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FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
PUBLIC MEETING ON
PATIENT-FOCUSED DRUG DEVELOPMENT FOR NEUROPATHIC
PAIN ASSOCIATED WITH PERIPHERAL NEUROPATHY

Friday, June 10, 2016
1:00 p.m.

FDA White Oak Campus
10903 New Hampshire Avenue
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Silver Spring, MD 20993

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P R O C E E D I N G S

WELCOME

MS. GIAMBONE: Well, good afternoon, everyone. Let's go ahead and get started. My name is Soujanya Giambone, and I'm with the Center for Drug Evaluation and Research, here at the FDA. And I'm with the Office of Strategic Programs. And on behalf of all of my FDA colleagues here, we'd like to welcome you all to the D.C. Metro area, for those of you that traveled outside of the Metro area, and for all of our local neighbors, thank you for coming to our nineteenth patient-focused drug development meeting on neuropathic pain associated with peripheral neuropathy. We have a really great day of discussion ahead. And what I'd like to do is just over a few housekeeping items, go over the agenda and then we'll get started.

So, next slide, please. Okay. So we're going to start off with some presentations from my FDA colleagues. They'll provide an overview of the FDA's patient-focused drug development

1 initiative, some background comments on
2 neuropathic pain and therapeutic options. We'll
3 have a presentation on clinical trial endpoints
4 and then I'll come back and go over the discussion
5 format for the day.

6 So as you know, we have two topic
7 questions, two topics today for today's
8 discussion. Topic one is on disease symptoms and
9 daily impacts that matter most to patients. So
10 we'll have a panel discussion, followed by a
11 larger group facilitated discussion. And then,
12 we'll take a break. We'll come back and we'll do
13 the same thing for topic two, which is on patient
14 perspectives on current treatment options. So
15 again, we'll do the same thing. We'll have a
16 panel discussion, followed by a group discussion.
17 And that'll take us to the last half-hour of the
18 day, which we've reserved for open public comment.

19 Open public comment is a time for
20 anybody in the room, not just patients or
21 caregivers, but others in the room to share some
22 comments that come to mind. So we have a sign-up

1 for open public comment out on the registration
2 desk. I believe we've already had several people
3 sign up for it. We'll take sign-up through break
4 time and we'll see how many people signed up and
5 how much time each speaker will have. And then,
6 we'll wrap up the day with closing remarks from my
7 FDA colleagues.

8 And so, you can see it's a pretty packed
9 agenda. But it will be a really, really great day
10 of listening to you and definitely learning from
11 you. So thank you for being here. So what I'd
12 like to do is quickly do a round of introductions.
13 If I could look at my -- turn to my FDA colleagues
14 here and if you could please state your name and
15 your office?

16 DR. EGGERS: Good afternoon. I'm Sara
17 Eggers. I'm in the Office of Program and
18 Strategic Analysis here at FDA.

19 DR. HERTZ: Hi. I'm Sharon Hertz. I am
20 currently the director for the Division of
21 Anesthesia, Analgesia and Addiction Products, here
22 at CDER.

1 DR. HORN: Hi. I'm Pamela Horn, and I'm
2 a clinical team leader in the same division.

3 DR. GALATI: Hi. I'm Steven Galati.
4 I'm also a clinical reviewer from the same
5 division.

6 DR. PATEL: Hi. Nikunj Patel. I'm a
7 clinical outcome assessment reviewer in the Office
8 of New Drugs.

9 DR. PARKS: Hello. I'm Mary Parks. I'm
10 deputy director in the Office of Drug Evaluation
11 II.

12 MS. GIAMBONE: Thank you. And then, I'm
13 going to turn to my colleagues to my right.

14 MR. THOMPSON: Graham Thompson, CDER.

15 MS. WOODWARD: Shannon Woodward, CDER.

16 MS. GIAMBONE: Great. And we have a few
17 others that are floating around and they are
18 Yewande and Meghna. So you'll see them throughout
19 the room too. And so, just a few last-minute
20 housekeeping items. Bathrooms are back out into
21 the lobby area. If you go down to where that
22 registration desk is and make a right and go all

1 the way to the end of the hallway, you'll see
2 bathrooms there. And there's also a kiosk out
3 there that sells basic sandwiches and snacks and
4 drinks. So this is definitely a more informal --
5 I want you to feel very comfortable to be here.
6 So if you need to get up to have a snack break, to
7 have a stretch break, bathroom break, whatever it
8 is, please feel free to do so. We want you to be
9 as comfortable as possible.

10 And last but not least, this meeting is
11 being recorded and transcribed. And just about a
12 week after the meeting, the recording and the
13 transcript will be posted onto the meeting
14 webpage. Okay. So with that, I would like to
15 turn it over to Pamela for opening remarks. Thank
16 you.

17 OPENING REMARKS

18 DR. HORN: Good afternoon, everybody.
19 Welcome to the meeting on patient- focused drug
20 development for neuropathic pain associated with
21 peripheral neuropathy. As I just said, I'm Dr.
22 Pamela Horn, clinical team leader in the Division

1 of Anesthesia, Analgesia and Addiction Products.
2 And that's in the Office of New Drugs in FDA. Our
3 division reviews drugs for the management and
4 treatment of pain, including neuropathic pain. So
5 we're happy to see so many patients, caregivers
6 and advocates in the audience today. I understand
7 that we also have a lot more of you joining us
8 remotely on the Web, and I want to thank you all
9 for being a part of this meeting and sharing your
10 experiences with us. We're excited for this
11 opportunity to engage directly with all of you.
12 In our discussion today, we will be focusing on
13 the symptoms that matter most, the impact that
14 neuropathic pain has on your daily lives and what
15 factors you take into account when selecting a
16 treatment.

17 We understand that neuropathic pain
18 associated with peripheral neuropathy is a serious
19 condition with physical, emotional and social
20 impacts and that there is an unmet need for
21 treatment for patients. Dr. Steven Galati, from
22 our division, will provide a bit more background

1 in a few minutes on neuropathic pain associated
2 with peripheral neuropathy and the current
3 treatment options.

4 It is FDA's responsibility to ensure
5 that the benefits of a drug outweigh its risks.
6 Therefore, having this kind of dialogue is
7 extremely important and valuable for us because
8 hearing what patients care about can help lead us
9 in figuring out how to best facilitate drug
10 development for neuropathic pain and understand
11 how patients view the benefits and risks of
12 treatment for neuropathic pain. So I know that we
13 also have representation from industry, from
14 academia and some healthcare professionals today.
15 And while FDA plays a critical role in drug
16 development, we're just one part of the process
17 and I'm glad to see a high level of interest from
18 those of you who also play an important part of
19 the drug development process.

20 FDA protects and promotes public health
21 by evaluating the safety, effectiveness and
22 quality of new drugs. But we do not develop drugs

1 or conduct the clinical trials ourselves. Drug
2 companies, sometimes working with researchers or
3 patient communities, are the ones who conduct
4 trials and submit applications for new drugs to
5 FDA. It is then FDA's responsibility to ensure
6 the benefits of a drug outweigh its risks. This
7 benefit-risk decision-making is an integral part
8 of our review process. We look forward to
9 incorporating what we learn today from all of you
10 into the agency's thinking and understanding of
11 how patients view benefits and risks of treatment
12 for neuropathic pain.

13 Once again, we are all here today to
14 hear the voice of the patient. So thank you for
15 your participation and coming to share your
16 experiences, your personal stories and your
17 perspectives. I'll now turn it over to Sara
18 Eggers, who will provide background on the FDA's
19 patient-focused drug development initiative.

20 OVERVIEW OF FDA'S PATIENT-FOCUSED
21 DRUG DEVELOPMENT INITIATIVE

22 DR. EGGERS: Thank you, Pamela, and

1 welcome. I am happy to tell you a little bit more
2 about the initiative that brings us all together
3 today under this large umbrella we call patient-
4 focused drug development initiative. This
5 initiative is something that has stemmed out of
6 years of conversation and a growing awareness that
7 -- by FDA that the use in having a more systematic
8 way of gathering patient input and perspective on
9 their condition and available treatment options,
10 you and your caretakers, as the experts of what
11 it's like to live with your disease, it helps
12 inform our understanding of the context of the
13 benefit-risk assessment and decision-making for
14 new drugs, as Pamela mentioned.

15 It can also, as she mentioned, help
16 inform our oversight and advice during drug
17 development and review of the marketing
18 applications of those -- of drugs that want to go
19 on the market. Patient-focused drug development
20 is a program that came out of a commitment FDA
21 made as part of the Prescription Drug User Fee
22 Act, or PDUFA V, which is a series of commitments

1 that we make to advance drug development, drug
2 review and FDA's role in that. As part of that
3 commitment, we are convening more than 20 public
4 meetings on specific disease areas over a five-
5 year period. As Soujanya mentioned, this is the
6 nineteenth meeting. So we have learned a lot from
7 the meetings that we've conducted and we continue
8 to learn as we go along this journey. We hope
9 that the meetings will help develop a systematic
10 approach to gathering patient input. What we're
11 learning from you can help translate to how we
12 engage with patients and caretakers and advocates
13 and other stakeholders in the future.

14 In the selection of -- and the
15 identification of the meetings, we went through
16 both a public process and an internal look at the
17 areas that -- disease areas where a meeting would
18 be extremely helpful. We announced a preliminary
19 set of meetings approximately five years ago now
20 and collected input on the nominations for the
21 meetings and we've reviewed the public comments
22 and all the input we received to come up with a

1 final set of 24 meetings that would be the focus
2 of our efforts for this five-year period. And
3 here you have the meetings that we have conducted.
4 You can see since 2013, we have conducted meetings
5 on a range of conditions, a range of severity, a
6 range of the types of populations they have --
7 that they -- that they mean and in the challenges
8 that the patient community has faced. Now, we've
9 learned a lot of similarities across these disease
10 areas. And so, what we hear from you will help
11 build on -- not only will we learn more about what
12 it's like with your condition at this time, but we
13 are building on what we're learning from others
14 and their conditions as well.

15 Each meeting -- these meetings are quite
16 unique for a public meeting at FDA, and I gather
17 elsewhere as well. As Soujanya mentioned, they
18 are designed specifically to listen to patients
19 and their caretakers and hear your input. We
20 focus on a set of questions, as she mentioned,
21 that elicit patients' perspectives on the disease
22 and treatment approaches and we have a general set

1 of questions that we built upon and tailor, as
2 needed, to the type of meeting that we're having
3 and the topics that were most important to our
4 review colleagues and others today.

5 We have learned through this meeting
6 that active patient involvement and participation
7 is a key to the success of this meeting and we
8 want to thank anyone who has spread the word about
9 the meeting, who has helped engage with patients
10 or caretakers in helping them navigate through FDA
11 and getting here and all of the other things that
12 it takes to come here on a Friday afternoon. So
13 we thank stakeholders, advocates and you,
14 patients, and your families as well.

15 Following each meeting, we publish a
16 "Voice of the Patient" report that summarizes what
17 we hear today and what we learn from the folks on
18 the webcast and what we learn from those of you
19 that we hope will continue the discussion through
20 our docket process, which Soujanya will describe
21 in a few minutes. We try to capture in these
22 reports your words and your thoughts in a way that

1 is most successful for our FDA colleagues to
2 understand your perspectives and your experiences.
3 They do serve an important function in
4 communicating to our colleagues here at FDA, but
5 also we hope as a resource for you as you continue
6 to engage with yourselves as patient communities
7 or engage with others throughout the drug
8 development process.

9 We believe that the long run impact of
10 this program will be a better and more informed
11 understanding of how we all might find ways to
12 develop new treatments for these diseases. And
13 with that, I would like to turn it over to Steven
14 to give a bit more background on peripheral
15 neuropathy.

16 BACKGROUND ON PAIN NEUROPATHIES AND AVAILABLE
17 TREATMENTS

18 DR. GALATI: Thank you. Good afternoon,
19 everyone. Thank you for being here. So I'm Steven
20 Galati. I'm a medical reviewer in the Division of
21 -- DAAAP. And what I'm going to do today is go
22 over very briefly what peripheral neuropathic pain

1 is. It's a very complex issue. So, but I'll keep
2 it simple and brief for today. So peripheral
3 neuropathy is -- and the pain associated with it
4 is associated with damage to the actual nerves
5 themselves. And when we refer to the peripheral
6 nerves, we think of the central nervous system as
7 the brain and the spinal cord. The nerves that
8 come out through the rest of the body, that would
9 be the peripheral nerves. And we all have sensed
10 pain in our lives, whether we have peripheral
11 neuropathic pain or just living our lives.

12 So for example, pain can actually be
13 adaptive. If you put your hand on a stove and you
14 feel the heat, your body then signals that there's
15 damage going on to your tissues. You then pull
16 away. That's an adaptive, appropriate response.
17 But people who suffer from peripheral neuropathic
18 pain, the damage itself is to the nerve, not to
19 that tissue. And it falls underneath chronic pain
20 and chronic pain is exactly how it sounds. It's
21 been going on for a specific period of time, and
22 we divide it into different descriptors.

1 So you may or may not have heard of
2 nociceptive pain. And no nociceptive pain would
3 be, for example, you break a bone. And in the
4 bone, the injury is to the bone, to the tissue and
5 in those nerves will then sense that there is
6 injury or inflammation to the brain and you can
7 react or you can go to your physician or however
8 you were meant to respond. When there's
9 neuropathic pain, the lesion is not in the bone.
10 It's in the nerve going to the bone. And that's
11 what causes an abnormal function, so people who
12 will have pain without a stimulus. So you may
13 just be sitting there in bed and feel pain.
14 That's why it's happening is because it's damage
15 to the nerve itself. And like I said, peripheral,
16 peripheral is because it's in the peripheral
17 nervous system. So it's outside of the brain and
18 spinal cord.

19 So how does this get diagnosed? So
20 those of you who suffer from peripheral
21 neuropathic pain know that you go through certain
22 procedures. Usually you go to your primary care

1 physician. And although peripheral neuropathy is
2 associated with a number of different symptoms,
3 pain is one of the main complaints because of the
4 discomfort. So you go to usually your primary
5 care physician, for example, and they may initiate
6 a treatment or workup. But often, it can be
7 referred to a specialist. Neurologists typically
8 are specialists that see these referrals. It also
9 can be a rehabilitative doctor.

10 And then, a number of different tests in
11 addition to a physical exam can be performed.
12 There are those of you who may recognize some of
13 these terms. So a nerve conduction velocity that
14 measures the speed of the nerve. EMG, which is
15 when they stick the needle into the muscle fiber
16 to see if it's firing appropriately. Lab tests
17 are often done. For example, can test for
18 different types of infection, can check for blood
19 sugars because diabetes can be associated with
20 this and many other studies. And it may even go
21 to a nerve biopsy where there may take a piece of
22 the nerve and send it off to a pathologist to look

1 at it under a microscope.

2 So based on this combination of
3 symptoms, history and physical examination and any
4 other tests that were needed, a physician can come
5 to a determination as to cause of the peripheral
6 neuropathic pain. Now, here's a list of a number
7 of neuropathic pain syndromes that deal with
8 neuropathic pain and the most common tends to be
9 painful diabetic neuropathy. And the reason why
10 that's the most common is because diabetes is so
11 prevalent. And as you can see, 10 to 20 percent
12 of diabetic patients may have neuropathic pain and
13 that's a pretty large number. But there's also a
14 number of other causes and this just lists some of
15 the main ones, but there are others. And it can
16 cause from infections. It can cause from trauma.
17 It can cause from other drugs. It can be induced
18 by substances such as alcohol and cancers and even
19 autoimmune disorders.

20 So despite all the numerous causes of
21 peripheral neuropathic pain, the symptoms tend to
22 be similar. And pain, of course, is a big portion

1 of the neuropathic symptoms. But common symptoms
2 that people might suffer from would be burning
3 sensation, shock-like pain, numbness and tingling
4 and it could be a combination of these symptoms.
5 It's not usually just one. There's some other
6 terms, such as allodynia and what allodynia is --
7 would be described as something that's normally
8 painless can induce pain in people who have
9 peripheral neuropathic pain. An example would be
10 if you're in bed and you rub your foot or your
11 hand across a sheet, all of a sudden that might
12 induce pain. Hyperalgesia is another term where
13 you may have increased sensitive to a normal
14 painful response. For example, if you were
15 getting an IV or you were giving a blood draw,
16 that's normally uncomfortable for the average
17 person. But these patients may have an extreme
18 response to that, where it's even more painful.

19 So all of this is beyond the scope of
20 the talk, because we're at the FDA, I thought I'd
21 say something about what FDA approval is. And
22 what happens is -- and the reason why I'm putting

1 this up here is because I want people to know that
2 you may be prescribed or given a treatment that
3 doesn't technically say FDA approval. It doesn't
4 mean it's not an effective treatment. It doesn't
5 mean it's not appropriate.

6 But when a company wants to get FDA
7 approval, they have to go through a rigorous
8 process. And generally speaking, there has to be
9 two successful trials. It also has to be
10 replicated. And what we're here today also is to
11 hear, well, what are the endpoints. What's the
12 most important things we want to hear from
13 patients is that what symptoms are bothering them
14 the most, that then a company can target to
15 improve. And then, there's more a general
16 indication, which isn't done as often, but it's
17 treating all different types of neuropathic pain.

18 So here's just a list of some of the FDA
19 or the FDA-approved medications for peripheral
20 neuropathic pain. As you can see, diabetic
21 peripheral neuropathy and postherpetic neuralgia
22 are the most common kind and these medications --

1 for example, Nucynta and Lyrica and Cymbalta are
2 all approved. And what that means is they met
3 those FDA requirements. And you can see there's a
4 range of different types of treatment. Some of
5 these started off as antidepressants. Some are
6 anticonvulsants, used for epilepsy and some are
7 just pain medications.

8 The reason I put this slide up here is
9 this is an expert review panel from 2015. They got
10 together and they provided guidelines and these
11 are just guidelines for physicians. These are not
12 hard and fast rules. These are just general
13 recommendations that physicians can go off of,
14 here from an expert panel who's reviewed the
15 literature and also given their own experience.
16 And what they recommend, when they call something
17 first line, what they're meaning is there's
18 effectiveness that's been shown in their
19 experience or through proof of literature. And
20 then, that is balanced against the risk of
21 treatment, so the side effects and potential
22 risks.

1 So what they're saying in these strong
2 recommendations is that this is what they would
3 consider trying first because they think that in
4 most patients, the benefit would outweigh the
5 risks. And then, they have some weaker
6 recommendations. And that doesn't mean they don't
7 work. The reason why they put that was it means
8 that maybe the evidence wasn't as strong. So
9 maybe they don't have as much proof that a
10 medication might work or a medication might work
11 but their concern is you don't want to jump to it
12 because maybe there's a lot of side effects that
13 make it difficult for a patient to tolerate. And
14 then, a lot of times, in reality, combinations of
15 treatments are used.

16 So for example, they may use two
17 different types of drugs or you may use one drug
18 and another treatment modality such as
19 acupuncture. The problem is that's much harder to
20 study and there's less evidence to prove it.
21 However, it's used commonly in practice and
22 physicians may even tell you when you see them

1 this is what I've used and this is what's been
2 shown to be effective in your case. Then, there
3 are other types of anticonvulsants that are used
4 sometimes and then there are also immunoglobulin
5 that's sometimes used for treatments, for certain
6 specific types of treatments.

7 Other components of therapy -- so one of
8 the most important things is to treat your
9 underlying cause and condition. So for example,
10 if you have peripheral neuropathic pain and your
11 diabetes isn't well-controlled, your physician is
12 going to of course want to control that as a
13 portion of it. Another component of therapy,
14 which can be very helpful, is exercise and/or
15 physical therapy, although it seems
16 counterintuitive because you may be in pain and
17 saying, I don't really feel like I can move or I
18 can do this activity because of pain, depending on
19 where it is. It's been shown that, well, in
20 diabetic peripheral neuropathy, for example, the
21 pain may improve with the exercise.

22 And then, there's cognitive behavior

1 therapy, which is a type of psychotherapy, which
2 has limited number of side effects, of course, but
3 it has been shown to have some evidence of
4 improvement. And then, there's other modalities
5 and these modalities may have limited evidence or
6 support from placebo-controlled trials. It
7 doesn't mean that they don't work. But it may be
8 that there's just not as much proof of them
9 because maybe there's been faulty studies. But
10 I've seen a lot of people, both physician's
11 recommending and patients, who have had success
12 with acupuncture, for example. Then you can see
13 some other ones here, spinal cord stimulation,
14 massage and TENS units are also used fairly
15 commonly. And when they are used, a lot of times
16 they're used in concert with another treatment.

17 So we all know that peripheral
18 neuropathic pain is a very serious condition and
19 it has a significant impact on the quality of
20 people's lives. So the key to success would be
21 to diagnose appropriately, identify it, find what
22 is modifiable, modify that the best you can and

1 then maximize the effectiveness of the treatments,
2 while keeping in mind the long-term adverse
3 events. Because peripheral neuropathic pain is
4 often chronic -- it's not something that happens
5 in a couple of days and then goes away -- you want
6 to make sure that the long-term plan, one, is
7 flexible and also you have to consider what the
8 long-term implications of treatment would be; for
9 example, consider long-term adverse events or side
10 effects.

11 So there are a number of challenges to
12 drug development. So although we've talked about
13 drugs being FDA-approved in all sorts of
14 modalities that may be effective, many patients
15 still are not completely satisfied with treatment.
16 So efficacy is incredibly important that we have
17 to target. Most trials compare single agents. So
18 as I mentioned, some people are having multiple
19 modalities of treatment. There are so many causes
20 of neuropathic pain. So although one medication
21 or one treatment might work for a specific type,
22 it doesn't work for others. And that has to be

1 proven over time. And also, medications have
2 their side effects. So although a medication, for
3 example, may be effective, it may not be tolerated
4 by that person or it may not be suitable long-
5 term.

