Food and Drug Administration

Fibromyalgia Public Meeting

Patient-Focused Drug Development

Wednesday, March 26, 2014

1:00 p.m.

Food and Drug Administration, White Oak Campus

10903 New Hampshire Avenue

Building 31, The Great Room, Section B and C

Silver Spring, Maryland 20993

A G E N D A

PROCEEDINGS

DR. EGGERS: Let's get started with this important meeting. My name is Sara Eggers, and I'm the Center for Drug Evaluation and Research here at FDA. I'm in our Office of Strategic Programs, and I'll be the facilitator for today's meeting. I'm going to have my colleagues introduce themselves in a minute, but what I want to do is just thank you all for being here, and welcome.

This is the Fibromyalgia Public Meeting. It was originally scheduled to be for December 10th. Now, you might look outside and say, well gee, it looks like it could be December 10th today, but no, this is March 26th and we are very appreciative that you stuck with us through the December snow, and then stuck with us again through the March snow to be here today for this important meeting.

This meeting is also being webcast, and we have several -- many, many people signed up to join the meeting by webcast. We thank you; your voice is very important to this effort, and there will be several ways that you can contribute as well.

I just want to let everyone know that this meeting is being recorded through the webcast, and there will also be a transcript of the meeting that we will post on our website some days after the meeting.

There are restrooms located out about as far away as you can be, out down the end of this hall, and then to the right. There's a drinking fountain there as well. There's a kiosk that you might have noticed near the registration table that sells basic food. Feel free to get up at any time. If you need to stretch, if you need to walk around, if you need to use the restroom, this is a very informal meeting, so please feel free to do so.

With that I'm going to go through kind of the next slide and give just a high level overview of what we're going to be doing today.

My colleagues will be giving a few presentations just to set the context for what we are trying to achieve today, and some background on fibromyalgia. I will then come back and give an overview of the discussion format. This is a very different format than typical public meetings conducted by FDA.

Then we're going to delve right into the most important part of the day, which are the discussion topics one and two. One is focusing on the disease symptoms and daily impacts that matter most to patients, and two is the perspectives, patient's perspectives on current approaches to treating fibromyalgia.

There will be an open public comment period after that, which we enable anyone from the public, including the patients but also others, to give a comment on typically some issue that's not directly related to one of the two topics that we discussed today, and then we'll have some closing remarks.

So with that -- there's a break between discussion topic one and two, I forgot to mention, and you'll be able to use the kiosk and walk around.

With that I'm going to ask my colleagues to introduce themselves. This is all FDA staff.

MR. FREY: Good afternoon. I'm Patrick Frey, Director of the Office of Program and Strategic Analysis in CDER.

DR. RAPPAPORT: Hi, I'm Bob Rappaport. I'm the Director of the Division of Anesthesia Analgesia and Addiction Products in the Center for Drug Evaluation and Research, FDA.

DR. HERTZ: Hi, I'm Sharon Hertz. I'm a Deputy Director in Bob's division.

MS. FIELDS: I'm Ellen Fields. I’m a Clinical Team Leader in the same division.

DR. KILGORE: Yes, hi. I’m Elizabeth Kilgore, Medical Officer, Clinical Reviewer, in the same division.

DR. EGGERS: All right. Thank you. With that I'm going to ask Bob to step up and give some welcoming opening remarks to kick us off with this discussion. Thank you, Bob.

DR. RAPPAPORT: Thank you. So welcome everybody. I too am glad to see the excellent turnout and the large number of people who've registered to watch us on the web. That's great, and I'm sorry Mother Nature didn't see to bringing us our beautiful Washington spring for you. Unfortunately, she's just not cooperating lately.

So I'm the Director of the Division that would be approving, and has approved, drugs for fibromyalgia.

Over the last eight years we've had the responsibility for that class of drugs. So we're very, very interested, and very excited to be part of this, and to have this opportunity to hear from you what kind of issues you're concerned about in relation to pharmaceutical products for the treatment of fibromyalgia. Obviously, there are -- fibromyalgia is a disorder that should be treated with multiple modalities, and drugs are just one of them. But that's our area; we're the drug people, so that's the area that we hope to hear a lot from you about, about how we can help you by finding better drugs.

It's great that there are a lot of patients here, that there are patient advocates, that there are caregivers, families, and I'm also really pleased that we have people, our colleagues from industry here, who are interested in developing these products.

As you can see the panel and the fact that I can assure there are others, my division, the group of people in my division who deal with drugs for pain and fibromyalgia, are very interested in hearing from you, and so we have a large representation here on the panel and in the room, and watching from their desks for who just don't have the time to come and sit here today.

So I want to just make sure that you all understand that we do, as FDA, we play a critical role in drug development. We work very closely with investigators and the industry folks, and during development we can give a lot of input and help, in terms of how drugs are studied, what the studies should look like, how we're going to interpret them, what our concerns would be in terms of the safety and efficacy of the drugs.

But we don't do the studies. Those are done by investigators from academia, or private industries, and by the drug companies themselves. But we do, as I say, work very close with them and I think they would acknowledge that we're pretty savvy about how to study drugs for pain.

We know a lot about this area, we've been really working hard over the last couple of decades to figure out the right way to study them.

But fibromyalgia is a little different, right? It's not just pain, and we we've been working through this, and since the -- before the first drug we approved for fibromyalgia, which was Lyrica in 2007, we've been trying to understand what features and parts of fibromyalgia the patients, you folks, really want to have treated and what -- which ones are most important to you, which ones -- how they all fit together, whether -- for instance, if we're treating the pain and your sleep gets better, that's great, obviously.

But if we're treating the pain your sleep is not getting better, of you're still having a lot of headaches, or you're just still fatigued; you don't hurt anymore but you're so fatigued you can't function, that's not good either.

So we need to know from you which of those things are being treated with the drugs that we've approved so far, and which are not, and which -- you know, what is the -- your sort of interest in seeing those various features of the disease treated with drugs.

Now, some of them may not be amenable to treatment with drugs, and there are, as I said earlier, there are other modalities that hopefully you're all looking into, but where we can be helpful, please let us know. That's really what we're here to do today, is to listen to you. We're not here to tell you much about what we do, or how we work; we're here to listen to you so that we can bring that back to our desks and sort through how to better develop drugs for your disorder.

The current drugs that are available; we've approved three since 2007 for fibromyalgia, and that's great, but we recognize that those have limited utility, don't work for all patients.

So we want to hear about that as well, which of those drugs are working for you, which are not, and in what ways are they working or not working. Some drugs work fairly well generally for people with a particular disorder, and others only work for small subpopulations, and so those are the kinds of things we would also hope to hear from you today.

Then, you know, ultimately the key thing that we look at in a study of a new drug is whether it is safe, obviously. You know, if it the -- that would be something that we would look at with any drug, but the key thing that we're looking at for a new drug is how effective it is and what that balance of safety and efficacy are.

So a topical ointment that you put on your skin to treat arthritis, and that it doesn't get into your blood system, and really doesn't have side effects except maybe a little rash, is -- if it's not terribly effective, we still probably are going to approve it because it's a little bit effective and it's not -- and it's relatively benign.

But there are drugs out there that really may do a gangbuster treatment for a disorder like fibromyalgia, but they're really, really toxic. They have all kinds of side effects. So the other thing we want to hear from you is what is your thinking about the risk benefit profile? How much risk are you willing to tolerate? No drug is completely safe; you all recognize that, hopefully. But there's a scale there and we need to hear from you how much risk you're willing to tolerate.

So those are some of the things we hope to hear from you. I'm sure there will be other things that you bring to the table, and again, thank you so much for coming today and participating, and I'm going to turn this over to Patrick who's going to give you some -- an overall picture of our patient focused drug development efforts. Thanks.

MR. FREY: All right. Thanks, Bob. So Bob touched on a number of topics that are really critical for our decision-making in CDER, and this is really why we have patient focused drug development.

When you talk about the severity of the condition and an analysis of the current treatment options, that information is very important in setting the context in which we make our decisions, because our decisions aren't made in vacuums, and this was a topic during our discussions with the regulated industry and public stakeholders during PDUFA V.

We would often hear about the patient perspective in the context of a specific drug at an advisory committee meeting, but we didn't have a meeting mechanism that could allow us to systematically get at the patient perspective, which we should get as good of an understanding as we can about the patient's perspective on the disease and current treatment options.

So that's really where patient focused drug development came from. It was a proposal put on the table and discussed during the PDUFA V discussions, and that wound up in the final package, and that's why we're here today. To develop that systematic way of gathering the patient perspective on the condition, it helps us inform that understanding in the context of our decision, and it informs our oversight both during drug development and during the review of marketing applications. So not just one or the other, but the full drug development timeline.

All right. In September 2012 we announced a preliminary set of diseases. This is how we began the process. We took public input on these proposed nominations; I think it was 39 in total, to see what the public -- where the importance was from the public's perspective on which diseases to treat.

We held a public meeting in October 2012 to also hear face to face from patients. We filled up one of these rooms in the great room. It was quite a busy meeting. We took over 4,500 comments that were submitted in the public docket and analyzed them. In sum total they addressed over 90 different disease areas.

From this we had to, ultimately throughout PDUFA V, choose 20. So we carefully considered these public comments and the perspective of the review divisions in the Office of New Drugs in CDER, as well as the corresponding offices in the Center for Biologics, to develop that list of 16 disease areas that we were going to address in fiscal years 2013 through 2015.

We published this list in April 2013, the same month that we had our very first patient focused drug development meeting, and next fiscal year we'll establish and start off another public process to nominate the disease areas for the remaining two years of PDUFA V.

So here you see the four meetings that we had in fiscal '13. Chronic fatigue was our first, followed by HIV, lung cancer, and narcolepsy. We had sickle cell disease, was our first meeting in fiscal '14 last month, and we have the pulmonary arterial hypertension meeting for May, I believe.

We'll be following up with additional meetings towards the end of 2014 and into 2015 with some of the disease areas that you see on the right hand side.

So how do we run these meetings? We really begin with a set of questions that are targeted to eliciting the patient perspectives on the disease and the treatment options. The set of questions that we begin with can apply to any disease area, and they're taken from FDA's benefit risk framework, which is where patient focused drug development came from. They represent important consideration in our decision-making.

Then we meet with the review division to understand and tailor those questions to be targeted towards the particular disease area that's being addressed in each meeting.

So our general questions, we published them when we started that initial process back in the fall of 2012, but then which each patient focus meeting devoted to a disease area, you'll see a variation of those questions published, as you did for fibromyalgia.

We focus on relevant current topics, and the drug development for the disease, for the particular disease of that meeting. For example, for the HIV meeting last June we had some questions that focused on cure research.

We've learned that active patient involvement and participation is what makes these meetings a success for us and for you.

So what we do with this information then? Well, so far we've published, I believe, two of our Voice of the Patient reports, which represents a lot of work in summarizing both what we heard at the meeting, unique perspectives that we heard from people on the webcast, as well as additional comments that are submitted to the public docket after the meeting.

The reports serve an important function in communicating both to our review staff, as well as the regulated industry, what is important from the patient perspective, as far as improvements that they'd like to see in their daily life.

We believe that in the long run the impact of this program will be a better more informed understanding of how we might find ways to develop new treatments for these diseases, both for the FDA review staff, and for the regulated industry in that effort.

And I think that's all I have. All right. Who do we go to next? Okay. We have Liz Kilgore from the division.

DR. KILGORE: Good afternoon. I'm Elizabeth Kilgore, a Clinical Reviewer in the Division of Anesthesia, Analgesia, and Addition Products. I will be presenting this afternoon's slides on the background of fibromyalgia and therapeutic options.

Fibromyalgia, also known as fibromyalgia syndrome, is a chronic disorder that affects the body's muscles and soft tissue. Although chronic widespread pain is the defining feature, other symptoms include sleeping difficulties, fatigue, irritable bowel syndrome, headaches, mood disorders, and cognitive issues.

Fibromyalgia affects approximately five million adults in the United States, and women are disproportionality affected, making up about 80 to 90 percent of those diagnosed.

The precise cause of fibromyalgia is unknown, and a variety of etiologies have been theorized, such as possible factors that include viruses that affect the central nervous system's ability to perceive pain, injuries, and physical stress, or emotional distress. Other postulated theories include sleep disorder and immunological disorders.

Fibromyalgia may be more common in those with spinal arthritis, rheumatoid arthritis, and Lupus. According to the America College of Rheumatology, 1990, the two major diagnostic criteria are pain in at least 11 of 18 different specific points of the body, referred to as trigger points, and pain that has lasted for three or more months, referred to as chronic pain.

There are multiple systems involved in fibromyalgia. As previously noted the primary symptom of fibromyalgia is pain. Painful areas known as tender points develop in various parts of the body and may spread.

The pain characteristics may differ among patients. For example, the pain may be described as feeling hot and sharp, or it may be described as feeling like a deep ache. The intensity of the pain can vary with the time of day, cold weather, activity level, and stress.

Some patients may have abnormal pain perception processing, which leads to strong reactions to the things that others would not find painful.

In addition, pain may contribute to sleep problems for many with fibromyalgia. This is characterized by difficulty both falling and staying asleep. Poor sleep may lead to stiffness and aches, especially in the morning, as well as a general sense of fatigue.

In addition to pain, sleep problems, and fatigue, patients with fibromyalgia may also experience the following symptom complex; problems with memory, concentration, and other cognitive functions, sometimes referred to as 'fibro-fog', depression or mood problems, irritable bowel syndrome, migraines, and other headaches, and muscle issues including weakness, tingling, and spasms.

Symptoms may vary over the course of time. Occasionally symptoms will improve; however, in some cases symptoms, especially pain, may worsen over time.

Just as there are multiple symptoms in fibromyalgia, there are also multiple treatment options. The goal of treatments for fibromyalgia is typically focused on symptom management and pain reduction.

Treatment may require visits to multiple healthcare professionals with different areas of expertise. It often begins with non-drug therapies, such as physical therapy, exercise regimens, and fitness programs, massage and relaxation techniques. If initial treatment does not help, various medications and additional non-drug therapies may be prescribed.

Three drugs are currently approved by the FDA for managing pain and other fibromyalgia symptoms; Lyrica, approved June 2007; Cymbalta, approved June 2008, and Savella, approved January 2009. Lyrica and

Cymbalta were approved for other indications before being approved for the management of fibromyalgia.

Savella is the first drug approved only for the management of fibromyalgia, based on response to three different measures: 30 percent or greater decrease in pain severity, a patient rating indicating significant symptom improvement, and significant progress in at least one of two different measures of physical function.

Of course, all medications pose potential risk. Possible side effects from one or more of the three approved medications include, but are not limited to, increased risk of suicidal thinking, peripheral edema or swelling in the arms or legs, serotonin syndrome, or neuroleptic malignant syndrome, which are potentially life threatening conditions, sudden in onset, seizures, liver damage, elevated blood pressure and heart rate, and abnormal bleeding.

Clinical response to medication varies. Not all patients who take approved therapies for fibromyalgia will see an improvement. Other drugs that patients and health care providers use to treat fibromyalgia include sleeping aides, pain relievers, anti-seizure drugs, anti-depressants, and muscle relaxants.

There is a need for additional treatments to both better manage symptoms and treat the underlying condition.

In addition to medications, non-drug therapies used to help manage pain and other symptoms of fibromyalgia include behavioral therapies, such as setting activity limits, light exercise, massage, yoga, acupuncture, dietary changes, practices methods of improving sleep, and psychological therapy or other emotional support.

Combinations of drugs and non-drug therapies can be effective for some patients. Many patients develop a custom treatment regimen aimed at treating the symptoms that impact them most.

In diseases like fibromyalgia, which is not fully understood, input from patients is especially important. Patient related outcomes, or PRO's, can represent direct measures of treatment benefit in clinical trials. However, all measurements need to be evaluated in well-conducted placebo controlled, or double blinded randomized clinical trials.

Patient reported outcomes highlight the patient's unique ability to contribute to the field of drug development.

The FDA encourages the development of well-defined and reliable PRO instruments that capture clinical benefit concepts that are important to patients and the reason for today's meeting. Thank you.

DR. EGGERS: Thank you to my FDA colleagues for setting the stage for this meeting. I'm going to now provide a little bit of information on what the day discussion will look like, and give you an overview of the discussion format.

As we said we have the two topics that we're going to be discussing. The first one is the symptoms that matter most to you, and in that one what we're really looking for is which symptoms have the most significant impact on your life, and what are the specific health effects and how they affect you.

How do these symptoms affect your ability to do specific activities, and the more concrete you can be about this, the better that we understand in the types of terms and the ways that we have to think about symptoms, and how they relate to treatments.

We'd also like to know a little bit about the specific impacts that you have from a flare, when you have an exacerbation, or a worsening of all of your symptoms, how does that compare to a more average day, if you have an average day?

Then after we finish that discussion we'll move into the topic two, which is the current approach to treating fibromyalgia. So what are you doing to treat your fibromyalgia?

We'll be focusing on the pharmaceutical treatments, but we also do want to hear about the full range of treatments that you do to address your condition, how well these treatments work for you, and what specific ways. What specific symptoms do they address? What are their biggest downsides? And what would you look for in an ideal treatment, if we assumed that there's no yet -- a cure for fibromyalgia, what could treatments do to help improve your life right now?

As our format we're going to first hear from a panel of patients, and I'm going to ask the patients from topic one to make their way up to the front, and you've got some nametags. We've been working with these panels since December. They've been with us along the way.

They are -- I'm proud to say that all the panelists identified for the first meeting are all able to be and participate here today. That is how committed you all are this, that you're willing to go for round two of this meeting.

The panels have prepared comments, about three minutes, to describe their story, their responses to the first set of questions, and give us a good foundation that we can build on, on a facilitated discussion to build on what we hear from them.

The panelists reflect a range of experiences with fibromyalgia, and some also represent fibromyalgia or pain organizations.

Once we hear from these panel -- all the patients up front, we will then move the conversation out into the audience and we'll all be able to participate, again, building on the experiences shared by the panel.

So we'll ask questions. My FDA colleagues up here are the real experts on this condition, so they'll help me by asking detailed follow-ups as they see fit. And just please raise your hand to respond, and we have some mic runners coming out who will be working the microphones for you. This is very talk show style, if you haven't seen one of our meetings run already.

Please state your name before answering. If you're comfortable, state your full name, but if you -- at a minimum, please just state your first name.

So we also have a chance for poling questions, and this has worked well in the past, and I'm going to ask for the clickers to be handed out.

We've got these, you know, great technology in these little clickers that will enable the patients, primarily the patients and maybe the patient representatives for a few questions, to directly participate in the discussion by responding to a few polling questions. This gives us an idea of what experiences are in the room, who's here today, and some thoughts on a few of the discussion topics that we have so we can get a sense of the range of experiences in the room.

It's not at all a survey, and if you don't feel comfortable answering any questions, it's completely voluntary. We're not using this for any kind of scientific purposes. We do ask that it's patients and patient representatives only, and we also ask please return the clickers. They do absolutely no good outside of FDA's campus. I don't even that they're that pretty to put on the coffee table; just give them back to us.

