 give all that up because it was the only thing I could
14 do to haul myself to work every day, and I actually
15 didn't even realize that until my pain doctor asked me
16 if my life had become limited to the four walls in
17 which I lived, and I broke down crying because I had
18 not realized how much I'd given up or had been stolen
19 from me because of pain. I began long-term opioid
20 therapy back around 2006-2007 which allowed me to keep
21 working at my very high-pressure career that I loved
22 for another 7 years. And I remain on opioids to this

1 day.

2 In 2013 the severity of my symptoms led me to
3 be declared fully disabled by Social Security
4 administration and I agreed. In addition to constant
5 severe pain, I routinely experience flares of worse
6 pain and inflammation in all of my major joints
7 depending on the day, as well as extreme fatigue like
8 when your body is constantly battling inflammation,
9 it's exhausting. And that leads to some cognitive
10 deficits, memory, attention, focus, losing words. And
11 it's severely lifestyle-limiting. I take prescription
12 NSAIDs, muscle relaxants, incredibly expensive biologic
13 injectables to suppress my immune system and long-term
14 opioids. I've tried and failed SSRIs, SNRIs, other
15 NSAIDs, other biologics, and to be clear I am not
16 depressed. I'm in pain.

17 (Applause)

18 MS. BIGGAM: Thank you. I've stopped dozens
19 of medications due to insurmountable side effects like
20 racing heart rate, sudden horrific sweats and flushing,
21 blood pressure spikes, skin rashes, open wounds, meds
22 that just knocked me unconscious, including while

1 driving to work in which I caused a car accident when I
2 was still driving to work. And I stopped a bunch of
3 them because they just didn't work. I've tried the
4 following intervention and modalities; cortisone
5 injections in my hip, feet, back and neck. Don't
6 recommend that ever. Radiofrequency ablation, my
7 facet, joint nerve endings in my spine. Luckily my
8 test was an epic fail, so they never actually did it
9 for which I am grateful. Physical therapy,
10 acupuncture, massage therapy, I still see an osteopath,
11 aquatic physical therapy, yoga. I use a TENS unit and
12 ice at home, and I have innumerable adaptive devices.
13 I could afford all of those things because I was still
14 working and like you had excellent health insurance.

15 And because I live in a metropolitan area,
16 those services were available to me. But people in
17 rural areas and with lower incomes don't have those
18 luxuries. And now that I'm disabled, most of those are
19 beyond my reach too. On my best days and with meds, my
20 pain levels hover at around a 7 usually on a scale of 1
21 to 10. On bad days, I can barely move. My condition
22 is progressive, there's no cure, it's only going to get

1 worse. My biggest nightmare used to be that I'd be in
2 a car accident or suffer some sort of injury and a
3 paramedic would strap me in a backboard and shatter my
4 spine. That was my worst nightmare. Now I wear a
5 medic ID bracelet with all kinds of information on it.
6 My new worst nightmare is being admitted to the
7 hospital, being in agony and being denied pain relief.

8 (Applause)

9 MS. BIGGAM: Which is happening all over this
10 country today.

11 (Applause)

12 MS. BIGGAM: Despite all that modern medicine
13 has to offer, my pain is not well-managed. I should
14 probably be on a higher dose of pain medication than I
15 am now, but I can't be because I live in Washington
16 State which led the country with the first opioid
17 prescribing legislation back in 2009. The atmosphere
18 in Washington State is such that most doctors won't
19 prescribe pain medication to anyone. If you can find a
20 pain specialist, you might be okay, but no primary care
21 and no specialist will prescribe. It's so bad that
22 Human Rights Watch in New York has led an investigation

1 into the inhumane treatment of chronic pain patients in
2 this country with a special focus on Washington State
3 because it's that bad. It's medical torture.

4 I'm here representing the 250,000 people in my
5 state and the roughly 10.5 million people in America
6 who suffer from incurable chronic pain severe enough to
7 need medication. The 2016 CDC mandates, which is what
8 they quickly became for our veterans and most of the
9 states, have done irreparable harm to the millions of
10 people in incurable pain.

11 (Applause)

12 MS. BIGGAM: I am here to ask the FDA what can
13 you do to fix this. Less than 1 percent of people ever
14 develop an opioid addiction from prescriptions, and the
15 first opioid people misuse today is heroin, not
16 prescriptions, yet the 99 percent of us who have never
17 misused the medication ever are forced to suffer and
18 are treated like criminals by our providers and the
19 healthcare system.

20 (Applause)

21 MS. BIGGAM: We are now, I think all of us,
22 forced to choose between getting your pain managed if

1 you're lucky, and anything else which might bother you
2 like anxiety or depression because God help you, you
3 can't take opioids ever and you certainly can't take
4 them with a benzo even though they have been prescribed
5 jointly for decades.

6 (Applause)

7 MS. BIGGAM: When you want to talk about
8 barriers to care, the biggest barrier to pain care is a
9 lack of providers who are brave enough to prescribe.

10 AUDIENCE MEMBER: Yes.

11 (Applause)

12 MS. BIGGAM: There are some other factors like
13 CMS telling insurance companies it's okay to routinely
14 deny pain prescriptions unless you get prior
15 authorization even though you've been getting those
16 pain medications for decades. I was denied myself in
17 January by my Medicare insurer even though I have been
18 on pain meds for ever with no change in dose. FDA, we
19 are begging you, correct the CDC's egregious mistakes
20 and tell the country the truth about prescription
21 opioids. They are safe and effective for 99 percent of
22 us even for long-term use. Thank you.

1 (Applause)

2 MS. CHALASANI: Thank you, Rose. Next we have
3 Hilary.

4 HILARY: I kind of feel like you said
5 everything. I'm just going to go through what I've got
6 here. Hi, I'm Hilary. I am a support group leader,
7 events coordinator and member of the board of the
8 Richmond Fibromyalgia and Chronic Pain Association.
9 I'm also on the HF (ph) mailing list, so I've been
10 keeping up with things that way. My pain scale, a 1 on
11 my pain scale is like my best day ever. A 1 would be
12 like if you haven't ever worked out and you go to the
13 gym and you lift weights, much weight everywhere, with
14 every part of your body possible. The next day when
15 you realize how bad you've kicked your rear, that's my
16 best day ever. I've been in chronic pain so much I
17 really don't know what it feels like to not be in pain.

18 (Applause)

19 HILARY: Unfortunately it seems I'm not alone.
20 An 8 on my scale would be when the nerve pain is so bad
21 it feels like all of my skin has been removed and my
22 joints have been packed with a combination of glass

1 shards and gravel. I have Lupus, fibromyalgia,
2 narcolepsy, bursitis, arthritis and I could go on, but
3 you'll be bored, so. So I guess on my scale, a 9,
4 which I've never experienced, would be childbirth, and
5 then a 10 would probably be like if your arm got ripped
6 off and you pass out, so, yeah. Haven't been there.
7 So I take opioid medication every day so that I can get
8 comfortable enough so that I can actually go to sleep
9 and I have narcolepsy. So, yeah, that's fun. I get
10 dry needling done as part of my physical therapy, and
11 that helps for a day or two. I do get cortisone shots
12 into my trigger points and my back as well as into my
13 joints. I've had my shoulders, elbows, knees, and hips
14 done as well as into the muscles in my back.

15 I practice yoga and I stretch several times
16 daily. I go to the gym a couple of times a week and
17 that hurts. It hurts to exercise, but I know I need to
18 do it. And I think I have Lyrica to thank for gaining
19 100 pounds. But, yeah, it was -- actually, I doubled
20 my weight. I went from 104 to 208 within a year.

21 I use ice packs and heating pads, including a
22 mattress pad. That's like -- it's a heated mattress

1 pad and it's dual zone, so I don't have to roast my
2 husband. So that's a -- I recommend that for anyone
3 married.

4 I just -- I do a lot of things that are not
5 necessarily taking pills. I do take a lot of pills. I
6 take a lot of medication. I have a spreadsheet. But I
7 do things that aren't necessarily drugs to help -- to
8 try to help the pain. I'm looking at what I wrote and
9 it's really just -- people said this stuff already.

10 MS. CHALASANI: Okay. Tell them your version.

11 HILARY: Yeah.

12 MS. CHALASANI: So tell them about yours.

13 HILARY: My version? Well, before medications
14 I would cry myself to sleep every night and I would
15 really hope that I didn't wake up because I couldn't
16 deal with another day in pain. Then I would cry when I
17 woke up because I knew I had another day to deal with.

18 I think that chronic pain is a job in and of
19 itself. I don't know how anyone can possibly work when
20 they feel like this. I can't see. On a good day, I
21 can volunteer at an animal shelter for a few hours. On
22 a bad day, I can't get out of bed. You know, I might

1 be able to meet a friend for coffee if it's a good day.

2 The current regulations in Virginia at least,
3 I have to go to my doctor's office to get the piece of
4 paper for my opioid prescription and then take that to
5 the pharmacist and then they fill the pain
6 prescription.

7 However, what happens when I'm in a flare and
8 I can't drive because I'm in so much pain? How am I
9 supposed to do that? There aren't taxis where I live.
10 I live on kind of like the outskirts, you know. And my
11 husband has to work, so he can't take me back and
12 forth. And if I'm in bed and can't get out of bed and
13 run out of pain medications -- there's just a serious
14 gap there.

15 AUDIENCE MEMBER: And do you have to go every
16 month?

17 HILARY: Yeah, every month. Yeah.

18 AUDIENCE MEMBER: You have to go every month?

19 HILARY: Yes. Yeah. About 15 years ago I
20 made the mistake of -- I actually had just gotten my
21 pain meds for the month and they were on the counter
22 and I knocked them over into the toilet and the cap was

1 off. So I did get the bottle out and I just -- I
2 couldn't deal with actually removing the pills from the
3 toilet. It was just not going to happen.

4 So I called my doctor's office half crying and
5 half laughing at myself and explained to them what I
6 had done. And they said, "Oh, it's no big deal. We'll
7 call the pharmacist and we'll figure out what we can
8 do." And my insurance wouldn't cover it, but it was a
9 generic, so I just paid full price for it.

10 Okay. Well, that's pretty cool, right? What
11 would happen if that happened today?

12 AUDIENCE MEMBER: Yeah.

13 HILARY: Someone said it. I heard it. Yeah.

14 AUDIENCE MEMBER: (inaudible)

15 HILARY: Yeah. Yeah, you --

16 AUDIENCE MEMBER: (inaudible)

17 AUDIENCE MEMBER: You wouldn't get it.

18 HILARY: Yeah, you wouldn't get it. You would
19 just have to suffer through.

20 AUDIENCE MEMBER: Suffer.

21 AUDIENCE MEMBER: That's right.

22 HILARY: Suffer, yeah, that's what all of us

1 do in one way, shape or form.

2 MS. CHALASANI: Thank you, Hilary. Thank you
3 so much.

4 AUDIENCE MEMBER: (inaudible).

5 (Applause)

6 MS. BIGGAM: If I can clarify for Hilary.
7 Because that would mark you as drug seeking because you
8 lost your prescription, like addicts tend to say. You
9 would be refused. You'd be red flagged as a addict.
10 And they would not give you something to taper down.
11 You would face immediate withdrawal, which would
12 possibly send you into seizures and threaten your life.

13 HILARY: Yeah.

14 MS. BIGGAM: And that's what would happen in
15 any state in the country --

16 AUDIENCE MEMBER: Absolutely.

17 MS. BIGGAM: -- full stop. So --

18 (Applause)

19 MS. BIGGAM: Thank you.

20 HILARY: Thank you.

21 MS. CHALASANI: A round of applause for all of
22 our Topic 2 panelists please. Another round of

1 applause.

2 (Applause)

3 MS. CHALASANI: Okay. So we have a few
4 polling questions, three polling questions for this
5 topics, and I want to give you an overview of what
6 those topic questions will be just so you know what to
7 expect.

8 The first one, we will ask you to identify the
9 range of medications or devices or interventional
10 procedures you may have and experienced while managing
11 your chronic pain. The second one will ask for you to
12 identify alternative or complementary therapies you may
13 have tried or that you are using. And the third
14 question -- yes, you may select all that apply for all
15 these -- for these questions. And the third one will
16 be asking for the downsides for your medication. So
17 that's kind of the agenda for the afternoon.

18 Before we go into that, though, one of our FDA
19 panelists did have a follow-up question on something
20 that we talked about in the morning. So if I could
21 just ask you to please be patient before we jump into
22 Topic 2. I'll turn to Elektra, if you would like to

1 follow-up.

2 MS. PAPADOPOULOS: Yes. We heard several
3 people mention fatigue and I just wanted to probe a
4 little bit on that and see by a show of hands how many
5 people have fatigue and just how impactful is it.

6 Okay. For those of you on the web, most of
7 the hands went up, if not all. And maybe we'll take a
8 comment or two from folks to speak about the fatigue.
9 Sarah, if you wouldn't mind?

10 AUDIENCE MEMBER: I live in chronic pain. I
11 have fatigue all the time. Fighting chronic pain is
12 tiresome. It wipes you out. Meds can help, but you're
13 still tired from the meds. It's chronic.

14 MS. CHALASANI: Maybe one or two more
15 comments.

16 AUDIENCE MEMBER: I wanted to say as far as
17 fatigue goes, I can speak from my experience. I've got
18 rheumatoid. I've got a whole handful. I'm not going
19 to go into it. But what I can say is the fatigue at
20 times is as burdensome or even more than the pain.
21 When you put those two things together --

22 (Applause)

1 AUDIENCE MEMBER: -- it can be unconscionable.
2 But on the flip side of that what I will also say is
3 for someone like myself who is on opioid medication, I
4 can tell that when I was properly medicated, utilizing
5 opioids as well as other medications, I found that in
6 fact some of those side effects you would expect like
7 fatigue, fog and stuff like that, I did not experience.