6 So the overall conclusion, the FDA is
7 aware of the unmet need and that is experienced by
8 patients with peripheral neuropathic pain and one
9 of the points of this meeting today is to gain
10 input from the patients and caregivers that helps
11 us then communicate the appropriate information to
12 drug companies trying to design these trials. So
13 thank you very much. I appreciate it.

14 [Applause.]

15 THE ROAD FROM PFDD MEETINGS TO CLINICAL TRIAL
16 ENDPOINTS

17 DR. PATEL: Good afternoon. Excuse me.
18 Good afternoon, everyone. My name is Nikunj
19 Patel. I am a clinical outcome assessment
20 reviewer here at the FDA. Our team, Advisory
21 Review Divisions, on matters concerning clinical
22 outcome assessments such as patient

1 questionnaires, which we commonly refer to as
2 patient-reported outcomes or PROs. We evaluate
3 these PROs to ensure that they are assessing the
4 most important signs, symptoms and impacts to
5 patients and that they are assessing these
6 concepts in an accurate and reliable manner.
7 Today, I will briefly go over how we use
8 information from these patient-focused drug
9 development meetings and how we intend to
10 incorporate patient input into clinical trial
11 endpoints. Here is my disclaimer.

12 You may be wondering, we have these PFDD
13 meetings where patients such as yourself are here
14 to discuss. But where do we go from here? What's
15 the end game? How do we take what we learn today
16 and generate clinically relevant, patient-focused
17 endpoints to incorporate in clinical trials? So I
18 hope in the next few slides I can answer some of
19 these questions.

20 One of the main advantages in having
21 this meeting is that it gives all stakeholders,
22 patients, drug companies, questionnaire

1 developers, clinicians, FDA and others the
2 opportunity to listen to your voice, patients'
3 voice, your experiences, particularly to hear
4 what's important from your perspective and how you
5 describe your symptoms and impacts in your own
6 words. These meetings also inform us on how we at
7 FDA review PROs in drug applications to ensure
8 they are adequately assessing your perspective.
9 PFDD meetings also help us to think about
10 incorporating patient-focused endpoints in
11 clinical trials, as appropriate.

12 So what is an endpoint? In the context
13 of a clinical trial, our goal is to measure key
14 disease-specific outcomes of interest, reflecting
15 how patients feel, function and survive. To do
16 this, we sometimes use PROs, patient
17 questionnaires. In this case, the study endpoint
18 would be how the patient questionnaire will be
19 measured and analyzed in a clinical study to
20 address a particular research question reflecting
21 specific outcomes of interest and these outcomes
22 can be safety, can be efficacy-related. There are

1 many things that are important to patients that
2 are discussed during PFDD meetings. However, not
3 all of these things lend themselves to being
4 measured in clinical trials for drug approval, as
5 they may be impacted by many factors beyond the
6 treatment itself, such as socioeconomic factors,
7 so therefore, making it challenging to interpret
8 as results.

9 Here at FDA, we focus on safety and
10 efficacy. So for example, financial well- being
11 may be an important factor, an important concept
12 to patients, but may not be impacted by treatment
13 in a clinical study setting. So we encourage drug
14 sponsors, drug companies to consider selecting the
15 most important and relevant concepts to support
16 key study endpoints that are likely to change as a
17 result of a treatment. Financial well-being and
18 other important concepts that are unrelated to
19 treatment can still very well be assessed and
20 measured, but perhaps for exploratory purposes.

21 While there are many benefits of having
22 PFDD meetings, I want to underscore this is just a

1 starting point. We also have to be mindful about
2 considerable amount of work that needs to be
3 continued after we are done today. We encourage -
4 - we strongly recommend that drug companies or
5 other researchers who are developing these patient
6 questionnaires to engage additional patients,
7 those patients who are not here in the room today,
8 as well as gather input from physicians, other
9 experts, as appropriate. Such an engagement may
10 help confirm the questionnaires, include patient-
11 relevant information and to ensure the questions
12 and instructions in the questionnaires are clear
13 and understandable across patient populations
14 before they are incorporated in clinical trials.

15 So my job here at FDA as a reviewer is
16 to apply our drug laws and regulations. Within
17 these regulations, there are regulatory standards
18 for assessments such as patient questionnaires.
19 Our goal is to make sure these PROs are well-
20 defined and reliable. In other words, are they
21 measuring what they are supposed to measure, both
22 accurately and reliably? We want to make sure they

1 are not misleading in any way.

2 So not only do we recommend drug
3 companies to engage patients to develop
4 questionnaires using qualitative research, we also
5 recommend them to perform quantitative studies as
6 well -- statistical testing, for example -- to
7 show that they are well-defined and reliable. In
8 addition, patient input can be quite valuable and
9 powerful, along with other methodologies in
10 determining how to interpret what is clinically
11 meaningful change in the context of a clinical
12 trial. Therefore, we recommend that sponsors to
13 engage the agency early and throughout drug
14 development for FDA input.

15 So how can we help you and other
16 stakeholders who are involved in this area of drug
17 development? So there are three pathways to
18 provide advice on clinical outcome assessments
19 such as PROs. The first one is within the context
20 of an individual drug development program while
21 the other two are outside. This is where an
22 individual, an organization has opportunity to

1 engage the agency.

2 In the first pathway, the IND and the
3 BLA pathway, we encourage drug companies to begin
4 this discussion as early as the pre-IND stage. So
5 if they have -- if any work needs to be done on
6 proposed questionnaires, there is time to do so
7 before the pivotal studies are conducted. The
8 second pathway, this is through our drug
9 development tool, or DDT qualification program,
10 through this pathway, we work with questionnaire
11 developers to develop and qualify PROs for use
12 across multiple drug development programs in a
13 pre-competitive space. The last, the third
14 pathway, this is relatively new. This is through
15 another avenue to engage the agency through our
16 critical path innovation meetings program.
17 Through this program, a person or an organization
18 has opportunity to discuss and receive general
19 feedback on questionnaires such as PROs. It could
20 be any other subject as well. But in this case, a
21 PRO or other clinical outcome assessment.

22 In conclusion are three key takeaways.

1 First, PFDD meetings are a starting point for
2 developing and using patient-focused outcome
3 measures and endpoints. Second, the outcomes of
4 PFDD meetings will support and guide FDA's
5 assessment of clinical benefit in drug reviews.
6 And the third point is patients' input ultimately
7 helps determine what is measured to provide
8 evidence of treatment benefit, how best to measure
9 what matters most to patients and what amount of
10 change is meaningful to patients. With that, I
11 conclude my presentation. Thank you so much for
12 your attention.

13 [Applause.]

14 OVERVIEW OF DISCUSSION FORMAT

15 MS. GIAMBONE: Okay. Great. Thank you
16 to my FDA colleagues for your presentations. And
17 now, you have a background on why we're all here
18 today and you've heard that your input is very
19 important to the work that we do here at the FDA
20 and the work that others do to really give us a
21 good understanding of what matters to you most in
22 your management of neuropathic pain. So what'd

1 I'd like to do now is to go over the discussion
2 format. So as I mentioned early on, just a little
3 while ago, that there are two topics. And so,
4 topic one is one disease symptoms and daily
5 impacts. So here, what we're going to be
6 listening for is what are your most bothersome
7 symptoms of living with neuropathic pain. How
8 does your pain manifest and how does it -- you
9 know, what's a good day like? What's an average
10 day like? What's a bad day like? How does it
11 impact your ability to do certain activities or to
12 not do certain activities? And really, what
13 worries you most about your condition?

14 And then, in topic two, we're going to
15 be listening for your perspectives on treatment
16 approaches. So what are you doing currently to
17 treat your neuropathic pain and is it working and
18 what's not working about it? What are the
19 benefits of your treatment? What are the
20 downsides of your treatment? And how has your
21 treatment regimen changed over time since you've
22 been diagnosed? And then, lastly, we're

1 definitely going to be spending some time on what
2 you look for in an ideal treatment. What are the
3 aspects of an ideal treatment that are important
4 to you? And we'll also spend a little bit of time
5 on what factors you consider when deciding whether
6 or not to participate in a clinical trial. So
7 we'll have a scenario question that we'll pose to
8 you and we'll get your immediate -- you know, your
9 initial thoughts when you hear this type of
10 scenario.

11 So here's how this is going to work.
12 And as I mentioned earlier, we're going to have a
13 panel discussion, followed by a group facilitated
14 discussion. So we're going to first hear from a
15 panel of patients. And on that note, I'd like to
16 invite our topic one panelists to come on up and
17 have a seat at the panel table. So I'd like to
18 make a quick shout-out to our amazing panelists
19 that we have today, topic one and topic two
20 panelists. They've worked very hard to get their
21 panel summaries together and we're really grateful
22 that they're here and we're looking forward to

1 hearing from them.

2 So the purpose of the panel discussion
3 is to set a good foundation for our discussion.
4 Those panelists, they reflect a range of
5 experiences in living with neuropathic pain. And
6 so, they'll each have about three to four minutes
7 to present their comments. And once they've
8 completed presenting their comments, we're going
9 to then broaden the discussion and open it up to
10 other patients and caregivers in the audience to
11 build on what you've heard from the panelists.

12 So periodically, I will ask some
13 questions along the way. I'll turn to my FDA
14 colleagues to ask some questions along the way.
15 And we invite patients and caregivers in the
16 audience to raise your hand and share your
17 perspectives with us. We'll have microphone
18 runners around the room and they'll come to you
19 with a microphone. And so, if you're interested
20 in sharing some comments, just raise your hand,
21 and if you could state your first name, that would
22 be most appreciated.

1 So along the way, we have some other
2 ways that we'll be hearing from you. So in
3 addition to the group facilitated discussion,
4 we'll have some polling questions along the way.
5 And you should have -- for patients and caregivers
6 in the first two rows, where we encouraged you all
7 to sit, you should have these little clickers that
8 we've passed out. And we're going to test those
9 out in just a bit. And actually, Shannon, would
10 you mind passing clickers out to our panelists
11 also? Thank you.

12 So this is not a -- these are not
13 scientific surveys that we're going to be doing.
14 It's entirely voluntary. It's just a way for us
15 to learn more about the perspectives in the room,
16 and also on the Web, which I'd like to make a
17 shout-out to. We have about 150 people joining us
18 on the webcast today. So we can't see you, those
19 of you on the Web. But you are a very important
20 part of our meeting. We're going to be hearing
21 from you shortly. We'll do some phone comments
22 along the way. So those of you on the Web, please

1 participate in the polling. Please continue to
2 submit your remarks through the webcast and we'll
3 -- it's a very big part of our meeting today.

4 So we do ask that for the polling
5 questions, that it's only patients and caregivers.
6 I'm not sure why that says parents of patients
7 only. It should say patients and caregivers only
8 to participate in the polling. So -- and so,
9 that'll be another way for us to learn about
10 perspectives in the room and on the Web. And
11 then, Sara had mentioned earlier that we have a
12 public docket. And what this is, is a space that
13 we have online. You see the website here. We
14 highly encourage you to submit comments to the
15 public docket, which is basically another way to
16 continue this discussion. We can't possibly cover
17 everything about symptoms, impacts and treatments
18 that are important to you within a four-hour
19 meeting.

20 So we have a public docket that will be
21 open for two months after this meeting. So it
22 closes on August 10th. And it's a huge and very

1 important part of our -- you know, our
2 understanding of neuropathic pain. So please
3 continue to submit your comments there. And all
4 of those comments are going to be incorporated in
5 our summary report that Sara had mentioned, the
6 "Voice of the Patient" report. So we will look
7 for very helpful information through the docket as
8 well. And anybody is welcome to comment, not just
9 patients and caregivers.

10 So we have some resources here at FDA
11 that we always like to share during these public
12 meetings just to let you know of other ways that
13 you can sort of interact with the FDA, especially
14 as it relates to, you know, patients and what
15 matters most to patients. So within the Office of
16 Center Director, we have the professional affairs
17 and stakeholder engagement team, or PASE. We have
18 Chris Melton here, who is the primary contact that
19 you can contact for this meeting. And so, that's
20 one very helpful office that we collaborate with.
21 And the second very helpful office that we work
22 closely with is the FDA Office of Health and

1 Constituent Affairs, or OHCA. FDA is full of
2 acronyms. So we call this one OHCA. And there's
3 -- you can see their email address right here and
4 you can feel free to contact them. Again, they
5 serve as a liaison between FDA and stakeholder
6 organizations.

7 So we do have a few discussion ground
8 rules for the day. This is a meeting where we are
9 really focused on the patients and caregivers and
10 advocates. So we encourage patients and
11 caregivers and advocates to contribute to this
12 dialogue. FDA and industry and academia and other
13 government entities who are here, we're really
14 grateful that you're here. We know that this
15 meeting is going to be really important for you
16 too. But we ask that you stay in listening mode,
17 as this is really a day to hear from the patients
18 and caregivers.

19 The discussion will focus on symptoms
20 and treatments. We are going to do our very best
21 to stay on topic. We know that there's so many
22 aspects and so many considerations that you as

1 patients live with and think about as it relates
2 to neuropathic pain. But we're going to focus on
3 symptoms and treatments for today. So we'll stay
4 on topic. We do have the open public comment
5 period, which I had mentioned earlier, for aspects
6 or considerations that are outside of the scope of
7 topic one and topic two. So I hate to be a
8 stickler for time and a stickler for staying on
9 topic, but I will have to direct you to the open
10 public comment period or, more importantly, the
11 public docket if there are aspects that you'd like
12 to share that are outside of topic one and topic
13 two.

14 So the views expressed today are
15 personal opinions. And so, on that note, respect
16 for one another is paramount. And last but not
17 least, very importantly, we will have evaluation
18 forms that we'll pass out closer to the end of the
19 meeting. We read through each and every single
20 one of them. They're very important to us. So
21 let us know how the meeting went for you today and
22 it helps us as we prepare for our next one.

1 Okay, so what I would like to do now is
2 a quick test of our clickers to make sure that
3 everything is working. And we -- and those of you
4 on the Web, you can also participate. So the
5 first question, so patients and caregivers, if you
6 could please grab your clicker, the first question
7 is where do you live. Press A for within
8 Washington, D.C. Metro area or B for outside of
9 Washington, D.C. Metro area. Is it up? Okay.
10 All right. So it looks like two-thirds of you are
11 our neighbors, so welcome again. And it looks
12 like a little over a third of you are traveling
13 from outside of the D.C. Metro area. Thank you
14 for coming. We are so glad this is not a rainy
15 day because we went through a stretch in May where
16 it just rained for about three weeks straight,
17 which was no fun. So glad it's a sunny day and
18 that you're here for it.

19 Okay, let's do the next question. Have
20 you ever been diagnosed as having neuropathic pain
21 associated with peripheral neuropathy? Press A
22 for yes or B for no. Okay. So the majority of

1 you in the room, almost 90 percent have been
2 diagnosed as having neuropathic pain. So we know
3 that it's not easy to come here and to travel.
4 And so, it really means a lot to us that you're
5 here to share these perspectives with us.

6 And I think we have one more. Okay,
7 your age, A, younger than 18; B, 18 to 29; C, 30
8 to 39; D, 40 to 49; E, 50 to 59; F, 60 to 69; G,
9 70 or greater. Okay. So it looks like -- it
10 looks like we have a pretty good spread. The
11 majority of you are in the age 60 to 69. We've
12 got 50 to 59, 70 or greater and then we also have
13 some representation between 30 and 49. So lots
14 of perspectives in the room.

15 And lastly, do you identify as, A, male,
16 or, B, female? Okay. So we -- almost kind of the
17 same -- okay, so almost half and half, equal
18 spread of male and female. Great. What is the
19 length of time since your diagnosis of neuropathic
20 pain associated with peripheral neuropathy? So A,
21 less than a year ago; B, one to two years ago; C,
22 two to five years ago; D, five to 10 years ago; E,

1 more than 10 years ago; or F, I'm not sure. Okay.
2 So we definitely have a nice spread of experiences
3 and perspectives here, which is great. Everywhere
4 from one to two years ago all the way over to more
5 than 10 years ago and some that have identified
6 that they're not sure when the actual neuropathic
7 pain was diagnosed.

8 Okay. Okay. What is the underlying
9 cause of your neuropathic pain? Check all that
10 apply. A, trauma, physical injury or surgery; B,
11 metabolic or endocrine disorders such as diabetes;
12 C, medication toxicity; D, viral or bacterial
13 infection; E, other condition not mentioned; or F,
14 I'm not sure. Okay. All right. So it looks like
15 we have a few that identified some sort of trauma,
16 physical injury or surgery. We have medication
17 toxicity. We've got viral and bacterial
18 infection. There are definitely other conditions
19 not mentioned. So I will just point out now that
20 when we do our large group facilitated discussion,
21 if you could -- if you're comfortable to do so, if
22 you could mention your underlying cause of

1 neuropathic pain, that'll help us a little bit
2 understand the context of your comments also. And
3 then, F, I'm not sure.

4 Okay. Okay. We have a lot of polling
5 questions, don't we, to test these out? Okay.
6 What comorbid conditions do you have, if
7 applicable? Check all that apply. So A,
8 depression or anxiety; B, diabetes; C, cancer; D,
9 kidney disease; E, chronic bacterial or viral
10 infection; F, other comorbid conditions not
11 mentioned; or G, I don't have a comorbid condition
12 that I'm aware of. All right. So we have
13 depression mentioned. We have cancer, other
14 comorbid conditions not mentioned -- again, I'll
15 just, you know, put a plug in for, if you're
16 comfortable to do so, to share that with us and
17 many others that said they don't have a comorbid
18 condition that they're aware of. Let me check in
19 with the Web. I know we just went through a lot
20 of polling questions. Can you give us an idea of
21 who's on the Web?

22 MR. THOMPSON: Very similar. We have a

1 50/50 male/female split, a range of ages, with the
2 majority in 60 to 69 range, a similar range for
3 the length of time since diagnosis and similar
4 results also for the underlying cause and comorbid
5 conditions.

6 MS. GIAMBONE: Okay. Great. Thank you.
7 And I think -- is that our last one? Okay. So
8 thank you so much for going through those polling
9 questions with us. We know that the technology
10 works because every once in a while we get a
11 little, you know, unexpected clickers don't work
12 type thing. But I'm so glad it worked. All
13 right. So now, we're going to get started with
14 our -- the highlight of today, which is to hear
15 from you all, from patients and caregivers. So
16 once again, we have four panelists on topic one.
17 And we're going to start with Adam. What I'll ask
18 you to do is when it's your turn to speak, just
19 press the red button on your microphone and you
20 can go right into your comments. And then, when
21 you're done, just hit the red button again to turn
22 the microphone off. Okay, so Adam, it's all

1 yours.

2 PANEL #1 DISCUSSION ON DISEASE SYMPTOMS AND DAILY
3 IMPACTS (TOPIC 1)

4 MR. HALPER: Hello. First of all,
5 before I dive in, I'd just like to thank all of
6 you for having us here. I can probably speak on
7 behalf of a lot of neuropathy patients in saying
8 that it's wonderful to get this type of publicity
9 for the range of disease processes that cause
10 peripheral neuropathy. For me, in terms of the
11 sensations I personally experience, I really -- I
12 primarily experience three different types of
13 sensations. The first is what I would describe as
14 sort of a deep muscular soreness. And that is
15 primarily activity-dependent. So for example, as
16 I sit here right now, my legs feel almost entirely
17 normal. But if I were to stand for, you know,
18 let's say 10 minutes or, you know, walk a half to
19 three-quarters of a mile, I would start getting a
20 deep muscular pain down the back of both legs,
21 which primarily manifests in my calves, back of
22 the knees and hamstrings.

1 The second sensation that I experience
2 with some regularity is -- it's almost like a
3 heaviness. So I think the easiest way to think
4 about it would be almost like if you're riding an
5 exercise bike with resistance turned up and every
6 step would require some additional effort. And
7 that's also very much activity-dependent. So you
8 know, if I were to go walk to the exit sign, I
9 wouldn't feel it. But if I went and walked a
10 mile-and-a-half, I certainly would. The third
11 sensation that I experience is not activity-
12 dependent and that's -- it's more of a classic
13 burning sensation. So very much on the surface of
14 the skin, and I get that up and down both legs and
15 in my hands as well and it sort of comes and goes.
16 And that is, you know, very much this classic
17 sensation where you feel like your legs are on
18 fire, to a degree. And it can be at times quite
19 uncomfortable.

20 In terms of the specific activities that
21 peripheral neuropathy affects for me, you know, as
22 a young guy, I developed peripheral neuropathy

1 about two years ago at the age of 28. At that
2 time, I was very physically active, you know,
3 running 40 miles a week and in the gym seven days
4 a week. So within about a 24-hour period, post
5 onset, you know, that ability to really move in a
6 sense was dramatically reduced. So today, I would
7 say with some variation, you know, I'm able to
8 walk about a mile-and-a-half to two-and-a-half
9 miles over the course of a day with breaks. And
10 at any one time, you know, I can generally walk
11 about a mile comfortably. In terms of standing,
12 for me, it'd say it's within 10 minutes I'll start
13 to get uncomfortable. And within about a half an
14 hour, it's really time to find a seat.

15 And so, you can think about how that
16 plays out within one's daily life. So some very
17 routine activities like, you know, riding the
18 subway, if you can't find a seat, going food
19 shopping, anything that would require one to stay
20 on their feet for an extended period of time can
21 be dramatically impacted and it requires a lot of
22 strategic thinking in order to plan out one's day.

