

**Capital Reporting Company  
Food and Drug Administration Public Meeting**

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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

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

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

10 This is the Fibromyalgia Public Meeting. It  
11 was originally scheduled to be for December 10th. Now,  
12 you might look outside and say, well gee, it looks like  
13 it could be December 10th today, but no, this is March  
14 26th and we are very appreciative that you stuck with  
15 us through the December snow, and then stuck with us  
16 again through the March snow to be here today for this  
17 important meeting.

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

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

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

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

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

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1 by FDA.

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

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

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

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

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

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

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

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

9           DR. KILGORE: Yes, hi. I'm Elizabeth  
10 Kilgore, Medical Officer, Clinical Reviewer, in the  
11 same division.

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

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

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

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

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

21           As you can see the panel and the fact that I  
22 can assure there are others, my division, the group of

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1 people in my division who deal with drugs for pain and  
2 fibromyalgia, are very interested in hearing from you,  
3 and so we have a large representation here on the panel  
4 and in the room, and watching from their desks for who  
5 just don't have the time to come and sit here today.

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

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

21           We know a lot about this area, we've been  
22 really working hard over the last couple of decades to

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1 figure out the right way to study them.

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

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

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

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

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

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

22           Then, you know, ultimately the key thing that

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

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

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

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1 willing to tolerate.

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

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

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

20           We would often hear about the patient  
21 perspective in the context of a specific drug at an  
22 advisory committee meeting, but we didn't have a

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1 meeting mechanism that could allow us to systematically  
2 get at the patient perspective, which we should get as  
3 good of an understanding as we can about the patient's  
4 perspective on the disease and current treatment  
5 options.

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

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

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

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

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

22           So here you see the four meetings that we had

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1 in fiscal '13. Chronic fatigue was our first, followed  
2 by HIV, lung cancer, and narcolepsy. We had sickle  
3 cell disease, was our first meeting in fiscal '14 last  
4 month, and we have the pulmonary arterial hypertension  
5 meeting for May, I believe.

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

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

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

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

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

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

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

21           The reports serve an important function in  
22 communicating both to our review staff, as well as the

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1 regulated industry, what is important from the patient  
2 perspective, as far as improvements that they'd like to  
3 see in their daily life.

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

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

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

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

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1 issues.

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

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

13           Fibromyalgia may be more common in those with  
14 spinal arthritis, rheumatoid arthritis, and Lupus.  
15 According to the America College of Rheumatology, 1990,  
16 the two major diagnostic criteria are pain in at least  
17 11 of 18 different specific points of the body,  
18 referred to as trigger points, and pain that has lasted  
19 for three or more months, referred to as chronic pain.

20           There are multiple systems involved in  
21 fibromyalgia. As previously noted the primary symptom  
22 of fibromyalgia is pain. Painful areas known as tender

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1 points develop in various parts of the body and may  
2 spread.

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

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

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

18           In addition to pain, sleep problems, and  
19 fatigue, patients with fibromyalgia may also experience  
20 the following symptom complex; problems with memory,  
21 concentration, and other cognitive functions, sometimes  
22 referred to as 'fibro-fog', depression or mood

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1 problems, irritable bowel syndrome, migraines, and  
2 other headaches, and muscle issues including weakness,  
3 tingling, and spasms.

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

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

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

19           Three drugs are currently approved by the FDA  
20 for managing pain and other fibromyalgia symptoms;  
21 Lyrica, approved June 2007; Cymbalta, approved June  
22 2008, and Savella, approved January 2009. Lyrica and

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

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

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

19 Clinical response to medication varies. Not  
20 all patients who take approved therapies for  
21 fibromyalgia will see an improvement. Other drugs that  
22 patients and health care providers use to treat

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1 fibromyalgia include sleeping aides, pain relievers,  
2 anti-seizure drugs, anti-depressants, and muscle  
3 relaxants.

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

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

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

18           In diseases like fibromyalgia, which is not  
19 fully understood, input from patients is especially  
20 important. Patient related outcomes, or PRO's, can  
21 represent direct measures of treatment benefit in  
22 clinical trials. However, all measurements need to be

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1 evaluated in well-conducted placebo controlled, or  
2 double blinded randomized clinical trials.

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

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

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

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

22 How do these symptoms affect your ability to

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1 do specific activities, and the more concrete you can  
2 be about this, the better that we understand in the  
3 types of terms and the ways that we have to think about  
4 symptoms, and how they relate to treatments.

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

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

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

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1 now?

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

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

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

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

21           Once we hear from these panel -- all the  
22 patients up front, we will then move the conversation

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1 out into the audience and we'll all be able to  
2 participate, again, building on the experiences shared  
3 by the panel.

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

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

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

17           We've got these, you know, great technology  
18 in these little clickers that will enable the patients,  
19 primarily the patients and maybe the patient  
20 representatives for a few questions, to directly  
21 participate in the discussion by responding to a few  
22 polling questions. This gives us an idea of what

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1 experiences are in the room, who's here today, and some  
2 thoughts on a few of the discussion topics that we have  
3 so we can get a sense of the range of experiences in  
4 the room.

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

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

18           Web participants, you can also add comments  
19 through the webcast, and although they might not be all  
20 read or summarized today, especially if we have  
21 hundreds of people on the webcast, we will try to  
22 summarize what we can and they are all being recorded,

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1 and they will be included -- incorporated into our  
2 report.

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

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

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

17 So you'll go to the website, the slides will  
18 be posted after this meeting so you can go to this  
19 slide for this information, or we have this information  
20 on our website. You go to the link, you click on  
21 comment now, and you can submit a comment in a comment  
22 box, or you can upload a document that's on your

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1 computer to submit a comment. Anyone is welcome to  
2 comment; it doesn't have to just be a patient or  
3 patient representative.

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

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

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

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

22           Our discussion today is going to focus on

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1 those two topics that I outlined, the symptoms and the  
2 treatments. This does not mean there's not a range of  
3 other important topics around fibromyalgia and helping  
4 to ensure that patients get all the care and support  
5 that they need in their lives.

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

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

17 I want to say another thing about the flow of  
18 the discussion today. The discussion topic is going to  
19 focus on symptoms, and I think the best way to have  
20 that conversation is we will address symptom by  
21 symptom, and expand upon each. So I ask today is when  
22 you want to raise your hand to comment on something,

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1 please stay as close as you can to the question that's  
2 being asked. You will have your chance to address  
3 another symptom that you face later, or if you haven't  
4 yet talked about it, and we get to the end, then I'll  
5 ask if there were other topics that you wanted to raise  
6 that are relevant to this.

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

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

21           So let us, the FDA, know how we're doing. We  
22 have evaluations at the registration desk. These are

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1 very important to us and we really do take them to  
2 heart on how we can continue to improve upon our  
3 process as we go through other meetings.