8 In fact I was actually more engaged. I was
9 able to actually function more.

10 (Applause)

11 AUDIENCE MEMBER: And I think most
12 importantly, I was able to do activities of daily
13 living that I think anybody would want to have in their
14 life be able to accomplish. So fatigue, I think it's
15 like a double-sided, you know, sword. I mean, some
16 days I don't know which is worse, the fatigue or the
17 pain. And sometimes it's both. Sometimes it's one or
18 the other.

19 MS. CHALASANI: Okay. Any follow-up
20 questions, Elektra, or --

21 (Applause)

22 MS. PAPADOPOULOS: (off mic)

1 MS. CHALASANI: Okay, okay. Could we have our
2 first poll -- and that's -- fatigue would be a really
3 important aspect as you think about drafting your
4 docket comments and writing those. If you could
5 consider thinking about fatigue and characterizing that
6 for us and the impact that has on your daily life, that
7 would be very helpful for us.

8 Okay. There's a lot of text and there's only
9 one screen that's working, so I will read it. Please
10 be patient with me, because it's a bit small for me as
11 well.

12 AUDIENCE MEMBER: First, how many of these can
13 we answer?

14 MS. CHALASANI: You can check all that apply
15 for this option.

16 AUDIENCE MEMBER: All right.

17 MS. CHALASANI: Yes. Unfortunately, you will
18 have to click all of them. There's no check all that
19 apply option up there. So have you ever used any of
20 the following therapies to manage your chronic pain.
21 So whether you're currently using them or in the past,
22 please select all that apply: (a), transdermal or

1 topical patches; (b), acetaminophen prescription,
2 NSAIDs or over-the-counter products such as Ibuprofen;
3 (c), opioid medication; (d), antidepressants; (e),
4 noninvasive medical devices such as TENS; (f),
5 anticonvulsants medications; (g), implantable medical
6 devices and/or surgical procedures; (h), other
7 therapies, so drugs or medical devices that are not
8 mentioned here; or (i), I'm not using any therapies
9 such as drugs or medical devices.

10 And I'll give folks a couple of minutes to
11 respond. And we're collecting the same information
12 from those of -- the participants from the webcast as
13 well.

14 MS. BIGGAM: While they're collecting that,
15 can I just make a request of the afternoon and morning
16 panelists: if you would provide us with a copy of your
17 statement, I would find that helpful.

18 MS. CHALASANI: If you could submit that to
19 the public docket, that would be helpful. If you have
20 any other questions, feel free to reach out to us and
21 we'll help make sure that we have your statements.

22 AUDIENCE MEMBER: Okay. Could we go ahead and

1 get these results displayed, Graham?

2 MS. CHALASANI: Okay. A range of everything
3 except for the fact -- except for I'm not using any
4 therapy such as drugs or medical devices. 93 percent
5 indicated b, but it's a range of all of them.

6 Can I ask our webcast folks -- or webcast
7 moderators for what the --

8 MR. THOMPSON: Webcast had about 90 percent
9 with the -- like acetaminophen and opioid medications.
10 And all the rest were about 75 percent, expect for
11 implantable devices, which is about 30.

12 MS. CHALASANI: Okay, okay. Thank you,
13 Graham. Thank you. So I'd like to do now is probe a
14 little bit about what aspects of your chronic pain some
15 of these classes address well and then what aspects of
16 your chronic pain they may not address well. Is that -
17 - does that sound good? Why don't we start with -- in
18 the interest of time I'm going to lump A and B
19 together, if that's okay, as buckets.

20 And so for folks that indicated, which is many
21 of you, transdermal or topical patches or the
22 acetaminophen prescription, NSAIDs or the over-the-

1 counter products, what aspects of your chronic pain are
2 they managing well and what aspects are not being
3 managed well with those? We can start with Joe right
4 here.

5 LARGE-GROUP FACILITATED DISCUSSION:

6 TOPIC 2

7 AUDIENCE MEMBER: Yes. If I take NSAIDs, I
8 have ulcerative colitis and I start bleeding really
9 bad. In fact recently I took some Ibuprofen and, man,
10 it was bad; I was in bad shape. So not everybody can
11 take them. Like Jeff Sessions, you know --

12 (Applause)

13 MS. CHALASANI: Okay. Sarah? I think we have
14 a comment from here in the audience.

15 AUDIENCE MEMBER: Hello. Okay, thank you. So
16 I am a patient with Ehlers-Danlos syndrome, as some
17 other patients have been today.

18 MS. CHALASANI: Could you please, sorry, hold
19 your mic up closer? I think --

20 AUDIENCE MEMBER: Can you hear me now?

21 MS. CHALASANI: Yes.

22 AUDIENCE MEMBER: Okay. I am a patient with

1 Ehlers-Danlos syndrome like so many other patients here
2 today. All day today I've actually been in pain
3 shockingly. Normally it varies from today to today. I
4 actually wrote an article called "The Ups and Downs of
5 Living with Unpredictable Pain," because it's
6 unpredictable.

7 I try not to take medication to the extent
8 possible because I've had side effects from other
9 medications, which is actually what led me to the
10 diagnosis of Ehlers-Danlos syndrome ironically. The
11 one medication I finally decided to cave in to last
12 year was Naprosyn.

13 I was shocked to discover from the pharmacist
14 to CVS that this is not something that I can take
15 constantly, that I should not actually have to have it
16 re-ordered monthly. And yet that's what happened. I
17 actually got the phone call saying, "Do you want to,
18 you know, get more Naprosyn?" Naprosyn is useless. I
19 rarely take medication. On the days I'm in so much
20 pain, I will actually take it, but it does no good.

21 A tennis ball resting on my shoulder while at
22 work, that actually is more effective sometimes than

1 Naprosyn itself.

2 Right now I have no health insurance because
3 I'm a contract attorney. I work as a contractor, so I
4 have the flexibility. So I can go to physical therapy.
5 So I can see all the different specialists. And so
6 that I can change my work schedule as needed throughout
7 the day.

8 As a contractor I don't have health insurance.
9 So right now I'm managing my pain by taking my expired
10 Naprosyn. It expired in April. And yet that is the
11 only thing I can take, because if I were to go and get
12 more Naprosyn or any other medication, it will cost me
13 hundreds of dollars. It's better for me to just take
14 Naprosyn that's expired than for me to try to get
15 another prescription. That's my barrier right there.

16 MS. CHALASANI: Okay. Thank you so much for
17 sharing that. Thank you.

18 (Applause)

19 MS. CHALASANI: Okay. We'll take a couple of
20 comments from over here.

21 AUDIENCE MEMBER: So I too have Ehlers-Danlos.
22 So with that, unpredictable dislocations happen

1 sometimes daily. For me, I'm on a handful of
2 medications, anti- inflammatories. I'm on Gabapentin.
3 I'm no -- they've tried everything.

4 Before my diagnosis, I had 15 knee
5 dislocations. In 14 years, I had 15 knee dislocations.
6 The only thing that they could say to do is physical
7 therapy, ride a bike. And I found Lidocaine patches.
8 Those patches, they didn't so much help as they made me
9 sort of distracted by the pain -- the warming sensation
10 of Menthol patches. It's like putting a Band-Aid on a
11 severed artery.

12 (Laughter)

13 AUDIENCE MEMBER: Yeah.

14 AUDIENCE MEMBER: Sure it helps better than
15 nothing, but it may as well be nothing. The Naprosyn,
16 I take ridiculous amounts of Naprosyn everyday twice a
17 day and I worry that -- the side effects are not worth
18 what it is giving me. It's giving me a slightly better
19 range of motion. It's giving me the ability to grip
20 things that weigh more than 5 pounds. But it doesn't
21 fix everything. It doesn't even come close to dealing
22 with the inflammation. And the inflammation is just

1 the tip of the iceberg.

2 When people like us have the problems we have,
3 we can't just live our lives. I'm now facing a 3-month
4 recovery because I tried to mow my lawn to avoid
5 getting a fine from my city. Halfway through I can't
6 use my hand anymore.

7 MS. CHALASANI: Thank you.

8 AUDIENCE MEMBER: It's there's just not
9 enough.

10 MS. CHALASANI: Thank you for sharing that.
11 Thank you. We'll take one comment from perhaps this
12 side of the room. Sarah?

13 AUDIENCE MEMBER: This is about side effects
14 of medications that I have tried.

15 MS. CHALASANI: Or just kind of what --

16 AUDIENCE MEMBER: I get nervous. I have the
17 worst social anxiety, so I'm like "what?"

18 MS. CHALASANI: Well, thank you so much for
19 coming here to share your comments.

20 AUDIENCE MEMBER: When you ask about the
21 medications that's been listed, I've been suffering
22 chronic pain 18 years and I'm only 46. I've had the

1 worst side effects from drugs, FDA approved. Thank
2 you.

3 But there's not one thing on there except for
4 medical devices and the stim things that they plant in
5 your spine -- from Lyrica, causing me to obsess over
6 suicide. I'm a three time suicide survivor because of
7 these drugs that you guys approve. Thanks.

8 There are better medications. And I've
9 actually given up on FDA approved medications and I
10 only take herbs in the raw form. Because every one of
11 those drugs up there that you guys approved for me to
12 take led me to almost die between -- I'm also
13 narcoleptic. But almost every one of those drugs I've
14 been on either caused my heart to rush, where I almost
15 passed out, suicidal ideations or my blood sugar level
16 would drop -- I mean, every kind of side effect.

17 Some people just don't do well on drugs and
18 let them have alternatives. You know, stop controlling
19 everything any person wants to use to treat their form
20 of whatever disease they're dealing with. Let people
21 have the American choice what we put in our body as
22 long as we're proving that it's not killing people. I

1 haven't died from green tea.

2 (Laughter)

3 AUDIENCE MEMBER: I like ginger. That really
4 helps.

5 MS. CHALASANI: Thank you. Thank you for
6 sharing your perspectives. We do want to hear about
7 everyone's experiences with the range of products
8 they're using to manage their condition, and so I would
9 like to take maybe one more before I ask another
10 follow-up question. Perhaps if we can pass the mic all
11 the way down to you. Yeah.

12 AUDIENCE MEMBER: Okay. I'll get that.

13 MS. CHALASANI: Okay.

14 AUDIENCE MEMBER: Hi. I want to comment about
15 the NSAIDs. I've been in chronic pain for 44 years and
16 I'm 48. I was diagnosed with juvenile arthritis at
17 four. And back then, you know, it was aspirin, I
18 think, (inaudible) aspirin. And then Naprosyn came
19 along.

20 And as I got older, I also developed
21 Ankylosing spondylitis and the degenerative stuff in my
22 back. And I do find that the NSAIDs worked for me.

1 However, being on them 46 years and I -- my GI doctors
2 says I have chronic gastritis and I can't take them
3 anymore. So my antianginal doesn't work with this kind
4 of severe pain. It wasn't designed for severe pain and
5 it also causes liver failure.

6 And then I was surprised to find out that
7 NSAIDs expect for aspirin have an FDA boxed warning for
8 causing stroke and heart attack, but yet they are
9 pushed. And where's -- you know, why aren't we showing
10 the numbers of people dying from NSAIDs, you know, not
11 just stab -- I also worked as an RN and there was a lot
12 of people coming having to get on dialysis because of
13 Ibuprofen, but yet I'm on opioid medicine and I've been
14 on that for about 14 years. And I have never been with
15 one doctor. And because of the opioid medicine, I'm
16 able to do the other therapies I need to do to be
17 active, you know, the yoga, the walking, the
18 stretching.

19 But I don't think many doctors are telling
20 their patients, "Oh, by the way, you could have a
21 stroke or a heart attack even within the first week of
22 taking your NSAID."

1 And then of course the -- you know, the Vioxx
2 and all those were pulled off the market. Even the
3 COX-2 inhibitors we have one left. So I think that's
4 another reason we need to carefully screen and allow
5 doctors to prescribe what patients need.

6 I also have a spinal cord stimulator. I do
7 massages, acupuncture, which does nothing, it doesn't
8 help, just costs money. I've been on anticonvulsants,
9 you name it, antidepressants, all that. So-

10 MS. CHALASANI: Thank you. The follow-up
11 question after this will be really going into what else
12 you may use to manage your chronic pains, such as the
13 acupuncture, which you indicated that it didn't work
14 for you, but we'll see what other folks say.

15 But before we get into that, you kind of spoke
16 to your journey of how you tried various things and
17 then you're taking the opioid medication. Can a few
18 others speak to their medical journey perhaps and what
19 led to you taking opioids and perhaps what adding this
20 to your management approach has provided you with in
21 regards to improvements in your chronic pain -- the
22 aspects of your chronic pain?

1 AUDIENCE MEMBER: Hi. I have rheumatoid
2 arthritis, osteoarthritis. I've lost all my cartilage,
3 so I have bone on bone on all my joints. And I also
4 have lymphoma. So I can't take the drugs that they
5 approve for rheumatoid arthritis because one of the
6 side effects is getting lymphoma. So I don't want to
7 activate that in a worse place than it is now.