Web participants, you can participate too through the poling, through the webcast, and we encourage you to do so. It really give sustained a good snapshot of who's online.

Web participants, you can also add comments through the webcast, and although they might not be all read or summarized today, especially if we have hundreds of people on the webcast, we will try to summarize what we can and they are all being recorded, and they will be included -- incorporated into our report.

We'll also occasionally go to the phone lines to give you another opportunity to contribute, and that information will be provided through the webcast at the appropriate time.

You have other chances, patients and patient representatives have other chances to participate, even if you know people who aren't able to participate in the meeting today, encourage them to participate by sending us a comment, and we would like your comments as well, after the meeting.

We have comments through what we call the public docket, and this is a website that's run by the Federal Government that allows us to receive information from the public.

So you'll go to the website, the slides will be posted after this meeting so you can go to this slide for this information, or we have this information on our website. You go to the link, you click on comment now, and you can submit a comment in a comment box, or you can upload a document that's on your computer to submit a comment. Anyone is welcome to comment; it doesn't have to just be a patient or patient representative.

So there's a few ground rules that I like to be really clear about because they help ensure that we have the most productive and respectful conversation for FDA's sake, and for your sake as well.

We do encourage patients to contribute to the dialogue. We really want to hear from all of you, and if you're a patient and you're in the back please come to the front, as close as you can be to the front, is very helpful. Caregivers and advocates, you are welcome to contribute as well.

The FDA, and industry, and other government in the audience, we are so glad to see you; we just ask for you to be in listening mode today.

FDA is here to listen. As I said, they have an important role, the FDA panelist, to help me ask follow up questions. We can't provide -- we might not be able to provide information if you have questions today. So we're, again, here in listening mode.

Our discussion today is going to focus on those two topics that I outlined, the symptoms and the treatments. This does not mean there's not a range of other important topics around fibromyalgia and helping to ensure that patients get all the care and support that they need in their lives.

Our conversation today is intended to focus on the things that FDA can most concretely hold on to and address. So if there are other topics that you want to discuss, you can feel free to discuss those in the open public session of today's meeting, and the end of our discussion topics.

There's a sign up sheet out at the registration table; you can sign up. It's first come, first served, and it will determine how much time you have by the number of people that sign up, typically about three minutes.

I want to say another thing about the flow of the discussion today. The discussion topic is going to focus on symptoms, and I think the best way to have that conversation is we will address symptom by symptom, and expand upon each. So I ask today is when you want to raise your hand to comment on something, please stay as close as you can to the question that's being asked. You will have your chance to address another symptom that you face later, or if you haven't yet talked about it, and we get to the end, then I'll ask if there were other topics that you wanted to raise that are relevant to this.

This will make sure that the conversation goes as smoothly as possible, and that we let everyone who gets a chance to -- wants to have a chance to speak can do so.

The views expressed today are personal opinions, and so we just respect everyone's personal opinions as their own expressions. Of course, respect for one another is paramount, and in our other meetings that has always been the case. So -- these meetings have been so respectful. It's really a community, and for those on the webcast, I know you can't see the folks in the room, but there's really a connection here and it's -- there's a lot of energy that's in the room as we're having these conversations.

So let us, the FDA, know how we're doing. We have evaluations at the registration desk. These are very important to us and we really do take them to heart on how we can continue to improve upon our process as we go through other meetings.

With that we're going to test out the clickers, I think. Can we have the next slide? Okay. So this is our chance to test out the clickers. Does everyone -- up here, do you have clickers? Can we have a few clickers for the up front?

We ask the hardest questions first. Again, this gives us a chance to see who's in the room. So if you've got the clicker you're going to do the corresponding letter, and if you're on the web, you're going to do the Adobe.

The first question is where do you live? Within the Washington, D.C., metro area including the Virginia and Maryland suburbs, or outside of the Washington, D.C., metropolitan area? So if you can click your little clicker? Okay.

If we can have the results? Okay. So two-thirds of you came from outside of the Washington, D.C., metropolitan area. That is fantastic. We are so appreciative. We're appreciative of anyone who traverses the beltway to get here, but a special shout out to those of you who have travelled a long distance, especially if you were also planning to do the December, that unfortunate December meeting. So thank you.

On the web?

MR. THOMPSON: On the web we have about 90 percent from outside of D.C.

DR. EGGERS: Okay. So we have a very nice representation hopefully from all over. Okay. The next question, please. Do you have fibromyalgia? Yes-A or B-no. Okay. The responses? Okay.

So it looks like there's a lot of -- there's quite a few patient representatives, and caretakers, and loved ones here, and we also very much appreciate your support and your contribution as well to this. So it looks like we have about 30 people living with fibromyalgia in the room, if I did the math correctly in real time, and we -- again, we're so appreciative.

Let's have the next question. What is your age? Oh, and from now on let's stay only if you have -- if you answered yes to having fibromyalgia answer the rest of the questions.

So is your age younger than 30, 31 to 40, 41 to 50, 51 to 60, 61 to 70, or 71 and greater?

Okay. We have a very nice spread. Not representing as much people younger than 30, but that's to be expected knowing the condition. But we have quite a few people here who are in their 60's, and again, a range from the 30's to the 60's. So great to see that diversity.

On the web?

MR. THOMPSON: Yes, on the web we have a little bit different spread. For the younger than 30 we have about ten percent, 31 to 40 about 20 percent, as well as for 41 to 50. Then we see a jump for 51 to 60 up to about 30 percent. Then we have a little lower from the 61 to 70; we have about 18 percent.

DR. EGGERS: So we have a wide range across in both web and in person. Okay. Are you male or female? Okay. Can we have the results? Okay.

Okay. So 90 percent are female, and we have some male representation here. Again, it matches our expectations, but we thank everyone who's here, especially the men in the group.

On the web is it about the same?

MR. THOMPSON: It's about 20 percent male, 80 percent female.

DR. EGGERS: Okay. Thank you.

How long have you had the symptoms of fibromyalgia? Less than five years, five to ten years, 10 to 20 years, more than 20 years, or you're not sure? Okay. All right. So we have many, many people who have lived with this condition for a long time represented here today, with the more than 20 years being the largest group.

On the web?

MR. THOMPSON: It's similar. A little bit more skewed towards the shorter duration of having symptoms.

DR. EGGERS: Thank you very much. I think there's on last polling question here. Do you have a physician confirmed diagnosis of fibromyalgia? Yes, no, or I'm not sure? Okay.

Yes, over 90 percent of you do have one, have a diagnosis of fibromyalgia, and we understand that

that might have been a long road to get there. We do have a few folks in here who do not have one, who are not sure. So on the web is it similar? Okay.

MR. THOMPSON: Yes.

DR. EGGERS: I think that's it for the polling questions. Is that correct? Okay. Good.

Now I can stop talking and let the panelists talk. I'm going to let them introduce themselves, and we have one panelist, one person who was supposed to be here today. She's been working with us since December, as I said, but she informed us after the weekend that she is experiencing a very severe flare, so we are going to accommodate her and let her share her story over the web. And if she is available, I'm -- is she ready? Is it ready? Just give us a few minutes; we've never done this before.

MR. THOMPSON: Operator, is Lori ready to go to the phone?

DR. EGGERS: Okay. You know what we'll do, we will wait on Lori, and we will have her come on when we get all the pieces together. So what we'll do is we have the four up here and we'll let you go through --

MR. THOMPSON: Hold on -- do you want to go to her now?

DR. EGGERS: Is she -- is Lori ready?

MR. THOMPSON: I think so. Operator, you can put her line on.

MS. GALPEER: Hello?

DR. EGGERS: Lori, hi, this is Sara.

MS. GALPEER: Hi.

DR. EGGERS: Hi, Lori. Oh, we can see you great.

MS. GALPEER: (Inaudible 42:18) say I've had the opportunity to meet a lot of people, and possibly make some new friends.

DR. EGGERS: So we -- give us one second, one second, Lori. We're going to make sure there's volume so that everyone can hear you. Can you test? Can you say something?

MS. GALPEER: One, two, three.

DR. EGGERS: Is that okay? Can everyone hear good enough? We've got thumbs up in the back, and the transcriptionist? Give me one second. All right. Lori, go ahead.

MS. GALPEER: Can you hear me now?

DR. EGGERS: Yes, we can hear you.

MS. GALPEER: Okay. I just wanted to say that I hoped to be there in person to meet a lot of different people, make new friends, because all go through this, and thank you so much for accommodating me, because like everyone else, it means so much to be able to share my story. Okay. I don't want to take up all of your time.

Going right to the questions that were asked by the panel. Of all the symptoms, like everyone else, pain, fatigue, and memory difficulties are the most debilitating for me. Having had this insidious illness for 18 years now, I've experienced more types of pain that I've ever known the body could create. I have pain 24/7.

Normally I live with a deep mild throbbing that feels centralized in my body. During flares it becomes a deep grinding pain that feels as if someone is kneading my muscles. Other times I can experience spasming, burning, or a type of vascular sensation that makes a motion like riding in a car difficult to tolerate.

On a regular basis I have a mild to moderate fatigue. At it's mild state I feel like someone who's been on the go for over 24 hours, dragging but able to pull through. The standard for me is like someone with a bad cold where I'm forced to rest every so often after any form of activity. In a worse state I'm sleeping the majority of the day, awakening and still feeling lousy.

In terms of memory, I live with Post It notes, even having to record important information that may have been told to me just moments ago. In addition to the memory difficulties, we're finding another even more embarrassing symptom for me; I don't like having to speak to people during those times.

You have no idea how frustrating and humiliating, for example, being in a deli and trying to recall the name for tuna fish and ending up having to point to it (inaudible 44:59). The more I struggle to recall words, the more distressed I become, only worsening the ability to think. There are many times I can no longer (inaudible 45:08) and can no longer do and what I can do is very limited.

Anything that requires me sitting, standing, and leaning for long periods of time is challenged. Using my hands, arms, shoulders, without taking breaks, this can lead to locked muscles in my neck that can cause a headache that lasts up to three days.

On my good days I'm able to do a couple of things like walk my dog, or a portion of the housework, like a load of laundry or to load the dishwasher. On my bad days it's basically the world could fall apart and I wouldn’t care.

I remain in hibernation mode, being in bed the rest of the day. Climbing a couple of stairs is agonizing. My leg muscles feel leaded, stuff, and weak, and almost as if they were going to rip if I continue to walk.

Sometimes I'm too tired to even take a nighttime shower. I have heightened sensory modality during these times. Sounds are amplified, smell is intensified, and (inaudible 46:07). Touch, breathing, and irritating against my skin.

I feel like a car being revved up while in park. My mind is racing with thoughts making sleep difficult; everything seems annoying to me. The pain gets intense to the point that I want to rip my skin off.

Over the years my condition has gradually worsened. I was once in a beloved career in clinical research, and now I'm forced to go on disability for the past three years.

I have bad days and good days that are mixed, never knowing when they will occur and to what extend. Weather, stress, and over exertion of my muscles create my flares. Of all my worries the loss what (inaudible 46:48) I do have to the point of becoming wheelchair bound or bed ridden is most predominant. My worst fear is having to live the rest of my life this way.

DR. EGGERS: Thank you very much, Lori. We very much appreciate it. I'm going to ask my FDA colleagues if they have any follow up questions, if we still have Lori on the line. Any specific follow up questions for Lori?

DR. HERTZ: Lori, can you tell us a little bit about what you're doing for your symptoms?

MS. GALPEER: I'm sorry; could you repeat that?

DR. HERTZ: What types of things are you doing for your symptoms?

MS. GALPEER: Mainly I take medication; Cymbalta and Ultram, and then Neurontin for when I have flares and it helps me to get about three and a half of sleep at night, on a good night. I do a little bit of meditation.

I've gone to the chiropractor where they've manipulated and taught me exercises so that I can try to catch the intensity of my shoulders and arms so that I don't get the headaches, and it has helped a bit. I don't get as many headaches as I used to.

A lot of support. I have a big fan base, a lot of friends that I went to school with on Facebook, and a lot of friends that I've established over Facebook (inaudible 48:17) fibromyalgia, we support each other and validate each other. I have a very supportive husband who's helped me through a lot of this. So emotional support has been the biggest factor, or I would profoundly (inaudible 48:32).

I do try to go out and walk as much as I can. On a good day I walk up to a mile at a certain pace. Stretching sometimes seems to get this (inaudible 48:49), sometimes it locks that up.

Hot showers help a lot too. It seems to release something at times with the muscles. I really can't think of anything else, but those are the main things that I rely on to try to help decrease the pain and some of the other symptoms, as much as possible.

DR. EGGERS: Thank you so much, Lori. We have one other follow up question.

DR. KILGORE: Have you identified what causes the flare? What causes your flares? Do you know?

DR. EGGERS: What causes a flare for you, Lori?

MS. GALPEER: The worst is weather. Any change at all, an increase or decrease in the temperature. Cold days like this, humidity -- when it's humid and hot I get the nausea and the burning pain, and the exhaustion. The cold temperatures bring on the stiffness, the tightness, the burning pain more so, (inaudible 50:02) types of flares. That seems to be the worst.

Over the three years that I've been on disability I've had to really learn to handle stress, and learn to go through it -- we all go through sort of a believing process to learn to accept what we can't change, and the new lifestyle. The new life, whatever you want to call life, that we have. So trying to handle life, but trying to not get overwhelmed by the (inaudible 50:38) has reduced some of the stress. So mainly the weather is my biggest flare of all things.

DR. EGGERS: Thank you very much, Lori.

Lori's going to be having to jump off now, so I would like to give Lori a round of applause, especially if you hear your own experience shared in her story. Thank you very much, Lori.

MS. GALPEER: Thank you.

DR. EGGERS: Now we will start with Jacob. You'll have to just turn on your microphones with the little button.

MR. SMITH: Hello everyone. My name is Jacob Smith. I'm originally from Brooklyn, New York, but now I reside in the Bronx, New York. I'm a father of two beautiful girls, and one beautiful wife. In travelling from New York my purpose for addressing you today was really to assist you in gaining a deep understanding about my journey with fibromyalgia.

So let me begin by saying that in 2009, for no unexplained reason, I began experiencing swollen feet and hands, in which I was rushed to the emergency room. After no determined diagnosis I returned home only to experience an increase in body pain over the next year.

Unfortunately in February of 2010 when we got -- that my youngest daughter was born, I attempted to stand up, which led to me loosing my balance and falling on the floor. At that moment my wife assisted me in regaining my balance resulting in me resting in the bed for the next two days. Post those two days I scheduled my first doctor appointment to Columbia Presbyterian Hospital in Upper Manhattan.

Finally after numerous emergency room visits, and several x-rays and tests, it was diagnosed in May of 2013 that I has this central nervous system disease entitled fibromyalgia.

Over time I would regularly notice the daily impact the disease had on my life, relative to the symptoms involved. Of all of the symptoms that I have experienced due to the disease, the three most significant ones currently impacting my life today is the chronic body pain, which can range from a deep muscle pain, chronic headaches, feet pain, leg pain, chest pain, hand pain, and an unending back pain.

The second is the chronic fatigue, which can pretty much be described as like an overwhelming feeling of tiredness that is not relieved by sleep or any rest, and for which I'm experiencing right now.

The third is the, I would say, cognitive function aspect of it. I'm beginning to forget a lot and having to write a lot of things down, and my wife has begun a daily regimen of pretty much reminding me of what I have to do both for my company and my staff, and myself, and also our daughters.

So frankly put, the fatigue is not your normal tiredness. Again, it's an overwhelming feeling of tiredness.

The fourth, I would say, just to add in, is a restless leg syndrome, which my legs tend to hurt all of the time, and my feet tends to stay swollen at time. Or remain swollen.

Initially I was able to walk for a few days without any major swelling, but as the time progressed the immobility of my feet became evident. Now I'm at the point where able to only walk half a block before I experience that pain.

Once I return home, so I'm trying to rest, so I have to deal with the results, so you know, the feet swelling and throbbing, in which my wife has begun a daily regimen also of soaking them in alcohol and hot water.

To further elaborate on the point, the pain resulting from these short walks has also disallowed me to be able to give my seat on the New York City subway, in which that bothers me because sometime I will see an elderly person, or a mother with a child, and I'll be thinking that I really can't give up my seat, in which I really want to.

Unfortunately it's been recommended that -- by my physician that I may possibly have to look at the use of a power chair for mobility on the days that I cannot walk. With that recommendation reality is not only -- not totally set in regarding the use of a power chair as part of my daily life.

So I'm trying to incorporate a few daily and long distant travel methods to help decrease the pain. But let me put it like this; it has yet to work.

After reoccurring problems with my vision -- another reoccurring problem is with my vision. Where major flare-ups occur, I partially lose the use of my near sightedness, leaving me unable to read anything for hours at a time. I remedy these episodes by just relaxing my eyelids with a warm rag over them.

But the key aspects of the disease is with my living in isolation. In living with this I've experienced social isolation simply because I am in too much pain to keep with any social engagements. Unexpected flare-ups of pain and discomfort may surprise me, and I have gradually changed or limited my social activities.

Another sign of my social isolation resulted in my withdrawing from social activities, or feeling a loss of interest or pleasure in my usual activities. But I'm working to avoid social isolation by making an extra effort to stay engaged with my family and friends.

DR. EGGERS: Any final thoughts, Jacob? Any parting --

MR. SMITH: Yeah, I mean -- the parting thoughts is just -- what I'm trying to do now is now put together some form of comprehensive lifestyle plan that's really going to help me shape my mind, body, and spirit, so that I can remain holistically healthy to the disease.

DR. EGGERS: Thank you so much, Jacob. Thank you. And Michelle?

MS. DONCKEL: Hi. I want to say (inaudible 57:19).

DR. EGGERS: Oh, I'm sorry.

MS. DONCKEL: Well, I want to thank the FDA for listening to us because people don't listen, even people that aren't involved in medicine. They don't know what to make of it, and so they just don't want to listen.

Fibromyalgia has been my constant companion for 26 years. I am so sorry --

DR. EGGERS: It's okay.

MS. DONCKEL: I have all of the symptoms; the pain, the exhaustion, the fog, IBS, insomnia, sensitivity to hot and cold, to name the major ones. There's a lot of little ones that I deal with, and I believe that right now I'm on a good regimen of medication. I'm able to hold down a job. I'm able to work from home when I need to.

The group that I support are very supportive of me, and I feel really lucky that I have that in my life.

I don't really believe my condition has changed that much over the years. The only thing that really has changed is my ability to know what I can do and what I can't do, and thereby being able to do a few more things because -- okay, I can't go shopping tonight; if I do go shopping tonight, then I probably won't do anything tomorrow or the next day, and just working that into my daily life.

Getting sleep, making sure to go to bed at the same time every night, the same routine, and with the help of medication I have the best track record for sleep that I've ever had in my life, from the time I was a baby. Just ask my mother.

So I hope that I can be hopeful to the rest of you that it doesn't need to get worse than what you have it right now, and maybe you can continue to do what you do right now with modifications in your lifestyle.

