U.S. FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON PATIENT-FOCUSED DRUG DEVELOPMENT FOR CHRONIC PAIN

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WELCOME

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

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

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

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

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

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

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

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

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

MS. CHALASANI: Thank you all. And to my right, to your left, we also have Graham Thompson, Lila Lacki (ph) and Shannon Woodward who will be acting as webcast moderators and also our technical gurus, as you can see we're having some difficulties having our slides consistently stay live. So it will be going in and out but we're going to try to make this as efficient as possible and hopefully they will come back. Okay.

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

I'll explain the meeting format and the process at the start of those discussions. We have time set aside for open public comment later this afternoon. While the primary discussion is focused with individuals and families, the open public comment will give anyone in the audience the opportunity to provide a comment. To participate in the open public comment session, you will need to sign up at the registration table. Participation is first come first serve. The time allowed for each speaker will be 2 minutes.

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

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

AUDIENCE MEMBER: (Inaudible).

MS. CHALASANI: Sure.

AUDIENCE MEMBER: I do realize that

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

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

AUDIENCE MEMBER: Okay. Thank you.

MS. CHALASANI: Thank you for your question.

I will ask that at this time you please silence your cell phones. Thank you. This meeting is being transcribed and a live webcast is being recorded, both of which will be archived on our website. As you may have notices, there are a few media outlets also recording audio and visual. We appreciate that there is a lot of interest in our meeting today. We too believe that this is an important meeting.

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

OPENING REMARKS

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

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

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

And we've had about 25 of these meetings so far in different serious disease areas and every time it's been we just hear from patients. And I got to tell you every time we and the people who are experienced reviewers at FDA and her doctors learn something new. We learn stuff we didn't know about that disease even though we have -- some of our staff have treated patients with those diseases, we learn things we didn't know. We get insights about what it is really like to live with the disease and what would really be helpful in a treatment if a new treatment was developed. And these meetings really help inform our drug development and they help inform companies about what they should be trying to develop in new medicines to treat conditions where there really isn't a good alternative today. And frankly that's true for lot of diseases.

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

Although FDA does not develop new medical products we do oversee and advise drug product sponsors or -- and medical product sponsors in their development programs. We issue written guidance to them about what they ought to be doing in development programs and problems and mistakes to avoid. And we give them feedback and advice when they come in and request meetings on a specific development program.

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

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

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

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

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

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

BACKGROUND ON CHRONIC PAIN AND TREATMENT OPTIONS

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

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

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

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

Examples of nonvisceral pain include musculoskeletal pain or pain after orthopedic surgery. Neuropathic pain is due to primary damage or dysfunction in the central or peripheral nervous system. Examples of peripheral neuropathic pain include diabetic peripheral neuropathy or post-herpetic neuralgia. Examples of central neuropathic pain include pain after spinal cord injury or pain after stroke. In some cases chronic pain might be due to a combination of both neuropathy and nociceptive pain. Pain is complex. It may or may not be related to a specific disease or injury. Our focus for this meeting today is on chronic pain in general of any type, any etiology, any characteristic or any severity.

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

All of these pain-related characteristics and the terms mild, moderate or severe are often used both by patients and healthcare providers to describe the pain in different clinical settings. There are also other scales that are used for grading of the pain such as a zero to ten scale. However pain is a subjective experience, it is described differently by each patient and in each clinical condition. Chronic pain can have physical, social, emotional and functional impacts. Chronic pain can cause weakness, sensory changes, gait problem, difficulty with mobility, pain can result in sleep problem, pain can cause emotional stress, anxiety, depression or isolation.

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

How do we evaluate and assess chronic pain. As we mentioned, pain is a uniquely individual and subjective experience. The tests and imaging studies that we perform provide information about underlying etiologies and comorbid diseases. But these tests do not provide direct assessment of the pain. Different types of tests that might be done are neurologic exam, physical exam, different types of imaging studies, nerve conduction studies, but ultimately patient's input is the key factor in the evaluation and understanding of pain.

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

Cognitive behavioral therapy, stress

management, complementary and alternative medicine such as acupuncture, herbal medicine or biofeedback. Vocational rehabilitation and disability management are other important components in treatment of chronic pain. There are also different medical procedures available for chronic pain such as nerve blocks, pain pumps, spinal cord stimulator, peripheral nerve stimulator or different types of surgery.

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

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

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

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

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

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

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

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

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

Thank you for being part of this meeting today both in person and remotely on the web to share your experience and perspectives with us. And thank you for your attention during this presentation.

OVERVIEW OF DISCUSSION FORMAT

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

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

We will kick off each discussion with a panel of individuals living with chronic pain. We selected panel discussions from the pool of participants who indicated their interest at the time of their meeting registration and submitted summaries that address the discussion questions posted in the Federal Register notice. We identified individuals to reflect a range of experiences with symptoms and treatment approaches. We have four panelists for the first topic and I'll ask our topic one panelist to please come up front at this time. Thank you. After the panel speaks we will broaden the dialogue to include other individuals with chronic pain and family members here in the audience and on the web. The purpose is to build on the experiences shared by the panel. I'll ask a number of follow-up questions inviting participants to raise your hands to speak.

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

For transparency we request that at the time of your comment that you disclose if you are affiliated with an organization that has an interest in issues related to chronic pain or if your travel here today has been funded or if you have significant financial interests in chronic pain medical product development.

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

We will have some polling questions today as well. We ask that only individuals with chronic pain, family members or advocates respond. If you are in the room you will respond using clickers. Most of you should have received a clicker by now but if you have not received a clicker please raise your hand and Shannon will come around and provide you with a clicker. Thanks Shannon. For some questions, for the polling questions you'll have one answer, for others you may have multiple answers. You should feel a little buzz when you click, which means that our system captured your answer. And we'll have a few practice questions in a bit to make sure we're not having any technical difficulties. If your clicker doesn't work please just let us know by raising your hand again and we'll bring you another one. Web participants will also be able to answer the question through the webcast and I'll turn to our webcast moderators from time to time to summarize the results that we're seeing on the web. These polling questions are meant to be a discussion aid for today, they are not a scientific survey. For those of you joining us via webcast, in addition to responding to the polling questions you can also add comments through the web platform, there's a discussion pod. Although we may not be able to read all of the comments out loud today your comments will be incorporated into our summary report.

We also have a public docket that will be open until September 10th. I took a look at the docket this morning and we already have 973 comments received from your community and this docket will be open for 2 more months after the meeting and so we're really hoping that you'll add to the dialogue through this docket as well. We encourage you to share your experiences and expand on what we discuss today through this docket. And the docket comments will all be -- we will read all of them and we will include a summary of them in our report as well.

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

We are happy to see participants here today who represent health care provider research and medical product development communities. We believe the input we hear today will be important to you as well, we just ask that you stay in listening mode. Some of you may have requested to participate in the open public comment and we look forward to your input then. During the main focus dialogue we really are here to engage and hear from individuals with chronic pain and their family members.

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

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

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

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

Yeah, I think Graham is trying to advance my slides. Thanks Graham. We do want your feedback on the meeting. As I mentioned, we have evaluation forms outside on the tables. What we learn will help us to continue to design and implement patient-focused meetings that are useful to FDA and to individuals and their families. So please fill those out and we'll collect them at the end of the meeting. With that let's begin with a polling question. I'm always very nervous with the first one because technology, you know. Okay, so folks in the room please use your clickers. Where do you live? So if you live within the Washington, D.C. metropolitan area including the Virginia and Maryland suburbs press A. If you live outside of the Washington D.C. metropolitan area please press B. And you'll hear a small buzz, a short buzz if our system captured your response. If your -- if you don't get any buzzing please raise your hands and we'll bring another clicker to you.

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

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

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

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

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

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

MS. CHALASANI: Yes, you may be, correct. I think we may have set this to pick one, but there are some others later on where you'll be able to select multiple answers. But thank you so much for highlighting that point. Thank you.

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

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

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

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

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

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

I think we have one more polling question left. It's doing something new now, okay. What type of chronic pain do you or your loved one experience? Here you can check all that apply. A, cancer pain; B, postsurgical or posttraumatic pain; C, neuropathic or nerve pain; D, headache; E, orafacial pain such as mouth, jaws and face; V -- sorry V -- F, visceral organ pain; G, musculoskeletal pain such as arthritis; H, I don't know; I, other.

AUDIENCE MEMBER: (Inaudible) all --

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

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

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

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

TOPIC 1 PANEL:

SYMPTOMS AND DAILY IMPACTS OF CHRONIC PAIN

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

MS. PARTRIDGE: Shall I press the red --

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

MS. PARTRIDGE: (Inaudible).

MS. CHALASANI: Yeah, that looks good.

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

(Applause)

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

Wow, did I get one, adhesive arachnoiditis.

AUDIENCE MEMBER: Right here.

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

I fought my body to allow me to do even a fraction of what I was once able to do. The pain was excruciating and constant and one wrong move and it felt like there was a hatchet in my spine. Pain vary from jellyfish stings to a red hot poker being shoved into my hip. I missed some big events that year, weddings, funerals and countless functions. More difficult were the everyday things that I missed, being able to stand long enough to braid my daughter's hair, sitting long enough to eat Thanksgiving dinner with my family at the dinner table, the simple things that we take for granted. My husband took over, phenomenal man, every household chore, and my mom helped with errands and driving me to appointments. My children had to adapt to having a mom who is mostly bed-bound. Our lives were turned upside down but I fought, I fought my mind to accept that at 38 I was in fact disabled. I fought back tears as I ordered myself a wheelchair, an electric mobility scooter so that I could get out of the house more often only to find that I could really sit long enough to use them.