8 So the first drugs they started giving me for
9 my pain management was NSAIDs and they gave me
10 Naprosyn, and within 3 days it burnt a hole in my
11 stomach and I started bleeding from it. So I can't
12 take NSAIDs. So I went on opioids and I've been on
13 opioids for years without an increase. It gives me
14 some quality of life. Could I use more? Yes. I won't
15 take more, but, you know, I'm dependent on it. I don't
16 want to say I'm addicted, like everybody is out there
17 wanting to say. Just like a person on insulin is
18 dependent on it for their diabetes, like high blood
19 pressure is --

20 (Applause)

21 AUDIENCE MEMBER: -- dependent on high blood
22 pressure medicine, we're dependent on it, not addicted

1 to it. Yes, it would be hard to get off it, but if you
2 have chronic pain you're not getting off it. And I
3 don't want to take Gabapentin because it was originally
4 made for epileptic seizures. I don't have epilepsy.
5 Why do I want to take Gabapentin and do something to my
6 brain that may not be there?

7 But anyway, so about using other drugs, yes,
8 there's a lot of side effects with the other ones. And
9 the only side effect with opioids that I see is an
10 addiction if you had to get off it. But if you have
11 chronic pain, you're not coming off it and it works.
12 And --

13 MS. CHALASANI: Okay, thank you. Thank you
14 for sharing that. Can we have a few more comments?
15 Okay, right here. Yeah, go ahead.

16 AUDIENCE MEMBER: My name is Gary Snuck and
17 I'm sorry I didn't introduce myself. I want to talk
18 about something different because I have been blessed
19 with having the best treatment and the best doctor --

20 MS. CHALASANI: So, Gary, could you just put
21 the mic a little bit closer. Yeah, thank you.

22 AUDIENCE MEMBER: Anyway, I have been blessed

1 with having the best pain treatment for years. So I've
2 been sick for 18 years and I have a genetic variant and
3 so it took real high doses to kill my pain. And so
4 when I ended up at Dr. Forest Tennant -- I know many of
5 you know him -- I was north of 3,000 DME. And I've
6 been part of his pain research for several years. And
7 some of the non-opioid breakthroughs that he has made
8 that has allowed me to reduce my opioids from over
9 3,000 to 360 milligrams.

10 The first big one was HCG, and taking that
11 hormone allowed me to cut my opioids in half. And then
12 he introduced Oxytocin, which I was directed to take
13 before I took a painkiller. Now sometimes that
14 Oxytocin worked almost as good for me as a 30 milligram
15 Oxycodone. Sometimes it didn't. But Dr. Tennant
16 continued to attack adhesive arachnoiditis from several
17 different directions. And the next direction he looked
18 at was the information and what anti-inflammatories
19 will pass the blood-brain barrier. So for me, the
20 anti-inflammatory that really worked for me was a metha
21 (ph) pregnenolone troche, which allowed me to cut my
22 dose even further.

1 And just a few weeks ago he discovered how to
2 interrupt -- well, there's three kinds of pain, right?
3 There's descending brain pain. There's, you know, your
4 baseline pain and flare pain. But anyway, he figured
5 out how to interrupt that descending brain pain that
6 every AA patient has in the morning when they wake up.

7 I used to get up in the morning, sit on the
8 edge of the bed and pray to die and cry for hours
9 before I met Dr. Tennant. And the doctors incidentally
10 used my pain to pressure me into epidural steroid
11 injections. If you want to help AA patients -- we have
12 an incurable disease. Black box injections, spinal
13 injections for us --

14 (Applause)

15 AUDIENCE MEMBER: -- because they won't help
16 us. We have an incurable disease. And we are the
17 goose that laid the golden egg for interventional pain
18 doctors.

19 Anyway, I think this new discovery that's non-
20 opioid of Dr. Tennant that he just figured out in the
21 last few weeks to interrupt the descending pain in the
22 morning, I don't have a pain flare anymore. And I

1 haven't counted my meds, but I'm guessing that I'm
2 going to be able to further reduce at least by 50
3 percent my opioids.

4 And, you know, what really -- what breaks my
5 heart? I don't want to be sick and on opioids. I have
6 been disabled for 18 years. And my small family
7 business, I made \$1.3 million in the year of my
8 disability. I'm a super achiever and I want to recover
9 and I work at it. And it was my hope that Dr. Tennant
10 would come up with a cure for this horrible malady.

11 And he told me once, he says he thinks
12 adhesive arachnoiditis is the largest public health
13 crisis in the United States has ever faced, that
14 there's 3 million people who have AA. I disagree with
15 him. I think there's 30 million. But his non-opioid
16 treatments will work for just about any painful
17 condition. And --

18 MS. CHALASANI: Okay. Thank you, Gary.

19 AUDIENCE MEMBER: Well --

20 MS. CHALASANI: -- for sharing your
21 perspective. I know you've travelled far --

22 AUDIENCE MEMBER: Anyway --

1 MS. CHALASANI: -- so thank you so much for
2 coming here. And I see that you have your comments
3 written down, so I really encourage you to type them up
4 and submit them to the public docket as well so that
5 they become part of the public record.

6 I do want to take a quick moment to go to the
7 webcast and see what we're hearing from our webcast
8 participants.

9 AUDIENCE MEMBER: Hi. Lots of the same things
10 that have been said in here. Several people have
11 mentioned the problems with NSAIDs and being able to
12 tolerate them. They agree that there's no one-size-
13 fits-all. Things like Ketamine or Gabapentin may work
14 for some people, but don't work for others.

15 A few comments -- many comments about opioid
16 use for long-term, been effective for them. And one
17 question for Hilary. What's the brand of the mattress
18 pad you use?

19 (Laughter)

20 HILARY: What was it, Sunbeam? Sunbeam. I
21 got it from Amazon, I know that.

22 AUDIENCE MEMBER: Apparently the company is

1 Sunbeam?

2 HILARY: Yeah.

3 MS. CHALASANI: Okay, I'm going to take one
4 more comment and then I'll see if my FDA panelists have
5 any follow-up questions before we move on to our next
6 discussion point.

7 AUDIENCE MEMBER: Hello, everyone. My name is
8 Coco. I'm here to represent my father. It all goes
9 back to -- I'm going to kind of echo back what we
10 mentioned this morning and then talk about what therapy
11 he has been using, which helped him a lot.

12 About 25 years ago, my dad was an
13 international student coming here and he didn't really
14 know how to drive in the snow. So unfortunately
15 someone hit him and he had a really severe car
16 accident. And he didn't have a lot of money because he
17 come here for a full scholarship, so he didn't have
18 extra money to go to the -- to get therapy after the
19 injury.

20 And I still remember like he used to work
21 really hard because he had a family of six people
22 depending on him. He worked 14 to 12 hours every

1 single day. And I could somehow remember when he was
2 in a room and kind of crying all day, because it was
3 just -- he didn't have the money to buy drugs.

4 And so a good day -- I remember until years
5 later, a good day for him is when a doctor -- an
6 acupuncturist really listens to him what his day to day
7 looked like and also telling him it's not going to be
8 like drugs where you could take it and you're going to
9 recover super fast and cover the pain, but it's going
10 to take a while as long as you keep consulting and
11 seeing him every day to day.

12 And so I remember when my dad eventually had a
13 chance to take us out, and he feel happy because I
14 could see him that the pain was relieved with all the
15 therapies that he took. And I'm thankful -- and for
16 FDA I was just saying what you could do is: why do you
17 want to join to the healthcare field? Your people up
18 there could actually make a difference for people or
19 patients. Say, a small thing could change a life.

20 So I would just want to say thank you everyone
21 here listening and help people who could have the power
22 to take an action and help those who are in need.

1 Thank you.

2 MS. CHALASANI: Thank you so much. Thank you.

3 (Applause)

4 MS. CHALASANI: Okay. If we could see our
5 next polling question, Graham? And I'll just follow-up
6 with the FDA folks here. Any follow-up questions that
7 you may have?

8 AUDIENCE MEMBER: No.

9 MS. CHALASANI: Okay. So this question is
10 asking what else are you doing besides the list that we
11 had already spoke to earlier. So besides the therapies
12 mentioned, what else are you doing to manage your
13 chronic pain? And here once again you can check all
14 that apply: (a), dietarian herbal supplements; (b) diet
15 modifications and behavioral changes; (c),
16 cannabinoids; (d), complementary or alternative
17 therapies; (e), physical or occupational therapy; (f),
18 mobile applications; (g), counseling or psychological
19 treatment; (h), other therapies not mentioned; (i), I'm
20 not doing or taking any therapies to treat my chronic
21 pain.

22 AUDIENCE MEMBER: Meghana, we have a question

1 here.

2 MS. CHALASANI: Yes.

3 AUDIENCE MEMBER: So is it what are you
4 currently doing or if they used it in the past?

5 MS. CHALASANI: It's what else that you have
6 done or are currently doing.

7 AUDIENCE MEMBER: Or currently doing. Okay,
8 go ahead.

9 MS. CHALASANI: Similar then as the last
10 question.

11 AUDIENCE MEMBER: Okay.

12 MS. CHALASANI: Thank you.

13 HILARY: I have a question. If you could --

14 MS. CHALASANI: Sorry, I'm not sure where the
15 question -- oh, yes, Hilary.

16 HILARY: What is -- what are mobile
17 applications?

18 MS. CHALASANI: Sure. I will speak to it
19 briefly and then I may turn to our colleague from the
20 Center for Devices to expand. But I believe there's
21 some relaxation apps perhaps or things that may help
22 you cope perhaps. I don't know if, Michelle, you

1 wanted to expand to speak about some of these mobile
2 applications.

3 MS. TARVER: So we're just speaking about any
4 kind of things which you may be using on your cell
5 phone or on a computer to help you manage your chronic
6 pain.

7 AUDIENCE MEMBER: But one thing I should note
8 that if you are under a pain contract, you're not
9 allowed to use the medical marijuana in most places.
10 They'll kick you off your thing, you know, and then
11 you'll lose your medicine.

12 AUDIENCE MEMBER: Right.

13 AUDIENCE MEMBER: And they're finding out now
14 that it helps a lot of people.

15 MS. CHALASANI: Okay. Thank you for the
16 clarification, Joe. Okay. I'm just going to take a
17 moment to see what the results look like and then we'll
18 ask for folks to comment and add to the dialog.

19 Okay. We had a range of experiences for folks
20 in the room. Okay. And could I have -- Graham, would
21 you mind telling me what the results on the web look
22 like?

1 MR. THOMPSON: Fairly similar on the web. A
2 lot of -- complementary or alternative therapy is
3 around 80 percent, same with dietary and herbal
4 supplements, and 70 percent physical therapy and diet
5 modifications, everything else 50 or less.

6 MS. CHALASANI: Okay, okay. Thank you. If I
7 could ask for folks who indicated that they use the
8 mobile applications or any of these really, what are
9 these other therapies providing you that the
10 prescription therapies or the interventions that we
11 spoke to earlier on the previous slide that those are
12 not providing you with? So where is that unmet medical
13 need, perhaps is one way for me to phrase that?

14 Okay, I see that we have lots of hands. So
15 we'll start here.

16 AUDIENCE MEMBER: As I mentioned earlier, I
17 have sickle cell disease, and so anytime our hemoglobin
18 numbers drop, that increases the pain. And so most of
19 us have had blood transfusions or exchanges, where they
20 take out our sickle cell blood and they give us normal
21 people's blood through a needle that goes into our
22 groin to increase the hemoglobin level -- well, to try

1 to increase the hemoglobin levels so that we have less
2 crisis. So that's one thing that I didn't see on the
3 screen.

4 MS. CHALASANI: Okay. Thank you so much for
5 sharing that. We have someone here. Okay. I'll just
6 go here and then here, if that's okay. Thank you.

7 AUDIENCE MEMBER: Hi. I feel like these kinds
8 of treatments, I had to build trust with my doctor
9 first. I felt like I almost had to prove that the
10 medicines weren't working first. And then it was,
11 "I've heard about physical therapy. Can we try that?"
12 And I did that for probably 6 months or at least until
13 the insurance was like "no." And that was really
14 helpful.

15 I have CRPS in my right foot and it regained -
16 - I've been limping on it for 3 years or so and it
17 regained the muscles, you know, through physical
18 therapy. It was the physical therapist who said, "Have
19 you tried a TENS unit?" I was like, "What? No." I
20 thought -- anyway, I guess -- sorry, I'm a little
21 nervous.

22 But the overall point is, I felt like to get

1 these therapies, it was almost the secret level, where
2 I had to keep going back to my doctor. And it was a
3 combination of all of these, plus some of the
4 prescriptions that have been really helpful for me and
5 my pain.

6 MS. CHALASANI: Okay. Thank you so much for
7 sharing. I know you said you were nervous, but you
8 shared your experiences beautifully. Thank you. We'll
9 go here.

10 AUDIENCE MEMBER: Hi. So based on the
11 questions that you're asking, I'm getting the feeling
12 that what FDA might have been expecting to hear was
13 that the biggest problem is people are having trouble
14 accessing alternatives to opioid pain medication. And
15 I think for some people that's true. That has not been
16 my experience.

17 My difficulty has been that I've been through
18 all of the alternative therapies. And --

19 (Applause)

20 AUDIENCE MEMBER: -- at 22 I had a choice, in
21 that I was presented with a choice. I could go on high
22 dose long-term opioid therapy for the rest of my life.

1 I have IC/BPS refractory. So what that means
2 essentially is that my bladder is lined with open
3 wounds that don't heal. And so I had long-term high
4 dose opioid therapy for the rest of my life barring
5 some sort of research miracle or I could sit at home on
6 a toilet and pee every few minutes for the rest of my
7 life. And I'm pretty sure that my husband and my kid
8 and all the students I've taught over the years would
9 say I made the right choice.