1 In terms of the fluctuation for me
2 between the best and the worst days, for me, on
3 the worst days -- and for me, it's not really a
4 day-to-day fluctuation. It's more of a week-to-
5 week or a month-to-month fluctuation. But on the
6 worst days, I've had problems, you know, taking a
7 five-minute walk from my home to a subway station.
8 So it's gotten to that point at times. And in
9 terms of the burning, you know, I've had nights
10 where, you know, it can really impact my ability
11 to sleep comfortably. Conversely, during the best
12 stretches, you know, I'm able to walk, you know,
13 well over three miles in one day. So there is --
14 or there has been some variability in my
15 experience.

16 In terms of the change over time, since
17 onset, I would say there isn't one long- term
18 trend, either positively or negatively. There
19 certainly have been fluctuations over the period -
20 - over a period of months. But if I look back a
21 year-and-a-half, I would say I'm in roughly the
22 same position that I was in. And for the final

1 question, in terms of my biggest fear, I think it
2 would be that there might be some dramatic uptick
3 in symptoms which would, you know, quite literally
4 disabled me or require, you know, some heavy
5 hitting pain medication, which would, you know,
6 dramatically impact my quality of life.

7 MS. GIAMBONE: Thank you so much, Adam.
8 Okay, next we have Susan.

9 MS. WALDROP: Good afternoon. I'd like
10 to echo Adam's thanks to the organizers of this
11 meeting, for coming and listening to all of us.
12 My neuropathy resulted from the chemo I received
13 for colon cancer in 2009. Throughout my
14 treatment, peripheral neuropathy is a very
15 recognized and anticipated side effect of
16 oxaliplatin, which is one of the drugs I was
17 treated with. And so, throughout my treatment, I
18 was monitored very, very carefully for the
19 development of neuropathy, pain level, function
20 level. And my neuropathy stayed within expected
21 range. So I was able to get my entire -- my full
22 course of chemo, which is of course what I wanted.

1 But I completed that chemo. I was on
2 the home stretch and six weeks after is when I was
3 struck with this debilitating pain of peripheral
4 neuropathy. My feet were on fire. My lower legs,
5 my hands. It was what others have described, that
6 burning sensation. You feel like you're stepping
7 on frying pans and electric shocks going up my
8 arms, my legs, the sides of my feet. I certainly
9 couldn't walk and I certainly couldn't sleep. My
10 oncologist started me on gabapentin and promised
11 that with time, it would get better, and it has.

12 So nearly seven years now, I'm cancer-
13 free, which is a good thing. I'm on 3,300 mg of
14 gabapentin. Without it, I couldn't function. My
15 pain level today is greatly reduced. It's that
16 sort of constant numbness, unpleasant numbness.
17 Tingling's not pleasant. I can't feel my feet.
18 They sort of feel wooden. So my balance is lousy
19 and it's something that I work on all the time. I
20 have an increased sensitivity to cold. I love a
21 good, crisp winter day. But I can't take my
22 grandkids ice skating or teach them how to ski.

1 And the summertime, like today, normal air
2 conditioning, particularly on my feet, just turns
3 them into blocks of ice. If I sit -- I can stand
4 and walk okay -- but if I sit for long periods of
5 time, the pain is worse. So travel in a car or
6 airplane has become for me very difficult.

7 And even on my very, very best days,
8 when I'm able to do what it is I want to do, I
9 constantly have to be mindful not to do too much.
10 Don't have too much fun because if I get over
11 tired or stressed, that for me is when the
12 neuropathy kicks in. so after one of those really
13 good days, I sometimes have a really bad night.
14 And in that bad night, the pain intensifies. It's
15 what I described on my worst days. It's
16 impossible to sleep. And I'm not a heck of a lot
17 of fun on those evenings. And as I lie in bed,
18 the neuropathy reminds me that I'm living with
19 cancer. It's a constant trigger in my mind that
20 I'll always be living or battling my cancer.

21 I know I'm lucky. I can function. And
22 plenty of people out there can't. They have a

1 much harder time. The disease for them is much
2 more debilitating. But I bet there's hundreds,
3 and I bet thousands of people like me. They
4 probably aren't even in this room because they've
5 accepted peripheral neuropathy as a consequence of
6 the chemo. They just -- you just accept it. I'm
7 happy to be cancer-free. But yet, ironically, the
8 drug that may have cured my cancer has left me
9 with peripheral neuropathy. And it's the
10 neuropathy that makes me unable to really fully
11 enjoy the life that the successful cancer
12 treatment has given me and that's what makes me
13 really mad.

14 So what do I worry about? I worry that
15 I take a heck of a lot of a drug that was
16 developed to keep people from having seizures.
17 And if I'm really lucky, I may be taking it for a
18 really long time and who knows what that's going
19 to do and how it's going to impact, you know,
20 where I go in this next sort of chunk of my life.
21 So anyway, that's where I am today. I'd like to
22 thank again the people on the panel who are

1 joining me and the organizers of the committee.

2 And I look forward to our discussions this
3 afternoon.

4 MS. GIAMBONE: Thank you so much, Susan.
5 Next, we have David.

6 MR. MORROW: Yeah, hi. I'm David
7 Morrow, and I'm senior vice president of the
8 Neuropathy Support Network. And I have a very
9 similar story to Susan. My neuropathy started in
10 2009 as well as a result of chemotherapy and
11 surgery I received for colon cancer. And my
12 symptoms started probably -- I had 12 sessions of
13 chemotherapy that were scheduled. And it started
14 probably on my ninth session. And by my tenth --
15 my eleventh session, my doctor stopped me and
16 wouldn't let me take the last session of
17 chemotherapy.

18 It began -- the symptoms began slowly.
19 They were sort of mild, more of tingling and
20 numbness in my hands. And I would get this weird
21 sensation that I was wearing socks, even when I
22 wasn't. And then, before I knew it, I began

1 fumbling with things. And it was -- you know,
2 when I dropped my first cup of coffee, I thought
3 it was because I was just being clumsy. And then,
4 I dropped another cup of coffee. And then, I was
5 seasoning my food and I dropped my salt shaker.
6 And I would drop my keys. And it wasn't because I
7 couldn't feel things. It was like I could put my
8 -- if I could put my hand in my pocket and I
9 scraped my fingers up against my keys, it almost
10 felt like I was scraping them up against shattered
11 glass. It was very painful. But when I would
12 pick something up like a cup of coffee, I couldn't
13 feel how hard I was gripping it. So ultimately
14 what would happen is when I would pick something
15 up, it would slip through my fingers.

16 But as bad as it got for my hands, it
17 really became worse with my feet and my legs.
18 What would happen is at night I'd be woken up in
19 the middle of the night with like these stabbing
20 pains in the bottom of my feet that would shoot up
21 my legs. And then, it felt like I was walking on
22 rubber pads, rounded rubber pads, which is a very

1 weird sensation. And ultimately what that
2 resulted in was it affected my balance. I
3 couldn't really balance. So like, for instance,
4 if I was taking a shower and I was rinsing my hair
5 and I closed my eyes, I would fall. I would fall
6 against the wall. Or if I -- you know, when I'd
7 get up in the morning, first thing when I'd get up
8 in the morning, I'd have the pain also in my feet
9 and tried to move around. But if I tried to put
10 my pants on and I lifted one leg up off the floor,
11 I would fall. So what I learned to do was I
12 learned that I would have to lean against the wall
13 or sit down and do certain particular things.

14 And where this became a problem was at a
15 certain point I realized I couldn't really tell
16 where my feet were. And this manifested in a
17 situation where I was driving to a restaurant to
18 meet a friend and I pulled into a parking space.
19 And I hit the gas pedal instead of the brake and I
20 ended up on top of a cement bumper. And at that
21 point, luckily there wasn't a car in front of me.
22 But I realized at that point how a person could

1 actually drive through a store window. So
2 ultimately what ended up happening was I had -- in
3 my worst times, I had to get people -- you know,
4 someone to drive me because I couldn't drive
5 myself. And then, because of the balance issues,
6 when I would get out of the car, there was like an
7 instance where I got out of the car, because I
8 couldn't feel where my feet were, I was in a
9 parking lot, got out of the car and my feet were
10 up against a curb and I ended up falling flat on
11 my face. I fell a couple of times because not
12 knowing where my feet were.

13 So as far as specific activities that --
14 you know, that I wasn't able to do, you know,
15 through the symptoms I described to you, pretty
16 much all those were due to the chemotherapy. But
17 also, because of the surgery that I had, I had
18 abdominal surgery, I lost sensation in my stomach.
19 So I have no feeling in the top layer of my
20 stomach, which is -- which is -- it's a very
21 strange feeling because I can feel underneath it
22 but I can't feel on top. So in an intimate

1 situation like with my girlfriend, if you have
2 stomach-to-stomach contact, it's not painful. But
3 if there's any friction, there's a great deal of
4 pain underneath my skin and I don't know how to
5 describe it. The other thing that occurs is that
6 occasionally I'll develop itching on my stomach
7 that's down below my skin that I can't reach. So
8 I could scratch all I want, but the itching is not
9 going to go away.

10 So basically, over time, a lot of these
11 symptoms have dissipated. Now, the neuropathy in
12 my hands, I really don't feel it or notice it
13 unless I think about it. I do still have the
14 feeling on walking on rubber pads sometimes and
15 sometimes it's painful when I've been sitting for
16 a long time and get up. And I still have the
17 issues with balance, which still bothers me. You
18 know, if I try to climb something a little steep,
19 it's not going up that's so bad. It's coming
20 down. You know, it gets scary. And it's hard for
21 me to run and -- because of the balance issues and
22 stuff. As far as the surgery goes, you know, my

1 stomach is always going to feel the way it is. I
2 don't have any hope that that's ever really going
3 to change.

4 So the thing that really worries me the
5 most is as I get older, I'm a little worried about
6 the balance issues because I'm afraid the balance
7 issues may end up affecting my mobility. But I
8 have to admit I really feel a little guilty
9 sharing this because I'm getting better. And I
10 know that there are so many people out there that
11 are so much worse off than what I am. And I just
12 wanted to share something that I think is very
13 important and really impacts this and really
14 speaks to this one question about what worries you
15 the most about your condition.

16 The Neuropathy Support Network just
17 recently did -- with the Western Neuropathy
18 Association, just recently did a comprehensive
19 survey. And we received a great deal of responses
20 from people. And we asked this very specific
21 question, what worries you most about your
22 condition. And we found that there was a common

1 underlying thread that was very similar to all age
2 groups within the people that responded. But
3 there was one response that really stood out for
4 me and I think really underscores the need for
5 meetings like this that we're having today.

6 And it was from a young woman who had
7 just turned -- as she says in her own words, she's
8 just barely 20 years old. And she had been
9 diagnosed with diabetes 1. But her diagnosis for
10 her peripheral neuropathy was idiopathic. And so,
11 when she reached the survey question, what worries
12 you most about your condition, she simply
13 answered, my future. Now, understand this is a 20
14 -- this is a girl who's just turned 20. She
15 answered, my future. I'm still very young and the
16 prospect of being in this kind of pain the rest of
17 my life makes me not want to live it. And that
18 was a common theme through many of the responses
19 that we received.

20 MS. GIAMBONE: Thank you, David. And
21 last, we have Beth.

22 MS. LANNON: I'm glad I'm old when I got

1 this. I do feel bad for you young people. My
2 problem began with minor bilateral pain in my feet
3 in 2009. I was a triathlete. I noticed it when I
4 was running. It was such a slow progression that
5 I didn't even think of going to a neurologist. I
6 saw an orthopedist and podiatrist. And it wasn't
7 until my hands started tingling and going numb
8 that I said, oh, neuropathy. I need to see a
9 neurologist and --

10 MR. THOMPSON: Could you move your mic a
11 little bit?

12 MR. LANNON: I'm sorry. So it wasn't
13 until I actually started feeling some tingling in
14 my hands that I went to a neurologist. But for
15 like 18 months, I was just -- had no clue. I
16 describe my pain as sharp, constant, bruised, like
17 somebody took a hammer to my feet. I know that's
18 not typical and most people don't describe it that
19 way. It's true whether I'm sitting, standing or
20 laying down. And when I'm walking, it's kind of
21 like I'm walking on rocks. So I wouldn't say this
22 is just bothersome. It's debilitating. You know,

1 I spent 16 hours a day laying down. And not --
2 actually not all at once. I intersperse it with
3 what I need to do to live. So I just do things in
4 short bursts.

5 Besides the pain, I do get electrical
6 shocks. It's like sticking your finger in a light
7 socket. I get them in my toes, my hands, my feet,
8 my hips, my eyes. That's the worst. Doctors
9 don't know what that's -- what causes that. They
10 just say it's progression. So I don't know. And
11 they go away. I'll be plagued with them for a
12 month and then they disappear and I'll be fine for
13 a few months and then the electrical shocks start
14 up again. At least they're short, you know, short
15 bursts.

16 The other bothersome thing is that one
17 doctor described it as he doesn't think my nerves
18 know how to open and close my veins and arteries
19 because they can't find anything wrong with my
20 veins and arteries. But my lower half of my body
21 takes on the temperature of the air. So my toes -
22 - first it started with my toes. They would be

1 freezing. Then, you know, my feet. Now it goes
2 all the way up to my hips. So in winter, I do not
3 want to be outside during the winter. Let me see.
4 Oh, and I do understand the tingling and burning.
5 That's on the top of my feet, the not wanting to
6 wear socks, the brushing of the sheet against your
7 feet that sends you jumping. I know those are --
8 those are kind of the common neuropathy feelings.

9 It usually happens when I'm overtired,
10 you though. You know, I've been standing or
11 walking for more than a few minutes. And that's
12 when I tend to think of my feet as being on fire.
13 It's like, oh yeah, they're on fire. Need to get
14 them in ice. And like I said, I do have the
15 numbness in my toes in particular. So my feet,
16 they've got the pain at the bottom, the tingling,
17 the burning at the top and my toes are numb. My
18 hands are, you know, typical neuropathy, the
19 tingling and burning, numbness there.

20 Things that I can't do, gee, well yeah,
21 sleeping's a problem. Everybody knows that. How
22 do you sleep in pain? How do you fall asleep in

1 pain? And it wakes you up in the middle of the
2 night. But you know, I struggle through every --
3 I struggle to make it through every day. I know I
4 look really normal to most people, you know,
5 especially when I'm at work. So people don't
6 realize that no matter what I'm doing -- what, in
7 the foremost part of my brain, is what I'm
8 thinking, my feet hurt. And they will be hurting
9 so bad by the end of today that I will probably be
10 in bed all day tomorrow. I just know that. If
11 you're going to do something, you plan for a day
12 and then you pay for a day. That's okay.

13 I lost my ability to do just about
14 everything. I think I mentioned I was a
15 triathlete. I worked 50, 60 hours a day. I can't
16 -- I can't sit for long periods of time. So even
17 just going to movies or plays or, you know, a game
18 are uncomfortable. I do it sometimes. I'm
19 untreated. None of the medications worked or gave
20 me such bad side effects that the doctor said,
21 nope, you can't take that any longer.

22 I can still do daily hygiene. But it

1 makes me tired. You know, I have the shower
2 handles and the seats. But you know, okay, then
3 you've got to sit down and rest for a while before
4 you go onto the next thing. I also have a rolling
5 walker to get around the kitchen. So even
6 preparing -- oh, I changed my diet. I guess
7 that's for a good thing. I now only eat things
8 that can be prepared in less than five minutes.
9 You know, raw fruits and vegetables, nuts, peanut
10 butter sandwiches, anything that doesn't make me
11 have to stand on my feet and cook. I live alone,
12 so that's a problem.

13 I used to be a veterinary technician. I
14 worked 50 to 60 hours a week. I loved the job.
15 It's a job I took -- got late in life. I'm glad I
16 quit corporate America in my forties and went back
17 to school and got a chance to do it. So that's
18 what I said. I'm really sorry for those of you
19 that are young. A lot of people think that's a
20 very strange profession for me to have. But I
21 only work two hours a day. I work Monday,
22 Tuesday, Thursday and Friday, two hours a day.

1 This job's good for me because I can stand when I
2 want to, sit when I want to and walk when I want
3 to. There aren't many jobs that let you come in
4 for two hours a day and do that. But I've been
5 working there for a very long time, so that helps.
6 But I miss it. Gee, what have I not said? One
7 more -- one more thing.

8 MS. GIAMBONE: Beth, you want to tell us
9 what worries you most about your condition?

10 MS. LANNON: Oh, I fall. I live alone.
11 So I guess that's --- you know, that's the worst
12 thing. I've had some really bad falls. I've torn
13 my MCL. I've broken toes. I end up bruised. I
14 knocked myself out once falling down the stairs.
15 So living alone, that's the main thing that I
16 worry about.

17 MS. GIAMBONE: Thank you.

18 MS. LANNON: And who's going to take
19 care of me? I don't know.

20 MS. GIAMBONE: Thank you so much, Beth.
21 Thank you for your comments. Okay. Is this on?
22 Yeah. So let's give our panelists a round of

1 applause for putting together -- [Applause.]

2 MS. GIAMBONE: Thank you for preparing
3 so well and for writing and sharing such personal
4 stories with all of us. So it really means a lot
5 to us. And I want to ask to the audience, how
6 many of you feel as though, you know, the
7 experiences that you've had, that what the
8 panelists have said -- how much of that resonates
9 with your own experiences? Yeah, so a lot of the
10 patients in the room are able to have similar
11 experiences. And I know there's different
12 experiences too.

13 I did take a few notes as the panelists
14 were talking. And so, I just want to do a really
15 quick show of hands. Adam, you mentioned that you
16 feel like your legs are on fire. Do others share
17 something similar, that your legs are on fire?
18 Okay. And then, Susan, you mentioned that you
19 have an increased sensitivity to cold. Others?
20 Okay. Yeah. David, you mentioned balance issues.
21 Balance issues, others? Absolutely. Okay. And
22 then, Beth, you mentioned -- so while you were

1 talking, you said that -- you said -- I think you
2 said you're not sure how many others feel this
3 way. You said you feel like a hammer on your
4 feet. How about others, a hammer on your feet or
5 walking on rocks I think is what Beth said? So
6 there are others that share your perspectives.

7 So that's -- glad to see so many similar
8 experiences. Looking forward to hearing some of
9 the different experiences in here as well. I do
10 also want to ask how many of you are in pain right
11 now as you're sitting here sharing -- you know,
12 ready to share your experiences with us? Let's
13 see, almost 12 or 13 hands that I see raised for
14 those of you in pain right now.

15 Okay, so let's -- actually, we're going
16 to do another polling question to sort of kick off
17 our discussion now. So everybody get your
18 clickers out again. Okay, what parts of your body
19 do you experience your most severe neuropathic
20 pain? Check all that apply. A, head, face or
21 neck; B, hands or arms; C, feet or legs; D, trunk;
22 E, back; F, genital area; or G, other areas not

1 mentioned. Okay. So it looks like those of you
2 answering have said that C, feet or legs is where
3 you experience your most severe neuropathic pain.
4 We also see some hands or arms and trunk, genital
5 area. And let's see, are there other areas not
6 mentioned? Not too much. But please be sure to
7 tell us if there's anything else that comes to
8 mind. How about on the Web? What do we see
9 there?

10 MR. THOMPSON: We see 95 percent for
11 feet or legs, 38 percent for hand or arms and
12 between 15 to 20 for all the rest.

13 LARGE-GROUP FACILITATED DISCUSSION, TOPIC 1

14 MS. GIAMBONE: Okay. Okay. So would
15 somebody like to start us off with feet or legs?
16 Now, we've heard different ways our panelists
17 mentioned how they're experiencing it in their
18 feet or legs. But would somebody in the audience,
19 other patients or caregivers like to tell us how
20 you experience it in your feet or legs? And what
21 do you experience? What is that sensation that
22 you feel?

1 MR. KLITZMAN: Well, one thing that we
2 haven't talked about, and maybe it's not within
3 the scope of this discussion, but I experience
4 more numbness than pain. To the extent that I'll
5 be walking or standing for a long time. And then,
6 I lose the contact with the ground, which David
7 referred to, and I have to hold on to something or
8 shake my foot. I was in a department store with
9 one of my kids, buying clothes for him, and we
10 finished that and then we met some family that we
11 knew. And we started talking in the department
12 store area and they kept chatting away and
13 chatting away. I had to go on -- I had to look
14 for something to hold on to. I found the tie
15 table and I sort of looked like I was looking at
16 ties, holding onto the edge of the table so I
17 could shake my foot.

18 It was a very scary sensation if you
19 feel you're losing contact with the ground. You
20 don't want to fall. And I know that numbness is
21 not on the agenda necessarily. But it often gets
22 overlooked. And you know, if one day there could

1 be a medication to cure numbness or to regenerate
2 the nerves, you know, that would be a real
3 blockbuster, instead of just focusing on pain all
4 the time. But numbness shouldn't be disregarded.

5 MS. GIAMBONE: Steve, thank you so much
6 for your comments. And actually, we will be
7 talking some more about numbness. I know it's a
8 very important aspect of how you experience the
9 neuropathy. And can I just ask actually, while
10 we're on the topic of numbness, is it the numbness
11 that leads to the balance issues that we've heard
12 David describe, and now, Steve, that you've
13 described? I see heads nodding. Would somebody
14 like to -- sure.

15 MR. SHROUT: Sure. I'll speak up on
16 that. My name is Gary Shrout. I've had this for
17 a very long time. It's idiopathic. Nobody knows
18 why or what. As Dr. Galati was going through his
19 thing, it's like, yep, yep, yep, yep, both all the
20 pains and everything. So all the symptoms. I
21 certainly identify with the numbness and --

22 MS. GIAMBONE: We're going to see if

1 your mic is on. It doesn't sound like it's on.