The biggest challenge I have though, and it sounds the same as what Lori and Jacob have talked about, is those attacks. Mine type start in the morning, I will wake up like I have been hit by a bus, I am too exhausted -- like I lay there, I have to go to the bathroom, I have to go to the bathroom, and it will take me a half an hour just to be able to get out of bed to move to go to the bathroom.

The pain is so bad, like if somebody walks across the floor, I can feel that. It feels like there are knives sticking into my body.

Then the next thing that comes with that is I can't even tell you what's going on because I can't get the word out of the mouth. I can't get the word into my brain. They may come out in a different order.

My family is really good at understanding and helping me through that. But what it does to diminish is my ability to go to work, because I certainly cannot go in and be effective if I don't know what's being said to me, if I can't respond, which sometimes I just can't respond.

So those are the days I have to stay home, and just wait for it to pass. Because usually at that point, if it's that bad, any of the medication I normally take doesn’t work, and I'll loose two weeks. That is so depressing. On top of everything else, I've just lost two weeks I will never get back.

Things that I would have liked to do, I can't do, and my friends understand it, but extended circles, they just don't get it. So it's just a really hard thing to deal with.

The thing that made a huge impression on me was Jack Kevorkian. Dr. Death. One of his patients was a fibromyalgia patient, and I readily admit if I thought my life was going to be one long attack, fibro attack, and I would never have a day where I could get up and go to work, I would call him, because it's not living. It's just not living.

DR. EGGERS: Thank you so much, Michelle. Now we'll have Laura.

MR. THOMPSON: Just a quick reminder to speak pretty close to the microphone so people on the web can hear you. Thank you.

MS. DUGAN: Hi, my name is Laura Dugan. I am 32 years old, and I was diagnosed with fibromyalgia when I was about 16, which is a little younger than is traditionally diagnosed.

I had presented with chronic pain, chronic fatigue, and saw my primary care doctor, and I remember her coming out with this green book and opening it and there was a chart and she looked at the chart, and then you know, testing all the tender points on me, and I had pain in all of the tender points. That coupled with the fatigue and blood work to rule out things like Lupus and M.S., and other possible diagnoses, is how I ended up with fibromyalgia diagnosis.

So at this point I've had it for about half my life, which is sort of an unusual thing.

The level of fatigue is definitely the biggest impact on my life. As I've gotten a little bit older mine has gotten a little bit better. I generally don't have huge pain flare-ups, but the chronic fatigue is a huge part of my life and it affects just about every decision that I make.

It's impacted relationships that I've had with significant others. My family, I think because they grew up -- we all sort of grew up together with me having it, it was a little bit different, so they're just sort of used to it, as I've gotten used to it.

It is just a part of my daily life, but I do find that when I'm thinking of doing something, or making decisions, I'm thinking, well, what time am I going to get home, so what time can I get in bed, to make sure that I can get enough sleep.

Insomnia has been a big problem, and it wasn't until about two years ago that a doctor through to test me for a melatonin deficiency, and I was found at that time to be very deficient in melatonin. So taking that now has pretty much, so far, cured my insomnia, which is wonderful because I've tried just about every sleep aid on the market with more misses than hits.

At one point I was on -- my one doctor joked that I was on as much trazodon as they give prisoners to tranquilize them. So it's nice to be able to take something natural to help you to go to bed, and I'm a big proponent of that as well.

Most of the over-counter -- not over counter -- all of the prescription medications for fibromyalgia have not helped me in any way, in fact, coming off of Cymbalta, even though I tittered off of it, threw me into one of the worst flare-ups that I've ever had.

So it's sort of a catch-22 with trying to find something that works to alleviate the symptoms, particularly of fatigue, but the whole risk/benefit scenario that was mentioned earlier -- it's hard for me to tell overall if things have gotten better or worse.

I do feel like my pain is a little bit better, like I said, but the fatigue -- as you mentioned -- it was interesting too, my mother had said too, that I have never slept well from the time I was an infant. So it's interesting to see that there's some parallels there as far as that goes.

I have yet to find anything that really helps alleviate the fatigue. I have had, I think at this point, even ten sleep studies. I've had things like periodic limb movement syndrome, I think is what it is, and delayed sleep phase syndrome, and all these things thrown at me, but no real solutions to fix it.

More than anything I would like to be able to wake up in the morning and not be tired, not have my first thought be, I want to go back to sleep.

DR. EGGERS: Thank you very much, Laura. And finally we have Sabrina.

MS. DUDLEY-JOHNSON: Thanks, Sara. I'm Sabrina Dudley-Johnson. I am a Chicago Police Officer disabled by injury-induced fibromyalgia.

I had a series of injuries on the job, the first one was because I was arresting a person who thought I was Dionne Warwick, and got upset when she found out I wasn't, and she Judo flipped me I sprained my left arm. Then I had a fight with Stephen King -- not the writer -- in an enclosed small room with the lights off, and he was throwing me around the room like a rag doll.

Then finally I was in a squad car that was hit by a squad car that was driving by a drunk policeman. This all happened over a period of about nine to twelve months, so I know to the point when my fibromyalgia started.

As a result of fibromyalgia I am now divorced.

I'm going to go through -- I answered the questions, so I'll just go through and answer -- of all the symptoms that you experience because of your condition, which ones are the most significant? For me the top three are the unrelenting widespread chronic pain that won't stay in one spot. You know, it starts out in the morning in the neck, and then by the afternoon it's in my lower back, and by the evening it's in my legs and feet.

The next one is the ongoing fatigue. I start in the morning really well and about 3:00 p.m. I literally hit a brick wall. I'm like a cartoon character moving at 100 miles an hour and then all of a sudden come to a complete and total stop because of the fatigue.

Then for me is the constant sensory overload. I have a problem with lights, and noise, and smells, and touching, and you name it, and it affects me. Most significant is my problems with smells.

I live in a multi-cultural condominium complex so there's at least one family member from every culture, and when people cook the smells seep into the common hallway and then it seeps into my condo unit. So I can't even step out of my bedroom. I literally stuff towels underneath the doors at the meal times so that I'm not attacked by smells.

If I do have to step outside when people are cooking, I either faint, or I throw up. So I'm becoming a prisoner in my own home. That's why I'm in Milwaukee right now, instead of Chicago, because now I'm in a townhouse with my daughter and I don't have to deal with that.

Specific activities that I cannot do fully, or that I can't do at all? I do not sleep through the night. I can hear everything going on around me. You can come into the room and have a conversation and I will respond to you, and my ex-husband a bought a building because we had a conversation while I was sleeping. I can't move though, I'm paralyzed.

So as much I want to jump and say, no, don't buy that building, I couldn't react; all I could was talk to him and I couldn't get the words out no. I actually said yes.

I have not been able to perform in my chosen career of law enforcement since 1994. There were two incidents. Number one, I was acting court sergeant, and so I'm talking to an officer and my head bounced off the desk. I just fainted.

Then the second incident, I went to re-qualify with my service revolver and because of the pain in my hand, as soon as the recoil hit I dropped the gun, and then the gun discharged a second time, and they told me, we don't need you anymore.

Finally, I'm no longer married because of fibromyalgia. Back when I was diagnosed it wasn't something that was -- you know, you didn't see the commercials for it. You didn't hear about it, and a doctor told my ex-husband that it was a psychological disorder, and he went and asked his mother for advice and she told him to go beat me back to health. He tried; it didn't work. I still have fibromyalgia.

Next question. How do your symptoms and their negative affects impact daily life? On my best days I can go to physical therapy if they send the van to come pick me up. Or I can go visit a friend or relative, if they come pick me up. Or I can go to the movies, or I can go shopping, but I can't do all those of those things at once, and that was something I used to love to do, was multi-task and do everything all at once.

Just to come to this public meeting I had to go see my doctor, get a release saying, yes, you're fine enough to travel and sit on an airplane for an hour and a half, and make sure that I had all my medication, and I had massage, and then when I get back home I'll have massage.

Normally, I would not be leaving until the day after a meeting, but I'm babysitting my wonderful two year old granddaughter, so I have to go back tonight. So I know that tomorrow is going to be difficult for me.

On my worst days, I can't get out of bed. That's -- end of story. I pull the cover up over my head, and I answer people through the blankets, and that's it.

DR. EGGERS: Any final thoughts?

MS. DUDLEY-JOHNSON: Yes, the thing that really bothers me about fibromyalgia is the problems that I have with touch.

Having my two-year-old granddaughter hug me hurts so much, I would like to push her away, but I don't want to. You know, it's the most innocent thing that you can receive is a hug from a baby. And my worst fear is that one day I will become a prisoner in my own home because of fibromyalgia, because I can't get around.

DR. EGGERS: Thank you very much, Sabrina. Thank you to all the panelists again. I am going to suggest that we move right into the facilitated discussion, and there may be some follow up questions for you as we address the different symptoms that will go along.

Somewhere there is a microphone for me. This is the part that we call talk show style, so I'm going to be coming out into the front. Can you hear me? Okay. There's a lot of machines up here, so I'm not sure exactly where I'll stand for this. But the first thing I want to do is to give the panelists a round of applause. We thank you.

It takes a lot of courage, and a lot of preparation to come up here, and we are so thankful for you courageously sharing your stories, and as I said, they set a good foundation for the rest of the conversation that we'll have.

So I want to ask a question first about how many of you, how many patients, or loved ones if you're -- if the patient is not here, how many of you heard your own situations in at least one of the panel members who spoke today? Okay. So just about everyone did.

Did anyone -- I'm not going to ask you to explain now, but does anyone have a completely different experience than what as at all shared. Okay.

We'll come to you in a little bit then.

So we heard about the chronic pain, of course, and we are going to talk a little bit about that, but as my colleague said, that is more understood maybe than other aspects of fibromyalgia.

So then we're going to delve into fatigue, the cognitive problems as we -- I think we heard one call it the fibro-fog, and other things. So let's first talk a little bit about chronic pain.

We heard several ways that the chronic pain manifested -- oh, actually -- wait, I'm getting ahead of myself. We want to have a polling question first. I'm sorry. I've only done six of these; you think I would remember the order by now.

The important thing we want to do is to get a sense from you in the audience, and from the panel members, and on the web, of which of these symptoms are most significant to your daily life. This just helps give us a sense of what's in there.

This is a long list, and you can use your clickers to choose up to three symptoms that you would say would be your top three. Chronic pain, fatigue or lack of energy, difficulty concentrating or memory problems, and here I would say if you would put anything in the category of that fibro-fog. Sleep problems, sensitivity to light, sound, or other stimuli, gastrointestinal issues, depression or anxiety, headaches, or some other symptom that doesn't fit in any of the other categories. This is a hard question, I know.

Okay. I think we can go onto the results. Okay. So I don't think this is -- I think we might have a technical malfunction here. So let's just do a quick raise of hands, shall we? Then we'll come and see what the web is.

So how many would chronic pain as one of their top three? Okay. So just about everyone. Fatigue or lack of energy? A significant portion. Difficulty concentrating, memory problems, or fibro-fog? Okay. Sleep problems?

What's interesting to me as I'm looking out is that different people are raising your hands. There's -- you're not all experiencing the same -- we wouldn't put all the same in your top three.

Sensitivity to light, sound, or other stimuli? Okay. Not very many. I think we have a few. Gastrointestinal issues? Okay. A few. Depression or anxiety? Okay. A few more. Headaches? And something else that doesn't fit into any of these categories? Okay.

So it looked like the chronic pain, fatigue, and the difficulty concentrating, the sleep problems, were the top ones chosen.

And on the web?

MR. THOMPSON: On the web 98 percent of the people said chronic pain, 75 said fatigue, and then it was difficulty concentrating and sleep problems both around 40 percent, and then about 20 percent said depression or anxiety.

DR. EGGERS: Okay. Thank you. So now we can talk about chronic pain a little bit. We heard various ways that it manifested, including the tender spots, the muscle aches and joint pains, and the moving -- the pain moving in your body.

Just a quick show of hands; how many of you have the tender spots? And when I -- let's do the quick show of hand, let's say would you put that in your one or two top aspects of pain that are the most bothersome to you? Okay.

What about the stiffness pain, or the all over body pain? Okay. A throbbing pain all over? Okay. What about that pain to be touched that Sabrina talked about? All right. Were there any other types of pain that you didn't hear described that you want to talk about?

Okay. Right here. There's a microphone runner, if you could just state your name, please?

MS. WILSON: My name is Valerie. I get like a burning pain. The way I describe it to my doctor is if you were running or working out, and that like burning that you get exercising, I get that from just standing up and walking in the kitchen, or just standing there, you know, trying to cook a meal, or just standing there.

I just get this horrible burning coming over me, and it's excruciating pain, and it's miserable to live with. I get it mostly in my upper legs, my arms, sometimes my back and my neck, and it's just miserable to live with.

DR. EGGERS: Thank you. Valerie -- is it Valerie?

MS. WILSON: Yes.

DR. EGGERS: Okay. Valerie. How many of you experience what Valerie experiences? Okay. Are there other types of pain?

Yes. Right here, and then we'll go into the back over there, to the gentleman.

MS. WARD: Hot stabbing pain.

DR. EGGERS: Deborah?

MS. WARD: Hot stabbing pain.

DR. EGGERS: Okay. Stabbing? Like --

MS. WARD: Poker. Hot poker just going right in.

DR. EGGERS: Okay. Does that resonate with people? Okay.

And then the gentleman back there? You don't have to stand. You can stay sitting.

MR. OGDEN: My name is Louis, and I'd like to say that of all those things you had listed there's only one that I don't have, so it was very difficult to pick the top three. Headaches have always been my major problem, along with the real tight shoulders, and this kind of thing.

I would liken it to, if you can imagine making a mold of your head that's a quarter inch too small all the way around, and put it on. It's crushing from every direction. Just absolutely crushing type headache, and this goes on 24/7.

I'd also like to mention quickly that I feel a little odd in here because I've had it for so long. Virtually all of my adult life and part of my childhood, and I'm 63, will be 64 in a couple of days. So I was diagnosed with fibrocytis, back in those days.

DR. EGGERS: Thank you, Louis, for sharing your wisdom, then.

So the headaches, what Louis described, I saw some head nodding's. We are interested in hearing a little bit more about headaches, so can you raise your hand if you had headaches, and you'd put them kind of in the top?

Were there any follow up questions about headaches, how they manifest themselves, that the panel would like to know about? Okay.

Does anyone want to describe a situation, an experience, that's different than what Louis described regarding their headaches?

We have one in the back there. Let's go right here -- first, Jenny, let's go right here close to you. Right there, and then we'll go in the back. I think -- can you turn the mic on?

UNIDENTIFIED FEMALE: -- 1992, after eight years struggling. It came as a result of physical injury, followed by emotional trauma. I ended up with post distress traumatic syndrome. Any medication I did not stay long term because it just gave me side effect. But I have been able to manage it with three main things, that is watching about the diet, nutrition, exercise to my limitation and what my body can tolerate, and stress management.

Something that, as I aged, is coming now is movement. I think it is as a part of psychological, because movement gave me relief, and jumping from one movement to the other all the time. At the end of the day, exhaustion. I can't go to sleep.

Now I am at the point that I am very active. Sometimes I feel like I am hyperactive to do something; go around, pick up something light, move, walk and this is the way that my life is, and as a result of that a lot of exhaustion.

DR. EGGERS: Thank you very much. We'll be getting into the treatments and the management after the break in our second topic, so we'll be delving into that a little bit deeper.

I think we had one more comment on headaches in the back, the black shirt, that black sweater? Oh, okay, a different type of pain. So -- okay, we'll take one more headache comment from, I believe, Elizabeth?

DR. JONIAK-GRANT: Yes.

DR. EGGERS: Yes, from Elizabeth.

DR. JONIAK-GRANT: Hi, thanks. I have a huge issue with getting the headaches where they turn into severe migraines. For me it's if I try and carry any items that are more than like a half a pound. Computer work, and actually vibrations -- if I'm in a car, road vibrations, bumpy roads, that's a big thing that sets it off.

So I work with a neurologist. But with taking the Cymbalta you have to watch how much of Imitrex you take.

So it's always a balance, but for me actually what helps the most for the headaches is ice. Not heat, but ice.

Then the one other symptom that I just wanted to mention for me that is slightly different is hot feels like it's scalding. I have to have my husband, or use a thermometer, to check the temperature of bathes and showers before I get in because for about 20 seconds I feel like it's scalding me, and then my body adjusts.

So you know, I don't trust myself enough. I kind of know where the dial can be now, and that's okay, but that's something that I definitely have and has gotten worse over time.

DR. EGGERS: Thank you, Elizabeth. I saw some head nods as you were describing that, so I think others share that.

I want to move into fatigue because I think that all five of the panelists mentioned it, and at least two of you really focused on it in-depth. I believe that -- let's have another show of hands to see -- did you hear your experience with fatigue reflected in their comments on fatigue?

Okay. Did anyone experience something completely different about their fatigue? A different time of day when it hits, or under different circumstances? Okay. We have one in the back there. And if you could state your name, please?

MS. SHOEMAKER: Oh, Nancy Shoemaker. I'm exhausted in the morning. I mean, for me -- well, and the aches and pains are in the morning, and then once I get warmed -- or I think of it as warmed up, I don't really mean warmed up, but I mean once my body gets moving then I'm doing fine. Then I do have the crash in the middle of the afternoon.

So I've got like, you know, so many hours in the middle of the day there, it's like I'm a person, go for it, do it. Then it's gone. Then equally, you know, dumb as a day old woodpecker.

DR. EGGERS: So we've heard about that very slow start in the morning. Not to try to minimize that, but what I'll describe as a very slow start, and then the crash that happens sometime in the afternoon or later in the day.

Anyone else have a different way that fatigue hits you? Okay. Right here in the middle.

MS. FAUNTLEROY-COCKRELL: Early in the evening, I just have to go to bed. I can't sit up. I mean, I can watch TV, but I've just got to lie down. I have to lie down. My body feels like I've been -- like something road or flattened me with a big Mac truck, or something.

DR. EGGERS: Is this fatigue that you're talking about, when this crash happens, is it the type of fatigue where you have to stop what you're doing and you want to go to bed? Or is it the kind of fatigue where you don't feel like going to sleep, you just need to sit and veg?

So I'm hearing one or the other, or both. So we have -- you're nodding, so -- we'll take the microphone. Is it Helen?

MS. WALKER: Mine is the not the kind -- I'm sorry; my name is Sue Walker. Mine is not the kind where I have to go to sleep, it's the sit and veg. It's just -- and my pattern, as long as I've got the mic, is a little bit different as well. My crash is not so much dependent on time of day as on activity, and it's completely unpredictable. So it's very difficult for me go out and do things because I never know when that crash is going to strike.

DR. EGGERS: Okay. Thank you. More here -- there's one right behind. Kathy?

MS. KING: Yes. My name is Kathy King. For my fatigue, what I -- what generally happens to me is I'll have done something the day before, and I wake up the next day and it's just -- there's just total exhaustion.

There have been times when I've been sitting in a chair and thought about raising my hand, and literally couldn't do it. It wouldn't go. It's -- those are my days that I have to call in sick. Thankfully I'm still able to work full time, but it's -- the --

DR. EGGERS: A delayed response in the fatigue, I think is what I'm hearing.