10 MS. CHALASANI: Thank you. Thank you for
11 sharing that. Okay.

12 (Applause)

13 MS. CHALASANI: Once again I'm going to ask
14 for your permission to go a little bit into the break
15 if that's okay, because I do want to hear more
16 perspectives on what we're talking about right now. So
17 like 5 minutes over into the break if that's okay with
18 you all and take a few more comments. Maybe on this
19 side and then -- okay.

20 AUDIENCE MEMBER: Meghana, we --

21 DR. HERTZ: Hello. This is Sharon.

22 MS. CHALASANI: Yes.

1 DR. HERTZ: I just want to clarify so that it
2 doesn't influence comments one way or the other. We
3 don't have expectations for what you're going to tell
4 us. If we expect it that we -- if we thought we knew
5 we wouldn't be asking.

6 (Laughter)

7 DR. HERTZ: So please believe there's no
8 motive per se other than to truly get your full and
9 undirected feedback.

10 (Applause)

11 MS. CHALASANI: Thank you, Sharon. We'll take
12 a comment from here if that's okay. Can we -- okay.
13 And then I'll come to you. Okay, go head.

14 AUDIENCE MEMBER: Well, I initially -- because
15 I was diagnosed -- well, I began having pain at 17 that
16 was very, very significant. And the only reason I'm
17 going into this is because it plays into how my
18 treatment has changed over time.

19 So I was very athletic. I played basketball.
20 I was our cheerleader in middle school. By the time
21 high school came around, it started to get to where I
22 was beginning to have pain.

1 I actually had a doctor tell -- because it was
2 -- actually, my husband's family worked at the doctor's
3 office I was seeing, and it wasn't ever supposed to get
4 back to me, but they had actually told my husband's
5 aunt that I was a hypochondriac and there was nothing
6 wrong with me.

7 And I was 19 years old. Whenever the doctor
8 and the additional -- well, the same practice, she came
9 back from a seminar and she came and she checked me for
10 all the different places and all the different points.
11 She had been to a conference over fibromyalgia. And at
12 19 years old I was diagnosed with fibromyalgia and it
13 has continued to progressively be, you know, more and
14 more trouble as the years have gone by.

15 I have a particular problem with nearly all
16 medical interventions as far as medicine-wise. I'm
17 allergic to all but two antibiotics known to man as far
18 as infectious disease doctors know, including like
19 Vancomycin -- they told me I'm really going to be in
20 trouble. But I'm allergic to these medication options,
21 opioids, morphine.

22 I don't have, whatever, that enzyme or

1 receptor you have to have for that to be effective, but
2 the rest of them I'm allergic to. So I lived on
3 Ibuprofen from 19 until 4 years ago, and I'll be 40
4 next month. So for years I've been taking 800
5 milligrams of Ibuprofen three to four times a day and
6 my liver enzymes had began to be elevated about 3-1/2
7 years ago.

8 Four years ago I did find out about something
9 that's a super hot topic and it was Kratom. And from
10 Kratom then I began to get relief and then I began to
11 research additional herbal methods. And so I've
12 incorporated like cats claw because it's an anti-
13 inflammatory -- so instead of taking the Ibuprofen, I
14 can use it. Skullcap for like the nerve pain as I have
15 problems with my thoracic and my lumbar spine and it
16 will get to my sciatic nerve.

17 I tried physical therapy for a bulging disc at
18 L5 or L -- yeah, L5-S1. And I ended up being told, "We
19 can't help you. So here's a TENS unit and that's all
20 we can do."

21 I can't afford to continue going to massage
22 therapy and the chiropractor three times a week, but

1 they are helpful. But the most helpful thing I have
2 found has been the dietary and herbal supplements. And
3 they're so controversial, but yet it's the first time
4 in my life I've had a quality of life.

5 My son is 21 and my youngest son is 17 and I
6 did not get to spend time with them in the way that I
7 should have been able to when they were younger because
8 all I had was Ibuprofen.

9 I wouldn't have even attempted what I did this
10 past weekend. Now I may have had some not so great
11 outcomes because of it, but I went hiking in the
12 mountains with my 17 year old down to a creek in
13 Tennessee. Coming back up I had some significant
14 falls. These things aren't cures either. And, you
15 know, whenever you're hiking -- I didn't have it with
16 me, so honestly the pain had began to get increased
17 because I normally would use it like I would Ibuprofen.
18 So it's three times a day. And it helps and it has
19 made a difference in my life.

20 And my children could have had this mom while
21 they were young, but instead they had to wait until now
22 when they're almost grown. And this is my son's last

1 summer to be at home with me. And we'll do something
2 else, whether I have to go down tumbling again or not,
3 a broken toe possibly on my foot and two horribly beat
4 up knees, but I wouldn't have even tried it hadn't I
5 found out about Kratom four years ago.

6 MS. CHALASANI: Thank you. Thank you for
7 sharing.

8 (Applause)

9 MS. CHALASANI: We do want to hear about all
10 your experiences with everything that you think may be
11 helping you manage your chronic pain. We won't be able
12 to go too in-depth into all of the topics. We're
13 already over into our break right now. So I do want to
14 do a quick look again at my webcast moderators to see
15 what we're hearing on the web.

16 AUDIENCE MEMBER: Hi. Someone spoke of their
17 pain relief toolbox, which I think is what we're
18 hearing in the room as well, different types of
19 supplements that people take, vitamins and minerals,
20 dietary changes, using yoga, ice, heating pads,
21 acupuncture, massage, chiropractic care.

22 Some people have mentioned that things like

1 physical therapy are very helpful, but sometimes they
2 require a baseline level of pain control, which just
3 might not be possible for everybody.

4 MS. CHALASANI: Thank you, Leila.

5 MS. BIGGAM: Can I just jump in really quickly
6 for one second?

7 MS. CHALASANI: Sure.

8 MS. BIGGAM: The thing about all of these
9 therapies is that some of them work for some percentage
10 of the people, and that's awesome. Whatever works for
11 anybody should be available to them. But the kicker
12 is, aside from maybe physical therapy and counseling,
13 none of them are covered by insurance.

14 (Applause)

15 MS. BIGGAM: So it shifts the burden of care
16 from a safe, effective prescribed medication covered by
17 insurance to out-of-pocket costs for people like us who
18 are managing severe levels of pain, most of it 24 hours
19 a day.

20 When I've heard people say, "Hey, use medical
21 marijuana," it's awesome. I'm like "great." How much
22 will that cost me to use it 24/7, 30 days a month,

1 everyday of the year? Because that's on a -- I'm on
2 disability. I've got a fixed income already. I can
3 barely afford the co-pays of the covered medications.
4 But to expect somebody to cover the cost of all of
5 those things instead of getting the safe and effective
6 medication that we know works is just insane.

7 (Applause)

8 MS. CHALASANI: Thank you for sharing that,
9 Rose. Really quickly a show of hands question. These
10 are my favorite. Before we go into our break, by a
11 show of hands how many of you sitting here in the room
12 believe that your chronic pain is being managed well,
13 that you are managing your chronic pain well, whether
14 it's with a range of what we have listed here on the
15 previous slide -- you think that it's being managed
16 well? So for those on the webcast, I would say about
17 10 hands perhaps went up.

18 And how many of you do not believe that your
19 chronic pain is being managed well today? Okay. Many
20 hands. Okay. Sure. And with -- I do think after
21 this, we'll go for our break and then we'll come back
22 again.

1 AUDIENCE MEMBER: Hi. I just have a question.
2 To me I'm hearing everyone has legit medical diagnoses.
3 And why is it we have -- it seems to me that, when the
4 FDA came out or whomever decided with these new
5 regulations, came out with -- okay, whoever -- people
6 are regulating things.

7 So we have people that take drugs and they are
8 addicts, people who don't take drugs and they're not
9 addicts. And then what happen to the chronically ill
10 population that truly needs the drugs for what they
11 were made for, to block pain receptors, to do their
12 job.

13 It seems to me that we're just asking for our
14 right to just have a normal life and I don't feel that
15 we should have to beg others for our will to live.
16 It's not by another person's hand to dictate how my
17 daily life goes. I don't like that. It makes me angry
18 and it's violating me as a mother and a person and my
19 children.

20 MS. CHALASANI: Okay. Thank you so much. We
21 recognize that there are mixed views on efforts from
22 federal agencies, federal efforts and so forth,

1 particularly in regards to pain management.

2 And what we're really here today, as Sharon
3 mentioned, is to hear from all of you and hear your
4 experiences and your perspective, so that it can really
5 inform the work of FDA and other federal efforts as
6 well.

7 So with that, I do want to take a quick 15 --
8 how about a 12 minute break? Sorry. And we'll come
9 back and we'll spend the rest of the afternoon
10 discussing the barriers and challenges with access.
11 Okay. Thank you all.

12 BREAK

13 LARGE-GROUP FACILITATED DISCUSSION:

14 TOPIC 2 CONTINUED

15 MS. CHALASANI: Hi, everyone. If you could
16 please start taking your seat. And my topic to
17 panelists -- thank you so much. While, we're still
18 focused on Topic 2, you are welcome to sit back in the
19 audience and if you'd like wherever you feel most
20 comfortable. And we'll get started.

21 Okay. If you could slowly start making your
22 way back to your seats please. Okay, thank you. So

1 for the rest of the afternoon during the large
2 facilitated discussion, we really want to focus on a
3 topic that's come up quite a few times already, but
4 really the challenges and barriers to accessing your
5 therapies to manage chronic pain.

6 And to kick start and kind of structure that
7 discussion we do have a polling question. So if I
8 could see that. Thank you, Graham.

9 We are going to make you choose up to three
10 answers for this polling question. So please think
11 about this carefully.

12 For the therapies that you use what do you
13 consider to be the most burdensome or concerning
14 downsides?

15 Okay. A, how the therapy is administered? B,
16 the frequency and length of treatment? C, difficulty
17 in accessing treatment? D, the treatment only provides
18 minimal benefit or is effective only for short term.
19 F, bothersome short term side effects of the treatment
20 -- sorry, that was E. F, concern about serious risk of
21 the treatment. G, uncertainty about long term effects
22 of treatment. H, the risk of developing drug abuse and

1 addiction. I, other downsides not mentioned.

2 Okay, I'll give you a few moments and our
3 folks on the webcast, hopefully, you're able to see
4 this question and respond as well.

5 And as we discuss the access and barriers and
6 challenges, we will take a couple more callers, so if
7 you'd like to provide phone comments please call in
8 there. We'll try to take two to three callers as well.

9 Okay, if I could see the responses, Graham?
10 Okay. C, 69 percent, difficulty in accessing treatment.
11 That was the majority of responses for those in the
12 room. Followed by 30 percent, which is other downsides
13 not mentioned. And so we'll definitely want to probe -
14 - its 39 percent, sorry -- probe more into that to see
15 what those other downsides may be, and then arrange for
16 the other downsides that we have listed here as being
17 bothered -- burdensome or concerning as well.

18 Okay. What do we see on the webcast, Graham?

19 MR. THOMPSON: On the web, similar about 82
20 percent say difficulty in accessing treatment. About
21 50 percent say that the treatment only provides minimal
22 benefit. About 30 percent, concerns about either

1 serious risk of treatment or the uncertainty about the
2 long term effects. And similar to the room about 35
3 percent say other downsides not mentioned.

4 MS. CHALASANI: Okay. Thank you, Graham. So
5 we'll start within the room and then we'll see what we
6 hear from the webcast and then go to phones and last,
7 if that sounds reasonable to folks.

8 So in regards to difficulty in accessing
9 treatment, could we hear a few comments perhaps on how
10 this maybe for you and how this impacts your daily
11 life? And if it's something that we haven't heard
12 already throughout the day, let's start with some of
13 those comments, please. Okay. I see a microphone
14 here.

15 AUDIENCE MEMBER: Work okay?

16 MS. CHALASANI: Yes.

17 AUDIENCE MEMBER: I'm Richard Martin. I'm a
18 hospital pharmacist, disabled right now. And I spent
19 25 years working in a hospital, four years of that went
20 in an oncology ward.

21 I helped to console with the oncologist on
22 pain management, opioid, switching back and forth from

1 IV to oral, switching medications, dial out at the
2 morphine back and forth, whatever, you know that type
3 of thing. Included, NSAIDS, Tylenol and includes the
4 whole stuff.

5 We used the WHO scale back then in the 70s and
6 the 80s and it was in the 90s when things got better
7 with the long term medications. At last the fentanyl
8 patch came out, wonderful.

9 So what I've got here and I want to drop this
10 off for you to pass around. This is a great big stack
11 of comments, 60 of them are from patients that sent in
12 their diagnosis and what was going wrong with them and
13 everything, and the rest of them comments from two
14 different people.

15 I challenge you, the FDA, when you get all of
16 your comments in 860 or 900. How much you've got so
17 far?

18 MS. CHALASANI: 970.

19 AUDIENCE MEMBER: In two months, I challenge
20 you to provide print every single one of them off and
21 see how high of a stack you get. So I don't know if
22 you guys do that check -- print them all off and look

1 at them.

2 But I kind of tend to think nowadays everybody
3 just looks at the computer screen and scrolls through
4 them. I think if you print it off you'll be really
5 shocked at how big of a pile you get.

6 MS. CHALASANI: Thank you, Richard. And we do
7 read every single one of the comments.

8 AUDIENCE MEMBER: Good.

9 MS. CHALASANI: And I think we may be able to
10 scan these and put them into the public docket. But if
11 not, I may follow up with you after the meeting to make
12 sure that you still electronically submit them just so
13 that they're a part of the public record.