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

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

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

19           If we can have the results? Okay. So two-  
20 thirds of you came from outside of the Washington,  
21 D.C., metropolitan area. That is fantastic. We are so  
22 appreciative. We're appreciative of anyone who

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1 traverses the beltway to get here, but a special shout  
2 out to those of you who have travelled a long distance,  
3 especially if you were also planning to do the  
4 December, that unfortunate December meeting. So thank  
5 you.

6 On the web?

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

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

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

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

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1 rest of the questions.

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

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

10 On the web?

11 MR. THOMPSON: Yes, on the web we have a  
12 little bit different spread. For the younger than 30  
13 we have about ten percent, 31 to 40 about 20 percent,  
14 as well as for 41 to 50. Then we see a jump for 51 to  
15 60 up to about 30 percent. Then we have a little lower  
16 from the 61 to 70; we have about 18 percent.

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

20 Okay. So 90 percent are female, and we have  
21 some male representation here. Again, it matches our  
22 expectations, but we thank everyone who's here,

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1 especially the men in the group.

2 On the web is it about the same?

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

5 DR. EGGERS: Okay. Thank you.

6 How long have you had the symptoms of  
7 fibromyalgia? Less than five years, five to ten years,  
8 10 to 20 years, more than 20 years, or you're not sure?  
9 Okay. All right. So we have many, many people who  
10 have lived with this condition for a long time  
11 represented here today, with the more than 20 years  
12 being the largest group.

13 On the web?

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

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

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

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

4 MR. THOMPSON: Yes.

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

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

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

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

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

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

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

6           MS. GALPEER: Hello?

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

8           MS. GALPEER: Hi.

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

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

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

18           MS. GALPEER: One, two, three.

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

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1 MS. GALPEER: Can you hear me now?

2 DR. EGGERS: Yes, we can hear you.

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

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

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

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1 tolerate.

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

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

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

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1 and what I can do is very limited.

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

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

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

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

22 I feel like a car being revved up while in

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1 park. My mind is racing with thoughts making sleep  
2 difficult; everything seems annoying to me. The pain  
3 gets intense to the point that I want to rip my skin  
4 off.

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

9 I have bad days and good days that are mixed,  
10 never knowing when they will occur and to what extend.  
11 Weather, stress, and over exertion of my muscles create  
12 my flares. Of all my worries the loss what (inaudible  
13 46:48) I do have to the point of becoming wheelchair  
14 bound or bed ridden is most predominant. My worst fear  
15 is having to live the rest of my life this way.

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

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

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

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

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

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

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

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1           I do try to go out and walk as much as I can.  
2   On a good day I walk up to a mile at a certain pace.  
3   Stretching sometimes seems to get this (inaudible  
4   48:49), sometimes it locks that up.

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

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

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

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

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

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1 be the worst.

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

11 DR. EGGERS: Thank you very much, Lori.

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

16 MS. GALPEER: Thank you.

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

20 MR. SMITH: Hello everyone. My name is Jacob  
21 Smith. I'm originally from Brooklyn, New York, but now  
22 I reside in the Bronx, New York. I'm a father of two

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1 beautiful girls, and one beautiful wife. In travelling  
2 from New York my purpose for addressing you today was  
3 really to assist you in gaining a deep understanding  
4 about my journey with fibromyalgia.

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

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

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

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

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

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

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

22           The fourth, I would say, just to add in, is a

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1 restless leg syndrome, which my legs tend to hurt all  
2 of the time, and my feet tends to stay swollen at time.  
3 Or remain swollen.

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

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

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

21           Unfortunately it's been recommended that --  
22 by my physician that I may possibly have to look at the

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1 use of a power chair for mobility on the days that I  
2 cannot walk. With that recommendation reality is not  
3 only -- not totally set in regarding the use of a power  
4 chair as part of my daily life.

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

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

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

21           Another sign of my social isolation resulted  
22 in my withdrawing from social activities, or feeling a

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1 loss of interest or pleasure in my usual activities.

2 But I'm working to avoid social isolation by making an

3 extra effort to stay engaged with my family and

4 friends.

5 DR. EGGERS: Any final thoughts, Jacob? Any

6 parting --

7 MR. SMITH: Yeah, I mean -- the parting

8 thoughts is just -- what I'm trying to do now is now

9 put together some form of comprehensive lifestyle plan

10 that's really going to help me shape my mind, body, and

11 spirit, so that I can remain holistically healthy to

12 the disease.

13 DR. EGGERS: Thank you so much, Jacob. Thank

14 you. And Michelle?

15 MS. DONCKEL: Hi. I want to say (inaudible

16 57:19).

17 DR. EGGERS: Oh, I'm sorry.

18 MS. DONCKEL: Well, I want to thank the FDA

19 for listening to us because people don't listen, even

20 people that aren't involved in medicine. They don't

21 know what to make of it, and so they just don't want to

22 listen.

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

3           DR. EGGERS: It's okay.

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

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

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

22           Getting sleep, making sure to go to bed at

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1 the same time every night, the same routine, and with  
2 the help of medication I have the best track record for  
3 sleep that I've ever had in my life, from the time I  
4 was a baby. Just ask my mother.

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

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

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

21           Then the next thing that comes with that is I  
22 can't even tell you what's going on because I can't get

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1 the word out of the mouth. I can't get the word into  
2 my brain. They may come out in a different order.

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

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

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

19 The thing that made a huge impression on me  
20 was Jack Kevorkian. Dr. Death. One of his patients  
21 was a fibromyalgia patient, and I readily admit if I  
22 thought my life was going to be one long attack, fibro

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1 attack, and I would never have a day where I could get  
2 up and go to work, I would call him, because it's not  
3 living. It's just not living.

4 DR. EGGERS: Thank you so much, Michelle.

5 Now we'll have Laura.

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

9 MS. DUGAN: Hi, my name is Laura Dugan. I am  
10 32 years old, and I was diagnosed with fibromyalgia  
11 when I was about 16, which is a little younger than is  
12 traditionally diagnosed.

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

22 So at this point I've had it for about half

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1 my life, which is sort of an unusual thing.

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

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

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

18           Insomnia has been a big problem, and it  
19 wasn't until about two years ago that a doctor through  
20 to test me for a melatonin deficiency, and I was found  
21 at that time to be very deficient in melatonin. So  
22 taking that now has pretty much, so far, cured my

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1 insomnia, which is wonderful because I've tried just  
2 about every sleep aid on the market with more misses  
3 than hits.

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

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

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

19           I do feel like my pain is a little bit  
20 better, like I said, but the fatigue -- as you  
21 mentioned -- it was interesting too, my mother had said  
22 too, that I have never slept well from the time I was

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1 an infant. So it's interesting to see that there's  
2 some parallels there as far as that goes.