I fought for doctors to acknowledge how much pain I was in. I fought adrenal fatigue, exhaustion and episodes of intense sweating. I fought for a long-term disability. That first year I spent fighting for many things but mostly I fought for treatment. I fought side effects from countless medications and therapies that my doctors prescribed, none worked. I fought to change my diet, and I have a gallon Ziploc bag filled with bottles of supplements that didn't work.

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

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

(Applause)

MS. PARTRIDGE: Thank you. I then fought the DEA who raided my doctor's office and accused us, his patients, for trafficking drugs. I will never be pain free but with these medications the pain is manageable enough that I can usually leave the house for an hour or two without having to lie down. I still suffer, I will always suffer from debilitating pain that will never go away. I'll never work full time again. And I still have bad days where I miss events but on good days I'm able to live again. But I still fight, I fight the stigma of being a pain patient, a stigma that nearly cost me my life.

(Applause)

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

(Applause)

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

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

(Applause)

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

(Applause)

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

(Applause)

MS. PARTRIDGE: Thank you. Our lives literally depend on it and some day yours could too. So members of the FDA, will you stand and fight with me, with us because as Americans we have the fundamental rights of life, liberty and the pursuit of happiness, and the last time I checked those rights don't exist if you have a certain medical condition.

AUDIENCE MEMBER: So true.

(Applause)

MS. PARTRIDGE: Thank you.

MS. CHALASANI: Thank you, Amy. Thank you. Next Katie.

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

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

I have a neurological disease in which excess pressure is put on my brain causing nerve, muscle and joint pain in my extremities. In addition I have Ehlers-Danlos Syndromes, a connective tissue disorder which also impacts my joints upon many other bodily functions. It is very under-researched and very misunderstood by the medical community. I have chronic pelvic pain and interstitial cystitis, a very painful bladder condition that basically feels like a 24/7 UTI, 8 years. Burning, irritation, frequent infection and generalized pain. And I was diagnosed with Lyme disease officially along with several parasites or co-infections. In late-2016 after many years of valiantly and persistently fighting for answers my pain is not managed by over-the-counter drugs, my pain is not intermittent, my pain has kept me up at night for most of my adult life.

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

(Applause)

KATIE: Regardless of the cause it is there, it is debilitating and it is so all-encompassing that it is very difficult to manage effectively. As a young adult who has spent the majority of my adult life bedridden I would love to be able to have an active and fulfilled life but I can barely drive to my appointments let alone anywhere else without immense dizziness and writhing in pain. I managed to graduate college but often had a very difficult time feeling well enough to attend class. As no one understood what was going on for so many years it became very easy to blame myself for feeling so sick. I also developed severe anxiety. Many of us with chronic pain feel like we could be trying harder. And it's important to remember that no one can make that determination or observation for us.

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

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

(Applause)

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

(Applause)

KATIE: They often proceed to handle the issue by sending patients into psychiatric treatment instead of tackling the underlying cause. I went from being able to attend class occasionally to strictly bed bound these past 2-1/2 years. Our system needs to change if patients want to have a full and sustainable life.

(Applause)

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

MS. SYDNOR-CAMPBELL: Good morning. My name is Tien Sydnor-Campbell and I have rheumatoid arthritis, osteoarthritis, osteoporosis, bladah, bladah, bladah (ph). My chronic pain is both nebulous and rebellious. It doesn't have a specific daily routine or even an hourly location. It roams to different parts of my body like a nomad. Let me give you an example. I can start the morning with incredible pain in my feet so much so that I stay in bed for as long as my bladder allows. If I'm lucky the pain won't start wondering yet, if not something like my back or my shoulder or my neck is singing the blues. It ranges in intensity just as much it ranges in location. The only range I don't have is of motion. Of course I have some areas that are more frequently affected. That be my wrists, my neck, low back, my legs. I got bilateral knee replacement so luckily my knees don't affect me as much as they used to. My right foot is currently broken because, well, my feet don't always do what they're told to and I was trying to walk up the steps in my house. I've fallen like four times but this is the first time I broke something. Lucky me. Most significant mobility symptom I experience is that range of motion but it happens in any joint at any time. I can start eating dinner and before I'm done I might not be able to hold the fork because my fingers hurt so bad or my jaw might get that little bit of searing pain that's like an arrow shooting right through the TMJ joint to the other side of my head. So I have to stop eating until something goes away.

Chronic pain has completely changed my life and I'm still adjusting to this new existence 8 years into my diagnosis. I was used to doing stuff all the time. Physically I can't do 75 percent of what I used to. I used to be a massage therapist, nowadays I can barely rub lotion on my own hands let alone anyone else. So I bet you're wondering what activities I can't do anymore. I used to be a competitive swimmer, spending hours in the pool was second nature to me. Used to ride my bike 22 miles a day round trip to work, that as a teenager then even as a young adult, as a parent, as a wife. I was still working out. I was still doing this at 40. In fact I completed my first triathlon at the age of 40.

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

No more softball with my coworkers, no more dancing with the hubster, no more attending every friend and family gathering, walking and running gone. Putting on my swimsuit was such a painful experience that it left me in tears several times before I had to give it up. I don't even wear pants with zippers anymore because, you know, pained fingers and zippers they are like that kids in that commercial that says "Oh no, oh no, we have a situation."

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

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

(Applause)

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

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

Then there is the pressure, tight, hard pressure. Like a tight Spandex band has been wrapped around my upper arm and across my left shoulder and chest; a strange heavy feel to it. Well with this, I have skin sensitivity that creates a shocking sensation when anything touches me; there is an electrical shock similar to being zapped by an outlet. It makes wearing clothing difficult. I look for the lightest weight shirts I can find. I have to use a skin numbing spray before getting dressed to help erase some of this.

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

"Pain also consumes your thoughts. When I am sitting in a room with family, the family maybe watching TV and enjoying a movie; however, I am thinking about what I can do about my pain. What will make it better? I am thinking, I should get another pillow and put it under my arm. Maybe I should try the heating pad again. I bet my pain rub is wearing off again. My breakthrough meds are not helping me right now, God, why can't I get this to stop for just a few minutes.

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

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

"You may think that makes no sense, how was creating more pain going to help. Have you ever bit down on your lip when something hurt really bad? That is your subconscious way of dealing with the pain. If your lip hurts from you biting on it then the other pain just does just does not seem as bad. My pain is so severe my mind thought the only way to cope with the pain was to slam my body on to a hard surface at 65 miles per hour. I thank God doors are really hard to open with 65 miles per hour wind pushing on them. Thank God my husband thought fast enough to grab my arm and slam on the brakes.

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

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

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

(Applause)

LARGE-GROUP FACILITATED DISCUSSION ON TOPIC 1

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

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

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

And we have this polling question open for the folks on the webcast as well, so please feel free to respond through the webcast platform, thank you. Okay. We have a range of perspectives in the room. We have 75 percent of you indicated that your pain -- you always have pain and the intensity changes over time. 57 percent indicated that your pain appears suddenly. 40 percent for, my pain appears -- sorry, suddenly for 57 percent and then 40 percent subtly or one of the other options that I can't see right now. Sorry. I can't memorize all of that that fast. So can we have a summary of what we're seeing on the web, Graham?

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

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

MS. SYDNOR-CAMPBELL: Hello. Hi, I have pain all the time but I have -- which Dr. Lewis explained to me, the best way to explain it is metabolic storage disorder, hypercalcemia from sarcoidosis. So sunlight turns into calcium in my blood system; 20 minutes, I'm in agony; a few hours, my vital organs calcify. So basically I can't go out in the sun, and it's very limiting. I have other problems from sarcoidosis but that's the worst. So one of the things that everyone enjoys, the sun, I cannot enjoy. Not only I cannot enjoy it, it could be fatal to me.

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

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

(Applause)

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

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

MS. CHALASANI: Yes.

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

MS. CHALASANI: Okay.

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

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

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

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

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

MS. CHALASANI: Yes.

AUDIENCE MEMBER: And what a lot of medical professionals don't realize is when you live with chronic pain you can be in severe pain but physically look okay. You learn to live with a higher level of pain.

(Applause)

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

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

(Applause)

AUDIENCE MEMBER: Thank you. I have lost lots of friends due to the -- my chronic pain because they don't know how to deal with the changed person that I've become.

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

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

MS. CHALASANI: Sure.

AUDIENCE MEMBER: That right now we're medicated.

MS. CHALASANI: Okay.

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

MS. CHALASANI: Okay. Let me ask one more question then on this topic. By a show of hands, how many of you will experience severe pain by the end of the meeting today or at least by the end of the day, when you go to bed tonight because you're sitting here for many hours. Okay. Thank you so much. We understand that this -- this required a lot of effort and time and courage from all of you all to be here today. So, thank you so much for coming here. Could we have the next polling question, Graham? Or I'll read it.