2 MR. SHROUT: Oh. Okay, how's that?

3 MS. GIAMBONE: No. Go ahead and use
4 mine. Use mine.

5 MR. SHROUT: Okay. All right. Name's
6 Gary Shrout. I've had this for probably over 30
7 years, so not diagnosed officially until 13 years
8 ago. Idiopathic. Nobody knows why. All the pain
9 symptoms you could possibly have, I've had. I've
10 been very blessed. I'm still able to function
11 pretty much normally. Balance is a big deal.
12 Numbness is a big deal. I've classified my nerves
13 into three categories and I'm determined to hang
14 onto the ones that I really need. The good guys,
15 the normal ones are still doing fine. Hi, happy
16 Friday. The dead ones, it's like, dude, I'm gone,
17 you're not going to hear from me again and then
18 other ones that are screaming for help. And it's
19 the ones screaming for help I think that are
20 partially damaged, that are still communicating
21 that cause the problems.

22 Numbness is a huge deal. I've had the

1 feeling of wearing socks. That's like it right
2 now. And I'll make some comments later at a more
3 appropriate time about some interesting things
4 that I think are happening. But yes, numbness is
5 a deal. Balance is a deal. My pain has been
6 everything that you guys have listed up there,
7 including the ice pick going through the top of
8 the foot, which is real nice in the middle of the
9 night. Sleep is an issue. Get up, go the
10 bathroom. You may have been exhausted from the
11 day and, you know, you finally pass out, despite
12 the pain. Get up, go to the bathroom when you've
13 had a little bit of rest. Well, guess what,
14 getting back to sleep is not an option. So I hope
15 that contributes to what you're looking for.

16 MS. GIAMBONE: Yes, thank you.

17 MR. SHROUT: Thank you guys for doing
18 this.

19 MS. GIAMBONE: Thank you.

20 MR. MORROW: I do think there's
21 something also --

22 MS. GIAMBONE: Thank you.

1 MR. MORROW: -- that needs to be said
2 about the numbness so that people who don't have
3 this understand. Because you are numb doesn't mean
4 you don't feel pain.

5 MR. SHROUT: Right.

6 MS. GIAMBONE: Okay.

7 MR. MORROW: You can have numbness and
8 still feel severe pain.

9 MS. GIAMBONE: Okay.

10 MR. MORROW: And that's a -- it's sort
11 of a weird condition when you first experience it.

12 MS. GIAMBONE: Okay. I heard a lot of
13 people agree to what you just said, David. Okay.
14 Let's take one more comment. We'll -

15 UNIDENTIFIED AUDIENCE MEMBER: Okay. I
16 had Guillain-Barrésyndrome, or GBS, 42 years ago
17 and for the last 42 years, the first thing I want
18 to do at the end of the day or even in the middle
19 of a day is rip off my shoes and socks. My feet,
20 barefoot I feel a lot better. I was an aspiring
21 drummer and I had to kind of give that up due to -
22 - if you know anything about drumming, your feet

1 are a very important part of that. And my feet
2 simply didn't work and I'm up on stage trying to
3 do some drumming and everybody's kind of looking
4 at me like, you know, dude, what are you doing up
5 there. So but just numbness and pain. The only
6 way to really get rid of the pain is an ice
7 bucket, an ice bucket filled with ice water for
8 about 10 or 15 minutes and I'm good to go for a
9 little while, so --

10 MS. GIAMBONE: Okay. Okay, so numbness
11 in the feet is what I'm hearing a lot of, then.
12 Okay, other experiences that you'd like to share?
13 Right here, Meghna.

14 MS. CHARLESTON: Good afternoon. I had
15 a thyroid storm that led to Guillain- Barrsyndrome
16 and I have the pain, the numbness and the tingling
17 all over my entire body. There is not a specific
18 area that's worse than the other. I t's all bad,
19 all the time. So for me, I'm a very active
20 person. And in order to stay active and doing the
21 things like volunteering and things like that, I
22 have to not be on medications. So if I stayed on

1 the Lyrica and the tramadol and all the different
2 ones that I saw on the screen, then you're
3 sleeping 24/7.

4 MS. GIAMBONE: Okay.

5 MS. CHARLESTON: So the numbness and I
6 think the tingling together has me off- balance --

7 MS. GIAMBONE: Okay.

8 MS. CHARLESTON: -- because it seems
9 like a lot of times, it's a connection issue when
10 my body's in motion and I'm walking and I'm
11 walking and I'm looking at you and I'm coming over
12 to see you, I have to constantly say keep moving,
13 keep walking, pick up your legs, go, shake hands.
14 But if I look to the left, I just stumble. I
15 would fall before I get to you because I've taken
16 my sight off of where I'm going. And it's kind of
17 like that.

18 MS. GIAMBONE: Okay.

19 MS. CHARLESTON: So the balance issue is
20 tied into focus, concentrate, lift your feet, move
21 your arms, stay, go in one direction. Don't try
22 to do something else while you're going over there

1 because you just lose balance.

2 MS. GIAMBONE: Okay. So let's do a show
3 of hands. How many others feel -- and sorry, I
4 didn't catch your name.

5 MS. CHARLESTON: Tonya.

6 MS. GIAMBONE: Tonya. I saw some heads
7 nodding while Tonya was speaking. How many others
8 relate to what Tonya just said about having to
9 sort of focus and make sure that you're
10 concentrating on your next step, just so you can
11 keep your balance? Okay. Okay. So let me bring
12 us back to this polling question because what I
13 want to ask is can you -- can you tell us about
14 differences in how you experience the pain or the
15 tingling or the numbness in different parts of
16 your body? So how is it different, for example,
17 in your feet or legs than it is in your hands or
18 arms? Can -- is there -- is there a difference
19 between how you experience it in different parts
20 of your body?

21 MR. MURPHY: My name is Tim. I have a
22 chronic inflammatory demyelinating polyneuropathy,

1 specifically Lewis Sumner syndrome. And so, I
2 have symptoms in all my arms and legs and they all
3 differ. So with my feet, it's mostly a numbness,
4 maybe some tingling that's led me to several
5 falls, limited some activity. At its worst, I'll
6 take the elevator instead of the stairs. But my
7 worst symptoms are in my arms and that's where it
8 had started. And so, it's a dull, like somebody
9 hit me with a hammer, pounding. It feels like my
10 right arm is made out of wood. And then, the best
11 -- in addition to medication, I've had it all, but
12 I'm currently on Motrin and Neurontin and biweekly
13 IVIG treatments. But actually the best thing is
14 exercise, as much as I can do it, because the
15 persistent -- I like to swim -- pounding of the
16 water takes probably 50 percent of the symptoms
17 away, as long as everything else is working.

18 MS. GIAMBONE: Okay. Thank you, Tim.
19 Are there other areas that you'd like to share
20 with us before we move onto the next question?
21 Yes?

22 MS. LANNON: You asked about diagnosis.

1 I have CIDP too. That's probably why we have such
2 similar symptoms. And the thing about exercise is
3 I went to a physical therapist and I made him
4 realize the importance of letting me do exercises
5 where I didn't have to stand because they all
6 wanted to make me stand. I'm like, no, you don't
7 understand. I can't stand. I won't stand and do
8 exercises. We need to do them laying down. I
9 need to be able to work every muscle in my body
10 laying down and it works great.

11 MS. GIAMBONE: Okay. Okay. Thank you,
12 Beth. Let's take one comment here.

13 UNIDENTIFIED AUDIENCE MEMBER: It's sort
14 of a generalized question. We're telling all our
15 stories and so it's all very experiential. My
16 major question -- well, I'm a science writer --
17 what's it leading toward? What are these
18 individual stories -- where are they leading to in
19 terms of research priorities? What is the status
20 of the research that is going on? What do we need
21 to do about that research as it applies to our
22 individual problems? Because all of this is so

1 individualized.

2 Is there a field theory yet of
3 neuropathy? Some of you know what a field theory
4 is in science. But what are the generalized
5 questions that we need really to know about where
6 things are going? So we can tell our stories, you
7 know, on and on and on and on. But where is it
8 leading and how do we know, how do we keep track
9 of it? Where's the place to go to really get to
10 understanding? What are other areas of research?
11 By who? Where? Who to talk to if you really have
12 a real question, stuff like that would be useful.

13 MS. GIAMBONE: Thank you. Thank you for
14 bringing that up. And I think that's exactly why
15 we're here today, to hear from patients because
16 you're really the experts. You're the experts in
17 how you're living with the pain and the sensations
18 of pain and numbness and tingling. And I think
19 what we -- what you tell us is really important to
20 the work that we do and to the work of drug
21 developers. And as my FDA colleagues identified,
22 you know, at the start of the meeting, that's

1 exactly why we're here, is to learn from you so we
2 can move forward with this in drug development.

3 Okay. So I think we have -- let me check in with
4 the Web really quick because we're going to move
5 on to the next question, which I think is really
6 the bulk of our discussion.

7 MR. THOMPSON: So some of the symptoms
8 that have been mentioned on the Web, people having
9 issues with balance and coordination, for people
10 with pain in the face or head region, it's common
11 to also get migraines. Many people mentioned feet
12 issues, such as numbness in their toes, burning
13 feeling like sunburns, pain in the ankles or
14 feeling like you're walking on nails. A few
15 people mentioned sleep problems. And there's also
16 mention of Charcot disease, which is a syndrome of
17 bone deformation caused by peripheral neuropathy.

18 MS. GIAMBONE: Okay. Thank you. And
19 actually, before we go on, I did want to ask one
20 question. Can somebody describe to us what is the
21 different between numbness and tingling or can you
22 describe separately how these terms are different

1 from one another? We've heard burning, shocking
2 pain. We've heard tingling, of course numbness.
3 Can somebody tell us how -- what's the difference
4 in how you experience it? Can we come to -- oh,
5 yes. Tonya, let's start with Tonya.

6 MS. CHARLESTON: Hi. The numbing part
7 of it I guess best described is when I put my hand
8 in my bag and I want to pull out lip gloss or a
9 pen or something, I cannot feel it.

10 MS. GIAMBONE: Okay.

11 MS. CHARLESTON: I can't distinguish
12 what the item is without physically dumping the
13 back out and looking and saying, oh, there it
14 goes. The tingling is like something that's
15 creepy, crawling all through under your skin,
16 every which way. And you just feel like every
17 nerve end is yelling out you because it's like,
18 sit down, sit down, you know, put a blanket on,
19 warm up or be still, don't move, because you're
20 hurting so much. So the tingling is creepy,
21 crawly things just all over, in you, through you,
22 everywhere.

1 MS. GIAMBONE: So tingling is sort of an
2 all-over feeling. Numbness is maybe more
3 localized or is it --

4 MS. CHARLESTON: You can't distinguish
5 the feeling or it's like -- like with my hands, I
6 can't distinguish what the item is.

7 MS. GIAMBONE: Okay.

8 MS. CHARLESTON: With my leg, if you
9 were to squeeze my leg, I can't really tell. I can
10 see you're squeezing it but I can't initially feel
11 the pressure like that.

12 MS. GIAMBONE: Okay. Okay. Thank you,
13 Tonya. And I think Lou wanted to say something.

14 MR. SCHMITT: The best way I can
15 describe the difference between the numbness and
16 the tingling is the numbness -- we've all had the
17 sensation of our feet or legs going to sleep.
18 That's what the numbness feels like to me. It's
19 you can look at your foot, you can wiggle your toe
20 and you can't feel that you're wiggling your toe,
21 if you're able to do that. And it's the same thing
22 when your foot goes to sleep and you try to bring

1 it back. You move your foot and wiggle your toes
2 and you can see it but you can't feel anything.
3 That's kind of how the numbness is for me.

4 The tingling is kind of when you do --
5 your foot does fall asleep and you move it around.
6 And all of a sudden, the sensation starts coming
7 back. Then you start getting those pins and
8 needles and kind of the tingling feeling as the
9 sensation returns to your foot. Now, I don't get
10 that anymore because my feet are numb. So I don't
11 get sensation that comes back. But I still get the
12 tingling feeling. So it's -- so the numbness is
13 sort of like when the foot's asleep. The tingling
14 is sort of like when the sensation is starting to
15 return and you start getting that first feeling
16 that the sensation's coming back and it starts to
17 tingle. And that's kind of how my numbness and
18 tingling feels.

19 MS. GIAMBONE: Okay. So I'm hearing you
20 say that with numbness, it's not that it -- it
21 doesn't go away. It stays numb whereas the
22 tingling is sort of like an on and off type thing?

1 Okay. Do others feel that same way or is it
2 different for you? How about with --

3 MS. WALDROP: You know, one thing I'd
4 just like to emphasize is that numbness and
5 tingling as words don't sound so bad. You know,
6 it doesn't sound like it's that bad. But it
7 really is bad.

8 MS. GIAMBONE: Sure.

9 MS. WALDROP: It really is painful.
10 It's really uncomfortable. And it -- and I wish
11 there was another word that could better describe
12 what we all feel because I think we know what we
13 all feel.

14 MS. GIAMBONE: Okay. Let's take a
15 comment over here. Yeah? Sure.

16 MS. PAGETT: I'm Cherie, and the
17 numbness is like a block, like your foot -- it is
18 on -- like your foot is a block. But at the same
19 time, numbness is so dangerous. It's like -- it's
20 having your big toenail ripped off and not knowing
21 it for 10 minutes when you look down and you see
22 the blood. That's numbness. So I mean, it's --

1 you can really injure yourself because you can't
2 feel what's going on with your feet.

3 MS. GIAMBONE: Okay.

4 MS. PAGETT: The tingling, it can be
5 like jabs and darts and that Lyrica commercial
6 that we've all seen with the foot with all the
7 stuff going on all over it, that's the tingling
8 part and the -- there is a difference.

9 MS. GIAMBONE: Okay. Okay. Yeah.
10 Okay. And do you feel that there -- is there a
11 part of your body where you feel -- I know Tonya
12 said tingling was more of an all-over body
13 sensation for her. Is that the same for others,
14 where tingling is more of an all-over sensation or
15 do you find that it's more localized for you and
16 in a certain area of the body? We have a hand
17 raised back there. I'll just take one comment
18 here.

19 MS. COOK: Hi. I'm Evelyn and I have
20 CIDP. I went into relapse about three months ago.
21 And I get the tingling mostly in my hands and my
22 feet, although I have had it in my face. And

1 again, I just want to emphasize it's not mutually
2 exclusive. So when you're numb, you may also be
3 feeling tingling at the same time.

4 MS. GIAMBONE: Okay. Thank you, Sharon.
5 Sharon, right? I hope I got your --

6 MS. COOK: Evelyn.

7 MS. GIAMBONE: Evelyn, I'm sorry. Okay.
8 Thank you, Evelyn. And now, let's look to my FDA
9 panel. Sharon, you have a question?

10 DR. HERTZ: So by way of background, I'm
11 a neurologist and I actually was in practice prior
12 to becoming a bureaucrat. And so, what I would
13 like to know -- I certainly do understand the
14 difference between the numbness and the tingling,
15 the paresthesias, as we would call it, versus the
16 sensory loss or hypoesthesia. And you may have
17 heard some of those terms or seen them even in
18 your doctor's notes or in materials that you've
19 read.

20 When you think about treatment and when
21 we think about what we see coming in for
22 treatment, we tend to see two things that

1 sometimes overlap but also sometimes are
2 independent of one another. For painful
3 neuropathy, we also will see symptom management.
4 And what typically that refers to is a positive
5 symptom, like the occurrence of these pins and
6 needles, tingling sensations, what I will call
7 painful paresthesias --

8 MR. KLITZMAN: Can you speak up a little
9 bit? I can't hear you.

10 DR. HERTZ: Sure. Sorry, is that
11 better?

12 MR. KLITZMAN: Very.

13 DR. HERTZ: So we typically see one of
14 two approaches, two therapeutics. We see drugs
15 being developed to treat the positive symptoms
16 that you've been describing, predominately the
17 painful tingling, the painful pins and needles
18 sensations. But we also see people who are -- or
19 companies that are interested in what we would
20 call disease modifying treatment, trying to fix
21 what's wrong with the nerve and that would try to
22 either slow the development of the numbness or the

1 lack of feeling or even try to restore it,
2 depending on the nature. If you had a pick, what
3 was important to you, is it more important to
4 decrease the positive symptoms that are associated
5 with pain or is it more important to try and
6 restore the lost function, the numbness?

7 MS. GIAMBONE: So why don't we do this
8 by a show of hands then? So is it more important
9 to -- you said the first is decreasing the pain,
10 right? So who thinks between decreasing the pain
11 and restoring the function -- the sensory
12 function, who thinks decreasing the pain is more
13 important? Okay. So we have one, two, three,
14 four, five, six -- we have about 10 hands raised,
15 11 hands raised. And how about the flip side,
16 which is restoring some of that sensory function?
17 One, two, three, four, five, six, seven, eight,
18 nine, ten, eleven -- about twelve. So it seems
19 about the same for both.

20 MR. MORROW: You know, I think it's sort
21 of a misleading question though.

22 MS. GIAMBONE: Okay.

1 MR. MORROW: It's the wrong question to
2 ask. And the reason I feel that way is because it
3 depends at what level you're experiencing the
4 neuropathy. We have a tremendous amount of people
5 that contact us that have debilitating pain. You
6 know, it affects the way they function and the way
7 they react with people and just affects their
8 lives overall. It puts them into a deep
9 depression because it's pain all the time and it's
10 the type of thing that never goes away. And
11 because it never goes away, it may seem tolerable
12 in the beginning. But over time, it gets worse
13 and worse and worse. And at a certain point, some
14 of these people reach a breaking point.

15 And so, to ask that question -- I think
16 by all means -- I think pain has got to be very
17 important in this, that to alleviate the numbness,
18 that to me is after the pain is gone. And for
19 those people that are at that level, yeah, that's
20 important. But I think for the people that are
21 out there, there's too many people out there
22 suffering through the pain right now that really

1 need help getting rid of the pain.

2 MS. GIAMBONE: Thank you, David.

3 UNIDENTIFIED AUDIENCE MEMBER: [Off mic]

4 -- why is that an either/or aspect, why is --

5 DR. HERTZ: I'll just say why I was
6 curious about that piece of the question is
7 because it impacts how the products are developed.
8 Symptom management could be an earlier
9 measurement, reducing pain can happen quicker
10 because what we know, and I'm sure you all know as
11 well, is trying to see healing of a nerve is an
12 incredibly slow process. And it can take years
13 even in situations where it's possible.

14 So it helps me to know in the context of
15 when they are both present because I definitely
16 understand the concept of the progression in
17 certain types of neuropathic conditions where
18 early on it's predominately positive symptoms.
19 And then, as the damage progresses, it's more that
20 negative loss of feeling. But when we discuss
21 this with companies that are trying to develop
22 products and we're trying to see what makes sense

1 in terms of staging the clinical study and what to
2 try and get out of the study, it's just helpful to
3 hear some feedback on that.

4 UNIDENTIFIED AUDIENCE MEMBER: Can I
5 make a general --

6 MS. GIAMBONE: Yes.

7 UNIDENTIFIED AUDIENCE MEMBER: I think
8 it's a no-brainer on the question. Forgive me for
9 barging in. But yes, you do have to relieve pain.
10 There are products out there that relieve pain out
11 there now. How many products that are out there
12 actually cure neuropathy? I mean, you know, let's
13 get real, because once it's curable, you don't
14 need to worry about the pain.

15 MR. MORROW: Yeah, but I don't think
16 there's that many products out there -- I think
17 there's a lot of products that will help the pain.
18 But from what I'm hearing back from patients, it
19 doesn't completely alleviate it and there are too
20 many patients out there that have the pain so
21 severely and they can't get any sort of relief
22 from it. And the other aspect of it is for most

1 drugs that are available to them that they can get
2 some relief, the side effects for some of them are
3 awful. And so, it really comes down to I think,
4 again, is what situation, where you're at in
5 regards to where you're at with the neuropathy.
6 And the people that suffer from the pain and
7 they're in the severe pain are not here today.

8 MS. GIAMBONE: Okay.

9 MR. MORROW: You know, I think it's
10 great that Elizabeth made it because I know how
11 difficult it was for her to get here. But you're
12 not going to hear from the people that have the
13 really severe pain, you know, as much as you're
14 going to hear from the people that have maybe just
15 the numbness like myself.

16 MS. GIAMBONE: Thank you, David. And
17 you're all bringing up some very, very good
18 points. And I want you to hold onto the topic --
19 the points on treatment because we do have the
20 second session really dedicated towards what
21 you're looking for in treatment. So they're all
22 important and we are going to get to them, I

1 promise you. However, I do want to check in with
2 the Web because it sounds like we have some
3 updates coming in from the Web. And I know that we
4 have some -- to David's point, some people that
5 couldn't travel to come here today joining us on
6 the Web. And Adam, I promise I'll come to you
7 right after.

8 MR. THOMPSON: So we have a few people
9 who have called in. but before that, we've had a
10 couple of comments on numbness and tingling. Some
11 people described it as a confusing sensation, like
12 ants crawling or small cramping localized over the
13 body. Numbness has been described as just having
14 a lack of sensation or feeling in certain body
15 parts or localized tingling. And some people
16 describe tingling as mild to moderate electric
17 shocks.