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

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

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

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

17 I had a series of injuries on the job, the  
18 first one was because I was arresting a person who  
19 thought I was Dionne Warwick, and got upset when she  
20 found out I wasn't, and she Judo flipped me I sprained  
21 my left arm. Then I had a fight with Stephen King --  
22 not the writer -- in an enclosed small room with the

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1 lights off, and he was throwing me around the room like  
2 a rag doll.

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

8           As a result of fibromyalgia I am now  
9 divorced.

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

19           The next one is the ongoing fatigue. I start  
20 in the morning really well and about 3:00 p.m. I  
21 literally hit a brick wall. I'm like a cartoon  
22 character moving at 100 miles an hour and then all of a

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1 sudden come to a complete and total stop because of the  
2 fatigue.

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

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

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

20           Specific activities that I cannot do fully,  
21 or that I can't do at all? I do not sleep through the  
22 night. I can hear everything going on around me. You

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1 can come into the room and have a conversation and I  
2 will respond to you, and my ex-husband a bought a  
3 building because we had a conversation while I was  
4 sleeping. I can't move though, I'm paralyzed.

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

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

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

19 Finally, I'm no longer married because of  
20 fibromyalgia. Back when I was diagnosed it wasn't  
21 something that was -- you know, you didn't see the  
22 commercials for it. You didn't hear about it, and a

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1 doctor told my ex-husband that it was a psychological  
2 disorder, and he went and asked his mother for advice  
3 and she told him to go beat me back to health. He  
4 tried; it didn't work. I still have fibromyalgia.

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

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

20           Normally, I would not be leaving until the  
21 day after a meeting, but I'm babysitting my wonderful  
22 two year old granddaughter, so I have to go back

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1     tonight.  So I know that tomorrow is going to be  
2     difficult for me.

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

7                 DR. EGGERS:  Any final thoughts?

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

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

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

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1 go along.

2           Somewhere there is a microphone for me. This  
3 is the part that we call talk show style, so I'm going  
4 to be coming out into the front. Can you hear me?

5 Okay. There's a lot of machines up here, so I'm not  
6 sure exactly where I'll stand for this. But the first  
7 thing I want to do is to give the panelists a round of  
8 applause. We thank you.

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

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

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

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

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

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

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

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

20           This is a long list, and you can use your  
21 clickers to choose up to three symptoms that you would  
22 say would be your top three. Chronic pain, fatigue or

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1 lack of energy, difficulty concentrating or memory  
2 problems, and here I would say if you would put  
3 anything in the category of that fibro-fog. Sleep  
4 problems, sensitivity to light, sound, or other  
5 stimuli, gastrointestinal issues, depression or  
6 anxiety, headaches, or some other symptom that doesn't  
7 fit in any of the other categories. This is a hard  
8 question, I know.

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

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

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

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

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

10           And on the web?

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

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

21           Just a quick show of hands; how many of you  
22 have the tender spots? And when I -- let's do the

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1 quick show of hand, let's say would you put that in  
2 your one or two top aspects of pain that are the most  
3 bothersome to you? Okay.

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

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

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

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

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1 to live with.

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

4 MS. WILSON: Yes.

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

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

10 MS. WARD: Hot stabbing pain.

11 DR. EGGERS: Deborah?

12 MS. WARD: Hot stabbing pain.

13 DR. EGGERS: Okay. Stabbing? Like --

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

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

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

20 MR. OGDEN: My name is Louis, and I'd like to  
21 say that of all those things you had listed there's  
22 only one that I don't have, so it was very difficult to

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1 pick the top three. Headaches have always been my  
2 major problem, along with the real tight shoulders, and  
3 this kind of thing.

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

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

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

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

21 Were there any follow up questions about  
22 headaches, how they manifest themselves, that the panel

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1 would like to know about? Okay.

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

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

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

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

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

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

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

14           DR. JONIAK-GRANT: Yes.

15           DR. EGGERS: Yes, from Elizabeth.

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

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

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

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

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

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

21           I want to move into fatigue because I think  
22 that all five of the panelists mentioned it, and at

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1 least two of you really focused on it in-depth. I  
2 believe that -- let's have another show of hands to see  
3 -- did you hear your experience with fatigue reflected  
4 in their comments on fatigue?

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

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

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

21           DR. EGGERS: So we've heard about that very  
22 slow start in the morning. Not to try to minimize

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1 that, but what I'll describe as a very slow start, and  
2 then the crash that happens sometime in the afternoon  
3 or later in the day.

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

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

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

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

21           MS. WALKER: Mine is the not the kind -- I'm  
22 sorry; my name is Sue Walker. Mine is not the kind

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1 where I have to go to sleep, it's the sit and veg.  
2 It's just -- and my pattern, as long as I've got the  
3 mic, is a little bit different as well. My crash is  
4 not so much dependent on time of day as on activity,  
5 and it's completely unpredictable. So it's very  
6 difficult for me go out and do things because I never  
7 know when that crash is going to strike.

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

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

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

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

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

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

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

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

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

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

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1           Go ahead, Sabrina.

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

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

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

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

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

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1 MS. LONG: Shay.

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

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

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

19 DR. EGGERS: Thank you, Shay.

20 Nancy, would you like to follow up on that?

21 MS. JENIAK: Yeah, I just wanted to add that  
22 mine started with a six month period of not sleeping,

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1   literally for six months, and that's when I got the  
2   diagnosis. So I think sleep does definitely have some  
3   sort of connection. And then now, 18 years later, I  
4   found something for sleep and my symptoms are much  
5   better.

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

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

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

20               I also work for an institute that is vitally  
21  interested in the sleep/pain connection, and we're  
22  holding a workshop -- it's not open to the public

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1 because we're just beginning to really try to grapple  
2 with this intersection between sleep and pain, and in  
3 particular how do sleep disturbances impact chronic  
4 pain, and actually lead to chronic pain.

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

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

13           MS. ALEKEL: We'll talk about it.

14           DR. RAPPAPORT: Thank you.

15           MS. ALEKEL: Thank you.

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

21           You, in the room, didn't all get a chance to  
22 speak about your fatigue issues, so please take a

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1 moment and write a follow up on your fatigue, and if  
2 you submit comments to us through a website we'd really  
3 be interested in hearing more, exactly that  
4 relationship.

5 We have Sharon?

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

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

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

21 MR. THOMPSON: Yeah, there's been a lot of  
22 comments. Many have been echoing what's been said in

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1 the room, so I won't go through and talk about all the  
2 different pain and fatigue related symptoms.

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

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

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

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

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

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

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

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

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

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1           Vision problems -- one more thing -- Jan?