MS. KING: It's amazing how tired you can get.

DR. EGGERS: Okay. So I have a question in follow up. I'll ask my question first and then we'll -- what we'd like to tease out is how much your fatigue is related to your pain.

So a question is, if you are getting a good night's sleep, or if you feel -- if you don't feel fatigued, does that have an effect on the other symptoms that you feel?

I'm seeing some head nods. Maybe we can have someone over here describe?

MS. LYALL: My symptoms are directly related to how much rest I've had, and that's one of the ways that I manage my symptoms, is by making sure I get enough rest. If I get over tired, which like most everybody else I have the insomnia symptom as well, I'm guaranteed to have a flare up. So it's directly connect, the fatigue and the pain.

DR. EGGERS: Thanks, Sarah. Does that resonate with folks? I see a lot of heads nodding. Okay.

Go ahead, Sabrina.

MS. DUDLEY-JOHNSON: Yeah, I think that my pain is related to my sleep. I got a CPAP machine last year, and when I use the CPAP machine religiously my pain level is pretty low, and if I go a day or two and -- oh, I don't need it now -- then my pain level goes back up.

DR. EGGERS: Okay. Any other follow up questions -- oh, so Bob?

DR. RAPPAPORT: There's a theory, hypothesis, that we've heard a lot that it's the underlying sleep disorder that is really at the center of fibromyalgia, and that it is nexus for all the other symptoms, the pain and everything else.

I'd just -- I'd like to hear a little bit more from people by -- two people have said that that sort of fits the theory, but I'd like to hear more from other people. Because if we can find a drug that treats the sleep disorder, is that going to solve all the problems? Or not?

DR. EGGERS: Okay. So we'll go with someone who hasn't spoken. So how about --

MS. LONG: Shay.

DR. EGGERS: Shay? How about Shay, and then maybe next Nancy?

MS. LONG: Hi, I'm Shay. My disorder kind of started off with about a year of not sleeping at all, after I came back from a deployment, and definitely it was the worst then. But since then I've gotten all kinds of behavioral therapy to try to adjust my sleep, and I'm definitely sleeping way better now, and even sometimes without the help of medications.

I still am like fatigued to the point that sometimes I have -- I mean, I have left places, and gone -- like, I have to go sleep in my car right now, right now this minute. You know, even times when I'm not particular fatigued, my pain is level is still just as bad. I think the fatigue actually is sometimes -- almost kind of helps because I can focus on that, and go to bed.

DR. EGGERS: Thank you, Shay.

Nancy, would you like to follow up on that?

MS. JENIAK: Yeah, I just wanted to add that mine started with a six month period of not sleeping, literally for six months, and that's when I got the diagnosis. So I think sleep does definitely have some sort of connection. And then now, 18 years later, I found something for sleep and my symptoms are much better.

So finding something that helps with your sleep, I think, is something that people should look for.

DR. EGGERS: We have one more -- we'll go to one more in the back, but as we're going back there, how many of you agree with an answer of Bob's question, with that Shay and Nancy have said? Can you raise your hands? Okay. Then one more?

MS. ALEKEL: My name is Lee Alekel, and I work for the NIH but I have been diagnosed with fibromyalgia a number of years ago. I don't have true confessions, the kind of severe symptoms that many of you have in this room, but I do have a myriad of symptoms.

I also work for an institute that is vitally interested in the sleep/pain connection, and we're holding a workshop -- it's not open to the public because we're just beginning to really try to grapple with this intersection between sleep and pain, and in particular how do sleep disturbances impact chronic pain, and actually lead to chronic pain.

So we are vitally, vitally interested in this, and I think it's really good that you're having this today, and I think it's so important for researchers to be aware of this, and to really listen to the patients in the community. So thank you very much.

DR. RAPPAPORT: In follow up, could you please let us know when that conference is going to be?

MS. ALEKEL: We'll talk about it.

DR. RAPPAPORT: Thank you.

MS. ALEKEL: Thank you.

DR. EGGERS: So I think we're going to move on from the fatigue, and move on to other things, but I think what we've identified is a place that if you're on the web, if you can submit -- you know, write in a web comment in this; it's going to be captured.

You, in the room, didn't all get a chance to speak about your fatigue issues, so please take a moment and write a follow up on your fatigue, and if you submit comments to us through a website we'd really be interested in hearing more, exactly that relationship.

We have Sharon?

DR. HERTZ: Yes. Thank you. When you do -- if you are planning to provide us additional feedback, and we would love to see it, one of the questions that we struggle with sometimes is trying to differentiate the type of tiredness that comes from simply not sleeping, and is that the same or different from when a patient with fibromyalgia reports fatigue.

Is it qualitatively different, or is it simply just fatigue in the setting of apparent adequate sleep. So if you have some thoughts on that, we'd love to hear that as well.

DR. EGGERS: Thank you. All right. I'm going to take a moment and see if there have been any comments on pain or fatigue that have come in from the web.

MR. THOMPSON: Yeah, there's been a lot of comments. Many have been echoing what's been said in the room, so I won't go through and talk about all the different pain and fatigue related symptoms.

Just some of the highlights of what had been said that may have, you know, built upon, or a view slightly different from what was said in the room, there was a lot of talk about agreeing that either -- some people were saying that the fatigue and pain are very interrelated, and they're not sure which necessarily, you know, will cause the other.

Some people said that for them they've not seen any relation between the two, so there was a little bit of differentiation there.

There was a lot of talk about vision issues and eye movement pain, as well as vertigo and other balance issues that were related, or at least potentially related to when there was pain.

Then there were a lot of things related to these symptoms that kind of were secondary effects. An inability to work, social isolation, and there was a couple comments about how this is much more of a concern, especially for children. How that might affect them in the long term.

Then also, you know, inability to travel because of inability to sleep flat, and inability even to do things like clean your own house and stay up to date on normal daily activities.

Then there are also a couple points about stigma related to the pain, and needing to seek multiple doctors. You loose credibility, potentially, within the medical community. It looks like you're doctor shopping.

Also, in terms of just needed special accommodations for pain or fatigue. You know, one person described it as older people look at him like he's a liar or a fake when he requests accommodations in public.

Then others have mentioned that, you know, obviously need to rely on their spouse to help care for -- with pain and fatigue, and in many cases people said that this had led to divorce.

DR. EGGERS: So it's echoing what we hear, and if you're on the web you can't see it but you're getting a lot of head nods in the room with people agreeing with you on those.

Vision problems -- one more thing -- Jan?

MS. CHAMBERS: Hi, I'm Jan Chambers, the President of the National Fibromyalgia and Chronic Pain Association, and I appreciate this Sara. I have in my hand the survey that we completed 2,157 patients, and I want to just comment about this fatigue, Sara.

The kind of questions that we asked indicated that the fatigue was so exhausting that people could not pick up a pencil, could not trust themselves to hold a cup, and when we talk about sitting down, as Sue mentioned, just that overall, sometimes it's that complete exhaustion like there's no energy coming out of the cells.

DR. EGGERS: Thank you. Okay. I want to get into a few more of the other symptoms, because we want to make sure we address those and acknowledge those.

Just because it was on the web, before I forget, we had vision -- eye pain and vision problems were mentioned. I don't believe that was one of the symptoms that was up on the web, so I'm going to ask, can you raise your hand if eye pain, or vision problems, is significant for you?

Okay. We heard one or two examples on the panel; does anyone have a very different experience of how their eye pain -- handles -- we'll go with Andrea first over there, and then here. Go ahead.

MS. ATTERBURY: Hi, my name is Sharon. What I've noticed when my vision changes is I have days where I have to constantly blink because I just can't focus. Everything is fuzzy looking, and so that mean those are the days I hope I don't have to do computer work, or I hope I don't have to do a lot of tiny reading or proofing.

DR. EGGERS: Thank you very much. And up here to Heather?

MS. GROSSIN: Hi, my name is Heather. When I have a really bad pain flare, my vision will change. I go to the eye doctor, I have to go get new contacts because my old ones no longer fit properly because my eyes will swell up, and I -- the strength of the prescription also changes.

So it makes -- I mean, I can't buy new glasses every time they change. At least with contacts they're disposable, they're only for two weeks, so it's a little bit more cost effective. But it is a big strain, because I'm like, well, should I be driving now because I don't have the new contacts, and my old glasses don't exactly help me see. So it is a limitation.

DR. EGGERS: Thank you very much, Heather. Yes, so we'll go with Jacob first.

MR. SMITH: Yeah, I pretty much echo what this young lady over here said about the constant batting of the eyes.

I'm in the process of doing that right now here I have to bat my eyes because my vision is somewhat off, and I have to make myself deliberately cry in order to restore that vision to some degree. So I can totally relate to what you're saying.

DR. EGGERS: Okay. Great. Then Sabrina?

MS. DUDLEY-JOHNSON: My doctor just diagnosed me with dry eye syndrome, and I think that's what everybody's talking about with the batting of the eyes, so I'm constantly putting drops in my eyes.

I also have a problem when I wake up in the morning for about an hour, I can't see. It's like looking through a veil, and I just have to sit there and bat my eyes, and wait until my vision clears and comes back.

DR. EGGERS: Okay. I would like to -- if we could, I'm going to move on to the fibro-fog, because I think that was number two, if I recall, from the raise of hands, in terms of what you're experiencing. I'd like to delve into that a little bit.

We heard some very vivid descriptions of how that manifests itself, how you experience this fibro-fog, the lack of concentration and the forgetfulness.

I'd like to see if there's anyone who wants to describe a different experience with the fog. We'll go here first, back in the back.

MS. HERMAN: Hello, my name is Gwen Herman, and when I have fibro-fog it's usually -- I've been trying to ignore my pain, and I'm trying to work through something, so what will happen is that I don't realize barriers around me so I'll walk into walls, or I'll hit something, or I drop things. I drop glasses.

DR. EGGERS: So can I follow up on that? With a show of hands how many of you find that you're -

- that if you aren't in pain, that you are not experiencing the fog? You're not in pain, and you don't -- so you can have the fog even if you're in the pain; let me put it that way. Okay. I'm sorry -- yes, I -- that was a -- I stand corrected. Thank you very much, Deborah.

If you are not in your more extreme levels of pain, is that -- is your fogginess clearer in some sense? Is it related?

No? They're not related? Okay. In the yellow shirt?

MR. THOMPSON: Real quick, for those in the web, we're going to go to the phone in about five minutes or so, so if you'd like to call in there's some instructions on the web for you.

DR. EGGERS: And when you go on the phone what we would like to really focus on, because we only get a few phone calls, is if you have symptom that just has not been talked about by the panelists, or in the audience discussion, that's what we'd really like hear.

Okay. So go ahead.

MS. WILSON: I have the typical fibro-fog where people are saying, you know, you forget your words, things like that, but I also have had times where it's been very scary for me; I've forgotten where I was going, I've forgotten where I am.

It's to the point where I try to always go out with someone because I will lose my way, I'll forget my surroundings. It's just kind of like my mind gives out on me, and it's scary.

I'm young, I'm 33 years old, and it's just like -- I don't know where I am, I don't know where I'm going, I've been in the car with my husband taking our dogs out on a walk, and we haven't gone far, we've gone maybe 20 minutes, and we're on the way back home and I've forgotten what we were just doing, and it's scary to me.

On the times when I've been out by myself and this has happened to me where I forget, you know, where I am or where my car is, or you know, what I'm doing, and I'm alone, then I start to have a panic attack because I'm alone and my mind has just given out on me, and it's extremely scary to think that your mind has just left you.

To be a young person and feel like -- it's almost to feel like you have Alzheimer's and your mind is just leaving you. It's a very scary feeling.

DR. EGGERS: Thank you, Valerie. I see a lot of head nods. Valerie, when you are experiencing that are you -- do you have more often -- are you tired? Are you fatigued? Are you in more pain when that happens than typical?

MS. WILSON: Not always. The one time I was saying when I was alone I had just come from a volunteer activity, so I was definitely tired.

The other time where I was saying I had forgetting where I was, or where we had just come from, I was in a great mood that day. I just -- my mind just gives out on me sometimes, and it doesn't always correlate with pain. Sometimes I just -- it's like I just forget. You know, it's almost like I forget who I am, where I am, it's just -- my brain just leaves me.

DR. EGGERS: Okay. Thank you. We only have a few minutes left and I want to hear if there any symptoms that -- in the room, that you experience that you would put in your top three that you haven't yet heard discussed today.

Okay. We have one -- we have a couple back there, so how about in the black sweater first? And then here.

MS. GIANNOLA: Hi, my name is Laurie. One of the symptoms that I experience constantly is feeling cold. I'm cold, I'm freezing, it feels like I've been packed in ice. Last year I turned my air conditioner on twice in the summer. I had people coming over thinking I was nuts. So that's my top three, is that freezing.

DR. EGGERS: Okay. Any other symptoms? Okay. Right here.

UNIDENTIFIED FEMALE: Paresthesia, mostly in front of the leg, upper leg, and twitching of the muscle, which is really annoying. Mostly the eyelid.

DR. EGGERS: One more and then I'm going to see if my colleagues want to ask -- okay. Two more.

MS. CHAMBERS: Jan Chambers speaking from our survey again; 39 percent of the people who responded have suicidal ideation because they can't find relief from their symptoms. That's a huge picture, 39 percent. Thank you.

DR. EGGERS: Thank you, Jan. We'll go to Laura.

MS. DUGAN: Just through some discussion with other people here a vitamin D deficiency is something that seems -- people seem to have in common, and I've also run into other people as well who have underactive thyroid.

DR. EGGERS: Okay. So can I ask -- I know we move quickly and not everyone gets a chance to say all they want. But can I ask if my FDA colleagues have any symptoms that they want to follow up on briefly? We covered a lot of material in a short amount of time.

Okay. If not, we'll have one more comment -- two more comments because you also haven't had a chance to speak. Then -- three more comments.

MS. GLEASON: Hi, Rae Gleason, and I'm the Medical Education and Research Director for the National Fibromyalgia and Chronic Pain Association. I just wanted to bring up, because it hasn't been mentioned here, and I know through the surveys that we've done here, and through the years that I've done at other fibromyalgia organizations, that stiffness is like the number one. It has come in ever number one above pain on some of those surveys, and these surveys are 5,000 people that responding, so it's not a small group of people.

I just want -- that I think is really important in what you're thinking about, and how you're planning, you know, what you're going to be doing here in the future. But spasticity is a definite problem.

DR. EGGERS: Thank you very much. We'll go back there and then we'll go to Louis.

MS. TORRES: Hi, I am Araceli Torres and I come from Mexico, and I have all those same things but I have another one, it's my movement. I start walking and then I start walking less, and less, and less, and I stop, and I can't continue.

It happens also to me when I am driving, I can't move my hands on my (inaudible 1:49:24) and then I have to stop, and somebody have to come and pick me. And so I cannot open sometimes one eye. I open one, another one is closed.

DR. EGGERS: Thank you very much. So we'll go to Louis, and then I'm going to go to the web and the phone.

Yes, Louis, I -- your experience is different than others.

MR. OGDEN: What I'd like to say that's different that hasn't been mentioned yet is I, in fibro-fog, have what I call a brain -- excuse me -- I have brain disconnect where I can be looking right at something and don't see it. I can't find it, and it's so obvious, it's three feet in front of my face, and I can't find it. She finds it for me. She's a very good helper.

DR. EGGERS: Our support networks are so important, aren't they? Is this -- very quickly, Jacob?

MR. SMITH: Yeah, one thing I wanted to talk about that hasn't been really spoke about or was listed, was the irregular bowl movement. That seems to be a symptom that a lot of people, I've found, have dealt with and I deal with that constantly. So that's mine.

DR. EGGERS: Okay. I see a lot of head nods, and I won't ask for a show of hands but I'm seeing a lot of head nods in the room from that.

On the web do we have any more new symptoms that have been discussed? We just need the -- anything new?

MR. THOMPSON: Yeah, there just are a couple of things. There seems to be a lot more of a focus on thoughts of suicide and actual knowing other patients that have committed suicide. There's a very, very -- conversation about motor control, both with the -- you know, either feeling numbness or the fluttering. Then a wide range of different GI related issues from nausea, IBS, constipation, etcetera.

DR. EGGERS: Okay. The mobility -- the erratic movements, or the things that were described over here, or are described on the web, is that -- can you -- with a show of hands if you feel comfortable, do you experience that as a type of symptom? Okay. Great. All right.

I know want to go on the phone. We're a couple minutes from our break, and we want to -- the phone allows us to give an opportunity for those of you on the webcast, a few of you, to contribute to the dialogue.

So I'm going to ask the operator for a caller.

OPERATOR: Yes, our first question is from Sharon Waldrop. Your line is open.

DR. EGGERS: Hi, Sharon.

MS. WALDROP: Hello. Thank you for this opportunity. I just wanted to mention that I have severe pain and fatigue in my legs to the point that when I married my husband at the age of 27 we put a chair lift in his home that was two stories.

After giving birth to my son those problems went away, and nobody's been able to figure that out. So while that hasn't been mentioned by other people; I wanted to bring up the affects that pregnancy had on that. So thanks for your time.

DR. EGGERS: Thank you very much, Sharon.

We will get into the discussion, but how many of you -- mainly ladies in the audience today, found that if you went through a pregnancy that that changed your symptoms in a significant way? Okay. We won't get into discussing that, but perhaps if you could elaborate on that in the docket comments?

Do we have another caller, operator?

OPERATOR: Yes, our next question is from Larry Knight. Your line is open.

MR. KNIGHT: Hello, I have a pain issue that wasn't really mentioned on here. I went to the University of Washington to get this diagnosis and he told me I had small fibro fibromyalgia (inaudible 1:53:39) affects my lower body.

Specifically the pain is intense in my legs. It feels like a combination of bee stings and the kind of pins and needles you get when part of your body falls asleep. I'm curious if anybody else has heard of that, or had any of the same issues.

DR. EGGERS: You want to repeat that -- you -- Sharon?

DR. HERTZ: I wasn't quite sure I heard, but did he say small fiber?

DR. EGGERS: Can you repeat what you had?

MR. KNIGHT: He told me I had small fiber fibromyalgia, and it affects only my lower body. It feels like a combination of bee stings and pins and needles in just my legs.

DR. EGGERS: Does anyone -- has anyone experienced this?

MR. SMITH: Yes

DR. EGGERS: You have? Jacob has. Okay.

MR. KNIGHT: Okay. I've met a couple of people online that have had some of the same issues, but theirs is of their upper body.

DR. EGGERS: Okay. Yes, Sabrina?

MS. DUDLEY-JOHNSON: There was just a study released a couple months ago talking about small fiber involvement in fibromyalgia, but they were looking at small fibers in the hand. I don't know if Jan would have that citation or not?

DR. EGGERS: Okay.

MR. KNIGHT: When the neurologist gave me the diagnosis he took skin plugs off my legs to confirm that. He sent it off to a lab in New York, if I remember correctly, and there was a difference in the nerve density in the nerve (inaudible 1:55:13) serving the legs. But I don't know if the study could correlate to the same thing, but only my lower body.

DR. EGGERS: Okay. Thank you very much for bringing that up. I think we can take one more caller. Operator?