18 MS. GIAMBONE: Okay. Thank you. Adam,
19 would you like to share your perspective?

20 MR. HALPER: Yeah. I just -- maybe I
21 misinterpreted the question. But the way I
22 interpreted it is almost like there's two separate

1 questions there, right? And so, I think if you
2 were to break it apart a bit and phrase it as, you
3 know, if we're thinking about priorities, should
4 it be symptom management or figuring out a way to
5 actually alter the underlying disease process, I
6 think you might -- and I could be wrong, but I
7 think you might get a different set of answers
8 because I think for people who have a progressive
9 form of neuropathy, you can treat the symptoms to
10 a degree. But if it's going to keep getting worse
11 and worse and worse, there's only so much you can
12 do. So speaking from my point of view, if you
13 were to phrase the question that way, I would
14 personally say unequivocally that modifying the
15 disease process would be my priority.

16 MS. GIAMBONE: Okay. I see some head
17 nods with what you just said, Adam. Thank you.
18 All right. Let's --

19 MS. LANNON: Yeah. I think that's
20 really true because I first chose to stop the
21 progression. I have CIDP. I could stop the
22 progression. We spent a long time doing that.

1 But once the progression was stopped, I don't have
2 any pain relief. So right now, yeah, my brain
3 thinks nothing but pain, pain, pain. But you're
4 absolutely right. When I was first -- started
5 getting the symptoms, I wanted it to stop
6 progressing. That was my -- the main thing, stop
7 the progression. You know, and if I don't just
8 think about myself and the pain that I live with,
9 yes, I would want them to stop the progression and
10 be able to stop the progression for anybody that
11 it happens to.

12 MS. GIAMBONE: Okay. Thank you very
13 much, Beth. Leslie, you have been waiting very
14 patiently. Can we bring a microphone over to
15 Leslie?

16 MS. LEVINE: I think I've been on both
17 sides of this. I have autoimmune small fiber. It
18 took three years to get that diagnosed --
19 diagnosis. But when my neuropathy came on, it
20 came on quite quickly and I went from being a high
21 functioning professional to being on disability,
22 practically unable to do anything. It felt like I

1 was having a blowtorch applied to my - - first my
2 feet, but then it went up my legs and my arms and
3 hands. And I don't know how long I could have
4 taken it. None of the drugs worked except for
5 opiates and my doctor -- I wouldn't have stood it
6 for three years without that. And there's a lot
7 of people now with the opiate issues that can't
8 get that.

9 For the last seven years, I've run a
10 support group for neuropathy patients of about 60
11 people. And the people who are in this level of
12 pain can't get to the group very often and they
13 usually drop out because they end up not being
14 able to leave their homes. They can't drive.
15 They can't function. I was in that status and
16 finally I got on IVIG and my symptoms largely went
17 away. And it was my life back. People are
18 paralyzed by depression after being in this level
19 of pain for very long. It pickles your brain. It
20 -- my -- well, I won't go into all the effects on
21 my life. But it was devastating and it was agony.
22 And I can understand why some people commit

1 suicide because of this. And so, I'm on both
2 sides of this issue. The pain control, when
3 you're in that level of pain, you can't go on
4 without it. But the disease modifying, where all
5 of a sudden you don't need the pain control, is
6 definitely worth research dollars, of which
7 neuropathy gets very few.

8 MS. GIAMBONE: Thank you very much,
9 Leslie. Let's do a polling question.

10 [Applause.]

11 MS. GIAMBONE: It sounds like your
12 comments really resonated with a lot of people in
13 the room.

14 MS. LEVINE: Thanks.

15 MS. GIAMBONE: So let's do a quick
16 polling question, if we could get our clickers out
17 again. How do your neuropathic pain symptoms
18 typically manifest? A, pain appears suddenly and
19 progresses rapidly; B, pain appears subtly and
20 progresses slowly; C, pain comes and goes; D, pain
21 is continuous; E, pain worsens over time; F, other
22 manifestation not mentioned; or G, I don't know.

1 Okay. So it looks like we have the majority of
2 people said that pain is continuous, which you all
3 highlighted early on when I asked how many of you
4 were actually in pain right now. Many of you said
5 you are. So pain is continuous. And C, pain
6 comes and goes. And we also have pain worsens
7 over time and other manifestation not mentioned.
8 So whoever answered that, I definitely want to
9 encourage you to share your comments.

10 So on this note, what I'd like to ask
11 is, you know, some of you have described -- and I
12 know that even some of you that provided your
13 comments and so forth mention that sometimes you
14 experience a flare-up or a time when your pain is
15 significantly worse than your average day of pain.
16 So I don't know if that's the right word to
17 describe it and I want you to tell us if flare-up
18 is the right word to describe it. But can you
19 share with us, you know, what an average day of
20 experiencing the pain or the tingling or the
21 numbness, what that is and then what your really
22 worse -- you know, what it feels like on your

1 worst day or your -- is there a flare-up and what
2 does that feel like. Oh, we have Lou and then we
3 have --

4 MR. SCHMITT: The way I describe -- my
5 pain's constant. It never goes away totally. But
6 the way I describe my pain is that it's as if
7 you're in a room and somebody comes in and turns
8 on a radio at kind of a low volume. When they
9 first turn it on, you hear the radio. But after a
10 while, you don't really pay that much attention to
11 the radio any more. So a good day for me is the
12 pain's there, but it doesn't get my attention all
13 that much. I go through my day. I do what I need
14 to do.

15 On a bad day, when there's a flare, it's
16 as if then somebody turns the radio up as high as
17 it can go and then now all you can hear is that
18 radio. And so, the pain becomes really, you know,
19 a kind of focus of my day when it's that bad. I
20 really can't focus on other things because the
21 pain is just so severe, you know, that it really
22 kind of takes over my consciousness at that point.

1 So that's kind of the way I experience the flares.
2 And by the way, when we talk about pain and we
3 talk about the symptoms that we get, my pain isn't
4 just different day to day. It's different moment
5 to moment. It is never exactly the same.

6 It becomes greater in intensity. It
7 becomes lesser in intensity. It moves to other
8 parts of my body. The sensations themselves go
9 from perhaps stinging then to stabbing, you know,
10 and burning. And it never is exactly the same
11 from moment to moment. But when there's a flare -
12 - that's what I call them. I call them flares.
13 When there's a flare, it's as if somebody just
14 turns the volume up on the pain way up and I
15 become much more consciously aware of it.

16 MS. GIAMBONE: And is it a certain
17 aspect? Like you mentioned stinging, shocking.
18 When you're having a flare, is it -- which one of
19 those is worsening or are all of those worse?

20 MR. SCHMITT: It becomes -- it becomes -
21 - instead of more -- instead of kind of a
22 stinging, a tingling, it becomes more of a

1 stabbing type of a pain. You know, it's as if --
2 when it's at its worst, it feels as if somebody
3 plunges a knife into my leg and just drags it down
4 my leg. And it's much more -- it's much more
5 focused in a certain area than the kind of
6 generalized stinging and tingling that I usually
7 get. It'll feel like somebody's pounding spikes
8 into my feet. You know, that sort of thing. And
9 that's how I describe the difference between, you
10 know, a flare and just the normal stinging and
11 tingling that I have pretty much all the time.

12 MS. GIAMBONE: Okay. Thank you, Lou.
13 Sharon, I know you had a question.

14 DR. HERTZ: We're hearing a lot of
15 similar descriptions or a spectrum for the painful
16 type of symptoms. And one of the things that we
17 try to do in clinical trials is have a consistent
18 endpoint to measure so that we can tell if the
19 drug is working. And because there are many terms
20 associated with the pain that is experienced with
21 painful neuropathies, it's challenging to know
22 what is the right question to ask so that the

1 effect can be measured.

2 So what I'm hearing, for instance, with
3 this last gentleman is that when the pain
4 intensity changes, there may be -- and this is --
5 I'm not sure if I'm hearing one or the other --
6 either just a much greater intensity that goes
7 from a pin to a knife or does it actually change
8 in quality? And I think what's important about
9 that is hearing that kind of feedback, when you --
10 if you were to be asked to keep a diary every day
11 as part of a pain study, how -- what is your
12 experience of trying to rate -- we usually ask for
13 like if you have multiple symptoms, what is the
14 most bothersome symptom and how would you
15 anticipate trying to rate that over time to see if
16 perhaps a new medicine was working?

17 MR. SCHMITT: Well, I mean, I do agree
18 that it's -- this pain can be very difficult to
19 describe. I mean, there are times when I have
20 sensations I really can't describe to other
21 people. And it would be very difficult and maybe
22 misleading for me to try and do that. But in

1 terms of a -- in terms of a pain diary, you know,
2 I think that I would obviously describe the
3 differences in the intensity of the pain and not
4 so much the location, because I can get it
5 anywhere, but more the intensity of the pain and
6 it seems when I get a flare, that the pain becomes
7 much more -- it becomes much more perceived in a
8 certain -- in more of a limited area.

9 I mean, usually I have pain and numbness
10 all over. But I'll start to get it, for instance,
11 for some reason on the outside of my right foot.
12 It will just feel like somebody's pounding a nail
13 into that over and over and over again and just in
14 that one location. And I may never have felt pain
15 like that ever in that location before. I may
16 never feel it in that location again. But it's
17 just at that point, that's what it -- that's what
18 I perceive. And that, to me, is something that I
19 could -- I'm sure I could catalog in some sort of
20 a diary and indicate where I'm getting it. And it
21 doesn't seem so much the location. It just seems
22 more of the change in the nature of the pain that

1 indicates a flare-up for me.

2 MS. GIAMBONE: Thank you. Thank you.
3 Graham, I'm going to look to you. How many people
4 do we have that want to dial in? we're
5 technically right into our break time. So if you
6 don't mind, can we take a few minutes of break
7 just to hear a few more comments, and then we'll
8 get right back on track? Okay. So can we take
9 one caller from --

10 CALL OPERATOR: Yes, the first comment
11 or question in the queue is from Eugene
12 Richardson. Your line is now open.

13 MR. RICHARDSON: Yes. Hi. I'm Colonel
14 Eugene Richardson, retired from the U.S. Army. I
15 have CIDP due to exposure to Agent Orange. And I
16 would be there today, except I'm in a wheelchair
17 most of the time, and I wanted to share about the
18 numbness if I walk more than 10 feet and attempts
19 to walk. I eventually become so numb, I will
20 collapse and then become so exhausted, I must go
21 to sleep. My legs are just basically gone, even
22 though I am on IVIG. But I didn't get that until

1 maybe 35 years after I was exposed and had
2 symptoms. And I'm grateful for IVIG because
3 otherwise I wouldn't be here talking to you. But
4 I am grateful for what you're doing and the work
5 of the FDA.

6 I remember that nortriptyline was the
7 only drug that helped me. The others, I ended up
8 tossing into the closet, which was not good. I
9 had nortriptyline until I got my IVIG started,
10 which I get every three weeks, go to the hospital
11 and get it and that's a godsend, but it's not a
12 hundred percent. It's not a cure. And to answer
13 that doctor, I would love have healing of the
14 nerves. I don't know whether that's realistic
15 because I'm 77 now, but would love to have the
16 healing and I'm fortunate now, even though I've
17 had hellish pains all over my body, including
18 screwdrivers being pushed out of my fingers, I
19 don't have quite as much pain anymore, I think
20 mainly because the nerves are pretty kind of
21 damaged. But I'm grateful for IVIG because that
22 keeps me going every 21 days. But I just wanted

1 to thank all of you for what you're doing today.
2 God bless.

3 MS. GIAMBONE: Thank you, Eugene. There
4 were a lot of heads nodding and -- [Applause.]

5 MS. GIAMBONE: And I hope you heard and
6 are seeing on the webcast that we are clapping for
7 you for sharing that personal story with us. So
8 thank you very much. And do we have -- Graham, do
9 we have a few more polling questions or is that
10 it? Okay. So as I mentioned, we are right into
11 break time. And just so we stay on time, what I'd
12 like to do is at least get your responses to the
13 polling questions so we capture those
14 perspectives. And we'll come back right after
15 break time to dive into more detail about
16 treatments.

17 So if you could get your clickers out,
18 and we did talk about this a bit, but just to sort
19 of I suppose revalidate it, what terms best
20 describe the most bothersome aspects of your
21 neuropathic pain, and you can choose up to three
22 terms. Numbness; B, tingling; C, burning; D,

1 stabbing or shooting pain; E, prickling, pins and
2 needles; F, electric shocks; or G, others not
3 mentioned. Okay. Oh, a nice wide spread here,
4 from numbness to others not mentioned. Okay, I see
5 a little bit of everything except for the electric
6 shocks and then we do see a lot of others not
7 mentioned. Can we quickly have somebody share, if
8 you identified others not mentioned, can you share
9 with us what you meant by that? Let's --

10 MARY: [Off mic] -- aching, which is --

11 MS. GIAMBONE: Aching --

12 MARY: -- not there.

13 MS. GIAMBONE: Okay. Thank you. And
14 your name?

15 MARY: Mary.

16 MS. GIAMBONE: Mary. Thank you, Mary.
17 Anybody else? Did you select others not
18 mentioned? Yes?

19 UNIDENTIFIED AUDIENCE MEMBER: Just real
20 quickly, cramping, migraines.

21 MS. GIAMBONE: Cramping, okay. Do
22 others experience cramping? One, two, three,

1 four, five, six, seven -- I'm seeing about seven,
2 eight -- eight hands raised. Okay. Anybody else,
3 other symptoms or other manifestations not
4 mentioned? Okay. I think we have one more
5 polling question. Okay. What are the most
6 bothersome impacts of your neuropathic pain on
7 your daily life? A, ability to participate or
8 perform activities; B, ability to fall asleep at
9 night; C, ability to stay asleep through the
10 night; D, ability to concentrate or stay focused;
11 E, ability to care for self, family or others; F,
12 impacts on sexual intimacy; G, emotional impacts,
13 such as fear or hopelessness; and H, other impacts
14 not mentioned. And you can choose up to three.

15 MARY: [Off mic] -- all of the above.

16 MS. GIAMBONE: All of the above, okay.
17 If we had an all of the above, would you select
18 that? How many of you would select that? Okay,
19 so we had about five hands raised for that.

20 MR. THOMPSON: Go ahead.

21 MS. GIAMBONE: Okay. So, okay, once
22 again, a wide spread. Let's see here. Really

1 everything, and it looks like we sort of captured
2 these biggest buckets of impacts. And on the Web?

3 MR. THOMPSON: Seventy percent said
4 ability to participate or perform activities and
5 50 percent emotional activities or ability to fall
6 and stay asleep.

7 MS. GIAMBONE: Okay. Thank you. All
8 right. So before we go to break, FDA panel, are
9 there any final questions that you'd like to ask?
10 I know that it's impossible to cover everything
11 that you're feeling about how you experience the
12 sensations of neuropathic pain and other
13 sensations in this timeframe. But we thank you
14 for what you've contributed. FDA, any final
15 questions? Okay. All right. So let's take a --
16 shall we say five-minute break or 10-minute break?
17 Let's take a 10-minute break and we'll be right
18 back.

19 [WHEREUPON, the foregoing went off the
20 record at 3:05 p.m., and went back on the record
21 at 3:18 p.m.]

22 MS. GIAMBONE: All right. So let's go

1 ahead and get started with our topic two
2 discussion. I know that topic one -- we had such
3 a robust and rich conversation in topic one, and
4 once again, I know that it's really impossible to
5 cover everything that you want to tell us and
6 there's so much I know to cover when it comes to
7 the way that you're experiencing the aspects and
8 sensations of your peripheral neuropathy. And so,
9 I'm going to put a plug in again for that public
10 docket. It is very, very important that if we
11 didn't get to -- that if you didn't get to share
12 what you wanted to say in topic one, please submit
13 it to the public docket. It is a very important
14 part. It is part of the public record. We will
15 read your comments and they will be incorporated
16 into the "Voice of the Patient" report. So please
17 don't feel that we didn't come to you. It's that
18 we're trying to stay on time, as best as we can.

19 Before we continue with topic two, I
20 want to look to Graham to hear from what came in
21 through the Web from the polling results. I know
22 that you mentioned there were some other aspects

1 not mentioned during our discussion.

2 MR. THOMPSON: In terms of when looking
3 at the terms that best -- most describe the
4 bothersome aspects of neuropathic pain, there was
5 a lot of focus on electric shocks and stabbing and
6 shooting pains and then for the question on the
7 most bothersome impacts of neuropathic pain on
8 daily life, 71 percent of people focused on their
9 ability to perform physical activities and
10 mentioned things like fly fishing, dancing,
11 driving and just basic social interaction.

12 And then, for -- whoops, hold on -- for
13 the question on how do neuropathic pain symptoms
14 typically manifest, I think we had zero percent in
15 the room saying these first two options, but on
16 the Web, we had 30 percent saying that the pain
17 appears suddenly and progresses rapidly and
18 another 30 percent saying that the pain appears
19 suddenly and progresses slowly and also a lot of
20 focus on how the pain has been worsening over the
21 duration since their diagnosis.

22 MS. GIAMBONE: Thank you, Graham. Yes,

1 Sara?

2 DR. EGGERS: Yes. So going back to the
3 comment that the gentleman on the panel made about
4 that maybe some of the people who are in the worst
5 pain aren't in the room, what I will suggest is if
6 you're on the webcast and you're -- and
7 particularly if your experience is different,
8 that's what makes the docket so important. If you
9 can -- if you're able to just write even a few
10 paragraphs and submit that in, it becomes very
11 helpful evidence that helps balance what we get
12 from folks who are able to come today in person
13 and folks who are not able to come today in
14 person. So --

15 PANEL #2 DISCUSSION ON CURRENT APPROACHES TO
16 TREATMENT (TOPIC 2)

17 MS. GIAMBONE: Thank you, Sara.
18 Absolutely. Okay. So let's get started with
19 topic two, which is on patient perspectives on
20 current approaches to treatment. Once again, we
21 have a panel of four. Our fourth panelist will be
22 calling in. but we're going to start first with

1 Linda. So once again, if you could press the red
2 button and start your comments?

3 MS. SPINELLA: Hi. I'm not as good as
4 the others. I'm going to read mine. I am 47
5 years old and I have had chronic neuropathic pain
6 for over 30 -- 13 years, excuse me. I have had
7 two low back surgeries. I work full-time and I
8 have a family. I am here to provide a summary of
9 my treatment journey, as I have had intermittent
10 relief from the pain that I experience and it
11 interferes with my activities of daily living, my
12 sleep and overall function.

13 Currently, I have multiple herniated
14 discs in my spine and my pain, on a scale of 1 to
15 10, ranges from six to eight while taking the
16 following medications: tramadol, diclofenac,
17 cyclobenzaprine, Lyrica, over-the-counter
18 supplements for bone and disc support, Tylenol as
19 needed and prednisone to reduce the inflammation,
20 as needed. I'm also seeing a chiropractor and an
21 acupuncturist twice a week.

22 I recently stopped physical therapy

1 because it was aggravating the pain in my neck and
2 lower back. I have a cervical traction unit that
3 I use at home. I had a cervical epidural in
4 February and I just had a lumbar epidural in May.
5 The following three days after the epidurals, I
6 had almost complete relief. The epidurals have
7 helped tremendously, but they usually wear off and
8 my pain goes back to between six and eight. The
9 current treatment regimen has been able to reduce
10 my pain as well. However, it causes drowsiness,
11 dizziness, lightheadedness.

12 I have trouble concentrating and
13 remembering information. I have gained weight. I
14 have swollen hands and feet. I have dry mouth and
15 a metal taste in my mouth. I also have occasional
16 leg cramps. I am so exhausted, yet I'm unable to
17 sleep through the night unless I take these
18 medications. Each time I roll over in bed, I wake
19 up from the pain. These were not the only
20 treatments that I've had. I got to where I am
21 today through a journey of treatments, beginning
22 over 13 years ago and it has included Percocet,

1 OxyContin or Vicodin, diazepam, cyclobenzaprine,
2 naproxen and prednisone. The dosages were
3 frequently tweaked and the side effects were hard
4 to manage. I was anxious, jittery and extremely
5 agitated. Under this treatment regimen, I had
6 difficulty driving a car, concentrating and
7 functioning.

8 I was also under chiropractic care,
9 which included traction, electrical stimulation,
10 ice and adjustments. The treatments would reduce
11 the pain, but it was temporary, meaning only a few
12 days to a week. I've also had multiple trigger
13 point injections, cortisone shots and epidurals,
14 which gave me temporary relief, meaning only maybe
15 a few months. But those procedures are limited,
16 if they actually worked. I've tried massages, a
17 therapeutic bed and pillows, ice, heat,
18 acupuncture, hydrotherapy, exercise, yoga and even
19 an inversion table.

20 Over time, the L5 herniation would heal,
21 but then reoccur maybe within 6 to 12 months, with
22 lower back and leg pain. Each time I went through

1 the same treatment process all over again, trying
2 to find relief and avoid surgery. But eventually,
3 I needed it.

4 In 2009, a discectomy was performed and
5 during recovery, I was on the similar medications
6 as before. After roughly six months, I achieved a
7 good level of pain relief and I was off all
8 medications and functioning well for almost two
9 years. In 2011, I herniated the disc again and I
10 was placed on the similar treatments. The pain
11 meds helped, but I was lightheaded, dizzy and it
12 was hard to concentrate. I also had the sensation
13 of feeling high. The anti- inflammatories made me
14 jittery and agitated and anxious. I was extremely
15 tired and I woke up feeling groggy. I had more
16 trigger point injections and was still under
17 chiropractic care. I was also in physical
18 therapy, but that aggravated it. I was unable to
19 get any relief from my back and leg pain. The MRI
20 showed that I was bone-on-bone in my lumbar spine.