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

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

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

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

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

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

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

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

20           So it makes -- I mean, I can't buy new  
21 glasses every time they change. At least with contacts  
22 they're disposable, they're only for two weeks, so it's

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1 a little bit more cost effective. But it is a big  
2 strain, because I'm like, well, should I be driving now  
3 because I don't have the new contacts, and my old  
4 glasses don't exactly help me see. So it is a  
5 limitation.

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

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

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

16 DR. EGGERS: Okay. Great. Then Sabrina?

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

21 I also have a problem when I wake up in the  
22 morning for about an hour, I can't see. It's like

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1 looking through a veil, and I just have to sit there  
2 and bat my eyes, and wait until my vision clears and  
3 comes back.

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

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

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

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

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

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

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

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

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

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

21           Okay. So go ahead.

22           MS. WILSON: I have the typical fibro-fog

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1 where people are saying, you know, you forget your  
2 words, things like that, but I also have had times  
3 where it's been very scary for me; I've forgotten where  
4 I was going, I've forgotten where I am.

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

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

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

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

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

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

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

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

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1 heard discussed today.

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

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

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

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

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

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

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1 percent. Thank you.

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

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

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

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

17 MS. GLEASON: Hi, Rae Gleason, and I'm the  
18 Medical Education and Research Director for the  
19 National Fibromyalgia and Chronic Pain Association. I  
20 just wanted to bring up, because it hasn't been  
21 mentioned here, and I know through the surveys that  
22 we've done here, and through the years that I've done

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1 at other fibromyalgia organizations, that stiffness is  
2 like the number one. It has come in ever number one  
3 above pain on some of those surveys, and these surveys  
4 are 5,000 people that responding, so it's not a small  
5 group of people.

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

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

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

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

22 DR. EGGERS: Thank you very much. So we'll

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1 go to Louis, and then I'm going to go to the web and  
2 the phone.

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

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

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

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

22 DR. EGGERS: Okay. I see a lot of head nods,

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1 and I won't ask for a show of hands but I'm seeing a  
2 lot of head nods in the room from that.

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

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

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

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

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1 on the webcast, a few of you, to contribute to the  
2 dialogue.

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

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

7 DR. EGGERS: Hi, Sharon.

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

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

18 DR. EGGERS: Thank you very much, Sharon.

19 We will get into the discussion, but how many  
20 of you -- mainly ladies in the audience today, found  
21 that if you went through a pregnancy that that changed  
22 your symptoms in a significant way? Okay. We won't

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1 get into discussing that, but perhaps if you could  
2 elaborate on that in the docket comments?

3 Do we have another caller, operator?

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

6 MR. KNIGHT: Hello, I have a pain issue that  
7 wasn't really mentioned on here. I went to the  
8 University of Washington to get this diagnosis and he  
9 told me I had small fibro fibromyalgia (inaudible  
10 1:53:39) affects my lower body.

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

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

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

20 DR. EGGERS: Can you repeat what you had?

21 MR. KNIGHT: He told me I had small fiber  
22 fibromyalgia, and it affects only my lower body. It

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1 feels like a combination of bee stings and pins and  
2 needles in just my legs.

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

5 MR. SMITH: Yes

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

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

10 DR. EGGERS: Okay. Yes, Sabrina?

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

16 DR. EGGERS: Okay.

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

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1 correlate to the same thing, but only my lower body.

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

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

7 DR. EGGERS: Hi, Mike.

8 MR. HERNESS: Hello. I guess the thing I was  
9 looking at was it seems over the years -- I've had this  
10 about nine years, and it seems to have progressed with  
11 symptoms similar to autonomic neuropathy or  
12 dysautonomia; those types of problems with things like  
13 postural orthostatic tachycardia syndrome, drop in  
14 blood pressure, dizziness, weakness, (inaudible  
15 1:56:04) at time. Always weak and unstable; those  
16 types of things.

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

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

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

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

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

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

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

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

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

7                           (Break between sessions.)

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

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

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

22           And as we understand it, it is a multi-

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1 modal treatment approach, many, many different --  
2 for some of you, many, many different aspects of  
3 your treatment. And we'd like to get a little bit  
4 of a sense of that, and then delve a little bit  
5 into the specifics, the specific pharmaceutical  
6 treatments.

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

14           Can I have the next slide, please?

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

21           And then, if we have time in our  
22 discussion to get at what specific things you look

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1 for in an ideal treatment for your condition.

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

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

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

20 MS. CHAMBERS: Thank you.

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

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

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

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

20           My illness included a lot of things --  
21 metabolic syndrome, migraines, polycystic ovarian  
22 syndrome, cognitive difficulties, functional loss,

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1 and unrefreshing sleep. I practically laid on the  
2 couch or on my bed for the next 16 months with  
3 pillows supporting my arms and legs so they  
4 wouldn't touch each other because it caused more  
5 pain. And during this time, and out of  
6 desperation, I convinced a very sympathetic surgeon  
7 to remove one-fourth of my breast because I  
8 couldn't lower my arm to touch my side. And that  
9 very sensitive spot, very painful spot, I now  
10 believe was a tender point.

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

18 I paid attention to the broadly accepted  
19 theory of central sensitization in fibromyalgia.  
20 To me, that meant that my central nervous system  
21 was out of control and affecting all of the systems  
22 in my body. It made sense that calming my central

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1 nervous system was going to be the answer for me,  
2 and to stop the life-altering changes that were  
3 occurring with fibromyalgia.

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

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

20           Through the physical rehabilitation, I  
21 reduced the cervical stenosis, or the narrowing of  
22 the spinal canal, and the constant stretch and

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1 pressure on my spinal cord was stopped. Reducing  
2 emotional stress and learning relaxation skills  
3 were also very important.

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

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

14 As a patient, I convinced my chiropractor  
15 to do a small clinical study on fibromyalgia  
16 patients with severe neck pain. The results were  
17 similar to mine. Since the initial year of  
18 physical therapy, my daily life has continually  
19 improved. I still have to be mindful of my posture  
20 and stress levels. If I overdo my physical  
21 activities, like carrying heavy grocery sacks and  
22 heavy housework, some pain does return. With heat

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1 and performing the physical therapy work for a  
2 couple of days, the pain can stop or reside.

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

12           Thank you for this opportunity today.

13           DR. EGGERS: Thank you, Jan.

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

16           MS. HERMAN: Hello. My name is Gwen  
17 Herman. I'm the Executive Director and founder of  
18 Pain Connection. We work with people in chronic  
19 pain. My pain started 19 years ago when I was in a  
20 car accident. I was rear ended, and my pain  
21 started in my neck, went up into my head,  
22 shoulders, and then throughout my body, so

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1 fibromyalgia, TMJ, autoimmune system problems,  
2 gluten-intolerant, dairy -- you know, dairy-  
3 intolerant, irritable bowel, a few things. And  
4 what I had to learn was just how to -- learn how to  
5 live again because of all of the changes in my  
6 life.