OPERATOR: Our next question is from Mike Herness. Your line is open.

DR. EGGERS: Hi, Mike.

MR. HERNESS: Hello. I guess the thing I was looking at was it seems over the years -- I've had this about nine years, and it seems to have progressed with symptoms similar to autonomic neuropathy or dysautonomia; those types of problems with things like postural orthostatic tachycardia syndrome, drop in blood pressure, dizziness, weakness, (inaudible 1:56:04) at time. Always weak and unstable; those types of things.

DR. EGGERS: Mike, let me follow up with a question to the audience of how many of you here experience some sort of blood pressure symptoms, dizziness, or the things that Mike was describing?

Mike, you've got a lot of hands -- several hands raising in the room. Thank you very much.

DR. EGGERS: We actually have time for one more caller. Operator?

OPERATOR: Yes. Our last question is from Clarissa Baron. Your line is open.

MS. BARON: Yes, hi, my name is Clarissa Baron. I'm 35 years old, and I thought it was important to point out; I struggle with low libido, and I was in my late teens, and I was diagnosed with fibromyalgia in 2012, but have the symptoms also when I was in my late teens, especially the chronic fatigue, and lower back pain. But I thought that low libido, or even a lack of it. I have no interest in any physical contact, and -- sorry -- and I do love my husband, he's great, but you know, I just don't think it's natural.

I'm 35, I'm not that old, but I've never had a big interest in it at all. My poor husband. Bless him, but you know, I thought it was important to point out, because in order to have a good quality of life, as a female, I just it's not natural that I don't have that. So thank you for your time.

DR. EGGERS: There are some heads nodding in the room, so thank you very much for sharing that.

With that I think we're going to move into the break. When we come back we will have the second discussion on the treatment approaches, and rally delve into that a little bit more.

Thank you all so much for a very, very productive topic one discussion.

(Break between sessions.)

DR. EGGERS: We are going to get started in a few minutes. I see some empty chairs. I just would like to wait until we have a little bit more of a full house.

And as we are waiting for others to join, I will just give a recap of what we are going to be discussing in the second portion of this meeting. I think there is a slide for that. Thank you, Laura.

So in the Discussion Topic 2, we are going to now shift gears a little bit, even though these are very interrelated topics, but we are going to now switch gears into the treatments, the treatment approaches.

And as we understand it, it is a multi-modal treatment approach, many, many different -- for some of you, many, many different aspects of your treatment. And we'd like to get a little bit of a sense of that, and then delve a little bit into the specifics, the specific pharmaceutical treatments.

In the discussion, I am going to ask us to focus -- to make distinct between treatments that you take on a day-to-day basis to target your underlying condition, and then also then the treatments that you have to add on once in a while to address specific symptoms or maybe address a flare.

Can I have the next slide, please?

Then, we would also like to focus on what aspects of those treatments -- what symptoms those treatments address, what are the downsides of those treatments, and how do those downsides, especially if they are health downsides -- side effects and other things -- that really affect your daily life?

And then, if we have time in our discussion to get at what specific things you look for in an ideal treatment for your condition.

I'm going to put another plug in for the docket, the website that you can submit comments. For those of you on the web, and for those of you sitting in the audience, if you want to submit your own responses to all of these questions, we very much encourage it, even if you brought it up today. It really helps add richness to our understanding.

We have -- can I go back to the previous slide? We have five panel members, just like we did for the first topic. I have asked them to prepare a few minutes of remarks, just to give us, again, a good foundation for the discussion. I'm going to let them introduce themselves as they come, as they begin.

And we will start with Deborah. Can we -- you know what? We won't start with Deborah. That is so unfair. That is so unfair. We will start with Jan.

MS. CHAMBERS: Thank you.

DR. EGGERS: Thank you, Jan. Just remember to speak into the microphone.

MS. CHAMBERS: Thank you. I sincerely appreciate the opportunity the FDA has provided the fibromyalgia community to speak today. This is important.

My name is Jan Chambers. I'm the President of the National Fibromyalgia and Chronic Pain Association. I have had fibromyalgia for eight years following a hysterectomy. In seeking a diagnosis to find out what was causing the increasing pains and debilitating symptoms, I spent over $100,000 of my personal money beyond what my medical insurance would pay to seek a diagnosis for what was happening to me.

I knew that an early diagnosis of fibromyalgia and treatment could make a positive difference in my quality of life in the long term. Yes, I received a diagnosis of fibromyalgia, after spending a lot of money, but that did not include any answers as to what to do next.

My illness included a lot of things -- metabolic syndrome, migraines, polycystic ovarian syndrome, cognitive difficulties, functional loss, and unrefreshing sleep. I practically laid on the couch or on my bed for the next 16 months with pillows supporting my arms and legs so they wouldn't touch each other because it caused more pain. And during this time, and out of desperation, I convinced a very sympathetic surgeon to remove one-fourth of my breast because I couldn't lower my arm to touch my side. And that very sensitive spot, very painful spot, I now believe was a tender point.

I was fortunate because my eldest daughter was in medical school at the time, and she was able to guide me where to look and what research to follow. It was difficult for me to read that research because I had such significant brain fog. But I knew that education is empowering, because so many parts of my body were becoming dysfunctional.

I paid attention to the broadly accepted theory of central sensitization in fibromyalgia. To me, that meant that my central nervous system was out of control and affecting all of the systems in my body. It made sense that calming my central nervous system was going to be the answer for me, and to stop the life-altering changes that were occurring with fibromyalgia.

Since electrifying pains were coming from my neck, I found a chiropractor who used more physical therapy than chiropractic techniques. From several whiplashes throughout my life, I knew from the X-rays that my vertebrae were severely misaligned. I was also diagnosed with forward head syndrome.

I used the FDA website to locate approved devices for spinal rehabilitation and found one called the Pettibon system. The chiropractor I chose knew how to use rehabilitative equipment. For almost two years, I worked three times daily with the physical therapy techniques and these tools. Gradually restoring the natural curve in my neck reduced the horrific pains and returned most of my daily functionality.

Through the physical rehabilitation, I reduced the cervical stenosis, or the narrowing of the spinal canal, and the constant stretch and pressure on my spinal cord was stopped. Reducing emotional stress and learning relaxation skills were also very important.

I still have some fibromyalgia symptoms, but they are not completely debilitating like they were eight years ago.

I believe that there is a large subset of people with fibromyalgia who have what is called positional cervical cord compression, or PC3. For several years, the fibromyalgia research has been available about the likely relationship between fibromyalgia and spinal cord compression, Chiari-1 malformations, and the upper part of the spine.

As a patient, I convinced my chiropractor to do a small clinical study on fibromyalgia patients with severe neck pain. The results were similar to mine. Since the initial year of physical therapy, my daily life has continually improved. I still have to be mindful of my posture and stress levels. If I overdo my physical activities, like carrying heavy grocery sacks and heavy housework, some pain does return. With heat and performing the physical therapy work for a couple of days, the pain can stop or reside.

The downsides of my treatment are that there are currently not very many chiropractors in the United States who know how to use effective physical rehabilitation and instead use a lot of spinal manipulation techniques. I look for holistic approaches to treating the fibromyalgia body as well as multidisciplinary approach. That may include medication, better nutrition, and psychological therapy.

Thank you for this opportunity today.

DR. EGGERS: Thank you, Jan.

And then we'll have Gwen. Can you pull the microphone? Yes.

MS. HERMAN: Hello. My name is Gwen Herman. I'm the Executive Director and founder of Pain Connection. We work with people in chronic pain. My pain started 19 years ago when I was in a car accident. I was rear ended, and my pain started in my neck, went up into my head, shoulders, and then throughout my body, so fibromyalgia, TMJ, autoimmune system problems, gluten-intolerant, dairy -- you know, dairy-intolerant, irritable bowel, a few things. And what I had to learn was just how to -- learn how to live again because of all of the changes in my life.

So what I use right now is a multi-modal approach in dealing with chronic pain, which consists of medications. I am on Cymbalta, and that helps -- that gives me energy. And I know a lot of people it makes them tired. And it helps with my overall body pain. I also use Trazodone to help me sleep at night. Sometimes have trigger point injections, I get a Myers cocktail infusion, which it helps with fatigue, so when I get really low on energy I will go in and I will have an infusion.

I do a lot of Chinese medications. I have a special formula that is made for me that helps with my sleep, because I -- you know, I can't sleep at night because of the pain. And my worst position is lying down in bed. So that's horrible when you’re feeling tired all the time, because to go to bed to me is the most painful thing, so that’s why I need something to knock me out right away.

I use guided imagery. That helps me all the time. You know, just sitting here, I could just use it and it helps lower my pain level. I do a lot of vitamins and supplements. I use different gels for my neck. I use patches, you know, for my back, my legs.

Ice, I use all the time, even though I go to a Chinese doctor and he tells me ice is not good for my neck because it’s stopping the blood flow, and I try not to do that, but nothing brings down that pain as ice will on my neck.

I go to weekly acupuncture now. In the beginning, I would go three times a week. I went to four acupuncturists before I found the one that I have now, and I have learned that there is all different types of acupuncture. So she does something that is called the balance method, and she does Taiwanese acupuncture, and she doesn’t go into the source of my pain, so she works on the outer extremities and that helps me a great deal. And then I use like little tacks during the week just to prolong the treatment.

I also learned how to pace myself, and I usually do that. But when I don't do it, that's when I have that brain fog, and that's when I fall or bump into things. I do fall a lot if I am in pain and I'm not -- you know, if I don't rest and take care of myself.

I do a lot of psychosocial techniques with myself by changing the pain messages in my mind of how I respond to pain. And I try to live in the present; I don't go back in the past, but I stay right now, what I'm able to do right now.

I have a number of different health care providers. Since it's 19 years, it has taken me a long time to get a team that I can work with. I have an excellent pain doctor now who is a physiatrist. I have a nurse practitioner who is an herbalist and also a nutritionist, so I'm on a lot of different herbs. And I had to change my whole diet because I'm gluten-intolerant and can't have dairy.

I also go to an acupuncturist. My primary care doctor is an osteopath, and she understands about chronic pain. I go to a Chinese doctor, you know, for my formulas, and I take rhubarb to help me, you know, stay regular. That's what Jacob was talking about; rhubarb is wonderful.

And I knew I was deficient on some vitamins, so I was taking Vitamin D3. My tests came back really low, but then I took a test, a spectra cell test, and it came back that I was deficient in five different nutrients. So I'm on all those vitamins now, and one of them I really believe has helped with my focus.

And another thing that helps with my focus is doing Sudoku crossword puzzles to keep my mind intact. So that's the main thing, of growing the gray matter back in my brain.

Let's see what else. I use all different lotions for my neck. You know, I use Voltaren gel. I make my own lotion that I learned from my herbalist with lavender, St. Johns Wort oil, aloe vera, and I use that. I grow my own feverfew for migraines. I can just pick it and, you know, eat a few of the leaves. That helps with migraines. Drink four to five glasses of jasmine green tea a day, which is really good. I take oil, fish oil every day. I don't eat fried foods.

I try doing gentle stretches, but exercise is very hard for me. I have gained a lot of weight. Some of the medicines just put weight on me unbelievably. And then I had to decide, you know, what were the pros and cons of it.

So exercise is very, very hard for me. So I try to do stretches. It seems like every time I work myself up I will hurt myself. And it doesn't take much to hurt myself, and then I'm back to zero again, and then I'm afraid to do it again. So even though people say it's really good to do exercise, you really have to be careful.

And then a lot of times, if I do go traveling, after what happens I may be out for a week, or a month even. It takes me a long time to get back to where I was beforehand.

DR. EGGERS: Gwenn, if I could ask you a question about --

MS. HERMAN: Go ahead.

DR. EGGERS: -- you've described so many of the many, many, many things. Overall, as your sort of whole approach, would you say that you feel that you are well managed a satisfactory amount of the time for you?

MS. HERMAN: Yeah. I mean, I function. I have a quality of life, you know. I'm happy I can do things, but I have pain 24 hours a day and I'm still looking for something to help me even have a better quality of life. So --

DR. EGGERS: So even with all of these things, you still have --

MS. HERMAN: Right.

DR. EGGERS: -- you are still looking for something else?

MS. HERMAN: Yes.

DR. EGGERS: Okay. Great. Did you have any other final thoughts that you wanted to share?

MS. HERMAN: There was just two other things.

DR. EGGERS: Yes.

MS. HERMAN: I use a sun box for seasonal, you know, effective disorder, and I use a mouthguard for grinding, and that has really helped a lot for migraines. So, you know, we just have to use different treatments to help ourselves.

DR. EGGERS: Thank you so much, Gwenn.

And now Sarah?

MS. LYALL: Okay. I learned earlier today that I'm representing the three percent, as I am not yet 30, so I have actually had fibromyalgia for five years. So I've had it since I was -- I have actually had fibromyalgia for five years. I was diagnosed when I was 22.

So prior to the onset of my symptoms, I was very active. I liked to run, play basketball, those kinds of things. And my symptoms came on slowly. At first I just had a stiff neck, but then the symptoms progressively got worse to the point where I was experiencing excruciating pain on a daily basis.

So naturally I went to my primary care physician for help, and they ran every test in the book. And, as we know, there is no test that is going to show up fibromyalgia. So my PCP looked at me one day and she's like, "I know you're sick, but I don't have a clue."

So that's when she referred me to the rheumatology clinic at UVA Charlottesville. And it took them about a second to tell me that I had fibromyalgia. They then told me that I was too young to take any of the medications that were currently FDA approved at the time. It was 2009. They said there were chemicals and I shouldn't put them in my body, and the recommendation was to spend just a little bit more time in a rocking chair.

So, naturally, I was devastated. I remember feeling alone and like the medical community just didn't understand me. So the turning point for me was when I discovered acceptance and commitment therapy. And basically the tenets of that is quit fighting it and find a way to live with the cards you’ve been dealt, basically.

So today I manage my symptoms by paying close attention to bodily cues. I know that pain in one of my shoulders means that I need to stop what I’m doing and rest immediately. Another cue for me is extreme fatigue. I need to stop and rest before I get overtired. Also, I know that I can’t sit, stand, or lie down for an extended period of time.

And in most cases, if I keep moving, I do okay. And I can offset most flareups by laying on a heating pad and just relaxing. And sometimes I will take an OTC pain reliever to help with that.

If I have a really bad flareup, I will take 500 milligrams of Hydrocodone and 100 milligrams of Imitrex. That’s my combination. But to give a little perspective, I take about one bottle of Hydrocodone a year. So I don’t take medications. I don’t take any like everyday medications or anything like that. So as long as I constantly monitor my bodily cues, I can engage in more activities.

Now, the downside of this is that my current treatment regimen does not make the pain go away entirely ever. It doesn’t treat the bodily fatigue or the cognitive fatigue. And as a graduate student -- I’m actually in the final year of my doctoral training program for psychology -- the cognitive fatigue is very difficult.

I know recently I had my oral comprehensive exams, and in preparing for that I was so worried that I would get up there and forget like common words that you should know as a psychologist in training that I actually had a panic attack and had to go to the doctor. So, I mean, that’s how bad the fibro fog can cause anxiety.

But getting back to the treatments, I don’t think there is a single pill out there that can treat all the symptoms of fibromyalgia, from the pain to -- from the -- well, the all-over pain to the bodily fatigue, the cognitive fatigue. I think there is going to have to be some kind of a treatment regimen.

And as a doctoral candidate in psychology, I have to recommend therapy as well, and I know that has been talked about. But I think it is going to take a combination of medications and therapy to be the proper treatment.

DR. EGGERS: Thank you very much, Sarah.

MS. LYALL: Thank you.

DR. EGGERS: And now we'll have Nancy.

MS. RYAN: My name is Nancy Ryan. I am 48 years old and live in Arlington, Virginia. I work full-time as a manager of a public library. I was diagnosed with fibromyalgia in 1995. The fact is, I'm a person that experiences more pain than many people. Some of it can be explained by biology or neurophysiology, but some of it is a mystery to me and others.

I appreciate the opportunity to share some of my story, what I have tried, what works and what doesn't, as well as my hopes for the future of fibromyalgia research and treatment.

Over the past 18 years, I have tried an alphabet soup of medications from Amitriptyline to Zoloft. I counted the ones I could remember; it was 22. I found the FDA approved drugs, Lyrica and Cymbalta, caused more problems and didn't alleviate the pain. Lyrica addressed sleep, but it did this too well. I felt like a walking zombie and wanted to sleep all the time and had no motivation. It did not address my pain at all. I had a bad reaction to Cymbalta.

Other medications I have tried, such as Elavil, Tramadol, Flexeril, and Effexor also caused problems and gave very little benefit.

Starting in 2008, I participated in three research studies. I am a human guinea pig. This included an FMRI brain scan study where all medications were eliminated and exercise was the only intervention. We discovered that exercise as a sole therapy is not a cure-all. In fact, I was in a mess of pain, anxiety, and depression when the study ended. After the exercise study, I embarked on a journey back to stability.

I share my experience with the exercise research study to illustrate that exercise is only one part of the treatment that has gotten me to where I am today. Treating fibromyalgia requires a multi-modal approach. I am happy to report that I have arrived at a custom system of treatments that works for me, and most of my symptoms are now well managed.

I exercise, mostly Pilates and some strength training and cardio. I have a physical therapist who helps by treating acute problems. I attend psychotherapy with an excellent psychiatrist, and this has helped me to understand that how I am feeling affects my life, and vice versa.

Biofeedback training and breathing exercises are also very helpful. And I treat myself to massages and dry needling for myofascial pain.

My medication cocktail includes medications targeted at my specific symptoms -- Verapamil and Botox injections for migraine control, a custom antidepressant mix of Remeron that gives much-needed deep sleep and low doses of Zoloft and Abilify to address depression, anxiety, and some of the pain.

With the insomnia and depression in remission, I am much more able to emotionally deal with the remaining pain symptoms. I am able to work full-time despite my symptoms, but this impacts my off-work downtime as I have to rest and recover when I am not working, or I may be in too much pain to enjoy activities.

This makes socializing and making plans difficult. I have gained a great deal of weight on my current medications. This has been disconcerting but manageable with diet.

The medications also seem to cause my brain fog and memory problems to be worse. An ideal treatment would address the all-over pain, insomnia, and fatigue while also allowing clear-headed thinking and memory without fatigue or weight gain. Tall order.

I have had a rough go of it, and it is

very complicated. I have left out a lot of details. I would say most experiences with fibromyalgia are complicated, but I have found a combination of therapies that works for me. I have broken down my symptoms and addressed them one by one. I am doing well.

My wish for the future of fibromyalgia research is that a more discrete definition of fibromyalgia can be developed and biomarkers found to potentially identify probable cause so that treatments can be more targeted. There is no plain vanilla fibromyalgia patient. We are a Baskin Robbins array of varied symptoms and presentations. To expect there to be one medication that will address all of the symptoms of this diverse population is naïve.

Fibromyalgia researchers do not appear to have generated scientifically acceptable and testable hypotheses of causation. Until efforts are directed to this very important matter, fibromyalgia research will continue to remain in a state of limbo and treatment will continue to be hit or miss.