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

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

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

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

AUDIENCE MEMBER: I would just like to say first of all that little scale with the smiley face. I hate that. And I tell the doctor you have a glass of water and it's half full. I have a 5 gallon bucket and it's running over the top. It's -- I have adhesive arachnoiditis, by the way. But it's just stupid and the degree of pain that AA patient suffers. Well, we'll die without care and the most irritating thing for me is no doctor knows what we are and how to treat us and -- or will treat us. And so, it's impossible to get diagnosed and to find care. And they just got rid of the only doctor in the United States that is doing research in our -- our disease. The only doctor in the world.

(Applause)

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

AUDIENCE MEMBER: Is it working? One thing I would say is with the -- you know pain comes on -- comes on suddenly, when you can't predict what it's going to do. And with the restrictions that have come into play with the rapidly acting medications, and which, you know, need to be -- you know, need to be used, you know, carefully. Of course like the, even the breakthrough meds or just the -- even the turf type medications, there are people just like with cancer that you know, even if they don't have cancer that, you know I mean, it can basically ruin your whole day. And what would be something that's not that bad just you know spirals into -- you know, you have something that, you know, just beats it -- you know, keeps on beating into itself, but if it was stopped earlier, it would -- had been a, you know, a non-issue and I think that's --

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

AUDIENCE MEMBER: Thank you.

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

AUDIENCE MEMBER: Hello. My name is Lynn and I'm one of the original research patients for 28 years for CRPS and RSD. And recently, I discovered I had adhesive arachnoiditis. And only one man in America would treat me. Because I went and I looked. Because we stopped doing the research. You want to know about the pain? For 28 years, I was deeper undercover than Deep Throat because if I admitted how sick I was, even though I went to work, I wouldn't be able to get a job because the discrimination against a contractor with chronic pain. I wouldn't be able to buy the meds that brought me enough relief, so that I could do my job. And every day the prayer was, I could just continue to work so I wouldn't be a burden on my family.

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

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

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

MS. CHALASANI: How much time --

AUDIENCE MEMBER: -- how much time you spend in pain, one of the aspects that doesn't get talked about with pain but contributes a lot to stigma is that people lose contact with the normal life continuum of benchmarks. That is for young people they enter employment, if you have chronic pain you don't enter employment. You can barely get through high school and college. If you are getting married or your friends are getting married you're not getting married because you can't keep relationships long enough.

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

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

AUDIENCE MEMBER: Hi. I have a 16-year old son and mine is the predictability that he was feeling it's predictable that I'm going to be in bed 80 percent of every single day. And he's -- was filling out his first application to get his first job and he didn't put me down as a contact, an emergency contact. Because he knows I can't be there for him. And that's the part is he knows, he asks, "Mom can we go for my driver's license? Do you think you'll be okay that day? What time is your best time? When can we go? What -- how many hours you think you'll be out of bed that day?" That's my problem is that he knows, 80 percent of the day. And all I think we have here is the only solution for Arachnoiditis is just palliative care and that's all we want; to have a life. Just give me my life back that I lost so I can build memories and that's all I want.

(Applause)

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

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

And I have just randomly fallen. What if I was holding my child -- my child or my friend's child? I've dislocated a shoulder, I've broken my wrist, you know, I've gotten hurt from falling. What if I did that with my own child? What if they're running out in traffic and I can't chase them? So that's what chronic pain took from me.

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

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

Anyway I had to find another doctor. Nobody will take over another doctor's prescription. I went to a pain management doctor who said, "Well, I'm going to start weaning you down because they're on my back. I got to fill out a lot of paperwork." Your -- and I'm not even close to the level, there's a number 90, whatever it is. I'm not near that. I am maintained on a normal nice dose, I guess, whatever -- however you want to say it. But this doctor said, "Well, if you don't like the way I'm weaning you, go find another doctor." So I go find another doctor and he says -- "Oh, I" -- you know, my doctor's gone. What do I do? Cold turkey. Put me -- what am I supposed to do? And every single new doctor I went to said, "We will not do this because of the paperwork the FDA and the CDC makes us fill out." We are not -- DEA -- whoever it is. But I have doctors telling me, "I don't want to do it because of the paperwork." I also have cancer, it's a chronic cancer. My oncologist says, "Your pain isn't coming from your cancer, so I'm not going to prescribe it because of the paperwork I have to fill out involved." This is disgusting, it's so disgusting.

MS. CHALASANI: Thank you for sharing that really important perspective. And in the afternoon we'll really be probing and hearing more about some of the challenges and barriers that you have in accessing your preferred or optimal therapy. Specifically, what may have changed over the past few years as well. But want to turn to the webcast really quickly and just see what's happening on the web. And see if we can get a summary.

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

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

DR. HERTZ: Sure, I am sorry. Hi, once again Sharon Hertz. And I'm the director of the review division that reviews new drug applications for analgesics including opioids and also is responsible for overseeing some of the post marketing information that we get about opioids. And what I would like to hear about -- not even necessarily right now but some of the comments about access, and I believe we will get into that more. I think we need to hear more about, not just from you, but from others that you might know and any consequences from that. So there's today but also you can write in to the docket. And it's very powerful to have the written statements on the docket.

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

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

MR. THOMPSON: Okay.

MS. CHALASANI: So the question is, what are the most bothersome impacts of your chronic pain on your daily life? And we've touched upon some of these already. We are going to ask you to please choose up to three impacts. And we did question it so that -- that was intentional, we do want to really find out what those most bothersome impacts are. It's all of the above -- okay, okay, okay, all of the above. Okay. It will only -- actually the system will actually only capture three as well, even if you were to select all of them. But we have it noted, all of them, all of them. And I will read them out loud to you, since -- okay, we have we -- okay, sorry just if you could wait for a microphone to come to you just so that folks on the web can also.

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

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

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

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

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

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

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

So 69 percent of you indicated the ability to participate in or perform activities as being a bothersome impact, or not being able to. One thing that we read in comments is that even -- it's not necessarily the physical ability to participate that's impacted but it's just the fear and the anxiety that you're going to experience chronic pain that you don't -- you don't even have the -- you don't even try to do some of the activities and so forth. I'm seeing head nods. Does that resonate? No, not necessarily with everyone? Could we get a microphone? Thanks.

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

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

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

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

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

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

AUDIENCE MEMBER: Hello everyone, I'm a caretaker, my daughter has sickle cell disease. So some people -- it hasn't been an onset for her, she's had it since birth. And we go back and forth about "Why don't you get your driver's permit." Well, she has anxiety, she could have a sickle cell pain crisis any time. So you know for the normal things she hasn't experienced family, and a boyfriend. Because, what if we go out and I have a pain crisis while we go out dancing. So, but one of the things I also wanted to say is, you all are not addicts, you are not standing in a corner scratching and digging, you don't have -- you don't have, you know, tracks up and down your arm. You are real people with real symptoms. And as a caregiver of someone who has had sickle cell disease her whole life I think I know better what she needs if she's in pain or not, rarely, and how extreme it is. And when we go to the hospital with our loved one and we tell you they need this, they need that because they can't speak, because they are in so much pain, listen to us.

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

And can we please have some fast-acting medicine. The only pain medicine if she doesn't take oxycodone, tramadol and naproxen at home is morphine. And I have to go through 4 phone calls before I can get through to someone to tell me, it's okay to bring her to the emergency room to get morphine. And it takes five doses for her sickle cell pain crisis to get to a level where she can speak to me. So if you guys can come up with something better, please do it.

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

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

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

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

MS. CHALASANI: Thank you, Joe. Thank you so much for that comment. Okay sorry, if you could just wait for a microphone just so that folks in the webcast can also hear what we're saying in the room. Thank you. I think we have one comment. Go ahead.

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

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

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

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

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

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

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

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

MS. CHALASANI: Thank you, thank you. You raise a really -- a really important point. And we do want to hear all of your experiences with everything that you're using to manage your chronic pain. And we really will elicit some of those perspectives more in the afternoon and really hear from all of you so that it can inform our work and those of other federal efforts as well. I see a comment all the way in the back.

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

A good day is to be able to have a

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

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

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

MS. CHALASANI: Okay, thank you, Leila. And for those of you on the web there were a lot of folks in the room nodding -- nodding their heads. So your comments really resonated with them as well.

Graham, do we have any phone callers? Okay should I just speak to the operator then. Okay. Operator, can we have our first caller please.

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

MS. CHALASANI: Susan.

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

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

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

(Applause)

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

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

AUDIENCE MEMBER: Thank you. Today, I'm here as a patient. I'm fortunate that my pain is now managed through spinal cord stimulation. But I remember when I was there -- and disclosure, I do work for a spinal cord stimulator, a medical device company, Nuvectra. But when I was in the throes of it, a good day was, with a fistful of medication, maybe I was functional just getting around. A bad day, it hurt to breathe. And one of the things that I wanted to address on the -- answers were the -- it was on question A. Could you put that up again? Or -- and the answer was an overwhelming on A. One thing that I think hasn't addressed and I would like to see if anybody else experienced this that I had two options. I was either in such excruciating pain that I couldn't participate in anything. Or if I took enough medication I could participate but I was in such a fog I really wasn't there any way. Anybody else experienced that? Thank you. So, no fog? Okay, so I saw some hands and there are others that didn't so you're fortunate.