21 So I finally underwent a lumbar fusion
22 in 2012. After the surgery, I was in physical

1 therapy, taking Vicodin, then Percocet and then I
2 began to feel better. About four months after the
3 surgery, I was medication-free and feeling good.
4 I was able to rejoin my bowling team and take long
5 walks with my dogs. However, I limited my
6 movement based on my own fear of reinjuring the
7 back. It took a while, but I began to feel
8 confident and started working out and exercising.

9 Just this past July, while exercising, I
10 herniated two discs in my cervical spine. I
11 started the same medication therapy all over
12 again. I also began cervical traction. I had
13 slight reduction in my pain. And in October, just
14 three months later, I herniated three more discs
15 in my lumbar spine. Same treatment continued and
16 physical therapy was added. I received a cervical
17 epidural in February, of this year, as well as a
18 lumbar epidural in May. The doctor has also
19 prescribed Lyrica for my lower back, neck and leg
20 pain. At the beginning, my pain was at an eight
21 or a nine. Now, I have days at five or six.

22 I have been on Lyrica since March,

1 starting at a low dosage. I am now up to 300 mg a
2 day. It has relieved a great deal of pain,
3 although I hope I can endure the side effects of
4 the medication, as it might be a long-term
5 treatment for me. It will hopefully give me
6 enough relief so I can sleep comfortably through
7 the night, walk and maybe endure some exercise so
8 I can lose weight without the drugs and I can
9 avoid another surgery. I realize this is my life
10 and the prognosis isn't great. The possibility of
11 reoccurrence will always be there. I hope there
12 is a treatment or a drug out there that can give
13 me some improvement in my condition and help me
14 consistently feel better and help me function at
15 the same time.

16 [Applause.]

17 MS. GIAMBONE: Thank you, Linda. Next,
18 we have Cherie.

19 MS. PAGETT: My diagnosis -- my
20 diagnosis is idiopathic small fiber peripheral
21 neuropathy recently expanded to autonomic
22 neuropathy. Although they say it's idiopathic,

1 there is some consideration given to the fact that
2 when I was 23, I had radiation therapy following
3 ovarian cancer and which resulted in radiation
4 ileitis. So you know, there's some doctors who
5 really like to make that connection. I
6 experienced my first neuropathic symptoms 18 years
7 ago, surrounding a 125-mile walking pilgrimage in
8 Northern Spain, beginning with neuroma symptoms
9 and toe numbness, then nerve pain, which have
10 increased over the years. I am now numb up to my
11 knees and in soul sapping pain at least three to
12 four nights a week, not as intense during the day,
13 and I'm totally unaware of foot injuries.

14 I've now begun having symptoms in my
15 fingertips and my left cheek. My current
16 treatment includes daily minimum prescription
17 medications: 3,000 mg of Neurontin, tramadol 600
18 mg and Mirapex 0.5 mg. I also take various over-
19 the-counter supplements. I sometimes use
20 prescription lidocaine ointment now that Medicaid
21 no longer covers the lidocaine patch, although I'm
22 not sure why, because that was helpful. I use

1 OxyContin and hydrocodone, cannabis oil and my
2 non-drug therapies include massage, ice packs and
3 heat pad for leg cramps. I meet twice a week with
4 a personal trainer, focusing on balance and core
5 strength, and I've recently begun an aqua-fit
6 class.

7 Over time, my medication dosages have
8 steadily increased, beginning with low- dose
9 Neurontin, now up to 3,000 mg a day, as I
10 mentioned, Lyrica, with which I gained 25 pounds
11 in six weeks and I couldn't stand that, Cymbalta,
12 I stopped after only a few days as I felt crazy
13 and like I was outside myself, topiramate
14 medication, which did help with weight loss, but
15 made the top of my head buzz and kept me on the
16 verge of tears.

17 Last year, I had four sympathetic nerve
18 blocks, which in no way changed my unpredictable
19 experience of good days and bad days. I've
20 resisted repeated suggestions of a spinal
21 stimulator trial and/or implant. It seems too
22 risky and difficult to remove. I've focused more

1 on balance with my personal trainer and I'm
2 contemplating the purchase of a TENS unit or the
3 rebuilder recommended by my neurologist, who
4 specializes in neuropathy.

5 How effective is all of this treatment?
6 I don't feel that the pain's really under control.
7 It attacks and abates when I least expect it.
8 However, I imagine the medication takes the edge
9 off. And despite the perceived side effects, I'm
10 reluctant to reduce dosages for fear of increased
11 pain. Massage and other therapies such as
12 acupuncture provide temporary relief. So I'm
13 thinking maybe it's time to explore meditation.
14 It seems I've been chasing this pain, increasing
15 medication dosages for the past 16 years or so.
16 The prospect of continuing on this same trajectory
17 not only contributes to my chronic pain-related
18 depression but also causes concern about what I'll
19 need 5 to 10 years from now.

20 For example, recently my peripheral
21 neuropathy led to Charcot arthropathy, which is
22 not Charcot-Marie-Tooth, in one foot, resulting in

1 a Lisfranc situation necessitating surgical
2 midfoot fusion. There's a possibility that the
3 same condition will develop in the other foot and
4 the prospect of a fusion fail worries me. I'm
5 also concerned that I'll be walker- dependent and
6 ultimately wheelchair-bound before my time. I
7 would say that my condition today is managed
8 certainly, but not well-managed. Significant
9 downsides to my current treatments include
10 debilitating, discouraging and downright dangerous
11 side effects such as weight gain -- 40 to 45
12 pounds since my initial diagnosis -- brain fog,
13 both of which are attributable to the Neurontin,
14 as well as drowsiness, difficulty focusing on my
15 writing and translating and positional vertigo.

16 Travel to Baltimore for neurologist
17 appointments and various clinical trials is time
18 consuming. Plus, driving any distance is risky
19 due to my tendency to drop off. Repeated nerve
20 biopsies, and most of us have suffered through
21 those painful nerve conduction tests. Numerous
22 negative treatment-related issues weight heavily

1 on my family, especially my husband. For example,
2 several years ago I asked my first neurologist if
3 there was any relation between my meds and
4 diminished libido and/or sexual arousal, to which
5 he too quickly replied in the negative. I was
6 curious then as to how the medication could block
7 pain only in neuropathy-affected nerves below the
8 knee. The connection is now recognized. I'm 70
9 and some might think it shouldn't matter so much
10 anymore. But in a healthy 45-year marriage, it
11 does continue to matter and we do lament that
12 loss.

13 Although I found it necessary to sell my
14 property management business five years ago due to
15 unpredictable pain, sleeplessness and lack of
16 focus and energy, I still have many regular
17 responsibilities relating to our family
18 investments and the care of our seven-year- old
19 granddaughter. I must often choose between
20 meeting these responsibilities or taking the time
21 to accommodate my pain and the treatment thereof.
22 We have an extensive wine collection, which is now

1 pretty much off limits to me due to the
2 restrictions imposed by my meds. Not a huge
3 sacrifice, but I don't think my husband will have
4 time to drink it all alone. Peripheral neuropathy
5 isn't going to kill me, in the short-term anyway.
6 But some of these medications can cause me to
7 entertain the idea.

8 I understand that my possession and use
9 of cannabis oil for pain relief is not approved in
10 the Commonwealth of Virginia, nor is medical
11 marijuana in other forms. There are those whose
12 constant pain is even more severe than mine. Even
13 at my worst times, when I'm doubled over by the
14 feeling of railroad spikes being driven into my
15 foot or rolling back and forth in bed and beating
16 the mattress because I can't tolerate the pain.
17 Surely, if medical marijuana can help anyone,
18 perhaps without the potentially devastating side
19 effects of opioids, it should be available to
20 peripheral neuropathy sufferers in all states.

21 [Applause.]

22 MS. PAGETT: And I think the rest of my

1 information here is pretty much shared by everyone
2 else. So I'll let you go ahead because I've taken
3 more --

4 MR. SCHMITT: Oh, thank you.

5 MS. GIAMBONE: Thank you very much,
6 Cherie. Next, we have Lou.

7 MR. SCHMITT: 2009 seems to have been a
8 bad year for a lot of the folks here, and for me
9 as well. I was -- I was stricken with CIDP in the
10 year 2009. I was diagnosed the following year and
11 I underwent 20 months of high-dose IVIG, which
12 sent my CIDP into remission. However, I suffered
13 significant damage to my peripheral nerves as a
14 result of my CIDP and the damage is permanent and
15 the pain that I suffer is constant.

16 What I currently do to help with -- to
17 treat my neuropathic pain is I do a lot. I think
18 overall I don't just focus on my nerve health and
19 trying to deal with my pain. I focus really on my
20 overall health in general. I think it's very
21 important to do everything you can for your
22 overall general well-being to deal with the

1 problem of your pain because it doesn't just help
2 with the pain, but it helps you feel better
3 emotionally if you are living healthier. I always
4 say that it's funny, I had to get sick to get
5 healthy because I never worried about my health
6 before I got CIDP. And once I got CIDP, it was
7 really all that I worried about. And I changed my
8 lifestyle. I became a vegetarian.

9 This lady mentioned meditation. I took
10 a 10-day course in Vipassana meditation, which is
11 a mindfulness mediation. And I highly recommend
12 that to anybody who has chronic pain. There are
13 studies I know that have shown that mindfulness
14 meditation helps to reduce your pain. It also
15 helps to reduce anxiety. It helps to reduce
16 depression. And there's a cycle here. There's a
17 mind-body connection between the physical
18 sensations and the physical symptoms and the
19 emotional and psychological components of it. If
20 you feel less depression, you feel less pain and
21 vice versa. If you feel less anxiety, you feel
22 less pain and vice versa.

1 And I always say that you don't have to
2 feel a lot better to feel a lot better. If you're
3 in chronic pain and you have pain every day of
4 your life, if there's a day that you feel even a
5 little better, trust me, you feel a lot better.
6 And that's a healthy spiral. And we can get into
7 unhealthy spirals, because I don't know anyone who
8 has chronic pain that hasn't suffered with a
9 depression as well. And you know, we were talking
10 earlier about would you rather have something that
11 helps with the pain or would you rather have
12 something that helps with the underlying disease.
13 And I will tell you there have been times I've
14 been in so much pain where I didn't think I could
15 keep going. And at that point, I didn't care
16 whether my nerves were healed. I just needed
17 something to give me relief from this pain.

18 There were times when I would -- I paced
19 for two or three days in a row. Forget about
20 sleeping and lying in bed. I couldn't sit because
21 of the pain. So some of the things I do -- some
22 of the things I've tried have been successful.

1 Many have not. I've tried -- massage and
2 acupuncture were not successful at all.
3 Acupuncture was in fact quite excruciatingly
4 painful. I don't know why I thought it would be a
5 good idea when I had damaged nerves to have
6 somebody stick a needle into them and twist it,
7 like that would feel better. It didn't.

8 I tried some medications that did not
9 help. I was on high-dose Neurontin initially,
10 over 4,000 mg a day. And it did nothing for my
11 pain. I will tell you all sitting here today that
12 Lyrica saved my life. There was a time when my
13 pain was uncontrollable and I could not sleep. I
14 could not even sit down. I couldn't do anything
15 but pace the house and vacuum the house. The
16 house was never cleaner than when I was in
17 terrible pain. But I tried Lyrica and almost
18 immediately got relief from the Lyrica. I take
19 450 mg of Lyrica a day, which is a fairly high
20 dose. I have been able recently to cut that back
21 to 300 mg. I kind of did that on my own. So don't
22 tell my doctor. But I wanted to see if I could

1 reduce it by doing some of these other things.

2 Another thing that I do that's very,
3 very helpful is exercise. I feel very blessed
4 that I don't have any physical limitations as a
5 result of my CIDP. I work out. I lift weights
6 three times a week. I hike four miles with my dog
7 in the woods, you know, four times a week. I do
8 those sorts of things and I found that those
9 things are extremely helpful to me physically with
10 my pain and mentally with the emotional aspects
11 that come with having chronic pain. At the
12 beginning, there was a time that I didn't know
13 what was happening when I was first coming down
14 with my CIDP and I had these symptoms, that all I
15 could do was take Advil and walk constantly. It
16 was the only thing that would allow me to reduce
17 the pain.

18 I feel my pain is very, very well-
19 managed. I do have days when I have significant
20 flare-ups. They usually last a week to two weeks
21 when I get a flare-up and they are quite
22 uncomfortable. But I think my pain is very well-

1 managed with the Lyrica and the other things that
2 I do. There are downsides, of course, to the
3 medication. I always describe the mental effects
4 as being in a speed boat and somebody throws an
5 anchor over the side. That's kind of how your
6 brain feels on Lyrica. It does cause drowsiness.
7 The side effects for me were worst the first month
8 that I took it. I felt intoxicated. I felt
9 dizzy. I was drowsy quite a bit.

10 My body seems to have adjusted and those
11 passed after about a month. I still am -- I get
12 some drowsiness with it. There is a potential for
13 weight gain. My weight's fluctuated a little bit.
14 I have swollen hands and feet. Sometimes they're
15 significantly swollen. A little bit of
16 forgetfulness. There are times when I -- my
17 short-term memory has been affected, I would say,
18 significantly at times. The Lyrica, sometimes
19 I'll be talking to people and in the middle of a
20 sentence, I won't be able to finish it because I
21 don't remember what I was saying when I started
22 the sentence. So those things -- those things do

1 come with the medication. You pay a price for it.
2 But it's been a miracle in my life and, as I said,
3 I think it saved my life.

4 An ideal treatment for me would be
5 something -- it would be a pill that I could
6 swallow that would take away all my pain
7 immediately and let me be the person that I was.
8 I don't think that's realistic. But I think a
9 medication that would control my pain, would
10 perhaps eliminate the flares that I get and would
11 have minimal to no side effects for me would be
12 the ideal -- and would be cheap, would be -- would
13 be the ideal, because Lyrica, by the way, is quite
14 expensive. So it would be, you know, reasonably
15 affordable, I think that would be -- that would be
16 ideal for me.

17 And if I had an opportunity to
18 participate in a clinical study, what would be the
19 factors that would go into that. I would have to
20 -- the first factor would be how I was feeling.
21 If I'm feeling pretty well, and as I feel now with
22 my pain, pretty well-controlled most of the time,

1 I don't think I want to be involved in a clinical
2 trial. I think if my symptoms were significantly
3 worse, I would probably be more receptive to being
4 involved in a clinical trial. I also would want
5 to know the potential side effects, of course,
6 long-term and short-term of whatever the regimen
7 would be in the clinical trial.

8 I am concerned, I will say, about Lyrica
9 because I have heard some things anecdotally about
10 long-term Lyrica use and perhaps an effect on
11 dementia. So that does -- that does concern me,
12 what effect it may have down the road. I know how
13 it affects me with the brain fog now and I think
14 long-term what might that do to me. So I am
15 concerned about that. So yeah, any clinical trial,
16 I would want to know what I was getting, what the
17 possible long-term and short-term side effects
18 would be and how effective it might be would be --
19 you know, if they could give me any kind of an
20 idea how effective the clinical trial might be, I
21 think that would also be very important to me.

22 MS. GIAMBONE: Thank you very much, Lou.

1 [Applause.]

2 MS. GIAMBONE: So our final panelist is
3 Jackie, and Jackie's going to be joining us on the
4 phone today. So here's a picture of Jackie. And
5 Jackie, are you on now? Are you on the telephone?

6 MS. EVANGELISTA: Yes, I am.

7 MS. GIAMBONE: Great. Welcome, Jackie.
8 And please go ahead with your comments.

9 MS. EVANGELISTA: All right. Well,
10 greetings, everyone, from Ohio. I'm sorry I
11 couldn't be there. My foot neuropathy is likely
12 secondary to nearly life-long Lyme disease that
13 was not uncovered until about five years ago when
14 I was 68 years old. I was given various diagnoses
15 over my life that, looking back, suggests that
16 Lyme was affecting me at a young age. Perhaps my
17 immune system was damaged, setting the stage for
18 the Lyme after I had the Asian flu in 1958 with a
19 high fever for 10 days. After that, my diagnoses
20 included inhalant allergies, paroxysmal atrial
21 tachycardia and adrenal fatigue in my 20s,
22 fibromyalgia in my 30s, Hashimoto's and food

1 allergies in my 40s, chronic fatigue syndrome and
2 osteoporosis in my 50s, CBO and Lyme in my 60s.
3 All of these may have been caused -- may have
4 caused a plethora of genetic defects to express,
5 which I learned about recently from the 2-3
6 immunogenic test.

7 Okay. Wait a minute here. I got lost
8 in my place. Okay. Foot neuropathy first
9 appeared in my mid-50s with the sensation that a
10 small child was standing on my feet and very
11 gradually escalated to the point about five years
12 ago that I was able to put the label of foot
13 neuropathy on what I was feeling. Since then, my
14 symptoms have included the feeling that I have a
15 wide band across my foot at the base of the toes,
16 numbness and tingling, as well as periodic
17 stabbing pains or electrical shocks and foot and
18 leg cramps.

19 Okay. My down arrow isn't working for
20 some reason. Sorry about that. Okay. These
21 however are only a small portion of those symptoms
22 caused by the Lyme itself. The doctor who

1 diagnosed my Lyme via the Western blot test tried
2 B-12 shots, which did not help. I don't recall
3 him having any other suggestions for therapy. A
4 Cleveland Clinic neurologist I consulted last fall
5 gave me a list of supplements, including alpha-
6 lipoic acid, which I had taken previously, and
7 resumed taking with no significant improvement, as
8 well as others which I was already taking. She
9 said I would probably have a lot of inflammation
10 and possibly the beginnings of an auto-immune
11 condition. But I was not offered tests for
12 inflammatory factors of Lyme disease or a possible
13 auto-immune condition. She admitted to not
14 knowing much about Lyme, and I suspect she's not
15 the exception.

16 Regarding my approaches to treatment, I
17 have generally eschewed drugs because of side
18 effects, which I discovered from the 2-3
19 immunogenic test may have resulted because I have
20 a gene that dictates I'd only need about half of
21 the normally prescribed dose of any medication. I
22 only started addressing my neuropathy a few years

1 ago because prior to that, it was an annoying but
2 tolerable condition. It seems that my neuropathy
3 continues to very gradually worsen and it's hard
4 to say because the change happened so slowly that
5 I think I get used to the new condition and can't
6 recall exactly how I was before.

7 Of late, I have sought out therapies
8 said to help the autonomic nervous system and
9 vagus nerve, which is what it seems Lyme has most
10 affected in my case, and that includes the heart,
11 the stomach, bladder, et cetera. I go for
12 acupuncture every two weeks in the summer and
13 weekly in the winter and get craniosacral therapy
14 as well as reflexology and chiropractic every two
15 weeks. It has helped some of my other symptoms
16 more than my foot neuropathy, probably because
17 foot neuropathy isn't related so much to the
18 autonomic nervous system. I take a number of the
19 supplements that should quell inflammation, if
20 that is the root of my neuropathy. But they have
21 not made a noticeable difference. Before bed, to
22 help with sleep, I use an essential oil foot

1 cream, homeopathic remedies and a low level light
2 therapy device on my feet that helps tone the
3 symptoms down, but does not eliminate them.

4 I have tried many dietary approaches and
5 do many things related to the larger Lyme issue.
6 The obvious downside of this approach is that it
7 only takes the edge off the neuropathy but does
8 not stop its advance and requires continuously
9 remembering and making time to comply with
10 therapies, even when traveling. More frustrating
11 is that I don't feel I understand the cause of
12 this symptom or the many others that I have that
13 are attributable to end-stage Lyme disease.

14 Given the lack of knowledge that
15 currently exists about neurological Lyme and the
16 fact that I usually have unpleasant side effects
17 to drugs, I doubt I would participate in clinical
18 trials should a drug be developed for my
19 condition. It would depend on the list of side
20 effects. I would underscore most emphatically
21 that more research is needed. Treatments with a
22 clear rationale really can't be developed until

1 the impact of Lyme on the nervous system over time
2 is fully understood. It has been reported that
3 300,000 people in the United States are diagnosed
4 each year with Lyme and a significant percentage
5 of them go on to develop the chronic form, often
6 because they aren't treated soon enough.

7 I realize that the concept of chronic
8 Lyme disease has not been totally accepted by some
9 doctors. However, it's hard for me to come up
10 with a rationale for all the medical issues I've
11 had over my life without seeing Lyme as being
12 involved or not causative. Knowing how slow the
13 wheels of research grind, I don't really have much
14 hope that treatments which might help me might
15 appear during my lifetime. But I do hope that
16 they will be developed in the next 20 to 30 years
17 and help the coming larger group of people who
18 will be presenting with foot neuropathy and other
19 symptoms of end-stage Lyme. Thanks for the
20 opportunity to give my input.

21 MS. GIAMBONE: Thank you so much,
22 Jackie.

1 [Applause.]

2 MS. GIAMBONE: Okay. So, so similar to
3 what I said for our topic one panelists, thank you
4 so much to our topic two panelists for all the
5 preparation you did. I know it's hard to put all
6 these thoughts down and get the short amount of
7 time to be able to express it all. But you did
8 such a great job, so thank you for doing that, and
9 thank you, Jackie, for joining us.

10 [Applause.]

11 MS. GIAMBONE: Okay. So I'd like to do
12 another show of hands and ask you in the audience
13 how many of you heard your own experience with
14 treatments reflected in the comments shared by at
15 least one of our panelists? Okay. So we have a
16 few hands here. But it sounds like probably other
17 experiences also then that were not shared. So
18 we'll get to those in just a minute here.