I read once that one FDA approved medication for fibromyalgia helps 30 percent of people get only 50 percent relief from their symptoms. This does not appear to me to be a very effective treatment.

Thank you to the FDA for this opportunity to share my experiences and thoughts for the future of fibromyalgia treatment.

DR. EGGERS: Thank you very much, Nancy.

And, finally, we have Deborah.

MS. WARD: First, I'd like to thank the FDA representatives for allowing us to have this day. Secondly, and most importantly, I'd like to thank Sara and her group that did an outstanding job to get all of us together, both in December and now.

My name is Deborah Ward. I'm 62. I'm married and I'm a writer. I was diagnosed with arthritic TM joints and fibromyalgia 28 years ago. I include my TM joints because they were the reason I was first diagnosed with fibromyalgia. My TM specialist, TMJ specialist, asked me certain questions and he said, “I think I want you to go to a friend of mine.”

My daughter calls my pill bag a drugstore, and I guess it does appear as that to a lot of healthy people. I take 15 different drugs a day, not willingly, grudgingly, but I still have to take them. The drugs associated with my TM joints and fibro symptoms are Neurontin, Zanaflex, Cymbalta, Motrin, Fioricet as needed, Trazodone for sleep, lidocaine patches, I use my TENS unit a lot, and Hydrocodone when absolutely necessary.

I also receive 200 milligrams of Botox injections every three months. This is my only treatment that isn’t covered by health care insurance. I also have radiofrequency nerve ablation done bilaterally from C6/7 to T7 every six and a half months, and now enjoy an epidural every two and a half months because of the shooting pain down into the top of both of my shoulder blades, and the hypersensitivity to my skin where it makes it difficult for anyone to even touch me.

In between these treatments, I try to swim and use the elliptical. Unfortunately, there is just too many times when there is a downtime in between the two different types of treatments, like with the Botox and the nerve ablations, where my body just gives up and I neither have the energy nor the motivation to try and do the swimming because I can’t turn my arm over.

Many years ago, I did try acupuncture and was disappointed when my acupuncturist sat me down and agreed that it wasn’t going to work for me. Nor did the herbal medicines I tried. Unfortunately, some of us are unable to handle our pain systems without the crutch of drugs, no matter how badly we’d like to try that.

My treatments help control most of the muscle spasms, some of the nerve pain, neck and back pain, but do nothing to help with the achy feeling I wake up every morning with, my constant lack of energy, the brain fog that is all too often embarrassing, as you’ve already heard, and the inconsistent sleep patterns. That worries my husband a lot.

Early in my treatment, I used a mild muscle relaxer, an anti-inflammatory, and a sleeping aid. I had trigger point injections using two percent lidocaine, physical therapy that included massage, chiropractic care, TENS unit, biofeedback, and exercise. And the last three I still continue.

Within two years after being diagnosed, both muscle -- I'm sorry -- both the muscle relaxer and the sleep aid had to be replaced to stronger drugs. And then four years later my trigger point injections stopped working.

So my rheumatologist referred me to a neurologist who was doing Botox injections. I had them done to my neck and my upper back, all around the shoulder blades and down the spine. It feels like a bee sting with every prick of the needle, but, believe me, it works. It hasn't for a lot of people, but it has worked for me for over 11 years.

DR. EGGERS: Any final thoughts about your -- what has worked and what hasn't?

MS. WARD: Yes. Naturally, the drugs have worked. There are always those side effects that are not helpful. The Botox has helped a lot, and now the nerve -- the radiofrequency nerve ablation that I have done every six and a half months makes a big difference in coordination now with the -- there we go, brain fog -- the other treatment I have to have.

I just -- I think all of those have worked well for me, and I think my physicians have seen where I'm at a roadblock and they know of different items that I need to try. And if it doesn't work out, then they go back to the drawing board and work with me.

DR. EGGERS: Great. Thank you so much, Deborah. And thank you to all the panelists.

I'm going to save clarifying questions, and then, as those topics arise, if you have questions that you want to address FDA.

Again, I want to thank the panelists. Please, a round of applause.

(Applause.)

It's a lot to be up here in front of everyone, and the web, and we very much appreciate it.

And what I think is so great about this panel that was up here is, to my understanding, they demonstrated the wide range of this complex treatment regimen. We heard everyone did something different, and everyone named, I believe, more than 15 things that they are doing.

And I just want to get a show of hands. I see a lot of heads nodding, but let's get a show of hands of how many of you saw your own treatments reflected in what you heard.

Okay. Yes. Great. And did anyone -- we won't get into this now. Does anyone do something completely different? Okay. So we have a few very different things. Okay. So we'll delve into those, and remind me if I forget to ask you that again.

Let's start with a polling question, if it works this time. Our fingers are crossed. Oh, do we still have clickers? If someone doesn't have a clicker, raise your hand.

And I'm going to go through this while you get the clickers. So what are you currently doing to treat your condition or its symptoms? And these are just very, you know, broad buckets of types of treatments, but this will give us a sense of the wide range of treatment approaches.

You can check all that apply -- prescription medications, over-the-counter medications, exercise, physical therapy, massage, or acupuncture, dietary supplements or other diet changes, lifestyle changes such as pacing activities or avoiding stressful situations, behavioral therapy such as pain programs or support groups, some other therapies that have not yet been mentioned that don't fit into one of those other categories, you're not sure, or you're not currently doing or taking any therapies.

So I'll give you a few minutes, because I imagine that many of you have many of these.

(Pause.)

Okay. It sounds like we -- people have

finished, so we'll go to the results. Okay. Not surprising based on what we heard from the panel comments. Lots of you are taking lots of stuff, with the highest being the lifestyle changes such as pacing activities or avoiding stressful situations by almost all of you in the room here.

And 85 percent of you are taking prescription medications, which I guess means that 15 percent of you are not.

Next, let's see. Exercise, physical therapy, dietary supplements and diet changes, I think the bottom line here is that it sounds like you're taking just about everything to tackle this condition.

On the web, what are we --

MR. THOMPSON: The webcast has very similar results, except 80 percent of people take some sort of over-the-counter product, and only 63 percent do some sort of exercise, and 53 percent for physical therapy.

DR. EGGERS: Okay. Thank you.

All right. So we want to -- just like we did in Topic 1, we want to delve a little bit more detail into some specific things. And we are going to start by asking you to talk a bit more about the prescription medications that you take on a daily or very regular basis with the hope of addressing the underlying condition.

The three drugs that are approved for the condition -- Lyrica, Cymbalta, Savella -- some other antidepressant or some other anti-seizure medications that you're taking on a daily basis.

I'm going to ask for a show of hands because we didn't tease that out in the polling question. How many of you in the room are taking one of those types of medications on a very, very regular basis? Okay. And just so we have a sense, how many do not? Okay. So it looks like more of you take them than not, but that there still is a sizeable number who don't take any of these.

We heard a little bit about some of these up here, but I want to ask if you could just focus on a symptom. What symptoms are you finding that these treatments are addressing the best? Okay.

We have over there.

MS. FAUNTLEROY-COCKRELL: My name is Cheryl. I gave you my name the first time when I got on here. But vertigo, basically, for the Cymbalta, Lyrica for the onset pain that you deal with when you have fibromyalgia. It kind of calms it some, but you still have that pain, but you can live with it when I'm on my Lyrica. And I also take Lorazepam for a sleep aid at night.

DR. EGGERS: Okay. Anyone else want to follow up on that? On what these treatments address best? Okay. Over here?

UNIDENTIFIED FEMALE SPEAKER: I've been taking Trazodone since my -- almost the beginning of my diagnosis, and it helps me sleep. I really don't have any sleep problems because of that.

DR. EGGERS: Anyone else? Okay. We've got a couple here. We'll go to -- we'll go in the back, and then we'll go to Elizabeth and Shay.

MS. GIANNOLA: I am taking a cocktail, and it has been trial and error. I have been on Ambien for years. I'd rather not be. Lyrica, Nortriptyline, and Tramadol for pain. I exercise regularly.

DR. EGGERS: How well are those that you are taking regularly -- how well are they addressing your sleep issues?

MS. GIANNOLA: Well, it's like this woman over here had said. It manages it. It doesn't take the pain away. I can feel it breaking through at certain times of the day. With the Lyrica, if I miss a dose, I feel it, the neuropathy, the pain, throbbing.

DR. EGGERS: Okay.

MS. GIANNOLA: So I take it twice a day, 250.

DR. EGGERS: Okay.

MS. GIANNOLA: Yeah.

DR. EGGERS: Great. We had Elizabeth and then Shay.

DR. JONIAK-GRANT: Just in terms of the prescription medications, I'm a little bit different with the Lyrica. I only take 100 milligrams a day. I work as -- when I can work part-time as a professor, so I get too many cognitive impacts with Lyrica. I also have to take it at sleep because about 40 minutes after I take it I get severely depressed. No reason why. My husband will say, "Why are you depressed?" I'm like, "No reason. Just feel miserable." That's one.

Imitrex I do a lot for the headaches. And then something that is slightly different, is kind of up for debate, the FDA has not approved it yet, may not, is Limbrel. It's a medical food and I take that because I have Von Willebrand's Disease, so I can't take NSAIDs. And for some reason the Limbrel doesn't cause my Factor VIII to go down as much and contribute to additional bleeding and bruising. So that's one that has worked for me that is sort of in this weird medical food, not sure what the clinical trials say in terms of efficacy compared to NSAIDs. But NSAIDs aren't an option for me, so --

DR. EGGERS: Okay. Thank you. Thank you.

Okay. We'll go to Shay.

MS. LONG: Hi. Shay here again. I want to kiss the people that created Lyrica. It doesn't make the pain go like away, by any means, but I was like crippled. I was just a huddled up mess, not accomplishing anything. And when I -- and I had been on a lot of different drugs already.

And when they finally put me on Lyrica, because I was in the military, so they have to try like everything before they get to the more expensive drugs, so after I came down off of all the other drugs and the fun experience that that is, and started with Lyrica, it was really -- I mean, my husband said it was the first time he saw me smiling in a long time.

So, you know, it doesn't fix everything, but it has helped a lot. But with it I take Wellbutrin in the morning. I am like probably a huge serotonin toxicity risk at this point because of the particular cocktail I'm taking, but I -- the Lyrica will keep me sleeping all day if I don't do something, like my energy level is so low. So they put me on Wellbutrin to try to help counteract that and it works pretty well, and also helps curb a little bit of the weight gain, because you don't have an appetite anymore. So --

DR. EGGERS: Okay.

MS. LONG: -- there you go.

DR. EGGERS: Anyone in the back there? Yes.

MS. WINE: My name is Bonnie. I'm hearing all of these -- everyone taking meds, pain meds, and they help t hem. I have been on I can't tell you how many over the last 18 years. I take a new one. It will last for maybe two years or something, and then nothing. So I go to another one for two years, and then it stops. I have been on, well, like I said, everything everybody is talking about.

The last ones that I have taken and had to stop was Ultram or Ultracet. I was on that for about the longest time, maybe five, six years, when it stopped. I am now taking 10-1/2 milligrams of Hydrocodone three times a day. It just barely helps. And I am also on 100 milligrams of

Neurontin two to three times a day. I swear by that.

I cannot take Lyrica. It did not help and it gave me -- it swelled my mouth and my tongue. Cymbalta did the same thing, plus it kept me from sleeping well. And the Savella did not help at all.

So this is where I am. I don't know -- I do go to a pain doctor in Hagerstown, Maryland. I don't know what is next if the Hydrocodone stops, because he has told me that he will not raise the dose anymore on that. I have been on --

DR. EGGERS: Can I ask a followup question to this?

MS. WINE: Yes.

DR. EGGERS: Because what you are talking about, these treatments, how long do you give a treatment -- approximately how long do you kind of take it before you would make a decision about whether it's working or not?

MS. WINE: It's years. Like I say, I was on Ultram for four or five years or longer. And actually I stayed on it -- it had stopped working completely, but I was still taking it, trying to give it a chance.

I have been told that my body does not absorb nutrients or vitamins or just about anything very well. And I think this is my top problem, that things do not help me as they do a lot of other people, or they don't help as long, because I've been told my body gets used to it and then it says, "Huh-huh. I don't want this anymore. I'm not going to take it."

DR. EGGERS: Okay. Thank you.

MS. WINE: So this is where I am at this point.

DR. EGGERS: Thank you. Can I ask this followup question kind of in the room of how long -- how long you typically would try a medicine before you would expect to be able to say whether it's working or just make the determination that it's not working for you.

I see in the back -- I'm sorry, I've forgotten your name. Yes.

MS. GIANNOLA: Laurie.

DR. EGGERS: Laurie. Laurie in the back, please? And then we'll come up -- and then we'll go over there.

MS. GIANNOLA: About five years ago I was prescribed Lyrica, and I was on it for two days before I decided I couldn't do it. I'm a psychotherapist. So having that, I felt like I was high, so I stopped.

Out of desperation, about six months ago -- I'm just coming out of a six-month flareup now. Six months ago, I was given the Lyrica again, asked for it. "Let me try it again. Let me try something else." It took a while for me to not feel that -- not have the side effects. I pushed past it. I pushed through it. I started with very small doses, and I'm now up to 500 a day. And I don't have any side effects at all from it. Doesn't work 100 percent. The pain is still there.

DR. EGGERS: Okay. Does this sound -- is this resonating with you, that you are trying it for a long time, having to push through some side effects to be able to determine its effectiveness for you? I see a lot of head nods. Do any of my colleagues want to follow up on this question?

Okay. All right. Let's -- you can keep talking about the effectiveness if you want to, but I want to make sure we get to the downsides of these treatments, if there are others. I know we have talked about waking. How many -- if you are comfortable raising your hand -- have heard of someone whose had a problem with waking or had your own issues with waking because of a medication you're on? Okay. Significant. I think we have heard about it enough.

Are there other downsides that you would like to raise? Okay. Oh, lots of hands going up. Let's go back over there, and then we'll come over here.

MS. ATTERBURY: Hi. I'm Sharon. I'm taking Cymbalta. My downside is that eight to 12 bowel movements a day. You know, you can't get a lot of work done if you're in the bathroom. And that's what I find. It also cut the appetite. I have lost considerable -- I've gotten back in some pants that I couldn't get back into. I've gotten back into some shirts I couldn't get back into. But, still, those bowel movements, I'm sore at the end of the day.

DR. EGGERS: Okay. Others?

MS. CASTAGNA: Hi. My name is Nicki. A lot of the prescription medications -- I have been on Tramadol, various doses, opiates, they all affect my sleep. So when I take them, they may help my pain a little bit, but I'm awake pretty much all night.

DR. EGGERS: Okay.

MS. CASTAGNA: Which then just starts this horrible feedback, this positive feedback of being in more pain because I'm not getting enough sleep, so I take more of the medication, and then I sleep even less. That's my biggest side effect with a lot of these drugs.

DR. EGGERS: Okay. I'm going to follow -- is it Nicki?

MS. CASTAGNA: Yes.

DR. EGGERS: Nicki, I'm going to follow up on Nicki's question, because we talked a lot about sleep difficulties earlier. And this is a very difficult thing to tease out, but in your experience, can you -- is it easy to attribute your sleep problems with your underlying condition, the treatments that you're on, or there is absolutely no way to tell?

So, first, you would say it's because of your underlying condition, if you want to raise your hand, and not treatments. Okay.

And then raise your hand if you think it's definitely to your -- within your experience, your treatments, because of your treatments that affects your sleep. Okay.

And if you can't tell at all? Okay. So there's a mix. There's a wide range of experiences.

Okay. Other downsides? Oh, wait, before we do that, let's let Gwenn and then Sarah go.

MS. HERMAN: Yeah. Nobody has mentioned that it affects your sexual life also, a lot of these medications, that men can't perform or women, you know, have problems also.

DR. EGGERS: Okay. So it's Sarah, and then we'll go back out here.

MS. LYALL: I was just going to say the only treatment that I use that is prescribed is I'll use an opiate pain medication when I'm having a really bad flareup. But the downside to that is it also -- basically, I almost feel high off of the pill, so, therefore, I can't sleep, I can't do anything. So that's the downside. I have to take it to make the pain go away, but then I can't sleep.

DR. EGGERS: Okay.

MS. LYALL: So it's a tradeoff.

DR. EGGERS: Okay. Other downsides?

MS. WILSON: I'm taking I guess two opiate -- or I'm taking Tramadol and a Butrans patch because the other things don't work for me. I have tried Savella. I ended up in the hospital because my blood pressure was so high and I was vomiting and I couldn't keep any food down. I just felt horrible.

I was actually diagnosed with fibromyalgia when I was on Cymbalta off-label for migraines, so, obviously, it wasn't helping my pain at all. It did help somewhat for migraines. It also made me gain a lot of weight and made me very sweaty. So I have also tried Neurontin. They didn't help for pain. Amitriptyline made me gain a lot of weight, did not help for pain.

So it's hard I think to find something that does help. And one thing I wanted to bring up is I think doctors, when they see -- if something doesn't work for you, and you are on opiates, I feel like they look at you as you are drug-seeking, even though it's well documented that I have tried multiple other things. It's in my chart. I have tried the other things; they see it. And the opiates, they don't help 100 percent, but it's something that I can get out of bed and I can walk my dog and I can function somewhat.

I'm not able to work anymore, but I can still function somewhat. If there was another treatment, sure, I would love to take it. But for now, this is what works.

DR. EGGERS: Thank you, Valerie.

I saw some head nods. We'll come here, and then --

MS. WALKER: I'll quickly run through all three of the approved medications. Lyrica made me sleepy, stupid, and angry. And those were like week one, week two, and week three. We weren't getting any less side effects; we were just adding one every week. I was getting ready to go back to work at that point after a period off, and I couldn't continue. So week four was when I said, "Can't do that anymore."

DR. EGGERS: Okay.

MS. WALKER: Cymbalta, after six days, gave me reduced vision to the point where I had to make the computer letters on the screen about the size of these slides. And so six days on that was all I managed.

Savella absolutely was wonderful for the pain, but after a year of kind of soldiering through I felt like I was in Groundhog Day in the first trimester of pregnancy. For all of the women who have been pregnant and had morning sickness, it was like a year of continual morning sickness. I never got past it. I reduced the dosage back to I think 25 milligrams. Still couldn't get past it. And I hated giving it up, but I couldn't do it.

My wonder drug was Vioxx. Thanks, guys. I took that one little pill every day and I felt normal for five years. But my current treatment regimen is -- my primary fibromyalgia drug is Neurontin. I'm actually taking G-Release, which is the -- you guys know -- the extended release version that has come out recently. And that doesn't take all the pain away, but it makes me functional.

The only thing that I take that has no side effects and works well for me is Hydrocodone, which I take for breakthrough pain. No side effects whatsoever, except pain relief, and that's the drug that allows me to live my life without fear of the pain because I have a tool to manage it.

DR. EGGERS: Thank you very much, Sue.

I want to ask a question -- we'll take -- two more. We'll take those two, and then -- we'll take three more. We'll take Louis, too. You have so much to say, everyone.

Okay. So let's go with Louis first.