14 One thing I do want to say about the public
15 docket though is that, it is public, so please don't
16 include any personal identifying information, because
17 we don't really have the feasibility of redacting or
18 anything that you submit to the public docket, so no
19 Social Security numbers or anything else that you may
20 not want publicly floating.

21 You can submit comments anonymous. But
22 sometimes we'll have folks identify as anonymous, but

1 then in the statement they still include their name and
2 so that's -- it still out in the public, so just
3 something to keep in mind.

4 Sorry.

5 AUDIENCE MEMBER: I ask them --

6 MS. CHALASANI: Sure. Yeah, but you can
7 definitely submit them anonymously. So thank you,
8 Richard.

9 AUDIENCE MEMBER: Well we need to talk about
10 the elephant in the room real quick and everything,
11 that's the CDC guidelines and you guys all know which
12 one I'm talking about.

13 That is the elephant in the room. And I'd
14 like to leave this here too. This is a letter from the
15 CDC -- from one of the top officials there. And
16 basically it's the one you've heard of. It's not a
17 rule, regulation, it's voluntary. It's for PCPs, et
18 cetera, et cetera, et cetera.

19 I'm the only damn person in this country that
20 got this letter, I think, because nobody else -- none
21 of the doctors got this or we won't be having the
22 problems we're having with doctors. So I'd like for

1 you guys to see this, if you haven't seen it.

2 MS. CHALASANI: Okay. Thank you, Richard.

3 Okay. And --

4 AUDIENCE MEMBER: And one final --

5 MS. CHALASANI: Okay, one final.

6 AUDIENCE MEMBER: -- and I'll get off, okay.

7 The workgroup members, before the guideline was
8 presented, suggested monitoring of the guideline
9 implementations for evidence of impact and unintended
10 consequences and modifications of guidelines when
11 warranted by the evidence.

12 The CDC has not been doing that that I'm aware
13 of. You give quarterly reports to the Commerce and
14 Energy Commission, usually that's Dr. Debra Houry, I
15 believe, the last time I saw one. They're not doing
16 that. So all of these comments that you've got and are
17 going to be getting everything or not being reported as
18 the monitoring committee recommended.

19 And so finally --

20 MS. CHALASANI: Excuse me. While you're going
21 through your pages, have you submitted these comments
22 to the people on the monitoring committee as they've

1 been identified in the CDC materials?

2 AUDIENCE MEMBER: I have submitted all kinds
3 of stuff to all kinds of people at the CDC.

4 MS. CHALASANI: Right. But what about the
5 monitoring committee?

6 AUDIENCE MEMBER: I don't know if it
7 specifically -- the monitoring committee, I don't know
8 if it exists anymore.

9 MS. CHALASANI: Have you sent it to the
10 members who --

11 AUDIENCE MEMBER: I've sent it to mainly Dr.
12 Debra Houry and Dr. Bell there at the CDC, because they
13 are the ones that have quoted that involuntary tapering
14 is not what the CDC guidelines recommended.

15 They both have quoted publicly that that's not
16 what they recommended. And all across the country,
17 that's what's happening to everybody. They are being
18 involuntarily tapered downward off their medications
19 and that is just cruel, wrong.

20 And I have here in everything 33 documented
21 suicides, because these patients were tapered
22 involuntarily down. They have been documented by Dr.

1 Thomas Klein and Max Lahn (ph), so we know they're
2 authentic.

3 You can contact a lot of them and the family
4 members and find out about it. I suspect the amount of
5 suicides is considerably more across the country than
6 we know about. Anyhow, I give you this and I'll
7 surrender the mic.

8 MS. CHALASANI: Okay. Thank you, Richard.
9 Sorry, one moment -- just -- we need a microphone
10 otherwise folks on the on the webcast won't be able to
11 capture.

12 AUDIENCE MEMBER: I'd like to say that I was
13 here in January at Opioid Policy Steering Committee and
14 I submitted the same -- from the same doctor and in
15 January that was 24. So -- and that's only what we
16 know of.

17 AUDIENCE MEMBER: I have over 150 --

18 MS. CHALASANI: Sorry, just the microphone, if
19 you wouldn't mind passing?

20 AUDIENCE MEMBER: I have over -- I've been
21 cataloguing suicides since 2014 and I have over 150
22 that I can definitely say are separate people and over

1 300 screenshots where some of those maybe one person
2 being mentioned more than once or twice.

3 But as far as the difficulty in accessing
4 treatment, I'm one patient that the currently available
5 treatments actually do work and have been absolutely a
6 miracle for. But now it's become practically like
7 winning the lottery, practically impossible to access
8 those treatments.

9 I'm like -- I keep saying this, like a white -
10 - like one of these, practically extinct white
11 rhinoceros --the white rhino rhinos.

12 And I say that because I've been on a stable
13 high dose over -- of around a 1,000 milligram -- MME
14 for over 10 years -- over eighteen years total on
15 opioids with no side effects, no ongoing tolerance, no
16 problems whatsoever other than the fact that I have to
17 live in fear of when I won't be able to find a doctor
18 that's willing to treat me.

19 And it's -- I'm not willing to go back to what
20 I was -- the way I was living before them. I'm not --
21 just not -- I'm not willing to do that.

22 Back in 2015, when the doctor who treated me

1 for nine years left his practice just out of being
2 scared to death, couldn't handle the stress anymore.
3 It was the worst thing that's ever happened to me in my
4 entire life.

5 I was basically just -- all the progress I had
6 made was completely ripped away. I have not been the
7 same since. I -- everything the -- from just pain my
8 blood pressure went to over 200 -- over 100 and stayed
9 that way. And I used to be a registered nurse for over
10 a month, but it was like that.

11 And I now have short term memory problems that
12 would make -- that's just another thing having to deal
13 with that on top of -- from having the high blood
14 pressure and that's verified through the neuropsych
15 testing.

16 And -- I mean that that was just -- I used to
17 drive. I don't drive anymore. I'm afraid to now
18 because of this.

19 And I -- through all this when I was just --
20 the spasms from the disc hernia were so severe that I
21 fell in the process and that's why my teeth are
22 missing, you see -- and that was crowns.

1 From having genetically just defective enamel,
2 I had crowns fell and knocked out you know three of my
3 teeth and knocked out fillings on the bottom and
4 basically getting dentures now. And that was over
5 \$10,000 worth of dental work. I mean this was the
6 worst thing that's ever happened to me.

7 And the only reason I'm here now is because of
8 Dr. Tennent (ph). I was -- I had -- that there was
9 somebody at my -- volunteered at my house to pick up my
10 cat, because I was done. I mean I was -- just whatever
11 was going to happen was going to happen and someone
12 would find me.

13 I wasn't going to practically take my life. I
14 was not going to do it, think to keep myself alive.
15 Not eat, drink -- eat anything. And that was -- yeah,
16 when we were printing out the vaccine reports for my
17 cat again, again for him that was when the letter from
18 Dr. Tennent came that said he would treat me.

19 I would be -- I mean I would not be here right
20 now without him. And I would not be here right now
21 without Dr. Aranda (ph) taking over from him.

22 Because basically once this -- and I'll shut

1 up in just a minute -- once the letter -- well, when
2 the announcement of this meeting came I thought, well
3 good, I'll be able to make this before I ran out of
4 medication, now that Dr. Tennent was retiring.

5 But in about two and a half, three weeks I
6 would have been completely out and this was basically
7 going to be the last -- it should not be that way. I
8 mean this is -- I mean I look like a completely
9 different person.

10 I mean this is like a 180. This should be
11 bravo, clap, cheer, you fixed your patient, at least
12 done a whole lot for them rather than being something
13 that's just in threat -- or in danger of losing.

14 I mean, this is not -- I mean it's -- and it's
15 not that I've not had multiple other things. I had an
16 intrathecal pump put in and wound up with incomplete
17 spinal cord injury from that and retinitis.

18 MS. CHALASANI: Thank you. Thank you for
19 sharing that. Thank you so much. Okay. We'll take
20 one more comment and then I do want to go to the
21 webcast and we have phone callers as well.

22 And one thing that several folks touched upon

1 and I know Hilary wanted to speak to this as well is on
2 this scheduling burden, especially if you have flares.
3 And then they were talking about how you have a flare -
4 - Lindsay, sorry wanted to speak to that.

5 Okay. So we'll go here and then we'll go to
6 Lindsay as well.

7 AUDIENCE MEMBER: Hi. Can you hear me? The
8 thing I wanted to talk about with accessibility right
9 now for me, mine is fairly good, because I have a pump.

10 But between what my doctor has said and other
11 people have said, they are pushing the pump on to
12 people that are completely fine on pills right now.

13 And the first time I had my pump in 2012, I
14 got sepsis. So I don't think that people should have
15 to pick these kind of risks if you're doing fine on
16 like medicine.

17 MS. CHALASANI: Okay. Thank you. Thank you
18 so much for sharing. Okay. And if we could get
19 Lindsay, I think, wanted to speak.

20 MS. LINDSAY: Sorry, I just didn't say it
21 earlier, because I'm tired like probably everybody else
22 this afternoon.

1 But I think that a huge burden in downside
2 right now with a lot of different treatments is
3 scheduling.

4 I know like from me, I'm having a flare up
5 right now, which is not fun. And we can go in and do a
6 nerve block for me -- occipital nerve block and it
7 really does help.

8 But as you guys already know, you have to make
9 the appoint with a doctor, go see the doctor. The
10 doctor, you will see him sitting three feet from you,
11 but he really actually can't do much then.

12 You have to put in the order. Then you have
13 to go to the insurance and have that approved which
14 takes how many days and then you have to be scheduled
15 for whatever interventional pain treatment, in my case
16 is a nerve block, which could take weeks.

17 And so you're not getting relief. And in the
18 meantime you're having to take more medications or just
19 not function the way that you just should. And so
20 there's a lot of just really difficult red tape right
21 now involved with people getting effective treatments.

22 I know for me, I really could probably come

1 off even more medicines if I could get access to nerve
2 blocks quicker and wasn't put into that pool and
3 waiting game, so.

4 MS. CHALASANI: Thank you, Lindsay. We'll
5 take one more comment from -- I'll give the mic runner
6 the hard task. And then I will look at the webcast
7 after this, if that's okay.

8 AUDIENCE MEMBER: Thank you so much. I have
9 something really important to share. I don't know if
10 you're aware, but pain patients are being extorted into
11 having dangerous invasive procedures.

12 It's happening all over the country. Pain
13 doctors are saying you want your meds, got to go have
14 an ESI. Guess what, the root cause of my debilitating
15 progressive permanent condition is from an ESI.

16 They are not without risk. Doctors are
17 putting these patients at undue risk. They are
18 harming. Their "first, do no harm", I don't know what
19 happened to that. But we need to get back to it,
20 because extorting patients into having procedures just
21 in order to get meds, it's not right.

22 MS. CHALASANI: Right. Thank you. Thank you

1 for sharing that very important perspective. Okay. I
2 am going to turn to Lila, if you could summarize what
3 we're hearing on the web, please.

4 MS. WOODWARD: So I just want to point out
5 that as of 2:00 p.m. we had over 2,000 comments through
6 the web portal. So we apologize that we haven't been
7 able to summarize everybody's input, but we are doing
8 our best to read everything.

9 In terms of challenges and barriers, I think
10 finding a doctor that can -- or provide pain medication
11 or is willing to prescribe pain medication is probably
12 the biggest challenge.

13 Once you find that doctor then people
14 mentioned having to go in for monthly visits, perhaps
15 being forced into tapering, and then stress that comes
16 when you have to go to the pharmacy and maybe denied
17 your prescription there.

18 MS. CHALASANI: Okay. Thank you so, Lila. I
19 do want to note for folks that while we may not be able
20 to summarize all the webcast comments live right now.
21 We do download all of them and we do read through all
22 of them and incorporate them in our summary report. So

1 we will look at all of them again, including while
2 we're writing our report.

3 I do have one other question. We kind of
4 started hearing a little bit about this. But what do
5 you do when you can't access your preferred or optimal
6 therapy?

7 So we've heard -- okay, I still want to pass
8 the mic around a little bit just so that it's captured
9 and we have it on the -- for the webcast.

10 But for those of you on the webcast, in case
11 you didn't hear, we heard suffer again and again and
12 again. Suffer, suffer, suffer.

13 Okay. Let's take a few a comment from back
14 here.

15 AUDIENCE MEMBER: So I'm a disabled veteran.

16 MS. CHALASANI: Thank you. Thank you.

17 AUDIENCE MEMBER: Because of injuries
18 sustained that I sustained while I was in the service,
19 I have chronic pain just not -- not just in my back,
20 limbs, I have fibromyalgia, a whole laundry list of
21 problems.

22 About a year ago I was still relatively

1 functional. I had a job that I could go to, because I
2 had access to pain medications.

3 With all the stuff with the CDC, my VA doctors
4 are now refusing to prescribe the medications that they
5 were two years ago. I cannot go to the pain clinic
6 because I am currently in physical therapy for my back.
7 So the pain clinic is where I'm supposed to get those.
8 I'm not allowed to go.

9 I can't take NSAID medications because I had
10 surgery that requires new bone growth, and you can't
11 take NSAIDs during that. So right now what I do is I
12 live from day-to-day.

13 Right now, this exact moment, because of
14 sitting here and being here so long, I have a blinding
15 headache and I can't see out of my right eye.

16 But if I went home, it was going to be the
17 exact same. So instead I'm staying here, because I
18 have no other options. I have no choice and something
19 needs to be done.