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

18           I do a lot of Chinese medications. I have  
19 a special formula that is made for me that helps  
20 with my sleep, because I -- you know, I can't sleep  
21 at night because of the pain. And my worst  
22 position is lying down in bed. So that's horrible

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1 when you're feeling tired all the time, because to  
2 go to bed to me is the most painful thing, so  
3 that's why I need something to knock me out right  
4 away.

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

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

16 I go to weekly acupuncture now. In the  
17 beginning, I would go three times a week. I went  
18 to four acupuncturists before I found the one that  
19 I have now, and I have learned that there is all  
20 different types of acupuncture. So she does  
21 something that is called the balance method, and  
22 she does Taiwanese acupuncture, and she doesn't go

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1 into the source of my pain, so she works on the  
2 outer extremities and that helps me a great deal.  
3 And then I use like little tacks during the week  
4 just to prolong the treatment.

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

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

16 I have a number of different health care  
17 providers. Since it's 19 years, it has taken me a  
18 long time to get a team that I can work with. I  
19 have an excellent pain doctor now who is a  
20 physiatrist. I have a nurse practitioner who is an  
21 herbalist and also a nutritionist, so I'm on a lot  
22 of different herbs. And I had to change my whole

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1 diet because I'm gluten-intolerant and can't have  
2 dairy.

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

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

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

20 Let's see what else. I use all different  
21 lotions for my neck. You know, I use Voltaren gel.  
22 I make my own lotion that I learned from my

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1 herbalist with lavender, St. Johns Wort oil, aloe  
2 vera, and I use that. I grow my own feverfew for  
3 migraines. I can just pick it and, you know, eat a  
4 few of the leaves. That helps with migraines.  
5 Drink four to five glasses of jasmine green tea a  
6 day, which is really good. I take oil, fish oil  
7 every day. I don't eat fried foods.

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

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

20 And then a lot of times, if I do go  
21 traveling, after what happens I may be out for a  
22 week, or a month even. It takes me a long time to

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1 get back to where I was beforehand.

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

4 MS. HERMAN: Go ahead.

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

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

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

17 MS. HERMAN: Right.

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

20 MS. HERMAN: Yes.

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

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1           MS. HERMAN: There was just two other  
2 things.

3           DR. EGGERS: Yes.

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

9           DR. EGGERS: Thank you so much, Gwenn.  
10 And now Sarah?

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

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

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1 daily basis.

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

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

18           So, naturally, I was devastated. I  
19 remember feeling alone and like the medical  
20 community just didn't understand me. So the  
21 turning point for me was when I discovered  
22 acceptance and commitment therapy. And basically

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1 the tenets of that is quit fighting it and find a  
2 way to live with the cards you've been dealt,  
3 basically.

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

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

16           If I have a really bad flareup, I will  
17 take 500 milligrams of Hydrocodone and  
18 100 milligrams of Imitrex. That's my combination.  
19 But to give a little perspective, I take about one  
20 bottle of Hydrocodone a year. So I don't take  
21 medications. I don't take any like everyday  
22 medications or anything like that. So as long as I

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1 constantly monitor my bodily cues, I can engage in  
2 more activities.

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

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

18           But getting back to the treatments, I  
19 don't think there is a single pill out there that  
20 can treat all the symptoms of fibromyalgia, from  
21 the pain to -- from the -- well, the all-over pain  
22 to the bodily fatigue, the cognitive fatigue. I

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1 think there is going to have to be some kind of a  
2 treatment regimen.

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

8           DR. EGGERS: Thank you very much, Sarah.

9           MS. LYALL: Thank you.

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

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

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

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

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

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

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

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

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

20           My medication cocktail includes  
21 medications targeted at my specific symptoms --  
22 Verapamil and Botox injections for migraine

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1 control, a custom antidepressant mix of Remeron  
2 that gives much-needed deep sleep and low doses of  
3 Zoloft and Abilify to address depression, anxiety,  
4 and some of the pain.

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

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

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

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

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

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

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

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1 hit or miss.

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

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

10 DR. EGGERS: Thank you very much, Nancy.

11 And, finally, we have Deborah.

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

18 My name is Deborah Ward. I'm 62. I'm  
19 married and I'm a writer. I was diagnosed with  
20 arthritic TM joints and fibromyalgia 28 years ago.  
21 I include my TM joints because they were the reason  
22 I was first diagnosed with fibromyalgia. My TM

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1 specialist, TMJ specialist, asked me certain  
2 questions and he said, "I think I want you to go to  
3 a friend of mine."

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

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

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

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

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

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1 husband a lot.

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

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

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

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

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

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

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

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

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

22           (Applause.)

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

4           And what I think is so great about this  
5 panel that was up here is, to my understanding,  
6 they demonstrated the wide range of this complex  
7 treatment regimen. We heard everyone did something  
8 different, and everyone named, I believe, more than  
9 15 things that they are doing.

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

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

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

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1 clicker, raise your hand.

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

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

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

21           (Pause.)

22           Okay. It sounds like we -- people have

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

7           And 85 percent of you are taking  
8 prescription medications, which I guess means that  
9 15 percent of you are not.

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

15           On the web, what are we --

16           MR. THOMPSON: The webcast has very  
17 similar results, except 80 percent of people take  
18 some sort of over-the-counter product, and only  
19 63 percent do some sort of exercise, and 53 percent  
20 for physical therapy.

21           DR. EGGERS: Okay. Thank you.

22           All right. So we want to -- just like we

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

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

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

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

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1 We have over there.

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

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

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

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

20 MS. GIANNOLA: I am taking a cocktail, and  
21 it has been trial and error. I have been on Ambien  
22 for years. I'd rather not be. Lyrica,

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1 Nortriptyline, and Tramadol for pain. I exercise  
2 regularly.

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

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

12 DR. EGGERS: Okay.

13 MS. GIANNOLA: So I take it twice a day,  
14 250.

15 DR. EGGERS: Okay.

16 MS. GIANNOLA: Yeah.

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

19 DR. JONIAK-GRANT: Just in terms of the  
20 prescription medications, I'm a little bit  
21 different with the Lyrica. I only take 100  
22 milligrams a day. I work as -- when I can work

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1 part-time as a professor, so I get too many  
2 cognitive impacts with Lyrica. I also have to take  
3 it at sleep because about 40 minutes after I take  
4 it I get severely depressed. No reason why. My  
5 husband will say, "Why are you depressed?" I'm  
6 like, "No reason. Just feel miserable." That's  
7 one.