MR. OGDEN: I can't remember whether I tried Savella or not, but both Cymbalta and Lyrica very quickly they made me so dizzy and with so much vertigo that I just couldn't do it. It seemed like the floor was 100 feet away from me, and I was clumsy, walking into things.

The best medications I have taken is, in fact, opioids. And I am on high-dose opioids because I have a -- I have intractable pain, but I also have -- I'm thinking of the -- a genetic defect which keeps me from metabolizing them very well. So it takes very large quantities for me to -- and it's very effective and it works.

DR. EGGERS: No side effects?

MR. OGDEN: No side effects. And for the

last three and a half years I have had the best quality of life that I have had since I was a teenager.

DR. EGGERS: Thank you, Louis. I see a lot of head nodding.

Okay. Two more over there, and then we'll -- and then I want to go on to the over-the-counter medications and ask a few questions about those.

MR. THOMPSON: Another reminder for those on the web, we'll be queuing up the phone in about 10 minutes, so you should dial in now.

DR. EGGERS: And what we are looking for on the -- when you are -- to preview what we are asking for on the phone is specific health aspects of a treatment that you would say that would make an ideal treatment, if they addressed this specific aspect of my health.

Okay. You know, I'm actually going to -- I want to make sure we get a question about the over-the-counter, because I think we are hearing a lot about the prescription medication, pain medications that you take on an as-needed basis, but I want to get the complement of that, the non-prescription.

We heard some non-prescription medications are taken. Can you raise your hand again for me if you take a non-prescription medication on what you would say is a not regular basis but when needed? Okay. And do you find those effective? Can you raise your hand again if you find it effective? Okay.

Can we just have a few examples of how well those are addressing your pain? Okay. So we'll go in the back there. Oh, no. I'll let you guys choose. You guys are better at that.

MS. ALEKEL: Well, this is not for pain, but it's for sleep.

DR. EGGERS: Okay.

MS. ALEKEL: I'll take Melatonin. And I think this young woman over here was talking about it. And three milligrams, one and a half to three milligrams per day. And you need to take it at the right time of day, and that's important.

It is non-addictive. It really has

virtually no side effects, and this is with clinical double-blind placebo studies. And the other thing I take is Vitamin D. And I take Vitamin D because most of us find it very difficult to get enough Vitamin D by synthesizing it in our skin, because most of us live indoors and we're not outside very much.

So get your Vitamin D levels checked -- 25 Hydroxy, D3. Get them checked and talk to your physician about how much you need.

DR. EGGERS: I think what you're talking about is something that you would take on a daily basis. So let me ask for a followup on looking at those -- the pain or sleep meds that you would take on a sort of as-needed basis and get a sense of how well those are working.

MS. DUGAN: I am a big user of Biofreeze. When my pain is bad on particular days, I just feel like for something that's topical, especially because I'm single and it's a spray, and it's hard to get your back when you have nobody to do it for you. So I found that Biofreeze gets me a lot of relief, particularly if I have pain and I'm struggling to fall asleep because of it. I'll spray it on shortly before I go to bed and that will freeze it enough to get me to be able to fall asleep.

DR. EGGERS: Okay.

MS. FAUNTLEROY-COCKRELL: I use Bayer Advance. It's 500 milligrams per pill. You get this package, two pills, which adds up to 1,000 milligrams. But when I told my doctor what I was doing, she said I was taking too much. So I cut back to PRN 500 milligrams as needed.

DR. EGGERS: Okay.

MR. SMITH: As an alternative, I take Isogenix, which is like a liquid food that I take normally like once a day, but then I supplement it with what they call an accelerator pill, and that helps to increase my energy throughout the day.

DR. EGGERS: Okay. Are there any web comments on -- oh, I'm sorry. Sharon has a question.

DR. HERTZ: There has been a little

discussion of opioids, and I have two questions about them. One is, I heard now twice something about a paradoxical reaction almost where people were having trouble sleeping on opioids. Usually it’s sort of the opposite.

So I’d be interested I knowing if that’s something that comes up a little bit more often in this population in patients with fibro. And I would also like to get a sense, if we could -- I don’t know if people are comfortable or not -- how many people are using opioids, either as needed or more regularly.

DR. RAPPAPORT: And then I have a follow up to that question, which is, of those people, how many of you are having trouble getting those pills?

DR. EGGERS: Okay. So maybe I can take the second one, the third one, and then the first one. So a show of hands just who is comfortable admitting taking opioids on a regular or a periodic basis? Okay.

And then, how many of you have difficulty getting your prescription? We heard an example of that. Okay.

MS. WARD: Difficulty getting a prescription through? It goes through DEA now.

DR. EGGERS: Okay. Oh. So you have to take a test. Okay.

And now to address Sharon's question about the sleep. How many taking those opioids are finding sleep difficulties? Is that correct? Okay. Okay. And I think we heard about that. Do you want more elaboration? Okay. Great.

So let's go into -- we're cutting close on time. I am going to -- we have I think about six people for the open public comment. So I'm going to steal a little bit of time for the open public comments so that we can ask a few more questions, and we need to go to the web and let the folks on the phone -- before we do that, James, are there any additional thoughts that have come up about the pain medications' or the prescription medications' effectiveness or downsides?

MR. VALENTINE: I think most of the comments have been very in line with what has been discussed in the room. You know, I think the overarching consensus is that it takes a long time to find the right combination of drugs, supplements, exercise, diet, lifestyle, alternative therapies. You know, there is a whole list of things, mostly overlapping with what has been discussed in the room.

I think one of the main things that hasn't been discussed in relation to pain is the use of marijuana to treat pain, and especially for breakthrough pain with -- for patients that are on opioids or other pain medicines.

DR. EGGERS: Okay. Thank you. Thank you.

All right. There are a few questions. We don't have much time to get into the non-drug therapies. But we did hear -- the panelists gave great examples of what they're on. So I am going to ask two show-of-hand questions.

So I think -- first -- three show-of-hand questions. Remind me who takes what are considered non-drug therapies to be a major component of their treatment regimen. Okay. So not everyone but a large proportion of you.

How many of you would say that collectively your non-drug therapies or lifestyle changes are as important as any prescription medications you’re on? Okay.

And then how many of you would say that they are important but they can’t match the benefit of those prescription medications? Okay. Okay. Thank you.

I think we’ve talked enough about that so we have the sense of how they are working and what works for you.

I want to conclude with a discussion about the overall management and some about the ideal treatment. And we have discussed a lot of this topic kind of throughout the other discussions that we have had, but I think it would be useful for us to see, with a show of hands, that thinking about -- this is what Nancy explained.

Think about all of your therapies together, that whole regimen. How many of you share Nancy’s perspective -- I’m going to try to paraphrase -- that although you still battle your condition every day, you feel like you are managing as best as you can expect? Okay.

And how many of you feel that -- the converse, although you're taking as much as -- whatever you can, that really you cannot say that your condition is well managed at all? Okay.

For those of you that raised your hand no, I want you to, at least some of you, to tell us what is -- if you could fix one thing that's not being addressed, what would it be? What one health thing about your treatments, about your condition that you wish the treatments would better address?

Okay. Elizabeth?

DR. JONIAK-GRANT: My biggest thing that I think impacts me the most are the migraines. And, as Deborah mentioned, I do bilaterally C3 through C7 cervical facet radiofrequency ablation, but the nerves grow back. So, and they find that over time that they grow back more quickly. The biggest problem with that is the treatment itself is extremely painful. You have to be awake. You have to be alert. And, you know, they're going into your spine.

And then I get a flareup from that for a good month, and then I start to settle down again. But I think that for me that's one of the biggest issues sort of in terms of that some of the treatments can be very painful in and of themselves and cause flares.

And, you know, finding doctors that know what they're doing, too, that -- luckily, I'm by Stanford, so that helps. But, you know, it's not -- everyone is not in that situation. And the expense. It is hard to -- we spend $25,000 a year out of pocket on medical treatments. And it has been 10 years, so there you go.

DR. EGGERS: Thank you. A couple others? We have back there and then Shay has her hand up.

MS. LONG: Oh, okay. Hi. I think that even if my pain levels stayed where I -- where they are right now, if I just had more energy I feel like I would be in such better shape, because it's really like being so exhausted that I can't get anything done. And then I haven't gotten anything done, so it leads to me being kind of depressed about having not gotten anything done, and then I eat a chocolate cake and gain more weight, and, you know, I mean, it's a vicious cycle.

So I think it's the fatigue thing, like Anita -- I need super-caffeine. That would be great.

MS. ATTERBURY: Hi. Sharon. If I could have a perfect treatment, it would be able to regulate my sleep cycle. In bed, I do not sleep. I stay awake. I'm fully awake. I know everything that goes on. I know when the dog gets up and I heard his toenails clicking on the wooden floor. I know when the deer peer through my window, because they make a little noise.

But anywhere else, I sleep. I sleep sitting at my desk. I sleep behind the wheel driving home to and from. I now take something to manage that just so I can stay awake during the day and hold a job. I got fired for sleeping on the job. I knew they knew I was sleeping, but I was too embarrassed to admit I was sleeping on the job. So they fired me and I just didn't say anything and I just went away.

DR. EGGERS: Thank you, Sharon.

FDA, do you have -- oh, so we have a followup question from Bob.

DR. RAPPAPORT: This is -- I neglected to ask this earlier. Have any of you been treated with or tried to take any type of stimulants to treat the fatigue? And if you have, of those people, how many of you have had success with that?

DR. EGGERS: Okay. So how many use stimulants or have tried them? Okay. A few. A few.

How many found them effective? Okay.

Would you like any description? They make me be the timekeeper, so I keep my eye on this clock. I'll let Jan go.

MS. CHAMBERS: One important component that has not been brought up here today is muscle relaxants as a class of medications. Some of the benzodiazepines really are useful for people with fibromyalgia.

DR. EGGERS: Okay. Thanks, Jan.

Okay. Gwenn, and then -- we'll let Gwenn, and then we'll go to Liz's question.

MS. HERMAN: Yeah. I feel like one of the most important components of our treatment plan is having a treatment provider that is educated about chronic pain, about fibromyalgia, and will sit with us and work with us because it is more than a 15-minute session, because you see how complicated, you know, our conditions are. It is just not one condition.

So we need a team of providers that are going to be working with us that are going to listen and believe us.

DR. EGGERS: So, Liz.

DR. KILGORE: I just wanted to ask, since your diagnosis, have you ever had a time where you're been pain-free or symptom-free? Or once you get the diagnosis, do you always have some level of symptoms? So I don't know maybe if you can ask as a show of hands or something like that.

DR. EGGERS: Sure. How many of you have periods where you are completely symptom-free? Okay.

So do -- maybe -- we haven't heard about that, I don't think, so can one of you explain that just briefly, what that -- when that happens, how long it happens? Okay. Right here.

UNIDENTIFIED FEMALE SPEAKER: I have been -- I was diagnosed in 1989. I -- directly afterward, I didn't have much trouble. One of the things I think that helped me a lot is I used to live in Colorado. The dry environment, the high pressure there, the sunny skies, I didn't have any trouble while I was living in Colorado.

And in 2002, I moved to Minnesota, and within two months of living in Minnesota I had -- I can't even call it a flare, because it lasted for a couple of years. It was just, you know, I had no control over my fibromyalgia at all. And ever since then I have been working at correcting it.

But even in Minnesota, though, usually during the winter months, January and February, I would go -- I would be without pain for two months. And I think, once again, it was the dry air, it was the high barometric pressure, because once the summertime came, once March came, I'd start feeling the pain again. Unfortunately, that was before and now it's pretty much constant, but I did have symptom-free.

DR. EGGERS: How many of you -- a show of hands -- find that weather can affect positively and negatively your symptoms? Okay. A show of hands.

Okay. And since we don't have time to delve into that, if you're going to put in your comments on the website -- I'm seeing some nods from my colleagues -- please describe that, and other triggers, other factors that trigger your symptoms to make them better or worse.

I want to make sure we can get to the phone. So, again, the question that we would really like to have addressed is if you -- if there was some aspect of your condition that is not yet -- it hasn't been talked about yet that you would find an ideal treatment would address.

Operator, can we have a caller?

OPERATOR: Yes. And we do have a question from Mike Herness. Your line is open.

DR. EGGERS: Okay. Hi, Mike.

MR. HERNESS: Well, I guess this is --

DR. EGGERS: Oh. And, Mike, can we ask you to speak as -- Mike, excuse me.

MR. HERNESS: Yes?

DR. EGGERS: We have a hard time hearing you, so can we ask you to speak as loud as you can directly into your phone?

MR. HERNESS: Okay. It's more of a statement than a question I guess --

DR. EGGERS: Okay.

MR. HERNESS: -- about fibromyalgia, it being a syndrome or a collection or, you know, of signs and symptoms, more than I think, which come under the category of a disease. It takes a very long time for most people, you know, to get the point of a true diagnosis. When you get to the diagnosis, because it's so much more generalized than specific, so many people do get caught up into the pharmaceutical end of it, and then try to find alternative types of treatment.

And if there was just a way of shortening up the curve on all of that, I think it would just be tremendous. So, you know, versus putting bad dates on things, trying to come up with more, you know, diagnostic-specific, I can't even talk -- you know, specific to the problem, so that things can be treated and -- diagnosed and treated better and in a shorter period of time.

DR. EGGERS: Okay.

MR. HERNESS: Thank you.

DR. EGGERS: Thank you very much, Mike, for that point.

Can we have one more caller, Operator?

OPERATOR: Yes. Our next question is from Lauren Horowitz. Your line is open.

DR. EGGERS: Hi, Lauren.

MS. HOROWITZ: Hi. I've been diagnosed in 2004, and I have been a guinea pig for 10 years. I don't understand -- I live in Florida. It is a chronic -- I've tried everything, the latest being low-dose Naltrexone, and I put all my hopes into that and it didn't work. So I'm currently on Cymbalta, but I don't understand what the problem is with doctors writing pain medicine for chronic pain. I'm 52. I live in bed. I live alone. And I don't understand.

The other thing that wasn't brought up, that I don't know if anybody else has, is I actually have pain even in my scalp.

DR. EGGERS: Lauren, you're getting head nods both for your first comment and the second -- and the symptom that you raised. So thank you very much for that.

I did promise -- I think that's all the time we have for the phone now. But I did promise that if those of you who raised your hand to my earlier question about that your experiences were completely different from those on the panel that I would come back to you and ask you. So if you had some important point to share about your experience with treatments, and it hasn't been talked about today -- depending on how many hands we have -- can we -- we can address those for a few minutes.

Okay. So we'll take the hands that are up. Briefly, please.

MS. DUDLEY-JOHNSON: Hello?

DR. EGGERS: Hi, Sabrina.

MS. DUDLEY-JOHNSON: Sabrina. I have a special circumstance. Due to stomach problems, I no longer have a stomach. I had 95 percent of my stomach removed. So I can't take my regular fibromyalgia medicine anymore. It has to be either dissolvable, chewable, or in liquid form.

So out of the multitude that I was taking before my surgery, I am down to two -- liquid Gabapentin and liquid Hydrocodone. So my goal would be that there would be -- whatever drug comes along next, that it would be either chewable, dissolvable, or in liquid form.

And then, a question you asked earlier about, how long do you go before you find out if it's effective or not? My doctor asked me to stay on the medication for eight weeks before I start crying that it doesn’t work. So at least eight weeks. And then if I have adverse or side effects within the first couple of weeks, we stop it right away.

DR. EGGERS: Okay. Anyone -- okay, there.

UNIDENTIFIED FEMALE SPEAKER: Briefly, I think the bottom line is the inflammation, and I do my best. I have created a combination of six different anti-inflammatory herbs, including -- I don’t remember all of it, but mainly turmeric, cumin, fenugreek, and a few others. And I take half a teaspoon almost every day, sometimes every other day.

The only medication I take when my pain and discomfort is about nine to ten on a scale of zero to ten, I take 400 milligrams of Ibuprofen, and it helps me a lot. Of course, as earlier I said, watching what I eat, right exercise, and trying to do stress management, I have been doing very well.

And one additional comment is, for ladies, that is my experience. As you age and as you get into menopause, you get better in terms with fibromyalgia.

DR. EGGERS: Thank you very much.

Okay. Two more comments. I saw two hands. We're going to go with Heather, and then we're going to end with Louis, and then the web comments.

MS. CROSSIN: Thank you. I represent about 100 people in southern New Jersey in my support group, and they would be really mad at me if I don't bring up low-dose Naltrexone, because our members who have tried it, it has changed their life because it has helped with lowering certain types of pain, not all of it, but certain types of pain. It has helped with improving fatigue. And it has also helped us with our immune system as far as not getting sick as often as we used to.

But it does take a good six months before you notice the difference. But since it is a generic, we feel like there needs to be so much more research done on it to see if it helps more people.

DR. EGGERS: Okay. Thanks.

And then, Louis, a final comment?

MR. OGDEN: I would just like to say in reference to his comment about stimulants, not only is it a good thing for your fatigue, a lot of schools of thought look at it as being a catalyst to make opioids work better.

DR. EGGERS: Okay. Thank you.

Okay. I know that there is so much more to talk about, but we are going to close this portion of the discussion. I want to thank you. We have had several meetings, and this meeting has been truly I think a very productive discussion on things that are very important to FDA about specific symptoms, about treatments, why -- how they're working, what is not working, what the downsides are.

And so I really want to thank everyone in the room for your contributions today and for your patience and for listening to one another and answering our questions and being quite open about things that are often very difficult to talk about in a roomful of strangers. So I want to thank you. I want to, again, thank the panelists.

I'm going to walk over to the -- to get the public comments set up. And while I do, James, are there additional web comments that are -- that struck you as being unique to the conversation?

MR. VALENTINE: I think I just want to emphasize a few things that were -- comments about what the web participants would want in new therapies. I think over the course of the entire day one of the themes was how many of the patients had to stop taking many of the treatments, whether they be the prescription treatments or some of the other prescription treatments that were not specifically for fibromyalgia and even over-the-counter products because of side effects.

So a lot of people said that they would like to see products that help address both pain and fatigue but with lower immediate and long-term side effects. I think the web participants agreed with the room that they would also like to see new therapies focusing on the fatigue first, that they seem to be able to manage their pain more so now with current therapies. And then ultimately they would like to see therapies that are not just focused on symptoms but trying to stop the underlying progression of fibromyalgia.

DR. EGGERS: Thank you very much, James.

If there are topics that are important to you that we haven't addressed, please, again, send us a comment through the website. Even if you sent us one already, feel free to send us another comment following up on things that we've talked about today or addressing something that we didn't get a chance to discuss.

And with that, I'm going to move into the open public comment session. Again, the purpose of this part of the meeting is to allow an opportunity for people to comment on topics other than our main discussion topics. And it is also a chance for stakeholders other than patients or patient representatives to contribute.

Keep in mind, we won't be addressing any comments that we hear during this session, but all of the comments that we have are being transcribed. We're listening. We're in listening mode.

We'd like this to be a transparent process, so we encourage you to note any financial interests that may be relevant to your comment. If you do not have any such financial interest, you may wish to state that for the record. But if you prefer not to state this information, you can still provide your comments.