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

AUDIENCE MEMBER: Thank you. I will say to start with that I'm here wearing two hats. I'm the wife, 45 years, of a severe chronic pain patient; who would be here today except that he's experiencing severe muscle spasms in his back and so he had to stay at the hotel. So, I'm responding on his behalf.

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

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

We attended European FDD (ph) for fibromyalgia in 2014 and he stood up and told you at that time that since he went on high dose opioids in 2010 he has had the best quality of life of his entire adult life. So far we have continued to be able to obtain medication he needs. But over the last year there have been many points in time when we were not sure that would be the case.

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

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

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

In addressing your question about being able to predict when we're going to be in pain or what triggers. Ehlers-Danlos Syndrome are one -- are somewhat unique in the medical world in that they cause both chronic pain and acute pain. And so we know that we're going to be in pain on any day or night that we're living. However, certain activities will cause acute injuries or acute pain. We can't always predict that. I might be able to give my son a high five one day and be fine. I may, another day, give my daughter a hug and have my rib go out of place. I may wake up one day all put together and I may wake up another day and my hip joint is out, it's dislocated. And my husband needs to help me put it in before he goes to work. And so some things we can predict some things we can't.

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

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

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

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

AUDIENCE MEMBER: Sorry. I think one thing that's really upsetting is what Amy said trying to be a mom. I've always been a disabled mom. My sons only know me as a disabled mom. I passed this on to my son. He also deals with chronic pain. He has a Chiari malformation. And what are we sending -- what message are we sending to our children when we are fighting for pain control and can't get it. Our doctors are looking at us saying, "I don't want to risk going to jail, so I want to reduce your dose." What does that say to my son? What hope does he have? And there are many Ehlers-Danlos children. And I just --

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

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

People in rural areas are desperate. They have no one. And when they're told there's no one they can't go anywhere when it's 4 and 5 or even 2 hours because they can't make the car trip. So they suffer in a single room alone from every one. And when you ask the question of how many years people are in pain. Imagine that for 3 years, 5 years, 10 years, 15 or more years.

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

But those who have medicine are terrified. It's going to be taken away at the next pharmacy visit, at the next doctor's visit, at any possible moment. That they go to their doctor's office and it's shuttered. So there's that panic that's there. And the people who have pain and aren't treated, you can't get treated for anxiety if you have anxiety due to your pain condition or due to just being terrified at the climate that chronic pain patients are in right now. And it's just really important for people to understand that and glad for you to listen, but what is the actionable event that's going to come out of this that will help pain patients because we need more than listening, we need action, we need it now with people dying, people terrified and people being tortured by their life. Thank you.

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

MS. TAYLOR: Hello, I'm Amy Taylor and as I said at the beginning, I'm with the division of Pediatric and Maternal Health. And I realize that the question where it was asked whether you or your family member is under 18, that was zero in the room, but I would suspect there are some people on the web and I have heard that there are some people who have had their pain from the time as a child up into adulthood. So we would be interested in hearing about the same questions, but from the perspective of children under 18. So either into the docket or if you have some comments here, both on topic one and topic two, so that we have a better understanding as we're developing treatments for pediatric patients.

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

AUDIENCE MEMBER: I'm actually 25 now, but I've had sickle cell my whole life and just as a kid being able to play with your sibling or your other friends in the neighborhood such as playing in the snow, can't do it. Just being able to live, period. As a child it's hard to deal with not being able to fully explain your condition to your friends to make them understand that it's not that I don't want to do it, but the result of doing it as my mom said, laying in the bed and having to take morphine five doses before out of the plane, I can't even tell my mom everything that's going on. Then going home after and the next two or three days on pain meds. And basically just lying in my bed, sleep and then as an adult you have your cycle and that increases the pain because you're losing blood and the more blood you lose, of course a crisis comes. So now birth control and using birth control of course gaining weight with that and being able to figure out a diet around it is a challenge.

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

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

AUDIENCE MEMBER: I'm 43 years old today.

AUDIENCE MEMBER: Happy birthday.

AUDIENCE MEMBER: Happy birthday.

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

MS. CHALASANI: Thank you for sharing that. Folks on the web, just really quickly, are we hearing anything regarding the pediatric perspective perhaps or the young adult, adolescent perspective?

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

AUDIENCE MEMBER: Okay. Thank you. Leila.

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

MS. FARRELL: Hi. I'll try to be fast. My name is Marianne Farrell (ph). I'm here for myself, suffering chronic pain after 34 years from two car accidents. I'm here representing my support group, Chronic Pain Support Group, for the American Chronic Pain Association which I ask all of the people in the panel up here, go online and find the American Chronic Pain Association. We are trying to help people like all of us here with pain. My life has been turned upside down by chronic pain. I've been in a Psychiatric Unit of a hospital for two weeks because of suicidal thoughts because of my pain. I had to give up my profession which was a music teacher. So it effects not just me, the people in my support group, it effects my families, my children, I hear all of you, I feel for you, I may be one of the older people here. It's been a lifelong struggle. Nobody ever heard of fibromyalgia when I was found and diagnosed with it. So I want to thank you for having this meeting, thank you for listening to me and I appreciate everybody coming.

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

I also do want to just touch upon one thing, topics that we're talking about today are sensitive and one of the topics that we heard about and may talk about this afternoon is self-harm or suicide ideation. We want to remind you to seek any help if you need it. We've the information for the national suicide prevention hotline on our slide, which will come up shortly and so we just wanted to put that out there.

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

LUNCH

AFTERNOON WELCOME

MS. CHALASANI: If I could ask that all of you please take your seats. Thank you. Thank you. So we'll now be kicking off our topic two discussion and similar to how we had our topic one, we'll be kicking it off with comments from a panel of individuals living with chronic pain and then we'll go back into that large facilitated dialogue format and then ask for folks in the audience and on the web to add to the questions that we're asking. Topic two, we'll really focus on management approaches to chronic pain.

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

I do want to make a couple of housekeeping announcements before we get started. One is we have a somewhat of a fix for our technical issue that we were having. We were able to get an in room projector. The pro is this should work and be consistent, the con is we won't be able to see it on the side screens or for our panelists up here, you won't be able to see it on the televisions, but this should work.

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

TOPIC 2 PANEL:

PATIENTS' PERSPECTIVES ON TREATMENTS FOR CHRONIC PAIN

MS. LINDSAY: No pressure, right, after lunch, it's great. As you said, my name is Lindsay and I am 33 years old. And basically every day the back of my head feels like its burning. In 2012 I was involved in a car accident and left with chronic head pain and a mild traumatic brain injury. Since that time I've gone on to have two additional concussions. They always forget to tell you that after you have one, it's very easy to get more. So a lot of my treatments are weighing the side effects of medicines versus the effects of having multiple brain injuries. I just feel like in my journey as so many others here, when I started, I kind of started on all the normal drugs they do.

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

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

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

I decided to try ketamine and for me it is what kind of keeps me going each and every day. I'm at a clinic where they've been doing it for probably 10 years and I know that there're also a lot of chronic pain patients who are also doing this throughout the country as well. Let me see what else I've got here.

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

Last year, I live in Atlanta, and I was in Atlanta traffic and somebody just plowed into me, back of my car. And so my pain went up, obviously I got another concussion and in those moments my pain physician at the time decided that he wanted me to go back on high dose morphine for weeks and I said, no, please say I'm not against opioids at all, I do take one every day and it starts with an N and it's very helpful for managing the day to day chronic pain. But for me it really was that morphine affected my judgment and it made me feel numb. I was really surprised to find out that when I decided to push back instead of then dealing with the situation, I was discharged.

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

So I can afford a lot of the drugs or have access to a lot of the drugs that many of you do not have access to. I can also afford things like acupuncture, chiropractor, physical therapy, occupational therapy, speech therapy, you name it and those are things that are off limits for a lot of people. I think that if the FDA, you're going to walk away from this and me and like, what can we do short term and long term. I think short term one thing that you can really do is to look at the drugs that are already out and see if they could have a use again instead of having to spend millions and billions of dollars creating new drugs, looking at things like ketamine that have been around for so long, but maybe Big Pharma doesn't want to do clinical trials on them because it's a generic drug and they can't make up the money that they spent on the type of exploration.

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

And so there needs to be more of a discourse and more research done on medications and drugs that do not affect people in that way and allow them to work and allow them to do things like I did last week which is to run the Peachtree Road Race which is 6.2 miles and then go a few days later to go surprise my sister on her 30th birthday. Those are things for me that were not a reality even three days ago, three years ago, sorry.

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

MR. MAZAWEY: Yeah, thanks Meghana and thanks Lindsay. Thanks everyone. Oh, sorry. Yeah, thanks everyone here for all the stories and you know, makes you -- I always say to my senior people I have chronic pain, 15 years, so it's like -- you know, over almost a quarter of my life. And it's definitely a challenge, you know, I'm always in some pain, and I'm going to talk about how the medication helps me, you know, manage the pain and I'm fortunate like Lindsay to have a full-time job, but it is -- it's a real -- hearing the stories, I always say that it has always -- folks that you have to admire for what they deal with and so many of them are here today and I'm sure online as well, and so I appreciate everything you all do and are going through. So peripheral neuropathy is a kind of an odd -- it's a neurological condition, there are 100-plus causes of it.