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

21           DR. EGGERS: Okay. Thank you. Thank you.  
22           Okay. We'll go to Shay.

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

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

15           So, you know, it doesn't fix everything,  
16 but it has helped a lot. But with it I take  
17 Wellbutrin in the morning. I am like probably a  
18 huge serotonin toxicity risk at this point because  
19 of the particular cocktail I'm taking, but I -- the  
20 Lyrica will keep me sleeping all day if I don't do  
21 something, like my energy level is so low. So they  
22 put me on Wellbutrin to try to help counteract that

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1 and it works pretty well, and also helps curb a  
2 little bit of the weight gain, because you don't  
3 have an appetite anymore. So --

4 DR. EGGERS: Okay.

5 MS. LONG: -- there you go.

6 DR. EGGERS: Anyone in the back there?

7 Yes.

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

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

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

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

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

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

15 MS. WINE: Yes.

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

21 MS. WINE: It's years. Like I say, I was  
22 on Ultram for four or five years or longer. And

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1 actually I stayed on it -- it had stopped working  
2 completely, but I was still taking it, trying to  
3 give it a chance.

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

12 DR. EGGERS: Okay. Thank you.

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

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

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

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1 MS. GIANNOLA: Laurie.

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

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

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

20 DR. EGGERS: Okay. Does this sound -- is  
21 this resonating with you, that you are trying it  
22 for a long time, having to push through some side

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1 effects to be able to determine its effectiveness  
2 for you? I see a lot of head nods. Do any of my  
3 colleagues want to follow up on this question?

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

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

18           MS. ATTERBURY: Hi. I'm Sharon. I'm  
19 taking Cymbalta. My downside is that eight to 12  
20 bowel movements a day. You know, you can't get a  
21 lot of work done if you're in the bathroom. And  
22 that's what I find. It also cut the appetite. I

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1 have lost considerable -- I've gotten back in some  
2 pants that I couldn't get back into. I've gotten  
3 back into some shirts I couldn't get back into.  
4 But, still, those bowel movements, I'm sore at the  
5 end of the day.

6 DR. EGGERS: Okay. Others?

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

13 DR. EGGERS: Okay.

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

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

22 MS. CASTAGNA: Yes.

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

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

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

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

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

21 MS. HERMAN: Yeah. Nobody has mentioned  
22 that it affects your sexual life also, a lot of

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1 these medications, that men can't perform or women,  
2 you know, have problems also.

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

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

14 DR. EGGERS: Okay.

15 MS. LYALL: So it's a tradeoff.

16 DR. EGGERS: Okay. Other downsides?

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

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1 horrible.

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

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

21 I'm not able to work anymore, but I can  
22 still function somewhat. If there was another

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1 treatment, sure, I would love to take it. But for  
2 now, this is what works.

3 DR. EGGERS: Thank you, Valerie.

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

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

15 DR. EGGERS: Okay.

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

21 Savella absolutely was wonderful for the  
22 pain, but after a year of kind of soldiering

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1 through I felt like I was in Groundhog Day in the  
2 first trimester of pregnancy. For all of the women  
3 who have been pregnant and had morning sickness, it  
4 was like a year of continual morning sickness. I  
5 never got past it. I reduced the dosage back to I  
6 think 25 milligrams. Still couldn't get past it.  
7 And I hated giving it up, but I couldn't do it.

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

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

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1 it.

2 DR. EGGERS: Thank you very much, Sue.

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

7 Okay. So let's go with Louis first.

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

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

21 DR. EGGERS: No side effects?

22 MR. OGDEN: No side effects. And for the

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

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

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

9 MR. THOMPSON: Another reminder for those  
10 on the web, we'll be queuing up the phone in about  
11 10 minutes, so you should dial in now.

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

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

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1 but I want to get the complement of that, the non-  
2 prescription.

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

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

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

16 DR. EGGERS: Okay.

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

22 It is non-addictive. It really has

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

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

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

17           MS. DUGAN: I am a big user of Biofreeze.  
18 When my pain is bad on particular days, I just feel  
19 like for something that's topical, especially  
20 because I'm single and it's a spray, and it's hard  
21 to get your back when you have nobody to do it for  
22 you. So I found that Biofreeze gets me a lot of

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1 relief, particularly if I have pain and I'm  
2 struggling to fall asleep because of it. I'll  
3 spray it on shortly before I go to bed and that  
4 will freeze it enough to get me to be able to fall  
5 asleep.

6 DR. EGGERS: Okay.

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

13 DR. EGGERS: Okay.

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

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

22 DR. HERTZ: There has been a little

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

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

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

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

21           And then, how many of you have difficulty  
22 getting your prescription? We heard an example of

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1 that. Okay.

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

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

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

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

21 MR. VALENTINE: I think most of the  
22 comments have been very in line with what has been

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1 discussed in the room. You know, I think the  
2 overarching consensus is that it takes a long time  
3 to find the right combination of drugs,  
4 supplements, exercise, diet, lifestyle, alternative  
5 therapies. You know, there is a whole list of  
6 things, mostly overlapping with what has been  
7 discussed in the room.

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

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

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

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

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1 large proportion of you.

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

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

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

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

20           Think about all of your therapies  
21 together, that whole regimen. How many of you  
22 share Nancy's perspective -- I'm going to try to

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1 paraphrase -- that although you still battle your  
2 condition every day, you feel like you are managing  
3 as best as you can expect? Okay.

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

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

14           Okay. Elizabeth?

15           DR. JONIAK-GRANT: My biggest thing that I  
16 think impacts me the most are the migraines. And,  
17 as Deborah mentioned, I do bilaterally C3 through  
18 C7 cervical facet radiofrequency ablation, but the  
19 nerves grow back. So, and they find that over time  
20 that they grow back more quickly. The biggest  
21 problem with that is the treatment itself is  
22 extremely painful. You have to be awake. You have

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1 to be alert. And, you know, they're going into  
2 your spine.

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

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

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

18           MS. LONG: Oh, okay. Hi. I think that  
19 even if my pain levels stayed where I -- where they  
20 are right now, if I just had more energy I feel  
21 like I would be in such better shape, because it's  
22 really like being so exhausted that I can't get

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1 anything done. And then I haven't gotten anything  
2 done, so it leads to me being kind of depressed  
3 about having not gotten anything done, and then I  
4 eat a chocolate cake and gain more weight, and, you  
5 know, I mean, it's a vicious cycle.

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

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

17           But anywhere else, I sleep. I sleep  
18 sitting at my desk. I sleep behind the wheel  
19 driving home to and from. I now take something to  
20 manage that just so I can stay awake during the day  
21 and hold a job. I got fired for sleeping on the  
22 job. I knew they knew I was sleeping, but I was

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1 too embarrassed to admit I was sleeping on the job.  
2 So they fired me and I just didn't say anything and  
3 I just went away.