20 MS. CHALASANI: On behalf of -- I'm sure all
21 of my FDA colleagues also want to thank you for your
22 service, and then to all of you, for taking the time to

1 come here and sit through your pain to share your
2 perspectives with us.

3 I do want to give a chance to the callers that
4 we have on the phone. I know that there's many. We
5 may be able to take. Let's start with two callers.
6 Operator, could I have my first caller please?

7 OPERATOR: Thank you. Our first question
8 comes from Lynette (ph). Your line is open.

9 AUDIENCE MEMBER: Hi, can you hear me?

10 MS. CHALASANI: Yes, we can.

11 AUDIENCE MEMBER: Okay. Hi, my name is
12 Lynette and I have been a pain sufferer for 32 years.
13 Since I was 18 I was hit by a drunk driver who
14 completely crushed my body, tore it to pieces, tore my
15 leg off and I just had multiple injuries, spent three
16 months in the hospital.

17 And over the years I've done every therapy.
18 Everything you can think of the shop. I've tried every
19 medication you can think of. And ultimately at this
20 point as 50 years old for the past at least 10, 15
21 years, I have added multiple other problems from
22 overuse, they keep telling me, of the good parts of my

1 body.

2 So, therefore, now I have just nothing but
3 pain everywhere. And the only thing that has worked
4 for me at this point is the opioid medication. And of
5 course like everyone else here, I suffer daily. I am
6 I'm being reduced like everyone else, which is a
7 terrible thing.

8 I know so many people out there who are
9 suffering. I hear it all the time and I'm going to
10 advocate for these people, I've been writing and I
11 wrote to CDC as well.

12 I do have to say one thing really quick, Rose,
13 you said it all. What a wonderful, wonderful statement
14 for everybody, and I want to thank you for that. Rosy
15 Rose, I think, it was. I really want to thank you for
16 your comments, because it's so true.

17 We have so many barriers out there, so many
18 things and no doctor out there right now wants to
19 prescribe medication.

20 Now I'm getting half a dose of what I should
21 be getting. My doctor is only giving medication
22 because I actually went to my medical board and I

1 fought for it, and I fought hard. And I should not
2 have to do that as a chronic intractable pain suffer.

3 I have been told I will never get better, only
4 worse. I cannot get palliative care. They can't find
5 it. I live in a rural area. They won't take Medicare,
6 Medicaid. I'm permanently disabled.

7 There is nothing anyone can do for me. They
8 can't do spine surgery or any of those things on me,
9 because I'm so bad. My pelvic was split in half, a
10 vertical shear during the accident and of course, many
11 other -- multiple injuries.

12 And over the years I have gotten scoliosis. I
13 have no nerve impingement and many other things. I'm
14 not going to name them all. My list is like three
15 pages long for my condition. It's terrible and there's
16 no cure or help for me.

17 And the only thing that works for me is the
18 opioids. I've tried the Lyrica, the Celebrex. I had a
19 terrible reaction. I thought I was going to die. My
20 heart was beating so fast, I thought it was having a
21 heart attack from some of these other medications.

22 Some of them -- and these are all FDA approved

1 medications, mind you, I have allergic reactions to.
2 So I have allergic reaction to some of these
3 medications and I'm so scared to try new things when I
4 know what works.

5 Now I can't take every kind of opioid, because
6 or opioid, because some of them make me sleepy and I
7 don't want to be sleepy. I want to be out of pain and
8 I want to be able to function and just have a life.
9 Just any kind of natural life like anyone else wants to
10 have.

11 I don't drink alcohol. I've tried the medical
12 cannabis. And for me that doesn't work, other than for
13 my nausea. But for the pain it doesn't work, it's too
14 intense. My pain is just on a scale of 15 out of 1
15 through 10 and there's nothing anyone can do for me.

16 I've been turned away by physical therapists.
17 They will not touch me anymore, because I'm at a point
18 now where my body is just going downhill. There's no
19 more getting better. After 32 years, there's no more
20 getting better for me. It's only getting worse.

21 And now since these guidelines have come out,
22 every doctor on the planet here thinks that these

1 guidelines are laws. That they have to follow these
2 laws and they don't want to be busted by the DEA. So
3 every single patient -- every single patient is being
4 reduced in medication all the time, including
5 intractable pain sufferers.

6 I can't do physical therapy because they
7 turned me away, as I said. I go through these pain
8 clinics and they don't know how to deal with someone in
9 my condition so bad.

10 I've tried the shots. They don't work. I'm
11 back to major pain within hours and they say it'll be
12 three or six months, whichever shot they give me,
13 before I can get another shot. Nothing works.

14 And for a patient like myself and others like
15 me, we should not have to suffer. We should have
16 access to palliative care. I do my work with my
17 heating pad every day. I have to lay in bed on my
18 heating pad.

19 I do use the Naprosyn -- now the Naproxen or
20 Naprosyn, it does work for me for one thing and one
21 thing only. I have a severe swelling in my pelvic and
22 in my back, in my pelvic and when I don't take the

1 anti-inflammatory that actually gets to a point where I
2 fall out in pain and I can't move my leg. And it's
3 really bad. So they have permanently put me on the
4 Naproxen to keep the swelling down in that part of my
5 back and my pelvic area. I wear a prosthetic leg, but
6 I'm not like any other amputee, because my leg was
7 slaughtered so bad I'm missing 2 inches of bone in my
8 femur.

9 I have a plate and a bolt in there that's
10 holding it in place, because they did a bone graft back
11 in '86 and it did not work. They tried to grow the 2
12 inches of bone. So now I have a part of my back in my
13 -- it's called the iliac crest back of my pelvic that
14 they chip bone out of, that they told me wouldn't be
15 any problem, but it hurt so bad there too and a bunch
16 of shards of bone inside my leg.

17 I can't walk properly. So I walk like a
18 penguin when I walk. And I have been nothing but
19 strong my whole life going through this for 32 years.
20 I do everything I can. I stretch, I've tried to herbal
21 supplements and thing nothing else works. And when you
22 get to a point where even your doctor says, "You are

1 not going to get any better only worse." And that I
2 should be on palliative care, but I cannot get
3 palliative care. Then there should be something for me
4 out there. There should be a way to get these doctors
5 to say, "Okay, you are a case that needs this
6 medication," that's what they were made for.

7 And I hear all these stories out there and I'm
8 so sorry for everyone out here today. And thank you
9 for coming, but I'm so sorry that you're suffering. I
10 know this is hard. I've been here for hours too laying
11 on my heating pad and I'm in massive amount of pain. I
12 could not imagine being there today.

13 MS. CHALASANI: Thank you.

14 AUDIENCE MEMBER: And I'm very grateful for
15 all of you for being there. But I just want to say,
16 you know, what you do when you get to the point where
17 there is nothing else to be done and then they want to
18 tell you, you're an addict or if you don't request, as
19 one of the guidelines in the new addiction stuff says,
20 if they ask for a medication by name they're an addict.
21 So what if we have been on medication for 32 years
22 we've tried them all and we know which medication works

1 for us. Does that make us an addict or does that make
2 us a pain patient who is dependent on a particular
3 medication that works and actually allows them to
4 function.

5 MS. CHALASANI: Thank you.

6 AUDIENCE MEMBER: And that's really what we
7 need to look at here today. I'm sorry I'm very nervous
8 and I've been waiting a long time and I am --

9 MS CHALASANI: Thank you so much.

10 AUDIENCE MEMBER: A lot of people touched on a
11 lot of things that are so true.

12 MS. CHALASANI: Thank you so much, Lanette
13 (ph). We're truly grateful for you to -- for you
14 taking the time to watch us via the webcast and share
15 your comments. You may not have seen this, but there
16 were a lot of folks in the room nodding their heads and
17 your comments really resonated with everyone here. So
18 thank you so much. Thank you.

19 AUDIENCE MEMBER: You're welcome.

20 MS. CHALASANI: Thank you. With that we will
21 have to move -- okay. So I was asking you, so I'm
22 going to have to ask you just because we do have a full

1 open public comment, I certainly do want to go into
2 that. So go ahead.

3 AUDIENCE MEMBER: I promise.

4 MS. CHALASANI: Okay.

5 AUDIENCE MEMBER: It's commendable again that
6 the FDA is here and listening to us about the treatment
7 strategies and outcomes and barriers our community is
8 dealing with. With -- you asked about, one of the
9 things you just asked about was what happens when you
10 can't access. And so there's a recent closing of
11 dozens of pain clinics in Tennessee, Arkansas,
12 Illinois, Indiana, Kentucky, Mississippi, North
13 Carolina and Ohio. There have been estimated 60,000
14 pain patients who have just lost access in the last
15 week and a half to their pain care completely.

16 These patients are some of the most
17 complicated, infirm and medically fragile. Within the
18 next 30 days you will see a new burgeoning health
19 crisis appear. There will not only certainly include
20 sudden death in many of these patients, but also, an
21 uptick in suicides and increase in overdose and
22 addiction as a result. And this is sadly not the

1 exception lately and it's becoming commonplace. The
2 truth of the matter is and I said this before, until we
3 have the right amount of pain specialists being able to
4 treat none of these strategies are going to be helpful
5 to us at all that's all I wanted to add.

6 MS. CHALASANI: Thank you so much. We really
7 are out of time and I know we've such limited time and
8 we barely scratched the surface. And so this is where
9 I'm really going to encourage you to please elaborate
10 more in your comments as you submit them to the public
11 docket and please ask others from your community as
12 well to share their perspectives. I do want to take
13 this time to once again thank you all very much for
14 participating in the meeting today. I'd like to give
15 everyone in this room and those who called in and those
16 on the webcast a big round of applause. Thank you so
17 much.

18 (Applause)

19 MS. CHALASANI: We truly are grateful to all
20 of you here and on the web for so, so thoughtfully and
21 courageously sharing such personal thoughts and
22 opinions with us all today. We really admire all of

1 you. Thank you so much.

2 And so with that I would like to invite
3 Shannon to kick off our open public comment section.

4 OPEN PUBLIC COMMENT

5 MS. WOODWARD: Hi everyone. My name is
6 Shannon Woodward. I'll be moderating the open public
7 comment session. And it was great meeting some of you
8 this morning. The purpose of this part of the meeting
9 is to allow an opportunity for people to comment on
10 topics other than our 2 main discussion topics today.
11 This is also a chance for stakeholders other than
12 individuals with pain or their caregivers or family
13 members to share with us.

14 Just keep in mind that FDA won't be addressing
15 the comments that we hear during this session, but all
16 of the comments are being transcribed and part of the
17 public record. We'd like this to be a transparent
18 process so we encourage you to note any financial
19 interest that may be relevant to your comment. If you
20 don't have any such interest you may wish to state that
21 for the record. And if you prefer not to provide this
22 information you can still provide your comment with us

1 today. We've collected signups before the meeting. We
2 have 15 speakers signed up. Each speaker will have 2
3 minutes to provide a comment. I don't have a timer or
4 a buzzer like a game show, but what I will do is nudge
5 you very kindly once you get close to the 2 minutes and
6 just kind of urge you to wrap up to be respectful of
7 everyone.

8 Also, if I get to your name and you feel that
9 you've already shared with us today and you'd like not
10 to provide your comment just let us know and I'll move
11 on to the next person. So with that in mind our first
12 speaker is Rhonda Posey. Could you raise your hand we
13 could try to get a microphone to you, Rhonda Posey.

14 MS. POSEY: Good afternoon. My name is Rhonda
15 Posey. I'm here as a charter member of Arachnoiditis
16 Society for Awareness and Prevention. And although I
17 have adhesive arachnoiditis I speak on behalf of all
18 chronic pain patients. We would like to express our
19 gratitude to all those who have made today's meeting
20 possible. And most especially the FDA Commissioner Dr.
21 Scott Gottlieb for recognizing in his recent statement
22 that appropriate access to opioids may be the only

1 medicines that work for some patients including those
2 with adhesive arachnoiditis. In 2013, I'm sorry, in
3 2013 I had an epidural steroid injection using Kenalog
4 40 to treat lower back pain from a bulging disc. This
5 resulted in dural tear at L 4, 5 causing me to wake up
6 screaming during the procedure from excruciating pain.

7 Five months later I found out why my body was
8 trying to destroy me from the inside out when I was
9 given the horrific diagnosis of adhesive arachnoiditis.
10 Instantly I went from being an active member of my
11 family, church and community as an award winning master
12 gardener to struggling with pain I didn't know a human
13 being could live through. And now it's terrifying to
14 learn that new legislation House Bill 5804 has been
15 proposed to include potentially dangerous injections as
16 a standard of care for post surgical pain relief.
17 Highly credible research shows the risk is so much
18 greater for dural puncture due to the obliteration of
19 the subarachnoid space after surgery.

20 In 2016 Dr. Forest Tennant, began treating
21 underlying cause of my disease neuroinflammation.

22 MS. WOODWARD: Any final thoughts?

1 MS. POSEY: I'm sorry, what?

2 MS. WOODWARD: Any final thoughts?

3 MS. POSEY: I just wanted to add that as Gary
4 Snook (ph) had mentioned with the use of a complex
5 multimodal treatment plan that's why I'm here, I'm able
6 to even attend. And I will end with this. He's -- Dr.
7 Tennant's philosophy is, if you treat the pain
8 improvement in function and quality of life will follow
9 and I stand before you as walking living proof. Thank
10 you.