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

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

It's very common for folks with peripheral neuropathy and I've always had fortunately good medical coverage like Lindsay at my job and so I was able -- I noticed sometimes they would put the dollar value of the prescription and I know that the Neurontin was like seven times more expensive than gabapentin. So initially I've had to increase the dosage over these years, so initially I was taking like 600 milligrams a day and now to get through I'm taking 1,500 milligrams a day. You know, and I try very hard to manage with that and not increase it although I know some PN patients take as much as 3,300 milligrams a day.

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

I do know, you know, in terms of the management that if I miss a dose, like I get busy at work and I kind of -- I keep the pills -- they're always right there, but even then you sometimes forget to take your dose every 4 hours. And within an hour or two, I will all of a sudden feel much more pain than I did before and obviously you kind of hit yourself on that, you know, how could I forget that. But -- and I've tried other treatments, I tried acupuncture, that didn't really do anything. Other folks have different experience I guess. I exercise regularly because it helps maintain, you know, the muscles that you still need to use to get around and I get regular massage which feels great, and it helps, you know, manage I think, you know, relaxes your muscles, and you feel more -- less tense generally.

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

And you know, in my nearly 15 years with neuropathy, there really haven't come any new treatments. There are some new medications, you know, LYRICA, things like that that are being touted for my -- for neuropathy, but my neurologist who's one of the gurus up at Johns Hopkins, which is another advantage of living near a place like that, says, you know, if this is the gabapentin that's working, it's milder, just stick with that and don't rock the boat is his advice.

So I welcome the FDA's efforts to evaluate and approve better treatment options for PN patients. If you want to learn more about PM (ph) -- PN, tomorrow's post, I mean a support group in D.C. and two of our members Lin (ph) and Robert Mogley (ph), are having an article published in tomorrow's health section which is the first, we've been pushing on this for years, and we -- in the support group until finally they are getting it published. So I think you might -- interested in reading their story. And in my other hat, I'm the president of the Foundation for Peripheral Neuropathy, which is a small nonprofit dedicated to peripheral neuropathy. We have a small staff in Chicago and the great website and for information about neuropathy, how to help yourself, medication, support groups, doctors and the like. So if you know anyone that has peripheral neuropathy, I recommend that to you. And thanks all for listening and being here today.

(Applause)

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

AUDIENCE MEMBER: Yeah. Thanks.

MS. CHALASANI: Next we have Rose.

MS. BIGGAM: Hello, I'm Rose Biggam (ph) and I'm here from the Seattle area where I worked at Microsoft for a little over 23 years before becoming disabled due to chronic pain. Full disclosure, I'm a member of the Alliance for the Treatment of Intractable Pain which is a advocacy group that has no money of any kind, accept no donations. We are self-funded and therefore broke always. And I am brought to you today by the wonders of Prednisone, so that's how I managed to get here from Seattle. Prior to my disability, I had something like seven major surgeries over many years, and each time I was prescribed opioid medications for post-op pain relief, and they worked. I recovered, I stopped taking the pain meds when my pain decreased, just like 99 percent of people routinely do.

(Applause)

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

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

(Applause)

MS. BIGGAM: Thank you. I've stopped dozens of medications due to insurmountable side effects like racing heart rate, sudden horrific sweats and flushing, blood pressure spikes, skin rashes, open wounds, meds that just knocked me unconscious, including while driving to work in which I caused a car accident when I was still driving to work. And I stopped a bunch of them because they just didn't work. I've tried the following intervention and modalities; cortisone injections in my hip, feet, back and neck. Don't recommend that ever. Radiofrequency ablation, my facet, joint nerve endings in my spine. Luckily my test was an epic fail, so they never actually did it for which I am grateful. Physical therapy, acupuncture, massage therapy, I still see an osteopath, aquatic physical therapy, yoga. I use a TENS unit and ice at home, and I have innumerable adaptive devices. I could afford all of those things because I was still working and like you had excellent health insurance.

And because I live in a metropolitan area, those services were available to me. But people in rural areas and with lower incomes don't have those luxuries. And now that I'm disabled, most of those are beyond my reach too. On my best days and with meds, my pain levels hover at around a 7 usually on a scale of 1 to 10. On bad days, I can barely move. My condition is progressive, there's no cure, it's only going to get worse. My biggest nightmare used to be that I'd be in a car accident or suffer some sort of injury and a paramedic would strap me in a backboard and shatter my spine. That was my worst nightmare. Now I wear a medic ID bracelet with all kinds of information on it. My new worst nightmare is being admitted to the hospital, being in agony and being denied pain relief.

(Applause)

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

(Applause)

MS. BIGGAM: Despite all that modern medicine has to offer, my pain is not well-managed. I should probably be on a higher dose of pain medication than I am now, but I can't be because I live in Washington State which led the country with the first opioid prescribing legislation back in 2009. The atmosphere in Washington State is such that most doctors won't prescribe pain medication to anyone. If you can find a pain specialist, you might be okay, but no primary care and no specialist will prescribe. It's so bad that Human Rights Watch in New York has led an investigation into the inhumane treatment of chronic pain patients in this country with a special focus on Washington State because it's that bad. It's medical torture.

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

(Applause)

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

(Applause)

MS. BIGGAM: We are now, I think all of us, forced to choose between getting your pain managed if you're lucky, and anything else which might bother you like anxiety or depression because God help you, you can't take opioids ever and you certainly can't take them with a benzo even though they have been prescribed jointly for decades.

(Applause)

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

AUDIENCE MEMBER: Yes.

(Applause)

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

(Applause)

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

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

(Applause)

HILARY: Unfortunately it seems I'm not alone. An 8 on my scale would be when the nerve pain is so bad it feels like all of my skin has been removed and my joints have been packed with a combination of glass shards and gravel. I have Lupus, fibromyalgia, narcolepsy, bursitis, arthritis and I could go on, but you'll be bored, so. So I guess on my scale, a 9, which I've never experienced, would be childbirth, and then a 10 would probably be like if your arm got ripped off and you pass out, so, yeah. Haven't been there. So I take opioid medication every day so that I can get comfortable enough so that I can actually go to sleep and I have narcolepsy. So, yeah, that's fun. I get dry needling done as part of my physical therapy, and that helps for a day or two. I do get cortisone shots into my trigger points and my back as well as into my joints. I've had my shoulders, elbows, knees, and hips done as well as into the muscles in my back.

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

I use ice packs and heating pads, including a mattress pad. That's like -- it's a heated mattress pad and it's dual zone, so I don't have to roast my husband. So that's a -- I recommend that for anyone married.

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

MS. CHALASANI: Okay. Tell them your version.

HILARY: Yeah.

MS. CHALASANI: So tell them about yours.

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

I think that chronic pain is a job in and of itself. I don't know how anyone can possibly work when they feel like this. I can't see. On a good day, I can volunteer at an animal shelter for a few hours. On a bad day, I can't get out of bed. You know, I might be able to meet a friend for coffee if it's a good day.

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

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

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

HILARY: Yeah, every month. Yeah.

AUDIENCE MEMBER: You have to go every month?

HILARY: Yes. Yeah. About 15 years ago I made the mistake of -- I actually had just gotten my pain meds for the month and they were on the counter and I knocked them over into the toilet and the cap was off. So I did get the bottle out and I just -- I couldn't deal with actually removing the pills from the toilet. It was just not going to happen.

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

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

AUDIENCE MEMBER: Yeah.

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

AUDIENCE MEMBER: (inaudible)

HILARY: Yeah. Yeah, you --

AUDIENCE MEMBER: (inaudible)

AUDIENCE MEMBER: You wouldn't get it.

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

AUDIENCE MEMBER: Suffer.

AUDIENCE MEMBER: That's right.

HILARY: Suffer, yeah, that's what all of us do in one way, shape or form.

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

AUDIENCE MEMBER: (inaudible).

(Applause)

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

HILARY: Yeah.

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

AUDIENCE MEMBER: Absolutely.

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

(Applause)

MS. BIGGAM: Thank you.

HILARY: Thank you.

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

(Applause)

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

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

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

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

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

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

MS. CHALASANI: Maybe one or two more comments.

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

(Applause)

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

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

(Applause)

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

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

(Applause)

MS. PAPADOPOULOS: (off mic)

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

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

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

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

AUDIENCE MEMBER: All right.

MS. CHALASANI: Yes. Unfortunately, you will have to click all of them. There's no check all that apply option up there. So have you ever used any of the following therapies to manage your chronic pain. So whether you're currently using them or in the past, please select all that apply: (a), transdermal or topical patches; (b), acetaminophen prescription, NSAIDs or over-the-counter products such as Ibuprofen; (c), opioid medication; (d), antidepressants; (e), noninvasive medical devices such as TENS; (f), anticonvulsants medications; (g), implantable medical devices and/or surgical procedures; (h), other therapies, so drugs or medical devices that are not mentioned here; or (i), I'm not using any therapies such as drugs or medical devices.

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

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

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

AUDIENCE MEMBER: Okay. Could we go ahead and get these results displayed, Graham?

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

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

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

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

And so for folks that indicated, which is many of you, transdermal or topical patches or the acetaminophen prescription, NSAIDs or the over-the-counter products, what aspects of your chronic pain are they managing well and what aspects are not being managed well with those? We can start with Joe right here.