19 Let's do our next polling question, so
20 if you could get your clickers out. Okay.

21 Have you ever used any of the following
22 drug therapies to help treat your neuropathic

1 pain, and you can check all that apply: A, anti-
2 arrhythmic drugs; B, antidepressant drugs; C,
3 anticonvulsant drugs; D, transdermal or topical
4 patches; E, opioid pain medicines; F, prescription
5 NSAIDs -- I'm sorry. I am going to butcher a lot
6 of these words. So I'm going to say them as best
7 as I can. -- G, over-the-counter products; H,
8 other drug therapies not mentioned; or I, I'm not
9 taking any drug therapies. So you can check all
10 that apply. And those of you on the Web, please
11 be sure to enter your thoughts in as well.

12 Okay, so what we have here, we have
13 antidepressant drugs, anticonvulsant drugs,
14 transdermal or topical patches, opioid pain
15 medicines and then we have quite a few over-the-
16 counter products, other drug therapies not
17 mentioned. So we'll definitely be hearing from
18 that and then also --- well, 23 percent of you
19 that said I am not taking any drug therapies. So,
20 so let's start with those of you that are taking
21 some of these drug therapies. How many of you, by
22 show of hands, take at least one of these things

1 daily? Okay, so one, two, three, four, five, six,
2 seven -- we have about 14 hands raised. And then,
3 how many of you take these drugs only when needed?
4 Okay, so we have about three or four hands raised
5 for that.

6 Graham, what are we seeing on the Web
7 with the polling results?

8 MR. THOMPSON: We actually have very
9 different results on the Web. We have 57 percent
10 say they take antidepressants. Eighty percent say
11 they take anticonvulsants, 41 percent transdermal
12 or topical patches, 53 percent opioid pain
13 medicines, 54 percent over-the-counter products
14 and 41 percent say other drug therapies not
15 mentioned.

16 LARGE-GROUP FACILITATED DISCUSSION
17 ON TOPIC 2

18 MS. GIAMBONE: Okay. Thank you. So
19 without focusing let's say on one drug in
20 particular, can you -- would somebody like to
21 share your experiences with what specific aspects
22 of your neuropathic pain -- and I understand that

1 the pain comes -- you know, you have different
2 sensations of pain and different severity of pain.
3 But can you talk about what aspects of that pain
4 does the drug address or not address well? So
5 maybe if you could tell us what you're taking and
6 then what -- you know, is it working, is it not
7 working. What aspects of the pain is it
8 addressing or not addressing?

9 MS. LANNON: Narcotics just -- I take
10 narcotics just to make me fall asleep at night.
11 That's it.

12 MS. GIAMBONE: Okay. Okay. And do you
13 find that they help you stay asleep through the --

14 MS. LANNON: They don't help at all.

15 MS. GIAMBONE: They don't help? Okay.
16 Okay.

17 MS LANNON: [Off mic.]

18 MS. GIAMBONE: Okay, okay. And --

19 MR. KLITZMAN: I rarely --

20 MS. GIAMBONE: Oh, sorry. I just want
21 to say we do have a comment back there. So can we
22 make sure we get to her too? Yeah, go ahead,

1 Steve.

2 MR. KLITZMAN: Yeah. I rarely have
3 pain. But if I do, it just takes the edge off of
4 it. You know, and just -- I forget about it
5 basically after I take something.

6 MS. GIAMBONE: Okay. So it takes the
7 edge off. Okay. Meghna, let's go to -- yeah.

8 MS. BENSON: Yes. I take a cocktail of
9 meds.

10 MS. GIAMBONE: Okay.

11 MS. BENSON: I'm on Lyrica -- excuse me.
12 I'm on Lyrica, baclofen, meloxicam and oxycodone.
13 And it just -- on a scale of 1 to 10, usually mine
14 is 11. And it just takes the edge off. I'm on --
15 I have chronic pain every day and I live with it.
16 And it just takes the edge off so that I can
17 barely get out of the bed.

18 MS. GIAMBONE: Okay.

19 MS. BENSON: But most of the time, I'm
20 living in my bedroom.

21 MS. GIAMBONE: Okay. And your name?

22 MS. BENSON: My name is Mona Benson.

1 MS. GIAMBONE: Mona? Can you tell me
2 what are the -- I know you said it takes the edge
3 off.

4 MS. BENSON: Yes.

5 MS. GIAMBONE: What are the downsides
6 that you're experiencing with the cocktail that
7 you're taking?

8 MS. BENSON: What is the -- I'm sorry?

9 MS. GIAMBONE: What are some of the
10 downsides that you --

11 MR. KLITZMAN: The side effects.

12 MS. BENSON: The side effects?

13 MS. GIAMBONE: The side effects.

14 MS. BENSON: I --

15 MR. KLITZMAN: Memory?

16 MS. BENSON: The worst part of it is it
17 -- I lost my job. Basically I had to stop what I
18 loved doing. I was a television news producer. I
19 did that job for 28 years, most of it right here.
20 Well, I'm sorry, in Philadelphia, P.A. I had to
21 be very sharp. I mean, it was a -- it was a -- I
22 worked the noon show, noon news and that was

1 always where it was always breaking news. I mean,
2 it was one of those shows where every time right
3 before you went on the air, something was always
4 breaking and it was always something that you had
5 to run in and scripts always changed, as soon as
6 the anchors were going down, you know, to the news
7 -- you know, to do the news. You had to tell
8 them, okay, we're changing everything everybody.

9 Something is -- there's been a four-car
10 pileup or somebody's just shot somebody or, you
11 know, and you had to be sharp and you had to tell
12 them in their ear while they're reading something
13 else. You know, you had to be sharp and tell them
14 while they're reading what you're changing. And
15 I'm here taking -- I never told anybody for a year
16 that I had been diagnosed with CIDP. Here I was
17 taking Lyrica and oxycodone and I didn't tell
18 anybody. And I was having memory gaps and it got
19 to the point where I was -- at one point, I was
20 taking at least two or three Lyrica and oxycodone
21 before a show.

22 And at one point, I couldn't even

1 remember some of the things they were telling me
2 and I'm supposed to be telling a news anchor in
3 his ear and I can't even remember the stuff.

4 MS. GIAMBONE: Okay.

5 MS. BENSON: And I realized I couldn't
6 do this job anymore. And that was one of the
7 downsides, I guess.

8 MS. GIAMBONE: Absolutely. Absolutely.

9 MS. BENSON: Memory gaps, because --

10 MS. GIAMBONE: Thank you.

11 MS. BENSON: -- I couldn't -- I was
12 having brain fogs.

13 MS. GIAMBONE: Okay. Thank you very
14 much. And I know a few others had mentioned the
15 brain fog also. So it sounds like it's definitely
16 a significant downside. How about others? Can
17 you talk about what medications you're taking and
18 what specific aspects of the pain or the
19 sensations that you feel that it addresses or does
20 not address?

21 MS. WALDROP: Sure. I take gabapentin.
22 I take a lot of gabapentin, 3,300 mg a day.

1 That's 11 pills. Without it, I couldn't function.
2 With it, I can function. So all the symptoms that
3 everybody's described are just a whole lot less
4 with the medication. In terms of the side
5 effects, I'm honestly not sure. Brain fog is
6 there. But is it the fault of gabapentin or the
7 chemo I had or the fact that I'll be 70 in August?
8 I'm just not sure. But anyway, I wouldn't -- you
9 know, I feel like wherever I go, I have that
10 bottle or jar of my gabapentin pills. I just --
11 I'm tethered to it because it's miserable without
12 it.

13 MS. GIAMBONE: So anybody else? Would
14 you like to -- oh, sure. Let's -- we're going to
15 hear from this gentleman right here first.

16 BOB: Okay. My name is Bob and I have
17 Guillain-Barrés syndrome. And I take gabapentin,
18 which works for me quite a bit of the time. But I
19 try to exercise and I'm still learning that if I
20 go very -- do too much, it's very easy for me to
21 do too much and not feel the pain for maybe five
22 days or so. And that's when the gabapentin

1 doesn't cut it anymore. And I really haven't
2 changed anything at this point to address that.
3 But that's what I find is when I do too much, the
4 gabapentin is not enough.

5 MS. GIAMBONE: Okay.

6 UNIDENTIFIED AUDIENCE MEMBER: I had a
7 question for --

8 MS. GIAMBONE: It was like your GPS is
9 ready to get you out of here.

10 BOB: I thought it was off.

11 MS. GIAMBONE: No, that's okay. Don't
12 worry.

13 UNIDENTIFIED AUDIENCE MEMBER: I had a
14 question for the FDA panel. I know you approved
15 the safety and the efficacy of the drugs. What
16 about the long-term effects of drugs? I mean, do
17 you periodically go back and evaluate or look at,
18 you know, what are the long-term impacts of taking
19 Lyrica or gabapentin for 20 years or 10 years or
20 whatever, what does it do to you and do you change
21 your certifications on the basis of long-term
22 effects or --

1 DR. HERTZ: So the 20-year question is a
2 tough one. What we do at the time of approval for
3 drugs like this is we usually have data for about
4 a year of exposure, some safety information. But
5 once a product is approved, it is followed on a
6 regular, continuous basis. Right now, we have a
7 standard look after a newly approved drug meets
8 certain criteria in terms of time and number of
9 exposures. But what you'll see over time is that
10 products that have been on the market, once we
11 become aware of new information, we continually
12 update the labels.

13 So for instance, when the association
14 with suicidal thoughts was discovered for some of
15 the antidepressants and the anticonvulsants and
16 then it was explored to see if it was a class
17 effect or a drug-specific effect, and then the
18 products were all updated with that. So it's an
19 ongoing, continual process. But we don't have a
20 systematic way of evaluating that kind of really
21 long-term exposure. I'm not sure that any country
22 really has that. But we do consistently look for

1 signals. So for instance, some of you may be
2 aware that we recently updated the labeling for
3 all of the NSAIDs because we've been following the
4 risk for cardiac events. And that's been a very
5 challenging thing to explore over time. But it's
6 something that we're continuously looking at. So
7 for pretty much all of these drugs, we have
8 ongoing surveillance.

9 MS. GIAMBONE: Thank you, Sharon. Okay,
10 so let me look to my FDA panel to see if you have
11 any questions at this point.

12 DR. HERTZ: If people will bear with me,
13 I'd like to just go back and explore maybe a few
14 more people's thoughts on if you were going to be
15 reporting your -- it's the same question. I just
16 would like to get a little bit more input, if
17 people are so inclined. In terms of being able to
18 rate your pain over time and how -- how you think
19 it makes sense for us to ask you, how an
20 investigator in a clinical study, or even your
21 clinician, but clearly I'm interested in it also
22 from the perspective of development of drugs, how

1 -- how to get at the painful aspects and are there
2 any particular ways you think would be helpful in
3 terms of instructions to people.

4 MS. GIAMBONE: It looks like we have
5 several hands raised. Okay.

6 MR. MURPHY: Again, my name is Tim. It
7 seems to me that pain is a very personal
8 experience. And so, my thought is that when
9 you're evaluating a patient, you need to get a
10 baseline on an individual basis as to how do you
11 describe it. What are the components? You can
12 certainly use some of the common terms that are
13 used. But I think they mean different things to
14 different people. We all experience things
15 differently. And then, from that baseline, we can
16 -- and intensity -- and then, moving forward, you
17 can rate the effectiveness of whatever we're
18 measuring based on that initial evaluation. But I
19 think it's going to be different for everybody.

20 MS. GIAMBONE: Thank you.

21 MS. LEVINE: I totally agree with the
22 last speaker. I would say something like asking a

1 patient a baseline and then during a trial,
2 something like does your pain allow you to -- how
3 many hours a week does your pain allow you to work
4 or how many hours a night do you lose sleep
5 because of pain, rather than asking how do you
6 rate your pain or something.

7 MS. GIAMBONE: Thank you. Adam?

8 MR. HALPER: I would I guess be the
9 third person here to highlight that theme. I
10 think for me, I keep what I would say is a quasi-
11 pain journal and the reason I do that is, you
12 know, I've experimented with some different
13 medications and different alternative approaches
14 to treating my neuropathy and I've found it's very
15 useful to have -- I basically have a two-year set
16 of notes that I can scroll back through and see,
17 okay, well, this correlated with this improvement,
18 et cetera.

19 What I have personally found is that the
20 easiest way to measure improvement is
21 functionality. So it's -- you know, for me, it's
22 how far can I walk before it's time to sit down.

1 How long can I stand before it's time to sit down?
2 And I think those might be a little bit more
3 specific and measureable than, you know, rating
4 your pain on a scale of 1 to 10. And I think
5 Leslie is absolutely right. You know, you could
6 also look at, you know, can -- you know, how long
7 can you sleep without being woken up or you can
8 certainly expand the criteria. But for me, it's
9 really been, you know, just you could actually
10 measure functionally -- you know, give people a
11 Fitbit and they can get very specific right there.
12 Yeah.

13 MS. GIAMBONE: Thank you, Adam. Let's
14 go to Beth.

15 MS. LANNON: Is that on? I agree. I
16 was going to say both of those things too. The
17 other thing I would add to a questionnaire is what
18 your mood is. You know, how are you doing today
19 because that has a lot to do with how I will
20 answer how painful I am, is how good a mood I'm
21 in. So I think it's a rather complicated question
22 and diary to keep. Like you, Adam, I kept one too

1 for years. I wanted to be able to go into my doctor
2 and say this is how I felt every single day, from
3 morning to night. And I did always include those
4 things like -- but today, you know, I was able to
5 work. And so, even though I was in pain, I was
6 feeling pretty good. You know, I assess my pain
7 out of five because I've found my mood helps a
8 lot.

9 MS. GIAMBONE: Thank you, Beth.

10 MS. LANNON: So it's a complicated --
11 you should ask people to write up samples of what
12 they think a good pain scale is, like out on the
13 Web or something.

14 MS. GIAMBONE: So it looks like we have
15 -- oh, yeah. Go ahead.

16 DR. PATEL: I do have a question for
17 you, Beth. I know you described mood, I guess.
18 Could you give a little additional context to the
19 mood? What do you mean by mood, I guess? Could
20 you describe it a little further?

21 MS. LANNON: Oh, well I mean, I am a lot
22 more painful when I am feeling alone and

1 depressed. You know, if there's a weekend I have
2 absolutely nothing to do and nobody's invited me
3 anywhere, nobody wants to come visit me, I would
4 just say that I am in extreme pain. My pain is
5 screaming and I don't want to live anymore. But
6 if I go to work and I save a life, because I'm a
7 veterinary technician, I'm feeling pretty good and
8 that pain's not so bad anymore. Does that answer
9 it?

10 DR. PATEL: Yeah, it does. And also, I
11 have -- just getting back to the question that
12 Sharon asked, I guess, you know, there are many
13 aspects that I think Adam mentioned about, you
14 know, cannot walk. You know, I used to be able to
15 walk 10 miles, I guess. Now I can only walk a
16 mile but with a lot of pain. What else is
17 important that you think that we should include in
18 questionnaire for clinical trials? You know, I
19 know the numbness I heard was one of the
20 questions. But again, you know, I'd like to hear
21 other thoughts.

22 MS. GIAMBONE: Sure.

1 UNIDENTIFIED AUDIENCE MEMBER: One of
2 the goofy things about this disease is that pain
3 not be an absolute indicator of the progression of
4 the disease. As mine has gotten worse over the
5 years and the numbness has come up, where it used
6 to really hurt and be oversensitive, now it's not.
7 It doesn't hurt. I'll get, you know, the
8 pitchfork through the foot thing at night. But
9 the daily kind of pain may not be as intense.
10 That may not be an indicator of improvement or
11 anything.

12 MS. GIAMBONE: Okay. Thank you. And it
13 looks like we have one more comment.

14 MR. YADLON: Two quick comments. Number
15 one, a lot of these questions are on the Social
16 Security Disability application that you may want
17 to read because a lot of that is similar
18 questioning about what you do and how long you do
19 it, et cetera. And second, nobody's really
20 mentioned water therapy. Anybody doing water
21 therapy, pool therapy? Yeah. I think it's an
22 excellent way of relieving and making you feel a

1 lot better mood-wise as well.

2 MS. GIAMBONE: Great. Thank you. And
3 sorry, your name?

4 MR. YADLON: I'm sorry? Oh, my name is
5 Jim.

6 MS. GIAMBONE: Jim. We have a question
7 coming up with other therapies outside of the drug
8 therapy. So I'm glad you brought that up, the
9 water therapies. Now, I do want to ask a
10 question. Several of you mentioned that you've
11 tried different therapies and that's brought --
12 you know, you talked about a treatment journey,
13 that it's brought you to your current set of
14 treatments. And I'm curious how long do your --
15 how long do you try a treatment before you know
16 that it's working or it's not working? And if you
17 can talk a little bit about that treatment journey
18 and how your treatments have evolved? Can you
19 share some perspectives on that? Jim?

20 MR. YADLON: I'd say a lot of -- a lot
21 of new pills or -- always say three or four weeks.
22 You have to give it some time to work. Some work

1 right away. But most of them take some time.

2 MS. GIAMBONE: Okay. And I guess on
3 that note, to ask you when you change -- you know,
4 when you've had to change your therapies, is it
5 primarily because they -- you know, the bothersome
6 side effects or was it some sort of -- did it lose
7 effectiveness? What were the reasons maybe why
8 you changed? Tonya?

9 MS. CHARLESTON: I would say it was the
10 side effects for changing because I would say my
11 first two years or so, I did IVIG, tramadol and
12 Lyrica. Somewhere around the third year mark,
13 third -- or three-and-a-half-year mark, I was
14 like, okay, no Lyrica, no tramadol because too
15 much fogginess, too much. I can't do anything.
16 I'm sleeping all the time. Let's try something
17 else. So then we switched to plasmapheresis and
18 another drug. Oh, and we got off the prednisone
19 because that makes you swell, too much swelling.
20 I didn't even recognize myself.

21 So about the fourth year, I would say
22 weaning off all of the heavy stuff and then going

1 more to over-the-counter and just more or less
2 recently, we've decided to try Celebrex because
3 the doctor was saying that a lot of people with
4 arthritis were using the Celebrex and they didn't
5 have foggy mind or sleepiness and fatigue. And
6 they were able to take the edge off the pain but
7 still be functionable. So I've been trying that
8 for about two months or so now. And it's a little
9 bit better, you know, as far as taking the edge
10 off. But I've not found a balance where there is
11 no pain or like total relief at any point in time.
12 So it's usually because of the side effects and I
13 want to be active.

14 MS. GIAMBONE: Okay. Now, a few of you
15 have mentioned that the treatments that you take
16 help take the edge off. And so, can you describe
17 what that means? What does it mean? And maybe
18 that's closer to Adam's point about how can I walk
19 a little bit longer or am I able to do an activity
20 a little longer? Would somebody mind describing
21 what you mean by that and sort of I guess how you
22 -- how does that define whether the treatment is

1 working or not, if that makes sense? Yeah?

2 MR. GLENN: Okay. Hi, my name is
3 Luther. That's a term I use all the time, and the
4 way I define it is if I had not taken my
5 medication today, I'd be in bed right now. So
6 it's a -- for me, it's a term I use that would get
7 me out of bed. But I'm always in pain. It's just
8 the degree of pain that I'm in. And so, getting
9 out of bed is a lot -- it's what I call taking the
10 edge off.

11 MS. GIAMBONE: Okay. And Luther, can
12 you elaborate a little on your treatment regimen
13 and, you know, what is working for you or what's
14 not working for you?

15 MR. GLENN: Well, I'm still living with
16 a great deal of pain and I've been through all the
17 gabapentin and the Lyrica and all of it still is
18 the same to me. All it does is take the edge off
19 for me. And I take Lyrica three times a day,
20 Neurontin twice a day, naproxen twice a day. And
21 all that together, it just takes the edge off.
22 I'm sitting here and I'm still in a lot of pain.

1 But when I'm around people and doing other
2 activities, it seems to help a lot. But mostly
3 it's if I can get out of bed, I'm pretty much
4 satisfied for right now.

5 MS. GIAMBONE: Thank you, Luther. I saw
6 a lot of heads nodding. And Meghna, you were
7 saying? Cherie, you had a comment or Linda?

8 MS. PAGETT: You have a lot more
9 experience than I. Go right ahead.

10 MS. SPINELLA: I was just going to add
11 that dull -- it would dull the pain to some
12 degree, to make it maybe a dull ache rather than a
13 stabbing or shooting pain. Maybe the jolt that
14 you -- or I feel when I have my herniated disc, if
15 I turn a certain direction or I move too quickly,
16 I get such a jolt that takes my breath away. So
17 those opioids and the Lyrica is helping to try to
18 take it down a notch and keep it so I can
19 function.

20 MS. GIAMBONE: Okay. Thank you. Okay.
21 An I think we have -- oh, Cherie? Yeah?

22 MS. PAGETT: I was going to say pretty

1 much the same thing. It's the sharpness that goes
2 away. It's the, oh my God, I can't stand this,
3 you know, I've got to have my teeth gritted to,
4 okay, I can take a deep breath and I can bear this
5 now.

6 MS. GIAMBONE: Okay.

7 MS. PAGETT: Or at night, it's the
8 difference between going asleep and not.

9 MS. GIAMBONE: Okay. Thank you, Cherie.
10 Graham, can you give us an update on what we're
11 hearing on the Web, and then we'll move to our
12 next polling question?

13 MR. THOMPSON: We've heard a wide range
14 of treatments mentioned on the Web, from
15 Neurontin, Lyrica, gabapentin, different
16 compounding creams. In terms of non-drug
17 therapies, meditation, audiovisual stimulation,
18 things like hand controls for steering wheels so
19 that your feet don't have to do as much and things
20 like that. In terms of side effects, a lot of
21 people have mentioned things like dizziness and
22 constipation and other sorts of things.