11 MS. WOODWARD: Thank you, Rhonda. We now have
12 Lynn Ashcroft (ph). My apologies if I butchered your
13 name. Lynn.

14 MS. ASHCROFT: My handwriting. Thanks. The
15 reason I'm here also is because of Forrest Tennant. As
16 one of the original research subjects 28 years ago for
17 CRPS been here, done that, everyone in this room who
18 spoke is touched on things. The current issue is the
19 fact that using the CDC guidelines as a whip to tell
20 people they can't get access to medication is no
21 solution to the opioid crisis. It's just hurting
22 everybody in this room and the whole country. And at

1 the end of the day what I resent most is that a
2 murderer in prison can get better access to medical
3 care than I can as someone who is self employed and
4 doesn't have to worry the same about being denied
5 medication.

6 Because what happens to everybody when we
7 don't get whatever our (inaudible) is, you go through
8 withdrawal, you're sick, and you hope you don't die or
9 lose your job in the meantime that's what happens. And
10 if you're lucky before either of those two things
11 happen you work through the issue your stuff comes that
12 was the old days. Now it's just deny and this is a
13 problem. So I hope that the 90 becomes a guideline in
14 fact, which means people need care and help rather than
15 a hard deadline where you cut them off. Thank you.

16 MS. WOODWARD: Thank you, Lynn. Now we have
17 Helen Sue Walker.

18 MS. WALKER: I know I am going to try to stand
19 out of the way of the camera. Hi. I'm Sue Walker.
20 I'm chronic pain patient and I'm the President of the
21 Richmond Fibromyalgia and Chronic Pain Association.
22 We're also a small organization with very little money

1 so I have no financial interests here. Thank all of
2 you for allowing so many of us to be here today to
3 speak about our experiences and concerns. And thank
4 you to all the courageous people who came out today,
5 many of you in pain to share your stories. I've been
6 moved to tears more than once today and it's just so
7 important that your voices be heard.

8 Like many others here have a laundry list of
9 pain issues that I won't go through. I'd like to add
10 all the good information already presented that
11 respectfully I believe the FDA and most everyone and
12 every agency tasked with battling the so-called opioid
13 crisis, which as others have said is more accurately
14 called a street drug crisis a Fentanyl crisis, are
15 going about it from the wrong end of the spectrum.

16 Pain patients aren't or never were the --
17 driving the crisis, we're just the low hanging fruit
18 for politicians, others. And with all the restrictions
19 opioid related deaths would be decreasing while the
20 reality of that is that they're still increasing. If
21 we were the problem that wouldn't be what was
22 happening.

1 We need to address the root causes of
2 addiction including finding the genetic markers that
3 render many of us able to safely take prescribed pain
4 medication for many years without becoming addicted or
5 constantly increasing our dosage. While a small number
6 of people may take a small amount of narcotic pain meds
7 for a brief time and will be driven to seek more and
8 still more to feed an addiction.

9 Out of the purview of your agency although it
10 shouldn't be as it's directly connected are the very
11 real society issues such as poverty that drive the
12 addiction crisis. We need --

13 MS. WOODWARD: Thank you, Helen. Any final
14 thoughts?

15 MS. WALKER: Yes. We need partnerships to
16 study and address the underlying causes of addiction
17 rather than punishing those who suffer from it, treat
18 them don't arrest them.

19 MS. WOODWARD: Thank you so much. Next we
20 have Sandra Flores (ph).

21 MS. FLORES: Hi. Just a small little tidbit
22 about me. I'm fundraised to get here. I'm out of work

1 now. For the past 2 years I was an ER nurse for 17
2 years active, loved my life and it was pulled from me
3 just like that. I had back pain and then I found out
4 that adhesive arachnoiditis we don't know where, how,
5 when or what. I'm losing everything from the waist
6 down slowly, but surely and it's progressing fast in 2
7 years. The way I've seen the medical field act the way
8 they act is an embarrassment to who I thought we were.
9 The entire 17 years that I was there faithfully giving
10 back to the community and literally giving my life to
11 give to others, letting my kids be home without me
12 during holidays as I helped people and I'm being
13 literally turned away. Not one doctor yet, one in 2
14 years has accepted me as a patient, because I am "a
15 liability" to them. That is the truth. I am being
16 thrown out with the trash. I am worth more than that.
17 Something needs to change. I have a diagnosis that
18 would be -- that -- I'm dying. I also have an immune -
19 - autoimmune disease because of the adhesive
20 arachnoiditis that's eating all my organs thinking that
21 they're foreign.

22 So I'm not -- I can't get on hospice yet,

1 because I cannot -- I'm not ready yet, which on which,
2 which I'm wishing to be ready but -- so I have to wait
3 and nobody will treat me. I'm -- I just can't even
4 think anymore just please give me my life back so
5 whoever you know, whoever can do it. Just give me my
6 life back that's all I'm asking. To be able to shower
7 myself. To be able to walk more than 20 percent of my
8 day and just this took 4 hours right here. I get up
9 and it takes me a 2 hour regimen just to get out of bed
10 of medicines. I don't take narcotics.

11 MS. WOODWARD: Thank you, Sandra. Any final
12 thoughts?

13 MS. FLORES: And then it takes 4 hours for me
14 to get dressed and I've learned how to get dressed
15 really well laying on my side. That's all.

16 MS. WOODWARD: Thank you, Sandra. We now have
17 the Thorna Klein (ph) Thorna or maybe it's Thomas.
18 Sorry, I'm struggling with -- thank you, thank you.

19 MS. KLEIN: It's all my in-laws. We're in the
20 worst healthcare crisis that I've seen in 40 years and
21 probably the worst healthcare crisis in the history of
22 the United States. We not only have people killing

1 themselves, we have 5 to 6 million people just like
2 these who are being tapered. So how do we deal with
3 this? Well, I'm standing before the only regulatory
4 agency with rulemaking for prescription drugs. Nobody
5 else can do that.

6 What I'm suggesting you do is a trick I
7 learned in Boston. Medicaid was having problems with
8 drug representatives talking doctors into prescribing
9 thousand dollar month drugs. So what do they do? They
10 sent out a counter detailing force that follow the
11 retailers to the doctor's office and they said, "Hey,
12 wait a minute, this is the real straight skinny." I'm
13 suggesting that FDA make its own manual. Not 100 page
14 manual from the VA. Not a 50 page manual from the CDC,
15 which incidentally had no indications for opioids.
16 None. Make your own manual like you would a label,
17 these are the indications, these are the side effects,
18 these are the good things about the medication. And it
19 might be an interesting thing to take input from other
20 people. I have a 20,000 people on Twitter and I ask
21 them questions and they give me answers. And that's
22 something you guys can do and develop a Wikipedia kind

1 of manual, use of opioids, opiates in acute and chronic
2 pain. Thank you.

3 MS. WOODWARD: Thank you. Next we have Kristen
4 Ogden. Kristen Ogden?

5 MS. OGDEN: Thank you. This time I'm speaking
6 as the co-founder and co-leader of Families for
7 Intractable Pain Relief. I will tell you very quickly
8 that Families for Intractable Pain Relief is comprised
9 of patients and family members of Dr. Forest Tennant.
10 You've heard him mentioned a number of times. There
11 are 9 families represented here out of his 150 patient
12 population from 8 states. This was that important for
13 us to be here. We, last month, had the opportunity to
14 meet with members of FDA's Professional Affairs and
15 Stakeholder Engagement staff and we presented a
16 specific recommendation that we think provides a
17 reasonable solution that could be implemented quickly
18 perhaps under FDA's Emergency Regulatory Authority to
19 start.

20 There is an urgent need to establish a
21 certification and registration program that would
22 authorize trained physicians to treat severe

1 intractable pain as needed without restrictions on
2 opioid dosing or duration of care and without
3 restrictions on non-oral routes of administration or
4 off label use of non-opioid medications.

5 This regulation should recognize that such
6 treatment as authorized would be authorized exceptions
7 to dose limits or thresholds imposed by CDC, Department
8 of Justice, DEA, Medicare, state laws and guidelines,
9 and insurers. Registration program would authorize the
10 filling of controlled drug prescriptions written by
11 certified physicians across state lines and it would
12 protect certified physicians for malpractice suits or
13 other liability provided the patient has consented in
14 writing to non-standard care.

15 It's our position that freedom from pain to
16 the extent achievable is a fundamental human right and
17 the withdrawal of readily available, effective, pain
18 relief is essentially torture. Our government is
19 torturing its citizens or allowing torture of citizens
20 who have done nothing wrong and when it continues and
21 continues and continues despite --

22 MS. WOODWARD: Thank you. Any final thoughts?

1 MS. OGDEN: -- the input from individuals, it
2 gets pretty close to homicide. And I mean that and I
3 hate to say it. But I appreciate the opportunity to be
4 here and I thank the FDA for its interest. Thank you.

5 MS. WOODWARD: Thank you. Next, we have Gary
6 Snook (ph).

7 MR. SNOOK: Thank you. I testified before the
8 FDA in 2014 about the pain that I suffer after I was
9 given an injection intrathecally and developing
10 adhesive arachnoiditis that that pain was beyond all
11 human comprehension. And as a pain patient I think I
12 can speak for almost everybody here; when I say that I
13 feel like a Jew in the Warsaw ghetto with no place to
14 run and no place to hide.

15 What I didn't tell you at that 2014 meeting is
16 that I am an outlier. I suffer from a genetic
17 variation called the CYP450239 that makes me metabolize
18 opioids quite quickly as well as prevents any other
19 modalities from working. And so I take a dose that is
20 several times higher than the CDC guideline because I
21 am a rapid metabolizer.

22 Now, when patients like me are forced into a

1 taper to the new guideline or are dropped entirely by
2 our doctors, who quite frankly are terrified to treat
3 people like me, we die. Just like my friend, Jennifer
4 Adams (ph), who was a highly decorated police officer
5 in Montana, who shot herself in the head after the DEA
6 raided her doctor's office leaving her, the love of her
7 life behind, her 12-year-old son.

8 MS. WOODWARD: Thank you so much for sharing,
9 Gary. Do you have any final thoughts for us?

10 MS. SNOOK: I do, I do. And so, on top of all
11 this Montana has seen a 38 percent increase in their
12 suicide rate, on top of leading the nation in suicide
13 rates in 2014. And most of this is because pain
14 patients cannot get treatment there. Only end of life
15 counseling and epidural steroid injections.

16 MS. WOODWARD: Thank you. Now we have Charity
17 Caldwell (ph). Charity Caldwell?

18 MS. CALDWELL: I'm trying to find my piece of
19 paper because I did have -- I know like I brought up
20 the kratom and I know that this is not just about that
21 in any way but it's what has worked for me for the
22 chronic pain and I do know the FDA's thoughts about

1 kratom has been in the news quite a bit and I have a
2 little bit of a different kind of mindset when it comes
3 to my opinion about kratom than even many of the
4 organizations that are here to represent the community
5 as a whole. And I did meet -- the first or second week
6 of June, I did meet with Senator Grassley's aide and as
7 well as Senator Feinstein's as part of a week-long time
8 that I was here. And in Senator Grassley's office they
9 specifically told my friend that was with me at that
10 time, that we needed to get an appointment with the FDA
11 and we have tried numerous times through e-mails to
12 request appointments and we haven't been able to.

13 So this is kind of the only way that I can say
14 what was so different about what we talked about. And
15 what sets it apart is I understand the scheduling and I
16 understand the concern because it is unknown. It's
17 been studied for over 15 years or at least 13 and a
18 half years, I know, by Dr. Christopher McCarthy. And I
19 understand there was a computational model done by the
20 FDA but it doesn't show what the science has shown in
21 the labs.

22 And so, my biggest concern is to make sure

1 that everybody is kept safe and I feel most comfortable
2 with being able to have access to raw leaf kratom, I
3 think that because in traditional use it is a chewing -
4 -

5 MS. WOODWARD: Thank you, Charity. Any final
6 thoughts for us?

7 MS. CALDWELL: Yes. I believe that it should
8 be regulated as a food product with the extracts made
9 as a Schedule 2 so they can continue to be a research
10 for potential medical uses by the community who's
11 already studying them. But I do believe plain leaf
12 kratom should be a food product so it can ensure that
13 it's safely handled and packaged for people to have
14 access to as a tool in the tool box.

15 MS. WOODWARD: Thank you, Charity. Now we
16 have Kelly Devine (ph). Kelly Devine? Is Kelly here?

17 MS. DEVINE: I have a terrible social anxiety
18 so pardon me if I stutter. I am a -- my name is Kelly
19 Devine and I suffer debilitating fibromyalgia, multiple
20 joints problems as you can tell. At one time I was
21 prescribed 13 medications, side effects of which left
22 me miserable, in pain, unstable, unable to function,

1 and suicidal.

2 About 4 years ago I began to research natural
3 remedies after I felt the medical field failed me with
4 their prescribed medications. That's when I learnt
5 about making herbal tea from dried kratom leaves.

6 Kratom is a tree that grows in Southeast Asia.
7 It's the same scientific --

8 AUDIENCE MEMBER: Family.

9 MS. DEVINE: -- yeah, it's in the same
10 scientific family as coffee and has been used for
11 centuries in that part of the world without a single
12 death ever occurring. Also in Thailand, they have
13 removed kratom and cannabis from the Schedule 1 list
14 and that just passed in Thailand.

15 While kratom does not cure or treat my medical
16 conditions, it does help greatly with my pain,
17 relaxation, and sleep difficulties. I've never
18 experienced negative side effects except for extreme
19 thirst. It makes you drink a lot more water. I have
20 been consuming kratom for almost four years. My
21 quality of life has improved. I suffer less pain.
22 There are at least 5 to 7 million kratom consumers in

1 the U.S., the number is growing. I'd also like to
2 point out that my Facebook group is just a group I made
3 up and we call it -- started out Kratom United. In 2
4 years we had 2,000 members, so that's 1,000 members per
5 year.