LARGE-GROUP FACILITATED DISCUSSION:

TOPIC 2

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

(Applause)

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

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

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

AUDIENCE MEMBER: Can you hear me now?

MS. CHALASANI: Yes.

AUDIENCE MEMBER: Okay. I am a patient with

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

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

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

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

Naprosyn itself.

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

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

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

(Applause)

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

AUDIENCE MEMBER: So I too have Ehlers-Danlos. So with that, unpredictable dislocations happen sometimes daily. For me, I'm on a handful of medications, anti- inflammatories. I'm on Gabapentin. I'm no -- they've tried everything.

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

(Laughter)

AUDIENCE MEMBER: Yeah.

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

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

MS. CHALASANI: Thank you.

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

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

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

MS. CHALASANI: Or just kind of what --

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

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

AUDIENCE MEMBER: When you ask about the medications that's been listed, I've been suffering chronic pain 18 years and I'm only 46. I've had the worst side effects from drugs, FDA approved. Thank you.

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

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

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

(Laughter)

AUDIENCE MEMBER: I like ginger. That really helps.

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

AUDIENCE MEMBER: Okay. I'll get that.

MS. CHALASANI: Okay.

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

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

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

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

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

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

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

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

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

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

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

(Applause)

AUDIENCE MEMBER: -- dependent on high blood pressure medicine, we're dependent on it, not addicted to it. Yes, it would be hard to get off it, but if you have choric pain you're not getting off it. And I don't want to take Gabapentin because it was original made for epileptic seizures. I don't have epilepsy. Why do I want to take Gabapentin and do something to my brain that may not be there?

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

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

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

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

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

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

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

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

(Applause)

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

Anyway, I think this new discovery that's non-opioid of Dr. Tennant that he just figured out in the last few weeks to interrupt the descending pain in the morning, I don't have a pain flare anymore. And I haven't counted my meds, but I'm guessing that I'm going to be able to further reduce at least by 50 percent my opioids.

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

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

MS. CHALASANI: Okay. Thank you, Gary.

AUDIENCE MEMBER: Well --

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

AUDIENCE MEMBER: Anyway --

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

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

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

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

(Laughter)

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

AUDIENCE MEMBER: Apparently the company is

Sunbeam?

HILARY: Yeah.

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

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

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

And I still remember like he used to work really hard because he had a family of six people depending on him. He worked 14 to 12 hours every single day. And I could somehow remember when he was in a room and kind of crying all day, because it was just -- he didn't have the money to buy drugs.

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

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

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

Thank you.

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

(Applause)

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

AUDIENCE MEMBER: No.

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

AUDIENCE MEMBER: Meghana, we have a question here.

MS. CHALASANI: Yes.

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

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

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

MS. CHALASANI: Similar then as the last question.

AUDIENCE MEMBER: Okay.

MS. CHALASANI: Thank you.

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

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

HILARY: What is -- what are mobile applications?

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

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

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

AUDIENCE MEMBER: Right.

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

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

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

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

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

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

AUDIENCE MEMBER: As I mentioned earlier, I have sickle cell disease, and so anytime our hemoglobin numbers drop, that increases the pain. And so most of us have had blood transfusions or exchanges, where they take out our sickle cell blood and they give us normal people's blood through a needle that goes into our groin to increase the hemoglobin level -- well, to try to increase the hemoglobin levels so that we have less crisis. So that's one thing that I didn't see on the screen.

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

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

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

But the overall point is, I felt like to get these therapies, it was almost the secret level, where I had to keep going back to my doctor. And it was a combination of all of these, plus some of the prescriptions that have been really helpful for me and my pain.

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

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

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

(Applause)

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

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

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

(Applause)

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

AUDIENCE MEMBER: Meghana, we --

DR. HERTZ: Hello. This is Sharon.

MS. CHALASANI: Yes.

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

(Laughter)

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

(Applause)

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

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

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

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

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

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

I don't have, whatever, that enzyme or

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

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

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

I can't afford to continue going to massage therapy and the chiropractor three times a week, but they are helpful. But the most helpful thing I have found has been the dietary and herbal supplements. And they're so controversial, but yet it's the first time in my life I've had a quality of life.

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

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

And my children could have had this mom while they were young, but instead they had to wait until now when they're almost grown. And this is my son's last summer to be at home with me. And we'll do something else, whether I have to go down tumbling again or not, a broken toe possibly on my foot and two horribly beat up knees, but I wouldn't have even tried it hadn't I found out about Kratom four years ago.

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

(Applause)

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

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

Some people have mentioned that things like physical therapy are very helpful, but sometimes they require a baseline level of pain control, which just might not be possible for everybody.

MS. CHALASANI: Thank you, Leila.

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

MS. CHALASANI: Sure.

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

(Applause)

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

When I've heard people say, "Hey, use medical marijuana," it's awesome. I'm like "great." How much will that cost me to use it 24/7, 30 days a month, everyday of the year? Because that's on a -- I'm on disability. I've got a fixed income already. I can barely afford the co-pays of the covered medications. But to expect somebody to cover the cost of all of those things instead of getting the safe and effective medication that we know works is just insane.

(Applause)

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

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

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

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

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

MS. CHALASANI: Okay. Thank you so much. We recognize that there are mixed views on efforts from federal agencies, federal efforts and so forth, particularly in regards to pain management.

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

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

BREAK

LARGE-GROUP FACILITATED DISCUSSION:

TOPIC 2 CONTINUED

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

Okay. If you could slowly start making your way back to your seats please. Okay, thank you. So for the rest of the afternoon during the large facilitated discussion, we really want to focus on a topic that's come up quite a few times already, but really the challenges and barriers to accessing your therapies to manage chronic pain.

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

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

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

Okay. A, how the therapy is administered? B, the frequency and length of treatment? C, difficulty in accessing treatment? D, the treatment only provides minimal benefit or is effective only for short term. F, bothersome short term side effects of the treatment -- sorry, that was E. F, concern about serious risk of the treatment. G, uncertainty about long term effects of treatment. H, the risk of developing drug abuse and addiction. I, other downsides not mentioned.

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

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

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

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

MR. THOMPSON: On the web, similar about 82 percent say difficulty in accessing treatment. About 50 percent say that the treatment only provides minimal benefit. About 30 percent, concerns about either serious risk of treatment or the uncertainty about the long term effects. And similar to the room about 35 percent say other downsides not mentioned.

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

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

AUDIENCE MEMBER: Work okay?

MS. CHALASANI: Yes.

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

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

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

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

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

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

MS. CHALASANI: 970.

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

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

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

AUDIENCE MEMBER: Good.

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

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

You can submit comments anonymous. But sometimes we'll have folks identify as anonymous, but then in the statement they still include their name and so that's -- it still out in the public, so just something to keep in mind.

Sorry.

AUDIENCE MEMBER: I ask them --

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

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

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

I'm the only damn person in this country that got this letter, I think, because nobody else -- none of the doctors got this or we won't be having the problems we're having with doctors. So I'd like for you guys to see this, if you haven't seen it.

MS. CHALASANI: Okay. Thank you, Richard. Okay. And --

AUDIENCE MEMBER: And one final --

MS. CHALASANI: Okay, one final.

AUDIENCE MEMBER: -- and I'll get off, okay. The workgroup members, before the guideline was presented, suggested monitoring of the guideline implementations for evidence of impact and unintended consequences and modifications of guidelines when warranted by the evidence.

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

And so finally --

MS. CHALASANI: Excuse me. While you're going through your pages, have you submitted these comments to the people on the monitoring committee as they've been identified in the CDC materials?

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

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

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

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

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

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

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

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

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

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

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

AUDIENCE MEMBER: I have over 150 --

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

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

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

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

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

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

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

Back in 2015, when the doctor who treated me for nine years left his practice just out of being scared to death, couldn't handle the stress anymore. It was the worst thing that's ever happened to me in my entire life.

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

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

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

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

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

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

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

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

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

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

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

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

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

And one thing that several folks touched upon and I know Hilary wanted to speak to this as well is on this scheduling burden, especially if you have flares. And then they were talking about how you have a flare -- Lindsay, sorry wanted to speak to that.

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

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

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

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

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

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

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

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

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

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

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

I know for me, I really could probably come off even more medicines if I could get access to nerve blocks quicker and wasn't put into that pool and waiting game, so.

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

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

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

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

MS. CHALASANI: Right. Thank you. Thank you for sharing that very important perspective. Okay. I am going to turn to Lila, if you could summarize what we're hearing on the web, please.

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

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

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

MS. CHALASANI: Okay. Thank you so, Lila. I do want to note for folks that while we may not be able to summarize all the webcast comments live right now. We do download all of them and we do read through all of them and incorporate them in our summary report. So we will look at all of them again, including while we're writing our report.

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

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

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

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

AUDIENCE MEMBER: So I'm a disabled veteran.

MS. CHALASANI: Thank you. Thank you.

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

About a year ago I was still relatively

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

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

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

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

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

MS. CHALASANI: On behalf of -- I'm sure all of my FDA colleagues also want to thank you for your service, and then to all of you, for taking the time to come here and sit through your pain to share your perspectives with us.

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

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

AUDIENCE MEMBER: Hi, can you hear me?