4 DR. EGGERS: Thank you, Sharon.

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

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

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

15 How many found them effective? Okay.

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

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

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1 fibromyalgia.

2 DR. EGGERS: Okay. Thanks, Jan.

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

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

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

16 DR. EGGERS: So, Liz.

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

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

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

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

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

21 But even in Minnesota, though, usually  
22 during the winter months, January and February, I

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1 would go -- I would be without pain for two months.  
2 And I think, once again, it was the dry air, it was  
3 the high barometric pressure, because once the  
4 summertime came, once March came, I'd start feeling  
5 the pain again. Unfortunately, that was before and  
6 now it's pretty much constant, but I did have  
7 symptom-free.

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

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

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

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1 find an ideal treatment would address.

2 Operator, can we have a caller?

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

5 DR. EGGERS: Okay. Hi, Mike.

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

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

9 MR. HERNESS: Yes?

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

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

15 DR. EGGERS: Okay.

16 MR. HERNESS: -- about fibromyalgia, it  
17 being a syndrome or a collection or, you know, of  
18 signs and symptoms, more than I think, which come  
19 under the category of a disease. It takes a very  
20 long time for most people, you know, to get the  
21 point of a true diagnosis. When you get to the  
22 diagnosis, because it's so much more generalized

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1 than specific, so many people do get caught up into  
2 the pharmaceutical end of it, and then try to find  
3 alternative types of treatment.

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

12           DR. EGGERS: Okay.

13           MR. HERNESS: Thank you.

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

16           Can we have one more caller, Operator?

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

19           DR. EGGERS: Hi, Lauren.

20           MS. HOROWITZ: Hi. I've been diagnosed in  
21 2004, and I have been a guinea pig for 10 years. I  
22 don't understand -- I live in Florida. It is a

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1 chronic -- I've tried everything, the latest being  
2 low-dose Naltrexone, and I put all my hopes into  
3 that and it didn't work. So I'm currently on  
4 Cymbalta, but I don't understand what the problem  
5 is with doctors writing pain medicine for chronic  
6 pain. I'm 52. I live in bed. I live alone. And  
7 I don't understand.

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

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

15           I did promise -- I think that's all the  
16 time we have for the phone now. But I did promise  
17 that if those of you who raised your hand to my  
18 earlier question about that your experiences were  
19 completely different from those on the panel that I  
20 would come back to you and ask you. So if you had  
21 some important point to share about your experience  
22 with treatments, and it hasn't been talked about

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1 today -- depending on how many hands we have -- can  
2 we -- we can address those for a few minutes.

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

5 MS. DUDLEY-JOHNSON: Hello?

6 DR. EGGERS: Hi, Sabrina.

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

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

19 And then, a question you asked earlier  
20 about, how long do you go before you find out if  
21 it's effective or not? My doctor asked me to stay  
22 on the medication for eight weeks before I start

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1 crying that it doesn't work. So at least eight  
2 weeks. And then if I have adverse or side effects  
3 within the first couple of weeks, we stop it right  
4 away.

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

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

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

21 And one additional comment is, for ladies,  
22 that is my experience. As you age and as you get

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1 into menopause, you get better in terms with  
2 fibromyalgia.

3 DR. EGGERS: Thank you very much.

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

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

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

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1 DR. EGGERS: Okay. Thanks.

2 And then, Louis, a final comment?

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

8 DR. EGGERS: Okay. Thank you.

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

18 And so I really want to thank everyone in  
19 the room for your contributions today and for your  
20 patience and for listening to one another and  
21 answering our questions and being quite open about  
22 things that are often very difficult to talk about

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1 in a roomful of strangers. So I want to thank you.

2 I want to, again, thank the panelists.

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

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

17 So a lot of people said that they would  
18 like to see products that help address both pain  
19 and fatigue but with lower immediate and long-term  
20 side effects. I think the web participants agreed  
21 with the room that they would also like to see new  
22 therapies focusing on the fatigue first, that they

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1 seem to be able to manage their pain more so now  
2 with current therapies. And then ultimately they  
3 would like to see therapies that are not just  
4 focused on symptoms but trying to stop the  
5 underlying progression of fibromyalgia.

6 DR. EGGERS: Thank you very much, James.

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

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

21 Keep in mind, we won't be addressing any  
22 comments that we hear during this session, but all

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1 of the comments that we have are being transcribed.

2 We're listening. We're in listening mode.

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

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

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

21 Okay?

22 So first we have -- I'm going to read all

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1 of the names, so you know your order. We have  
2 Sally Okun -- I apologize if I mispronounce any of  
3 these names -- Elizabeth --

4 DR. JONIAK-GRANT: Joniak-Grant.

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

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

16 I am happy to be here on behalf of our  
17 40,000 members who are living with fibromyalgia.  
18 When we did a four-day survey in December in  
19 anticipation of this meeting, we sent a survey out  
20 to about 8,000 members, and we had a 20 percent  
21 response rate within that four days. So there is a  
22 lot of interest in giving you feedback and giving

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1 you information.

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

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

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

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1 overall outcomes and their ability to cope.

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

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

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

18           The other thing I wanted to raise was the  
19 impact of side effects. We heard some about that  
20 today, but we did ask about their concern as well  
21 as some of the bothersome characteristics of this.  
22 So 72 percent of our patients are very concerned or

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1 concerned about side effects. Fifty percent report  
2 having some side effect to the medications that  
3 they have been taking that are prescription  
4 medications. And 35 percent are making adjustments  
5 to the dose or frequency, and 30 percent are  
6 stopping altogether.

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

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

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

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1           And, lastly, what I'd like to just really  
2 reinforce is the heterogeneity of this condition is  
3 significant. Only two percent of the patients who  
4 followed up on the survey reported fibromyalgia as  
5 their only condition. In fact, we collected over  
6 90 different comorbid conditions from that one  
7 group of patients. So the response rate, as I  
8 said, was about 20 percent. It was about over  
9 1,500 patients that contributed to the survey, and  
10 I received hundreds and hundreds of messages after  
11 the survey with additional information, which we  
12 will post to the docket.

13           DR. EGGERS: Thank you very much, Sally.

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

16           DR. JONIAK-GRANT: Hi, again. Very  
17 briefly, one thing I want to point out that other  
18 people -- I haven't heard mentioned is that the  
19 longer I'm on the medications the more side effects  
20 I seem to start developing. I saw it particularly  
21 around year three and year four. I started getting  
22 unexplained tachycardia, palpitations. I had

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1 petechial rashes. Now I'm getting skin lesions.  
2 And the longer I'm on the medicine, the more sort  
3 of of the infrequent ones from the clinical studies  
4 I'm developing.