6 After the CDC regulation any change --

7 MS. WOODWARD: Thank you, Kelly. Any final
8 thoughts for us?

9 MS. DEVINE: Yes, ma'am. Since the CDC
10 regulations, our members shot up 5,000 people in less
11 than 12 months and I think that says a lot about what's
12 happening to the American chronic pain sufferers.
13 Thank you. And thank you for your time.

14 MS. WOODWARD: Thank you, Kely. Now we have
15 Grace Cabalan (ph). Grace Cabalan?

16 MS. GAVERO: Thank you. It's actually Grace
17 Gavero (ph).

18 MS. WOODWARD: Oh, thank you.

19 MS. GAVERO: Full disclosure, I am an employee
20 of Nuvectra Medical. Nuvectra offers spinal cord
21 stimulators for the management of chronic intractable
22 pain but I am here today as a patient. I was injured

1 in 1995 while serving in the military and I am
2 fortunate that my pain is managed with the chronic --
3 with a spinal cord stimulator that wasn't always the
4 case, unfortunately.

5 I was injured in '95, I suffered for many
6 years before spinal cord stimulation was offered to me
7 and I would like for the promotion of alternative
8 therapies you know to be -- for that to be offered to
9 patients as well. Opioids did not work for me and I
10 know that they work for many of you and I'm glad that
11 they do. Unfortunately, that wasn't the case for me
12 and I -- and that's not the case for many other people.
13 So we need to have alternatives and access to those
14 alternatives.

15 I've been a patient advocate for over 10 years
16 and I've had the -- actually the honor of speaking to
17 literally thousands of patients seeking relief. And in
18 answer to some of the questions that have been posed
19 today regarding suicide many, many, many of them have
20 told me in our conversations that if -- if the spinal
21 cord stimulator hadn't worked for them or if it's not
22 going to work for them, they were going to commit

1 suicide. Many of them had attempted suicide.

2 Also just the impact it has on their families
3 as well. Many of them were angry because they weren't
4 given any information about alternatives. They also
5 suffered for many years before being offered something
6 other than opioids. So just --

7 MS. WOODWARD: Thank you, Grace. Any final
8 thoughts for us?

9 MS. GAVERO: No, thank you. Just -- well,
10 just one final thought. Just keep that in mind that
11 there are alternatives. If the opioids work that's
12 great but offer something else as well. Thank you.

13 MS. PAPADOPOULOS: Thank you. Now we have
14 Steve Chang (ph). Steve Chang?

15 MR. CHANG: I am Steve Chang, I'm from New
16 York. I am an acupuncturist and a massage therapist.
17 Currently, there are three bills in Congress waiting to
18 pass to allowing the acupuncture as a treatment method
19 for the people, okay? So, we need your support and
20 especially the FDA okay, because the acupuncture is
21 mostly efficient hindering the pain issues.

22 I heard that today many people are saying

1 about their pain, okay? But from the way I see is
2 probably your pain is because of when you -- for
3 example, like an accident causing the pain, causing the
4 lower back pain but because you didn't get proper
5 treatment and you didn't take the proper action so
6 that's why you are suffering and then the situation
7 getting worse and then the -- you any how is looking
8 for the opiods for the pain release. And pain release
9 using the opiods is not a solution, it's just temporary
10 cover, your symptoms. So we should be looking for the
11 solution, find out what really cause the pain and
12 address it. And then the acupuncture, and also massage
13 therapy are the best ways to end it.

14 MS. WOODWARD: Thank you, Steve. Any final
15 thoughts for us today?

16 MR. CHANG: Okay. So, since the time limit,
17 all right. I am just urging that everybody we can
18 support these three bills to pass to allowing the
19 federal -- the Medicare and Medicaid and also the
20 health insurance for the veterans to accept the
21 acupuncture as the treatment methods. Thank you.

22 Ms. PAPADOPOULOS: Thank you, Steve. Next, we

1 have Yam Fan (ph). Yam Fan?

2 MR. FAN: My name is Yen, acupuncturist. I
3 represent my -- another patient Lisa Wood (ph). She's
4 40 years old now. When she's 17 years old she had a
5 shoulder surgery. After surgery she back started
6 chronic pain but didn't know why. After 10 years
7 later, they found it and note it acanthosis (inaudible)
8 disease. She pained every day and the spine fused
9 together gradually. Also is losing her rigid motion
10 much.

11 For the problem she takes anti-inflammation
12 pill and pain killer and anti-immune function pill
13 every day. Because of medication side effect liver
14 function (inaudible). After she -- 5 years or so boy
15 diagnosed with children arthritis now she started to
16 come see me. After, you know, take his son 2 years
17 later, his son is much better. He doesn't want his son
18 taking medicine. Last year I asked his condition, you
19 know, (inaudible) he do acupuncture for he back
20 problem, actually he tell me he get acupuncture before
21 and (inaudible), just a little help. I explained, you
22 know, my skill different from before he had.

1 MS. WOODWARD: Thank you so much. Any final
2 thoughts for us?

3 MR. FAN: Yeah, he's got, you know, much
4 better this year. Last month, he traveled 2,000 miles
5 from Virginia to Alabama, Texas, Florida barrier
6 regimen. Then he didn't feel like before he kind much
7 in pain. So he's really happy, you know. He want to,
8 you know, tell people but it's strange people didn't
9 believe her, you know. Actually, you know, acupuncture
10 is a good solution for most chronic pain but not for
11 everyone, but most. You know --

12 MS. PAPADOPOULOS: Thank you.

13 MR. FAN: Okay.

14 MS. PAPADOPOULOS: Next, we have Terry Lewis
15 (ph).

16 MS. LEWIS: Members of the panel, I want to
17 introduce you to the experts in the room. They're
18 right here. These people know more about what you have
19 to do than you do, okay? I am a care partner, I am a
20 social scientist, I am a clinical educator. I believe
21 in data and I believe that we are talking about the
22 wrong set of questions.

1 If we want to know how to better address the
2 questions that are before us today, we have to have
3 regular input. We have to widen our stance, not narrow
4 it. Regression to the mean is killing us, okay? We
5 need to look at all the data. The thing that has been
6 flowing through our conversation today is Ehlers-Danlos
7 Syndrome. That's a really important piece of
8 information for us. We can't medicate that away but we
9 can prevent a lot of injury if we understand that. In
10 my own family we're finding out that that's a real
11 issue. It's more common than we think we understand.
12 Opiates help but prevention is the key.

13 I have been surveying and talking to patients
14 for 5 years intensively because I am the parent of a
15 young man whose natural history I have followed up to
16 the point where he's 35 years old.

17 MS. WOODWARD: Thank you, Terry. Any final
18 thoughts for us?

19 MS. LEWIS: Yes. I would like to see FDA
20 institute regular communication with patients and
21 regularly begin to document what is being suggested and
22 what were there is to learn and to change the way we

1 ask questions about this process.

2 MS. WOODWARD: Thank you, Terry. Now we have
3 Amanda Proctor (ph). Amanda Proctor?

4 MS. PROCTOR: Hi, my name is Amanda Proctor.
5 I'm representing Cauda Equina Foundation with about
6 2,000 members and growing of Cauda Equina Syndrome
7 patients.

8 Cauda Equina Syndrome is a spinal nerve root
9 injury of the lumbar spine. It's very similar to
10 arachnoiditis in its chronic stage but if it's caught
11 and the first 48 hours and treated, if it's a treatable
12 cause, not all causes are treatable, it can be
13 completely reversed. Unfortunately, it's misdiagnosed
14 85 percent of the time, which is something we're
15 working on but that's not why we're here today.

16 We're here today because 85 percent of the
17 time Cauda Equina Syndrome progresses to chronic Cauda
18 Equina Syndrome, again very similar to arachnoiditis
19 with periods of neuroinflammation which cause flare
20 ups. This obviously causes intractable pain and
21 periods of acute on chronic pain, something that we've
22 mentioned where you have your normal pain and then you

1 have your flare up.

2 So, we have members that are saying I've just
3 stopped going to doctors. They can't help me, they
4 don't listen to me, they treat me like a criminal, they
5 treat me like an addict. That's what I am hearing from
6 2,000 people.

7 I have people that -- I have had emergency
8 phone calls at 2 o'clock in the morning, "Hey, we have
9 a member talking about suicide on the support group.
10 Can you call them? Can you intervene?" Now, I am a
11 licensed healthcare professional. I do not practice
12 because I physically cannot but I am legally obligated
13 to intervene and report suicidal ideology.

14 MS. WOODWARD: Thank you, Amanda. Any final
15 thoughts?

16 MS. PROCTOR: We have to do better at treating
17 pain. We have to have better treatments, we have to
18 listen to our patients, we have to have empathy and
19 compassion. And if we don't have that hang up the
20 white coat and get out of the practice.

21 MS. WOODWARD: Thank you. Next, we have a
22 Adriane Fugh-Berman. My apologies, if I mispronounced.

1 MS. FUGH-BERMAN: Hi, I'm Adriane Fugh-Berman.
2 I'm a physician and I'm director of Pharmed OUT which
3 is a Georgetown University Medical Center project,
4 research and education project that examines
5 inappropriate pharmaceutical marketing tactics.

6 My plea to the FDA is to please do more to
7 combat pharmaceutical company influence in drug
8 approval. Remember Oxycontin and the fact that the FDA
9 allowed the original label to imply that the
10 formulation was thought to be less addictive, more
11 recently abuse deterrent formulations, a term -- a
12 marketing term that should never have been allowed has
13 really created a lot of harm. 46 percent of healthcare
14 providers think abuse deterrent formulations mean they
15 are less addictive. They are not less addictive,
16 they're only slightly less convenient to turn into an
17 injectable form.

18 In terms of chronic opioid use there are
19 certainly -- they are appropriate for some pain
20 patients including many in this room but there are many
21 others for whom it is not appropriate. We continue to
22 overprescribe opioids in this country and opioids

1 continue to be over promoted.

2 In 2016, 1 out of 5 Americans received an
3 opioid and 1 out of 12 physicians receive payments from
4 an opioid manufacturer.

5 Pain does not protect patients from opioid
6 overuse disorder. And even beyond opioid use disorder,
7 opioids can increase cardiovascular risks and suppress
8 the immune system among other problems. They are
9 appropriate for some -- some things.

10 MS. PAPADOPOULOS: Any final thoughts,
11 Adriane?

12 MS. FUGH-BERMAN: Yes, just to say that
13 there's been some attacking of the CDC guidelines here,
14 they're actually very rational. I just wanted to read
15 one thing which is who would disagree with the
16 statement, clinicians should consider opioid treatment
17 only if expected benefits for both pain and function
18 are anticipated to outweigh risks to the patient.

19 MS. PAPADOPOULOS: Thank you, Adriane. I'm
20 now going to turn it over to Dr. Sharon Hertz for our
21 closing remarks.

22 CLOSING REMARKS

1 DR. HERTZ: Hi, all. Thank you for those of
2 you who have been able to stick out this very long day.
3 I know those chairs are not necessarily the most
4 comfortable plus all that you went through to get here.
5 Appreciate that effort.

6 Like I said this morning, your comments are
7 incredibly important to us. So, in addition to what
8 we've heard today, we're going to be reviewing all of
9 the comments that go to the docket. And in addition,
10 there will be a report from this meeting that's
11 ultimately made available on our website as well.

12 I just want to mention a couple of things that
13 we're trying to do to help. We have been writing the
14 New Opioid REMS, the risk evaluation and mitigation
15 strategy which requires manufacturers not to create
16 educational programs but to fund them from accredited
17 CME providers so they have no input in the content. We
18 have created the blueprint.

19 The blueprint has been changed from the
20 original, which focuses on how to use the drugs, to a
21 more comprehensive approach to pain management and
22 that's what's expected in those educational programs.

1 There's already -- there's also ongoing
2 federal efforts that will hopefully be helpful
3 acknowledging that we have to be extremely careful to
4 avoid unintended consequences. I just want to mention
5 that one of these efforts is the pain management best
6 practices interagency task force, which was established
7 and mandated by the Comprehensive Addiction and
8 Recovery Act known as CARA of 2016.

9 The task force will propose updates and
10 recommendations to address gaps or inconsistencies in
11 pain management best practices. The task force
12 includes a broad spectrum of stakeholders including
13 patients, physicians, and experts in pain research as
14 well as others.

15 We had the inaugural meeting in May, I
16 represent our agency on this task force and that
17 meeting featured patient perspective as well as public
18 comments early on in the proceedings. When the task
19 force completes its development the proposed updates
20 and recommendations will be available for public
21 comment. So, we're trying, we're trying to do what we
22 can to help. Thank you once again.

1 If -- well, for now put all comments into the
2 docket and if other things arise and you need to
3 contact us, there's a variety of ways to do that
4 including e-mailing our drug information people. They
5 provide me or others with comments directly and it's a
6 way to have a central focus for any kind of input from
7 patients outside. So thanks again, safe and hopefully
8 comfortable travels home.

9 I can touch base with you offline but
10 basically I was describing a task force that was
11 mandated by legislation that took place in 2016 but
12 I'll catch up with you. Thanks.

13 (Whereupon, the meeting was concluded at 4:10
14 P.M.)

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CERTIFICATE OF NOTARY PUBLIC

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



SAMUEL HONIG

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

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July 19, 2018

DATE

JIMMY JACOB

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