MS. CHALASANI: Yes, we can.

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

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

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

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

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

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

Now I'm getting half a dose of what I should be getting. My doctor is only giving medication because I actually went to my medical board and I fought for it, and I fought hard. And I should not have to do that as a chronic intractable pain suffer.

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

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

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

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

Some of them -- and these are all FDA approved medications, mind you, I have allergic reactions to. So I have allergic reaction to some of these medications and I'm so scared to try new things when I know what works.

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

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

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

And now since these guidelines have come out, every doctor on the planet here thinks that these guidelines are laws. That they have to follow these laws and they don't want to be busted by the DEA. So every single patient -- every single patient is being reduced in medication all the time, including intractable pain sufferers.

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

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

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

I do use the Naprosyn -- now the Naproxen or Naprosyn, it does work for me for one thing and one thing only. I have a severe swelling in my pelvic and in my back, in my pelvic and when I don't take the anti-inflammatory that actually gets to a point where I fall out in pain and I can't move my leg. And it's really bad. So they have permanently put me on the Naproxen to keep the swelling down in that part of my back and my pelvic area. I wear a prosthetic leg, but I'm not like any other amputee, because my leg was slaughtered so bad I'm missing 2 inches of bone in my femur.

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

I can't walk properly. So I walk like a penguin when I walk. And I have been nothing but strong my whole life going through this for 32 years. I do everything I can. I stretch, I've tried to herbal supplements and thing nothing else works. And when you get to a point where even your doctor says, "You are not going to get any better only worse." And that I should be on palliative care, but I cannot get palliative care. Then there should be something for me out there. There should be a way to get these doctors to say, "Okay, you are a case that needs this medication," that's what they were made for.

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

MS. CHALASANI: Thank you.

AUDIENCE MEMBER: And I'm very grateful for all of you for being there. But I just want to say, you know, what you do when you get to the point where there is nothing else to be done and then they want to tell you, you're an addict or if you don't request, as one of the guidelines in the new addiction stuff says, if they ask for a medication by name they're an addict. So what if we have been on medication for 32 years we've tried them all and we know which medication works for us. Does that make us an addict or does that make us a pain patient who is dependent on a particular medication that works and actually allows them to function.

MS. CHALASANI: Thank you.

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

MS CHALASANI: Thank you so much.

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

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

AUDIENCE MEMBER: You're welcome.

MS. CHALASANI: Thank you. With that we will have to move -- okay. So I was asking you, so I'm going to have to ask you just because we do have a full open public comment, I certainly do want to go into that. So go ahead.

AUDIENCE MEMBER: I promise.

MS. CHALASANI: Okay.

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

These patients are some of the most complicated, infirm and medically fragile. Within the next 30 days you will see a new burgeoning health crisis appear. There will not only certainly include sudden death in many of these patients, but also, an uptick in suicides and increase in overdose and addiction as a result. And this is sadly not the exception lately and it's becoming commonplace. The truth of the matter is and I said this before, until we have the right amount of pain specialists being able to treat none of these strategies are going to be helpful to us at all that's all I wanted to add.

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

(Applause)

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

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

OPEN PUBLIC COMMENT

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

Just keep in mind that FDA won't be addressing the comments that we hear during this session, but all of the comments are being transcribed and part of the public record. We'd like this to be a transparent process so we encourage you to note any financial interest that may be relevant to your comment. If you don't have any such interest you may wish to state that for the record. And if you prefer not to provide this information you can still provide your comment with us today. We've collected signups before the meeting. We have 15 speakers signed up. Each speaker will have 2 minutes to provide a comment. I don't have a timer or a buzzer like a game show, but what I will do is nudge you very kindly once you get close to the 2 minutes and just kind of urge you to wrap up to be respectful of everyone.

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

MS. POSEY: Good afternoon. My name is Rhonda Posey. I'm here as a charter member of Arachnoiditis Society for Awareness and Prevention. And although I have adhesive arachnoiditis I speak on behalf of all chronic pain patients. We would like to express our gratitude to all those who have made today's meeting possible. And most especially the FDA Commissioner Dr. Scott Gottlieb for recognizing in his recent statement that appropriate access to opioids may be the only medicines that work for some patients including those with adhesive arachnoiditis. In 2013, I'm sorry, in 2013 I had an epidural steroid injection using Kenalog 40 to treat lower back pain from a bulging disc. This resulted in dural tear at L 4, 5 causing me to wake up screaming during the procedure from excruciating pain.

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

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

MS. WOODWARD: Any final thoughts?

MS. POSEY: I'm sorry, what?

MS. WOODWARD: Any final thoughts?

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

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

MS. ASHCROFT: My handwriting. Thanks. The reason I'm here also is because of Forrest Tennant. As one of the original research subjects 28 years ago for CRPS been here, done that, everyone in this room who spoke is touched on things. The current issue is the fact that using the CDC guidelines as a whip to tell people they can't get access to medication is no solution to the opioid crisis. It's just hurting everybody in this room and the whole country. And at the end of the day what I resent most is that a murderer in prison can get better access to medical care than I can as someone who is self employed and doesn't have to worry the same about being denied medication.

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

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

MS. WALKER: I know I am going to try to stand out of the way of the camera. Hi. I'm Sue Walker. I'm chronic pain patient and I'm the President of the Richmond Fibromyalgia and Chronic Pain Association. We're also a small organization with very little money so I have no financial interests here. Thank all of you for allowing so many of us to be here today to speak about our experiences and concerns. And thank you to all the courageous people who came out today, many of you in pain to share your stories. I've been moved to tears more than once today and it's just so important that your voices be heard.

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

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

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

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

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

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

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

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

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

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

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

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

MS. KLEIN: It's all my in-laws. We're in the worst healthcare crisis that I've seen in 40 years and probably the worst healthcare crisis in the history of the United States. We not only have people killing themselves, we have 5 to 6 million people just like these who are being tapered. So how do we deal with this? Well, I'm standing before the only regulatory agency with rulemaking for prescription drugs. Nobody else can do that.

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

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

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

There is an urgent need to establish a certification and registration program that would authorize trained physicians to treat severe intractable pain as needed without restrictions on opioid dosing or duration of care and without restrictions on non-oral routes of administration or off label use of non-opioid medications.

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

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

MS. WOODWARD: Thank you. Any final thoughts?

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

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

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

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

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

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

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

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

MS. CALDWELL: I'm trying to find my piece of paper because I did have -- I know like I brought up the kratom and I know that this is not just about that in any way but it's what has worked for me for the chronic pain and I do know the FDA's thoughts about kratom has been in the news quite a bit and I have a little bit of a different kind of mindset when it comes to my opinion about kratom than even many of the organizations that are here to represent the community as a whole. And I did meet -- the first or second week of June, I did meet with Senator Grassley's aide and as well as Senator Feinstein's as part of a week-long time that I was here. And in Senator Grassley's office they specifically told my friend that was with me at that time, that we needed to get an appointment with the FDA and we have tried numerous times through e-mails to request appointments and we haven't been able to.

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

And so, my biggest concern is to make sure that everybody is kept safe and I feel most comfortable with being able to have access to raw leaf kratom, I think that because in traditional use it is a chewing --

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

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

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

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

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

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

AUDIENCE MEMBER: Family.

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

While kratom does not cure or treat my medical conditions, it does help greatly with my pain, relaxation, and sleep difficulties. I've never experienced negative side effects except for extreme thirst. It makes you drink a lot more water. I have been consuming kratom for almost four years. My quality of life has improved. I suffer less pain. There are at least 5 to 7 million kratom consumers in the U.S., the number is growing. I'd also like to point out that my Facebook group is just a group I made up and we call it -- started out Kratom United. In 2 years we had 2,000 members, so that's 1,000 members per year.

After the CDC regulation any change --

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

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

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

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

MS. WOODWARD: Oh, thank you.

MS. GAVERO: Full disclosure, I am an employee of Nuvectra Medical. Nuvectra offers spinal cord stimulators for the management of chronic intractable pain but I am here today as a patient. I was injured in 1995 while serving in the military and I am fortunate that my pain is managed with the chronic -- with a spinal cord stimulator that wasn't always the case, unfortunately.

I was injured in '95, I suffered for many years before spinal cord stimulation was offered to me and I would like for the promotion of alternative therapies you know to be -- for that to be offered to patients as well. Opioids did not work for me and I know that they work for many of you and I'm glad that they do. Unfortunately, that wasn't the case for me and I -- and that's not the case for many other people. So we need to have alternatives and access to those alternatives.

I've been a patient advocate for over 10 years and I've had the -- actually the honor of speaking to literally thousands of patients seeking relief. And in answer to some of the questions that have been posed today regarding suicide many, many, many of them have told me in our conversations that if -- if the spinal cord stimulator hadn't worked for them or if it's not going to work for them, they were going to commit suicide. Many of them had attempted suicide.

Also just the impact it has on their families as well. Many of them were angry because they weren't given any information about alternatives. They also suffered for many years before being offered something other than opioids. So just --

MS. WOODWARD: Thank you, Grace. Any final thoughts for us?

MS. GAVERO: No, thank you. Just -- well, just one final thought. Just keep that in mind that there are alternatives. If the opioids work that's great but offer something else as well. Thank you.