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

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

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

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

10           But then, fertility issues also seem to  
11 come up from the medications, the SSRIs, like  
12 Cymbalta. They're showing that it's damaging sperm  
13 and the DNA of sperm. So I'm thinking, why not --  
14 why don't we look at some eggs and see what it's  
15 doing to the DNA. And then, also, practically  
16 speaking, what does a person do who wants to have  
17 children and is on the medications? Do you come  
18 off the medications, which is what I have chosen to  
19 do because of the very limited studies about some  
20 of the severe birth defects they have found, again,  
21 only in animal studies. And then, can you even  
22 manage to be pregnant without the meds? For me,

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1 the decision is, no, we are going through a  
2 gestational carrier eventually.

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

10           DR. EGGERS: Thank you very much.

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

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

16           We have Rae Gleason. Can you raise your  
17 hand?

18           MS. GLEASON: Again, my name is Rae  
19 Gleason. I'm the Medical Education and Research  
20 Director for the National Fibromyalgia and Chronic  
21 Pain Association. I have been doing this work for  
22 20 years. I helped create the National

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

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

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

18           And the other part of it is the medical  
19 costs themselves, you know, add to that financial  
20 burden. If you look at the Institute of Medicine's  
21 research -- I'm sorry, Pain in America Report that  
22 was published in 2011, it talks about a bill of

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1 about \$650 billion a year spent on pain. And there  
2 still really isn't a whole lot of answers for that  
3 in terms of, you know, how it is approached.

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

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

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

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1 DR. EGGERS: Thank you very much, Rae.

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

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

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

18 And when I say "not knowing whether we  
19 would speak about it," I do believe there remains a  
20 certain stigma associated with the use of these  
21 medications. Clearly, we are not insensitive to  
22 the fact that they are abused and that they have

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1 caused harm in some circumstances. But I can tell  
2 you, in all honesty, that this man has been  
3 benefited tremendously by them.

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

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

20           I was, I have to say, astonished at how  
21 helpful it was and how quickly. And there have not  
22 been any significant side effects. These

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1 medications do not, in his case, make him drowsy or  
2 drugged. Our lives have simply been made better.  
3 While these substances are disabling to some  
4 individuals, they have been enabling to my husband,  
5 and we have had the best life for the last three  
6 and a half years that we have had in decades.

7           It is difficult. There are no doctors in  
8 Virginia who use these medications at the doses  
9 Louis takes. So for the last three and a half  
10 years we have been traveling to California every 12  
11 weeks for treatment with a doctor who specializes  
12 in treating intractable pain. His name is Forrest  
13 Tennant, and he has been in practice there since  
14 1975.

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

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

5 DR. EGGERS: Kristen?

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

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

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

12 DR. EGGERS: Oh.

13 MS. OGDEN: We're sharing.

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

17 MS. OGDEN: I just need to let you know  
18 that we still have issues of stigma and lack of  
19 understanding. We are paying out of pocket while  
20 we fight this through the disputed claims process.  
21 We have, in our first step, cited the FDA decision  
22 letter that was issued in September 2013 that

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1 acknowledged that these medications in high doses  
2 are helpful to some people.

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

16           Louis?

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

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

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

12 DR. EGGERS: Thank you very much.

13 MR. OGDEN: Thank you.

14 DR. EGGERS: Thank you. Thank you, Louis.  
15 And we have -- I think it's Juan Mendoza?

16 MR. MENDOZA: Yes.

17 DR. EGGERS: Okay. Thank you.

18 MR. MENDOZA: Yes. Juan Mendoza, Vice  
19 President of the National Fibromyalgia Partnership.  
20 Our mission is to make medically accurate, quality  
21 resource information on fibromyalgia available to  
22 our membership, health care professionals, and the

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1 community at large. Our goal is provide  
2 informational tools so as to promote the timely and  
3 appropriate diagnosis and treatment of  
4 fibromyalgia.

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

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

21 One is the price of medication and  
22 treatments is often high. It is often, in the case

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1 of non-drug treatments, not covered by insurance.  
2 The other is long-term safety of a drug is not  
3 known. And, finally, effective medications without  
4 any adverse -- the ideal condition will be  
5 effective medications without any adverse effects -  
6 - effects will be ideal, of course.

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

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

22           Thanks.

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1 DR. EGGERS: Thank you very much.

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

4 Our closing -- oh, do you want --

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

7 DR. EGGERS: Sure.

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

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

19 There is power in numbers, and I strongly  
20 encourage you to join with your advocacy  
21 organizations, with Jan and others, to have your  
22 voices heard because that is how you make changes

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1 for yourself and for your community. So please do  
2 -- you know, there are ways that you can make your  
3 voices heard.

4 DR. EGGERS: Thank you.

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

13 Thank you, Sharon.

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

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

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

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

19           And I can't go into some of the details  
20 about what we did at the time, but we did do quite  
21 a bit. And we never say, "Well, it was positive in  
22 one and negative in another species. Therefore,

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1 we're not going to." Trust me, we are never that  
2 simple.

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

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

16           And so -- and I'm going to throw this to  
17 the advocacy organizations because I suspect they  
18 may have folks who can also help with navigating  
19 some of these paths. Today we heard some very,  
20 very helpful information from you folks and really  
21 appreciate you taking the time. We understand the  
22 challenge for many people who are suffering from

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1 chronic pain to travel and participate in these  
2 meetings, and we greatly value your effort.

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

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

17           And I think that the emphasis that we have  
18 heard on multi-modal therapy is very important. We  
19 will do our part to help facilitate the drug part  
20 of that treatment when we get applications coming  
21 in. We'll try and do our due diligence to make  
22 sure that we do identify all the safety-associated

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1 issues as well as the benefits, so that as you and  
2 your prescribers get together you can make informed  
3 decisions about the available risks. And we will  
4 continue to try and make sure that as information  
5 becomes available we update information.

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

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

16           MR. FREY: Okay. Before Sara wraps up, I  
17 just wanted to follow up with something Sharon said  
18 about our labeling and reviews. One fairly easy  
19 way of finding that stuff is just to Google "drugs"  
20 at sign, so drugs@fda. And there you will see the  
21 alphabet and you can search for your drug by name  
22 and eventually get to the approval document, the

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1 review memos that are written by our scientific  
2 disciplines, as well as the approved labeling.

3 So I just wanted to mention that.

4 DR. EGGERS: Thank you very much.

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

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

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

18 Thank you.

19 (Applause.)

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

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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.

\_\_\_\_\_  
CORINNE YANOSY

\_\_\_\_\_  
LISA SIKES

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