So we collected signups before the meeting and during the break, and we have six speakers lined up. I'm going to ask you to stay to three minutes for your comments. Again, you can follow up your comments with the public docket as well.

We're not going to use a timer for this portion, just like we didn't use a timer for any other portion. But I am keeping track of time, and I will be asking you to wrap up if you go beyond your three minutes, just to make sure we can keep everything moving along fairly and efficiently. Okay?

So first we have -- I'm going to read all of the names, so you know your order. We have Sally Okun -- I apologize if I mispronounce any of these names -- Elizabeth --

DR. JONIAK-GRANT: Joniak-Grant.

DR. EGGERS: You know your last name. Rae Gleason, Kristen Ogden, Louis Ogden, and then Juan Mendoza. Okay? So we'll start with Sally. You can stay where you are and the microphone will come to you.

MS. OKUN: Great. Thank you so much, and thank you so much for this hearing. My name is Sally Okun, and I'm from Patients Like Me. We're a web-based environment. It's a research-based platform with a social connectedness and networking component to it.

I am happy to be here on behalf of our 40,000 members who are living with fibromyalgia. When we did a four-day survey in December in anticipation of this meeting, we sent a survey out to about 8,000 members, and we had a 20 percent response rate within that four days. So there is a lot of interest in giving you feedback and giving you information.

One of the things that hasn't been brought up that I want to just reemphasize is that there is much to learn from real-world evidence, and we need a systematic way of collecting this data. These meetings are great, but we really need to hear the voices of more people in a systematic, quantifiable way.

One of the things that we have I think as an advantage on Patients Like Me is the ability to have that research-based component, so patients can actually tell us about their symptoms and their treatments and their side effects. And a number of things did come up in our survey when we asked questions about this.

So one of the things that hasn't been brought up in terms of the context of treatments is really the social connectedness dose effect. We learned that there is a significant amount of patients who are either using our site to provide some of their own support but other social media sites as well, and it is having an impact on their overall outcomes and their ability to cope.

Diet, nutrition, and personalized exercise programs were also high on the list.

Interestingly, 66 percent of the patients reported not taking any of the FDA approved products at this time or in the last month or so. Many have tried them in the past and have moved on to other things. So this is another opportunity for us to start thinking about what other things are they taking.

So 52 percent of those patients reported taking other prescription medication. We have the Medidata to start telling you what they are taking and why they are taking it, so that we have that off-label information that could be quite useful in terms of thinking about next steps and new drug development.

The other thing I wanted to raise was the impact of side effects. We heard some about that today, but we did ask about their concern as well as some of the bothersome characteristics of this. So 72 percent of our patients are very concerned or concerned about side effects. Fifty percent report having some side effect to the medications that they have been taking that are prescription medications. And 35 percent are making adjustments to the dose or frequency, and 30 percent are stopping altogether.

So these are adherence issues that we could begin to tease out and better understand.

Lastly, I'd like to just suggest that we have to have a better way of helping patients tell clinicians and others about the effects they are feeling. Sixty-three percent of these patients reported adverse events to their health care providers, but we really don't have any way of knowing whether those ever made it into any of the information that FDA gets because of the voluntary component of the reporting by health providers.

Thirty-seven percent have had an adverse event but never told anyone about it, and only one percent reported to the FDA or the manufacturer. So we are missing a huge amount of the information we may need to better understand this.

And, lastly, what I'd like to just really reinforce is the heterogeneity of this condition is significant. Only two percent of the patients who followed up on the survey reported fibromyalgia as their only condition. In fact, we collected over 90 different comorbid conditions from that one group of patients. So the response rate, as I said, was about 20 percent. It was about over 1,500 patients that contributed to the survey, and I received hundreds and hundreds of messages after the survey with additional information, which we will post to the docket.

DR. EGGERS: Thank you very much, Sally.

Next we have Elizabeth Joniak-Grant. Did I --

DR. JONIAK-GRANT: Hi, again. Very briefly, one thing I want to point out that other people -- I haven't heard mentioned is that the longer I'm on the medications the more side effects I seem to start developing. I saw it particularly around year three and year four. I started getting unexplained tachycardia, palpitations. I had petechial rashes. Now I'm getting skin lesions. And the longer I'm on the medicine, the more sort of of the infrequent ones from the clinical studies I'm developing.

The second thing is, if you read about Lyrica, they actually report that they had an unexpectedly high incidence of hemangioscarcomas in two different strains of mice. This is a very aggressive cancer that they usually only see in dogs. And they actually had one percent of the people in the clinical trials that developed new or worsening preexisting tumors.

And what it says is this could be significant. We're not sure if it's significant. And then, if you do any research, look through the medical stuff, look through journals, it is kind of like, oh, well, it didn't happen in the rats, though, and that's how it is left.

So I think, really, if people are looking at being on some of these medicines for decades, this notion of kind of reexamining this issue with hemangiosarcoma is important in terms of Lyrica.

And then, the other thing I wanted to bring up is this notion of fertility issues. I am in my mid-thirties, and for those of us that are diagnosed at a younger age where we haven't had children yet and want to consider having them, there is ideas that, one, fibromyalgia may be linked to fertility issues and infertility problems. Endometriosis is already established, but also low antral follicle counts.

But then, fertility issues also seem to come up from the medications, the SSRIs, like Cymbalta. They're showing that it's damaging sperm and the DNA of sperm. So I'm thinking, why not -- why don't we look at some eggs and see what it's doing to the DNA. And then, also, practically speaking, what does a person do who wants to have children and is on the medications? Do you come off the medications, which is what I have chosen to do because of the very limited studies about some of the severe birth defects they have found, again, only in animal studies. And then, can you even manage to be pregnant without the meds? For me, the decision is, no, we are going through a gestational carrier eventually.

And then that brings up the whole other issue of the discontinuation syndrome, which if anyone has gone through with the Cymbalta especially, or the Lyrica, is very, very, very difficult. I'd say it's the hardest thing I have ever gone through, and I just got through it in the last two weeks, and trying to get --

DR. EGGERS: Thank you very much.

DR. JONIAK-GRANT: -- the FDA mandates to start happening in terms of dealing with that and the tapering.

DR. EGGERS: Thank you. Thank you very much, Elizabeth.

We have Rae Gleason. Can you raise your hand?

MS. GLEASON: Again, my name is Rae Gleason. I'm the Medical Education and Research Director for the National Fibromyalgia and Chronic Pain Association. I have been doing this work for 20 years. I helped create the National

Fibromyalgia Research Association in Salem, Oregon, and was responsible for heading up five international research symposiums.

And so through the years, there has been a lot of work that has been done, and I do think that we're farther ahead at least in published papers than we were when I started so many years ago. But one of the things that we still are lacking is a diagnosis. And the problem with having treatments for fibromyalgia is if you can't get a diagnosis, there isn't any place to start.

And there is a couple of things that happen with that. Some of it is financial. If you look at the problems of not being able to function in a position, in a job, you lose productivity and eventually you lose a position, which isn't good for either you or your employer.

And the other part of it is the medical costs themselves, you know, add to that financial burden. If you look at the Institute of Medicine's research -- I'm sorry, Pain in America Report that was published in 2011, it talks about a bill of about $650 billion a year spent on pain. And there still really isn't a whole lot of answers for that in terms of, you know, how it is approached.

So for diagnosis, the other big problem in fibromyalgia is the lack of education for our medical doctors. We still have medical schools that don't teach anything about fibromyalgia, so we have all these new doctors that come out and they don't know anything about it, much less how to diagnose it or how to treat it.

And I have been working with that. We have put on about 20 medical education CME programs for that. And so the thing is is that with our diagnostic criteria now, there is three, going to four. It is very confusing for doctors to know how to diagnose it, and there is a blood test.

It's the FMA blood test that has been researched at the University of Illinois that is very specific, and I think it's something that we should think about to help people not take five years still today, even after three FDA approved medications, to get a diagnosis of fibromyalgia.

DR. EGGERS: Thank you very much, Rae.

We have Kristen Ogden, if you can -- okay.

MS. OGDEN: Thank you. I'd like to start by thanking the FDA for having this meeting. I think it is terrific. I only wish it had happened for me and Louis maybe 30 or 40 years ago, so that perhaps things may have gone a little better for him along the way.

We have been married 41 years. He is a great guy. You've all gotten to know him at least a little bit because he has spoken up a time or two here. I appreciate the atmosphere of courtesy and respect that was established at the beginning of this meeting. We came here not knowing whether we would speak about his recent use of high-dose opioids as the treatment that has, for him, been most helpful and most effective.

And when I say "not knowing whether we would speak about it," I do believe there remains a certain stigma associated with the use of these medications. Clearly, we are not insensitive to the fact that they are abused and that they have caused harm in some circumstances. But I can tell you, in all honesty, that this man has been benefited tremendously by them.

We have been pursuing, almost non-stop, help for his pain problems since 1997. We began seeking help for his illness in the 1980s, and at that time the answers were, "Mr. Ogden, you look like a young healthy man. Your labs are normal. If you say you hurt, I can't disprove it, but the implication is, well, it's all in your head."

I think a lot of people still don't get it about severe pain. I think there are a lot of pain doctors who don't still really get it about extremely severe, constant pain. When we made the decision in 2010 to pursue high-dose opioid treatment for him, it wasn't something that we approached lightly. All you have to do is read the newspaper to know that going down that path might likely produce challenges and difficulties.

I was, I have to say, astonished at how helpful it was and how quickly. And there have not been any significant side effects. These medications do not, in his case, make him drowsy or drugged. Our lives have simply been made better. While these substances are disabling to some individuals, they have been enabling to my husband, and we have had the best life for the last three and a half years that we have had in decades.

It is difficult. There are no doctors in Virginia who use these medications at the doses Louis takes. So for the last three and a half years we have been traveling to California every 12 weeks for treatment with a doctor who specializes in treating intractable pain. His name is Forrest Tennant, and he has been in practice there since 1975.

I couldn’t imagine my life getting much better until we recently were notified -- and I’m a federal employee. Let me just say that to you folks at the FDA. Like you, I’m a federal employee. I have 36 years of service. I always thought the Federal Employee Health Benefits Program was the best insurance anybody could get of middle income lifestyle. But we got a letter in

September from Blue Cross/Blue Shield saying they decided Louis' dose of medication is not medically necessary and that they were only going to pay for half of it.

DR. EGGERS: Kristen?

MS. OGDEN: And so we're paying out of pocket --

DR. EGGERS: Kristen, I'm going to ask you to just wrap it up, please.

MS. OGDEN: I'm taking Louis' three minutes. He's just --

DR. EGGERS: Oh.

MS. OGDEN: We're sharing.

DR. EGGERS: Okay. All right. Then, you've got three more -- you've got two and a half more minutes.

MS. OGDEN: I just need to let you know that we still have issues of stigma and lack of understanding. We are paying out of pocket while we fight this through the disputed claims process. We have, in our first step, cited the FDA decision letter that was issued in September 2013 that acknowledged that these medications in high doses are helpful to some people.

In that decision, responding to a petition from PROP, the FDA decided not to impose daily dose limits or duration limits because there was no scientific evidence to support doing that. When we replied to Blue Cross requesting reconsideration, we provided a copy of that letter. We quoted that letter; we provided other letters from AMA and the American Pain Society, American Academy of Pain Management, to say, look, some people need these medications. And they -- Blue Cross so far has blown us off, and it's costing us over $5,000 a month. And although I do have a good job, we cannot afford that.

Louis?

MR. OGDEN: I would just like to add that we need to do something to get rid of the stigma. It seems that it's looked at as being a drug of abuse, one, first. And the media, the doctors, you wouldn't believe some of the things I've been called -- a drug addict, these kinds of things.

God, I forgot where I was going because of fibro fog.

Oh. I'm an outlier, if you want to -- everybody, I'm sure, is familiar with the standard Bell curve. I'm somewhere over here at the very tip end of this as an outlier. And it seems to me that instead of spending so much time concerning ourselves with the number of people who abuse these medications, that we need to worry about people who have problems like I do and have such good results from them.

DR. EGGERS: Thank you very much.

MR. OGDEN: Thank you.

DR. EGGERS: Thank you. Thank you, Louis.

And we have -- I think it's Juan Mendoza?

MR. MENDOZA: Yes.

DR. EGGERS: Okay. Thank you.

MR. MENDOZA: Yes. Juan Mendoza, Vice President of the National Fibromyalgia Partnership. Our mission is to make medically accurate, quality resource information on fibromyalgia available to our membership, health care professionals, and the community at large. Our goal is provide informational tools so as to promote the timely and appropriate diagnosis and treatment of fibromyalgia.

Briefly, it was mentioned, trigger points and tender points. I consider that it's important to distinguish between the two. There is a condition which is misunderstood called chronic myofascial pain syndrome. That deals -- which is prevalent in fibromyalgia patients, this condition occurs when hyper-irritable spots called trigger points can cause severe pain and disability. And their pain can also complicate the assessment of fibromyalgia pain.

So it is important that, you know, to educate our health care providers between the two because they are not the same. Okay? Since -- because of lack of time and our statement is on the docket, I'm just going to move on to significant downsides of current treatments.

One is the price of medication and treatments is often high. It is often, in the case of non-drug treatments, not covered by insurance. The other is long-term safety of a drug is not known. And, finally, effective medications without any adverse -- the ideal condition will be effective medications without any adverse effects -- effects will be ideal, of course.

However, in the meantime, it would be extremely helpful to encourage head-to-head comparison trials conducted by fibromyalgia researchers with no stake in the outcome. More analytical assessments and meta-analysis will be helpful as well. Only a few of these currently exist for the newest fibromyalgia drugs.

And, finally, in an effort to find better ways to effectively treat the pain and fatigue of fibromyalgia, it is useful to develop a systematic approach -- this is important -- a systematic approach which can improve: a) sleep patterns that produce better sleep; b) physical rehabilitation to improve functionality; and c) psychological and emotional therapy when needed.

Thanks.

DR. EGGERS: Thank you very much.

And thank you to all those who contributed to the public comment.

Our closing -- oh, do you want --

DR. RAPPAPORT: Can we make a couple -- just a couple of clarifying comments?

DR. EGGERS: Sure.

DR. RAPPAPORT: I'll talk and you can do it. There were a number of comments today that I heard, just now and earlier, about sort of a range of problems that you're having. One is -- you know, is Rae I believe talked about the cost of chronic pain to society. And, Louis, you're having trouble getting your drugs.

And I heard from people at the break who came up and talked to me about, you know, how do we get our voices heard as fibromyalgia patients when people don't believe we're sick?

There is power in numbers, and I strongly encourage you to join with your advocacy organizations, with Jan and others, to have your voices heard because that is how you make changes for yourself and for your community. So please do -- you know, there are ways that you can make your voices heard.

DR. EGGERS: Thank you.

Okay. And now we'll have Sharon Hertz come up and give some closing remarks. And as she's walking up here, I'm just going to remind you all that there are evaluation forms up at the registration table. If you could take a few minutes to fill that out, tell us what we are doing well, what could be improved, it's really helpful to us. So thank you.

Thank you, Sharon.

DR. HERTZ: Hi, all. There is a lot to summarize. But before I even get there -- and very little time. But before I even get there, some of the comments that I have heard, I don't know how often people are accessing the actual approved labeling for these products, but I'm hearing things about side effects that aren't known, but in fact they're in the labeling.

And I was -- you may have seen me on the

Blackberry. I swear I wasn't emailing. I was looking some things up to be sure that I didn't misspeak. But some of the side effects, including sexual dysfunction and some others, are actually listed for some of these drugs. So I know that many of these products come with patient labeling, and that tends to be shorter. But please know that there is a lot more information available in the full product labeling -- or package insert we call it -- and you can access those a number of different ways, on our web as well as other resources.

The hemangiosarcoma issue in particular I did want to mention, because we -- when we follow a product through its development, we take these things quite seriously. And I was actually involved with our regulatory oversight at the time that signal became apparent.

And I can't go into some of the details about what we did at the time, but we did do quite a bit. And we never say, "Well, it was positive in one and negative in another species. Therefore, we’re not going to.” Trust me, we are never that simple.

We actually required the sponsor to do work to prove that there was a reason why one species was being more susceptible to this than another. And we got compelling data to suggest that was in fact a species-specific or -centric type of finding. So please know that we do take a very serious look at all of the information coming in as we are developing these drugs.

And a lot of this information is available online. Our reviews -- you know, from my desk I actually often revert to Google rather than our search window. But if you Google for an FDA review on a drug, it’s actually often very helpful.

And so -- and I’m going to throw this to the advocacy organizations because I suspect they may have folks who can also help with navigating some of these paths. Today we heard some very, very helpful information from you folks and really appreciate you taking the time. We understand the challenge for many people who are suffering from chronic pain to travel and participate in these meetings, and we greatly value your effort.

Some of the important things that I have heard are speaking to a lot of the heterogeneity within the symptoms in fibro, and we very much are aware that there is never going to be a one size fit all for the population, or potentially even to address all of any one person's symptoms.

We heard quite a bit about the different manifestations of pain and fatigue, some interesting symptoms that we haven't heard much about in the past, including the eye pain and visual symptoms, some of the other things including the feeling cold. The stiffness was very interesting for me to hear. That was one in particular I wasn't as familiar with.

And I think that the emphasis that we have heard on multi-modal therapy is very important. We will do our part to help facilitate the drug part of that treatment when we get applications coming in. We'll try and do our due diligence to make sure that we do identify all the safety-associated issues as well as the benefits, so that as you and your prescribers get together you can make informed decisions about the available risks. And we will continue to try and make sure that as information becomes available we update information.

And I think those are the key points that I wanted to just summarize. In addition, also, we heard the message about more targeting of certain symptoms, that it would be nice to see some therapeutics in those areas, including fatigue and sleep-associated issues.

So, once again, thank you and please take time once you get home and settled again to send in any additional comments to the docket. We will review them all.

MR. FREY: Okay. Before Sara wraps up, I just wanted to follow up with something Sharon said about our labeling and reviews. One fairly easy way of finding that stuff is just to Google “drugs” at sign, so drugs@fda. And there you will see the alphabet and you can search for your drug by name and eventually get to the approval document, the review memos that are written by our scientific disciplines, as well as the approved labeling.

So I just wanted to mention that.

DR. EGGERS: Thank you very much.

UNIDENTIFIED FEMALE SPEAKER: No dot com or anything? Just --

MR. FREY: Just Google "drugs at FDA," and it's the first hit.

DR. EGGERS: Okay. All right. Well, thank you again. I hope that everyone has safe travels home, whether, again, it's just around the beltway or whether you are traveling to further distances. And I just want to echo my colleagues again and say thank you so much. As patients and patient representatives, you are the input of this meeting, and it is very important and very valuable.

Thank you.

(Applause.)

(Whereupon, at 5:06 p.m., the Fibromyalgia
Public Meeting on Patient-Focused Drug
Development was adjourned.

CERTIFICATE OF TRANSCRIBER

I, CORINNE YANOSY and LISA SIKES, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, nor party to this action nor am I interested in the outcome of this action.

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CORINNE YANOSY

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LISA SIKES