MS. PAPADOPOULOS: Thank you. Now we have Steve Chang (ph). Steve Chang?

MR. CHANG: I am Steve Chang, I'm from New York. I am an acupuncturist and a massage therapist. Currently, there are three bills in Congress waiting to pass to allowing the acupuncture as a treatment method for the people, okay? So, we need your support and especially the FDA okay, because the acupuncture is mostly efficient hindering the pain issues.

I heard that today many people are saying about their pain, okay? But from the way I see is probably your pain is because of when you -- for example, like an accident causing the pain, causing the lower back pain but because you didn't get proper treatment and you didn't take the proper action so that's why you are suffering and then the situation getting worse and then the -- you any how is looking for the opiods for the pain release. And pain release using the opiods is not a solution, it's just temporary cover, your symptoms. So we should be looking for the solution, find out what really cause the pain and address it. And then the acupuncture, and also massage therapy are the best ways to end it.

MS. WOODWARD: Thank you, Steve. Any final thoughts for us today?

MR. CHANG: Okay. So, since the time limit, all right. I am just urging that everybody we can support these three bills to pass to allowing the federal -- the Medicare and Medicaid and also the health insurance for the veterans to accept the acupuncture as the treatment methods. Thank you.

Ms. PAPADOPOULOS: Thank you, Steve. Next, we have Yam Fan (ph). Yam Fan?

MR. FAN: My name is Yen, acupuncturist. I represent my -- another patient Lisa Wood (ph). She's 40 years old now. When she's 17 years old she had a shoulder surgery. After surgery she back started chronic pain but didn't know why. After 10 years later, they found it and note it acanthosis (inaudible) disease. She pained every day and the spine fused together gradually. Also is losing her rigid motion much.

For the problem she takes anti-inflammation pill and pain killer and anti-immune function pill every day. Because of medication side effect liver function (inaudible). After she -- 5 years or so boy diagnosed with children arthritis now she started to come see me. After, you know, take his son 2 years later, his son is much better. He doesn't want his son taking medicine. Last year I asked his condition, you know, (inaudible) he do acupuncture for he back problem, actually he tell me he get acupuncture before and (inaudible), just a little help. I explained, you know, my skill different from before he had.

MS. WOODWARD: Thank you so much. Any final thoughts for us?

MR. FAN: Yeah, he's got, you know, much better this year. Last month, he traveled 2,000 miles from Virginia to Alabama, Texas, Florida barrier regimen. Then he didn't feel like before he kind much in pain. So he's really happy, you know. He want to, you know, tell people but it's strange people didn't believe her, you know. Actually, you know, acupuncture is a good solution for most chronic pain but not for everyone, but most. You know --

MS. PAPADOPOULOS: Thank you.

MR. FAN: Okay.

MS. PAPADOPOULOS: Next, we have Terry Lewis (ph).

MS. LEWIS: Members of the panel, I want to introduce you to the experts in the room. They're right here. These people know more about what you have to do than you do, okay? I am a care partner, I am a social scientist, I am a clinical educator. I believe in data and I believe that we are talking about the wrong set of questions.

If we want to know how to better address the questions that are before us today, we have to have regular input. We have to widen our stance, not narrow it. Regression to the mean is killing us, okay? We need to look at all the data. The thing that has been flowing through our conversation today is Ehlers-Danlos Syndrome. That's a really important piece of information for us. We can't medicate that away but we can prevent a lot of injury if we understand that. In my own family we're finding out that that's a real issue. It's more common than we think we understand. Opiates help but prevention is the key.

I have been surveying and talking to patients for 5 years intensively because I am the parent of a young man whose natural history I have followed up to the point where he's 35 years old.

MS. WOODWARD: Thank you, Terry. Any final thoughts for us?

MS. LEWIS: Yes. I would like to see FDA institute regular communication with patients and regularly begin to document what is being suggested and what were there is to learn and to change the way we ask questions about this process.

MS. WOODWARD: Thank you, Terry. Now we have Amanda Proctor (ph). Amanda Proctor?

MS. PROCTOR: Hi, my name is Amanda Proctor. I'm representing Cauda Equina Foundation with about 2,000 members and growing of Cauda Equina Syndrome patients.

Cauda Equina Syndrome is a spinal nerve root injury of the lumbar spine. It's very similar to arachnoiditis in its chronic stage but if it's caught and the first 48 hours and treated, if it's a treatable cause, not all causes are treatable, it can be completely reversed. Unfortunately, it's misdiagnosed 85 percent of the time, which is something we're working on but that's not why we're here today.

We're here today because 85 percent of the time Cauda Equina Syndrome progresses to chronic Cauda Equina Syndrome, again very similar to arachnoiditis with periods of neuroinflammation which cause flare ups. This obviously causes intractable pain and periods of acute on chronic pain, something that we've mentioned where you have your normal pain and then you have your flare up.

So, we have members that are saying I've just stopped going to doctors. They can't help me, they don't listen to me, they treat me like a criminal, they treat me like an addict. That's what I am hearing from 2,000 people.

I have people that -- I have had emergency phone calls at 2 o'clock in the morning, "Hey, we have a member talking about suicide on the support group. Can you call them? Can you intervene?" Now, I am a licensed healthcare professional. I do not practice because I physically cannot but I am legally obligated to intervene and report suicidal ideology.

MS. WOODWARD: Thank you, Amanda. Any final thoughts?

MS. PROCTOR: We have to do better at treating pain. We have to have better treatments, we have to listen to our patients, we have to have empathy and compassion. And if we don't have that hang up the white coat and get out of the practice.

MS. WOODWARD: Thank you. Next, we have a Adriane Fugh-Berman. My apologies, if I mispronounced.

MS. FUGH-BERMAN: Hi, I'm Adriane Fugh-Berman. I'm a physician and I'm director of Pharmed OUT which is a Georgetown University Medical Center project, research and education project that examines inappropriate pharmaceutical marketing tactics.

My plea to the FDA is to please do more to combat pharmaceutical company influence in drug approval. Remember Oxycontin and the fact that the FDA allowed the original label to imply that the formulation was thought to be less addictive, more recently abuse deterrent formulations, a term -- a marketing term that should never have been allowed has really created a lot of harm. 46 percent of healthcare providers think abuse deterrent formulations mean they are less addictive. They are not less addictive, they're only slightly less convenient to turn into an injectable form.

In terms of chronic opioid use there are certainly -- they are appropriate for some pain patients including many in this room but there are many others for whom it is not appropriate. We continue to overprescribe opioids in this country and opioids continue to be over promoted.

In 2016, 1 out of 5 Americans received an opioid and 1 out of 12 physicians receive payments from an opioid manufacturer.

Pain does not protect patients from opioid overuse disorder. And even beyond opioid use disorder, opioids can increase cardiovascular risks and suppress the immune system among other problems. They are appropriate for some -- some things.

MS. PAPADOPOULOS: Any final thoughts, Adriane?

MS. FUGH-BERMAN: Yes, just to say that there's been some attacking of the CDC guidelines here, they're actually very rational. I just wanted to read one thing which is who would disagree with the statement, clinicians should consider opioid treatment only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.

MS. PAPADOPOULOS: Thank you, Adriane. I'm now going to turn it over to Dr. Sharon Hertz for our closing remarks.

CLOSING REMARKS

DR. HERTZ: Hi, all. Thank you for those of you who have been able to stick out this very long day. I know those chairs are not necessarily the most comfortable plus all that you went through to get here. Appreciate that effort.

Like I said this morning, your comments are incredibly important to us. So, in addition to what we've heard today, we're going to be reviewing all of the comments that go to the docket. And in addition, there will be a report from this meeting that's ultimately made available on our website as well.

I just want to mention a couple of things that we're trying to do to help. We have been writing the New Opioid REMS, the risk evaluation and mitigation strategy which requires manufacturers not to create educational programs but to fund them from accredited CME providers so they have no input in the content. We have created the blueprint.

The blueprint has been changed from the original, which focuses on how to use the drugs, to a more comprehensive approach to pain management and that's what's expected in those educational programs.

There's already -- there's also ongoing federal efforts that will hopefully be helpful acknowledging that we have to be extremely careful to avoid unintended consequences. I just want to mention that one of these efforts is the pain management best practices interagency task force, which was established and mandated by the Comprehensive Addiction and Recovery Act known as CARA of 2016.

The task force will propose updates and recommendations to address gaps or inconsistencies in pain management best practices. The task force includes a broad spectrum of stakeholders including patients, physicians, and experts in pain research as well as others.

We had the inaugural meeting in May, I represent our agency on this task force and that meeting featured patient perspective as well as public comments early on in the proceedings. When the task force completes its development the proposed updates and recommendations will be available for public comment. So, we're trying, we're trying to do what we can to help. Thank you once again.

If -- well, for now put all comments into the docket and if other things arise and you need to contact us, there's a variety of ways to do that including e-mailing our drug information people. They provide me or others with comments directly and it's a way to have a central focus for any kind of input from patients outside. So thanks again, safe and hopefully comfortable travels home.

I can touch base with you offline but basically I was describing a task force that was mandated by legislation that took place in 2016 but I'll catch up with you. Thanks.

(Whereupon, the meeting was concluded at 4:10 P.M.)

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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.

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July 19, 2018

DATE JIMMY JACOB