1 MS. GIAMBONE: Thank you. Now, many of
2 you indicated that there are other drug therapies
3 not mentioned. Would somebody mind sharing what
4 are some of those other drug therapies that you're
5 using? Why don't we come to Lawrence here?

6 LAWRENCE: Thank you. First of all, I'd
7 just like to say I am so impressed with your
8 facility. You've certainly come a long way since
9 you were on Wisconsin Avenue and impressed with
10 the conference and the leap that you've made is so
11 commendable to have us patients involved. Really,
12 you all are to be commended tremendously, your
13 time and effort.

14 [Applause.]

15 LAWRENCE: I have a very complex
16 situation. I have a myeloproliferative disorder,
17 polycythemia vera and I started -- my mother had
18 neuropathy and I started to develop the neuropathy
19 before I went on treatment. I'm going for the
20 world's record on interferon, which is sort of --
21 not a real chemical therapeutic agent, but it's an
22 agent which also can cause neuropathy. So with my

1 doctors, we can't figure out what aggravates what.
2 And I think this happens with a number of us, that
3 you really don't know. It's such a broad range of
4 things.

5 What I -- what I have found, I
6 discovered, first of all, tai chi has just done
7 wonders. I think it's really, really amazing.
8 I've noticed -- I go to the senior center tai chi
9 class, that all of a sudden, my balance has gotten
10 a lot better and my feet are numb too. And I've
11 found when I drive, I have to keep my foot on the
12 hump to make sure I don't go through the -- and
13 hit the brake pedal and the gas pedal. And so,
14 I've developed strategies.

15 And just in addition, what I feel about
16 this disease is that I wish I didn't have it, or
17 any of these. But I have had so many wonderful
18 experiences and met so many wonderful people. The
19 one thing I'm using now is called a rebuilder.
20 It's sort of like nerve conduction in water. And
21 I'm pretty sure temporarily it alters my
22 perception of the pain. And after I use it for

1 about six hours, my feet feel great. My
2 condition, my neuropathy is very intermittent and
3 I've lost a lot of my small muscle -- my small
4 nerve fibers. But I found that that was
5 excellent.

6 And then, I would just like to say I'm
7 hoping to hear about the use as a standard of
8 nerve biopsy. I think that might be one, concrete
9 tangible way, and also about the nerve
10 regeneration medications. I think in other
11 diseases, in certain carcinomas, they're making
12 headway into looking at that after -- post a
13 chemotherapeutic treatment. And then, the laser,
14 there's a program where they're talking about
15 rejuvenating nerve cells with a laser. So I don't
16 know. That's my thoughts.

17 MS. GIAMBONE: Thank you, Lawrence.
18 Thank you very much for -- yeah, and let's --

19 MR. SHROUT: The main thing that drove
20 me up here today to participate in this was being
21 in blind pig mode and stumbling on a gem, I think.
22 There are a lot of supplements out there in snake

1 oil land. I stumbled across one about six months
2 ago that has amazingly, surprisingly, unexpectedly
3 impacted my neuropathy. It's going to tell the
4 name so folks listening and in the room may be
5 able to take advantage of this. I'm not trying to
6 chauffeur these guys.

7 But it's Elysium Health and the name of
8 the product is Basis. There's five Nobel
9 laureates on their panel. these guys are selling
10 this as a mitochondrial cellular health supplement
11 and they're doing it as a supplement because you
12 get processed -- you guys know better than
13 anybody. I took it because I thought maybe I'd
14 get a little more energy out of this. I'm an old
15 guy too. I'll be 70 soon. I thought, yeah, maybe
16 a little more pep in the day. Two months later,
17 much to my amazement, my feet that were numb
18 aren't numb anymore and I think it is having a
19 healing effect on my small fiber nerves as a
20 positive impact on the neuropathy.

21 I would really love it if you guys could
22 go ping these guys and poke at them and say, hey

1 dudes, go do some clinical trials. They promise
2 they're going to do this. They promise they're
3 going to do it in scientific mode. I'd love to
4 see somebody on your side of the fence really work
5 with these guys. Make them hold true to their
6 word, and who knows, this could become a nerve
7 regeneration medication totally unexpectedly. So
8 that's why I'm here today. Thanks.

9 MS. GIAMBONE: Thank you. Thank you for
10 that. Any other drug therapies not mentioned that
11 you'd like to bring up? Sorry?

12 UNIDENTIFIED AUDIENCE MEMBER: IVIG.

13 MS. GIAMBONE: IVIG. Yeah. Okay.
14 Thank you. All right. So let's move on to --

15 FDA panel, any questions before we move
16 on to other therapies, non-drug therapies? Okay.
17 All right. Let's go on to our next polling
18 question. All right. So everybody get your
19 clickers out again. Besides the therapies
20 mentioned previously, what else are you doing to
21 manage any symptoms you have experienced because
22 of your neuropathic pain? And you can check all

1 that apply: A, surgical destruction of nerves; B,
2 TENS; C, cannabinoids; D, dietary and herbal
3 supplements; E, diet modifications and behavioral
4 changes; F, complimentary or alternative
5 therapies; G, physical or occupational therapy; H,
6 other therapies not mentioned; I, I am not doing
7 or taking any therapies to treat symptoms. And
8 we've actually -- we've touched upon several of
9 these and we've also heard aqua therapy. But
10 let's see what else people are doing.

11 Okay. So again, a pretty wide range.
12 We have touched on several of these. So I'm going
13 to look to H, which is other therapies not
14 mentioned. And so, I'd like to ask what are some
15 of the other things that you're doing to manage
16 the condition. Adam? And then, we'll come to
17 you. Go ahead.

18 MR. HALPER: Yeah. So I'd list -- and
19 I'm sort of discovering these through trial and
20 error as I go. But I'd say there are five in the
21 supplementary/alternative realm that I've
22 personally found to be helpful. The first is

1 Epsom salt baths. Epsom salt is magnesium
2 sulfate. You need to use a lot of it. But I
3 personally found that, at least in the short-term,
4 it can really take the edge off of the burning
5 pain and to say that is to say I can go into a
6 bath with a lot of pain and walk out feeling fine.
7 So that's something I would highly encourage
8 people to at least experiment with because it's
9 not exactly high risk.

10 A second, I know other folks in the room
11 have probably tried this, I've personally found
12 massage of my legs to be very effective as a
13 short-term remedy. The third point I would make,
14 particularly for folks who have functional
15 limitations like I do, is just experimentation
16 with different types of footwear. So I've found,
17 for example, that if the surface I'm walking on is
18 softer, it makes an extraordinary difference, so
19 different types of orthotics, different types of
20 orthopedic footwear at least in my situation can
21 really change the game.

22 A fourth is -- and this would tie in

1 with physical therapy, but different types of
2 stretches I think in my case have really made a
3 difference and particularly what I would call
4 dynamic stretching, which is, for those who aren't
5 familiar, instead of a fixed stretch, it's you're
6 actually moving as you stretch. So it's sort of
7 like a leg swing and those types of things where
8 you're actually getting the blood flowing. I've
9 found those to be pretty effective. And then,
10 finally, I would second Louis and I would say that
11 I'm a firm believer in both the physical and
12 psychological benefits of meditation practice.
13 And I was fortunate in that I had a practice
14 before I even developed neuropathy. But you know,
15 I can't say strongly enough how valuable it can be
16 if you're dealing with something like this.

17 MS. GIAMBONE: Adam, a quick follow-up
18 question for you. So when you talk about the
19 Epsom salt baths and the massage --

20 MR. HALPER: Yeah.

21 MS. GIAMBONE: And you mentioned it
22 gives you relief. How long is your relief?

1 MR. HALPER: Yeah. I think that's hard
2 to quantify. You know, certainly -- I mean, I
3 think the most useful situation is, you know,
4 there are just some days, for whatever reason, I'm
5 experiencing burning pain. And so, if I take that
6 bath at night, more often than not I'm able to
7 just go to sleep, no problem. Is it possible that
8 there's some carryover effect to the following
9 days? Absolutely. And my intuition is that there
10 might be. But it becomes a little harder to
11 quantify.

12 MS. GIAMBONE: Thank you. Any other
13 comments? Yeah, let's --

14 MS. WALDROP: Yeah. I'd just like to
15 third what Louis said about the importance of
16 exercise. I think any kind of movement has been
17 extraordinarily helpful for me. I too think that
18 the dynamic stretches -- tai chi has helped. I
19 work on my balance all the time. I mean, really
20 all the time. And I think this psychological
21 benefit you get as well as physical, functional
22 improvement just can't be overestimated. But I

1 also had a question and that is whether anybody in
2 the group here has tried reflexology, where they
3 really concentrate on your feet? And did it help?

4 MS. GIAMBONE: So we're hearing --

5 UNIDENTIFIED AUDIENCE MEMBER: [Off mic.]

6 MS. GIAMBONE: Okay. So it felt great
7 while they were doing it. Okay, and we'll take
8 one more comment.

9 JEREMY: My name's Jeremy. I don't know
10 whether this is placebo effect or not, but I've
11 had very good luck with yoga. I've been -- I can
12 work a lot further since I started yoga. But I
13 have been doing it for a couple of years.

14 MS. GIAMBONE: Great. Thank you,
15 Jeremy. I'm going to ask you a few questions.
16 I'm going to read a few statements out loud and
17 we'll do a show of hands and then I promise I'll
18 come to you. I promise. Okay. So since we are
19 talking about -- you know, we talked about
20 prescription drug therapies. We've talked about
21 some non-prescription drug therapies or non-drug
22 therapies. So how many of you would say that your

1 first focus for treatment is a non-drug approach
2 such as making changes to your lifestyle or pacing
3 your activities or -- okay. So we have four hands
4 raised for that.

5 How many of you would say collectively
6 your non-drug therapies or lifestyle changes give
7 you as much or more overall benefit than your
8 medications? So how many of you would say that
9 your non-drug therapies or changes that you've
10 made give you as much or more benefit than your
11 drug therapies? Two, three, two-and-a-half.
12 Okay. And then how many of you would say that
13 your non-drug therapies are important but that
14 they can't match the benefit of your medications?
15 Four, five, six, seven, eight, nine, ten, eleven
16 twelve -- 12 hands raised, 13 hands raised. Okay.
17 Great. Thank you. That really helps put a lot of
18 perspective around this.

19 Graham, are we hearing anything on the
20 Web?

21 MR. THOMPSON: Mostly consistent with
22 what we're hearing in the room.

1 MS. GIAMBONE: Okay. Great. Let's do -
2 - let's do another show of hands as we're
3 approaching, believe it or not, the closing of our
4 afternoon session shortly. So thinking about all
5 of your therapies together, how many of you feel
6 that you're managing your pain as best as you can?
7 Okay. We have about 16 hands raised for that.
8 And this sort of goes into our discussion on ideal
9 treatment. So let's talk a little bit about ideal
10 treatments before we move into our scenario. So
11 you know, we talked about specific aspects of your
12 neuropathic pain and we even talked a little bit
13 about sort of, you know, is there a particular
14 sensation that's worse than the other sensation
15 and so forth. So you know, for those of you that
16 said your condition is not well-managed -- you
17 know, many of you said your condition is not well-
18 managed. What are the aspects of an ideal
19 treatment that you look for? Leslie?

20 MS. LEVINE: This is something that's
21 not on the list, that at least most of the 60
22 people in my neuropathy support group feel, that

1 their pain is more manageable if you're -- if
2 you're in something like a support group where
3 you're with people who understand that neuropathy,
4 while it's invisible, produces real pain and know
5 what people are going through. It's very helpful
6 to have peers.

7 MS. GIAMBONE: Thank you, Leslie. And
8 we -- yes, Linda?

9 MS. SPINELLA: I think ideal treatment
10 includes a good night's sleep. I think sleep is
11 very underrated, should be very important, whether
12 it comes from the drugs or whatever. You feel much
13 better if you've had a good night's sleep. When
14 you don't, that's it. I would like to see a drug
15 that covers more, so I don't have to take a whole
16 list of drugs to cover certain aspects of my pain
17 or, you know, other side effects, take a drug to
18 cover that side effect or something like that. If
19 there is a broader -- like Lyrica is a broad drug
20 that covers a lot. So, but I would like to see
21 something like that.

22 MS. GIAMBONE: Linda, just to follow up

1 to your question -- or to what you just said,
2 thinking about your current treatment regimen,
3 what aspect of your neuropathic pain symptoms or
4 the way your symptoms manifest does your treatment
5 regimen not address at all? I mean, you mentioned
6 that you'd like something to help you sleep
7 through the night. So is that -- in your current
8 treatment regimen, are you not able to have --

9 MS. SPINELLA: Yes. I get that from a
10 muscle relaxer. I get that every night. Along
11 with everybody else, I also have the tingling that
12 the Lyrica -- they say that I have scar tissue
13 from the surgeries that I've had. So that's why
14 I'm getting the Lyrica. And that should help with
15 the tingling. So far, I haven't found any relief
16 from that, although it's helped with the pain.

17 MS. GIAMBONE: Okay.

18 MS. SPINELLA: So I understand what
19 everybody is saying about the numbness and the
20 tingling.

21 MS. GIAMBONE: Okay. Okay. Thank you,
22 Linda. Cherie?

1 MS. PAGETT: I think one of the reasons
2 I've said that my pain is managed but perhaps not
3 well-managed is I don't know how much longer I'm
4 going to live or live with this pain, whether it's
5 going to be another 10 years or 15. So I've not
6 maxed out on the meds I'm taking. Yeah, I could
7 go to every night and take up to the 3,600 or
8 whatever it is of the gabapentin and I could take
9 a couple of OxyContin. But I'm afraid what that's
10 going to do, not only short-term but long-term and
11 where am I going to turn in 10 years when the pain
12 is more intense. And so, I hold back until I
13 can't take it anymore basically.

14 MS. GIAMBONE: Sure.

15 MS. PAGETT: Last night, before I went
16 to bed, I knew it was important that I slept. So
17 I did take some oxy -- whatever it was. I don't
18 even remember what it was. But I did take some so
19 I could sleep.

20 MS. GIAMBONE: So Cherie, following up
21 to what you just said then, what would you look
22 for in an ideal treatment?

1 MS. PAGETT: Something that would not
2 have the side effects, I mean, because when I --
3 if I do take 3,600 mg of gabapentin, I'm not much
4 good the next day or wouldn't have the potential
5 addictive problems that the opioid products do.
6 So it's sort of a scary field out there and I
7 would just like something that I could take and
8 wouldn't have to worry so much about the
9 consequences.

10 MS. GIAMBONE: Sure. Thank you. Yes,
11 Linda, let's hear from you and then we'll go --
12 I'll go back to the other --

13 MS. SPINELLA: Sorry. One more thing.
14 As Cherie already said, you know, I'm only 47. I
15 am worried about what'll happen to me in 10 years,
16 15 years, 20 years. And with the mention of
17 Lyrica, if I am on this for long-term, what are
18 the long-term side effects. That would be in the
19 ideal treatment too, that you're going to have a
20 drug that doesn't have something so damaging as
21 dementia or some other long-term effect on your
22 brain.

1 MS. GIAMBONE: Thank you, Linda.

2 Meghna, yes? Yeah, Steve?

3 MR. KLITZMAN: Yeah, going back to one
4 of my earlier comments, ideally I would love to
5 see a drug that did reduce or eliminate the
6 numbness and regenerated the nerves. But
7 realistically, I'm not sure there's enough
8 research, you know, basic research going on now to
9 do that. And then, let me just follow up on this
10 woman's comment about the support groups. I lead
11 the only support group in Maryland, Virginia or
12 D.C. We have 150 members, a wide range of
13 neuropathies. We meet once a month in Annandale,
14 Virginia. We have speakers that come in that help
15 us, you know, professional neurologists and
16 podiatrists and physical therapists and
17 nutritionists.

18 But the main benefit we get from it is
19 we help each other psychologically, emotionally.
20 We can speak to each other's pain. We sort of
21 understand what we're dealing with. We have nine
22 people who are here today who are in the group,

1 including Cherie and Beth, and six or seven others
2 of us. And I have a flyer here about the group
3 and there's also one on the table outside. So if
4 anybody's interesting in joining a support group
5 in this area, D.C., Maryland or Virginia, you
6 know, speak to me. There's unfortunately not
7 enough of them in the country.

8 We did a -- we did a study in the state
9 of Virginia a few years ago and we had Governor
10 McDonnell at that time sign a proclamation and we
11 put it through the Department of Health in
12 Virginia. And we estimated that there were
13 500,000 people just in the state of Virginia that
14 had a form of neuropathy, 500,000, based on the
15 number that the neuropathy association came up
16 with, that there are about 45 million Americans
17 that have diabetes and about half of them have
18 neuropathy. So they estimated maybe 20, 25
19 million Americans have neuropathy. And so, just
20 in the state of Virginia, 500,000. And we're the
21 only support group in the entire D.C. Metro area.

22 So there's probably thousands, if not

1 hundreds of thousands of people around the country
2 that really could use the benefit of a support
3 group and certainly could benefit from medication
4 and treatment and other alternatives. And
5 unfortunately -- this isn't the forum for it --
6 there's a tremendous amount of underfunding to
7 study neuropathy. At the NIH, a \$5 billion
8 budget, they spend about \$150 million a year on
9 neuropathy compared to Alzheimer's and epilepsy
10 and stroke and other neurological diseases.
11 Neuropathy is an orphan disease. It doesn't get
12 very much attention and yet it affects millions of
13 people. And it seems to be increasing in recent
14 years. Younger and younger people are coming down
15 with it.

16 I mean, I'm 71. But we have people in
17 our group that are in their 20s and 30s and that's
18 really sad for me that, you know, they're that
19 young and getting this disease. And there's
20 really not enough basic research going on as to
21 why, what is causing the disease, why does it
22 progress. Just calling it -- just saying it's

1 caused by diabetes -- it's dealing sort of with
2 the surface symptoms of it. But there's very
3 little money being spent on basic underlying
4 research as to what is causing neuropathy and why
5 does it persist in this society.

6 And you know, people say, you know,
7 assuming there's no cure -- well, why should there
8 be no cure? There should be a cure for it and why
9 isn't more attention being given to it? There
10 should be more attention. If members of Congress
11 had neuropathy, you know, maybe we'd get more
12 funding for it. I don't know. They don't want to
13 admit that they have it, I guess. But I'm sure
14 there are probably dozens of members of Congress
15 that have peripheral neuropathy. But they haven't
16 spoken about it, so --

17 MS. GIAMBONE: Thank you, Steve. Thank
18 you. Okay. So I know we have a few people
19 waiting on the phone. Let's -- I'm going to tee
20 up the phone here and we'll get to them in just a
21 minute here. Let's go to our scenario question,
22 which is coming up next. Okay. So we're going to

1 do a short scenario. And what this is, is I'm
2 going to read you just a very short blurb. It
3 really doesn't contain a lot of information and I
4 know that information is very important. But
5 after I read this, I want you to just tell us the
6 first thoughts that come to mind. It could be a
7 question. It could be a comment. It could be a
8 decision. Whatever it may be is perfectly fine.
9 But we just want to hear from you.

10 So imagine that a new medication to
11 treat neuropathic pain associated with peripheral
12 neuropathy has recently been approved by FDA.
13 Your doctor believes that you may be a good
14 candidate for this medication. In the clinical
15 trials that were conducted, one-half of adults
16 treated for 12 weeks had a 50 percent reduction in
17 their pain. Common side effects of this
18 medication include nausea, fatigue and weight
19 gain. Rare but serious side effects of this
20 medication include nerve damage and liver damage.
21 The medication is unlikely to be addictive or to
22 be used for abuse, such as to get high.

1 So hearing this very, very short piece
2 of information, what are the first thoughts that
3 come to mind when hearing this scenario? And what
4 kind of questions would you ask your doctor about
5 this new treatment for neuropathic pain? There's
6 -- again, it could be a question. It could be a
7 comment. Anything is okay. Lawrence?

8 LAWRENCE: I think that's a great
9 scenario. I think what would be important is I'd
10 want to know what the protocols are. I would like
11 this medication. But I would want to know what
12 the protocols are when I started, what do I do
13 before, what do I do during and what do I do and
14 how long after to look for the nerve damage, the
15 liver damage. Are they going to follow me by
16 enzymes? What's been the experience? That would
17 be my point.

18 MS. GIAMBONE: Okay. Thank you,
19 Lawrence. Others? Adam?

20 MR. HALPER: Yeah. I think Lawrence
21 made some excellent points there. The only point
22 that I would add is I'd be curious to know the

1 statistical likelihood of the serious side
2 effects. Rare is an awfully vague term. So
3 that'd be the big one for me.

4 MS. GIAMBONE: Thank you. You wanted to
5 -- yeah, sure.

6 KATHLEEN: My name is Kathleen. And I'd
7 be interested to know how many people were in this
8 study and if there had been any longer term
9 studies, because 12 weeks isn't very long to see
10 if there's any long-term effects.

11 MS. GIAMBONE: Okay. Thank you very
12 much. Any other thoughts before we -- I'll turn
13 to the FDA panel. Any other questions? Okay.
14 Great. Okay. So why don't we take some phone
15 calls? I know we've had some people patiently
16 waiting. Operator, would you mind dialing in with
17 the first caller?

18 OPERATOR: Yes. The first caller on the
19 comment is Bruce Stewart. Your line is now open.

20 MR. STEWART: Hello. Thank you for
21 taking my call. I'd just like to say -- you know,
22 I lived in Florida and due to the DEA's aggressive

1 approach to, you know, policing opioids, I was
2 unable to fill my prescription and I basically was
3 run out of the state of Florida because each
4 pharmacy was left to their own devices as far as,
5 you know, not serving their clients and even long-
6 term clients such as myself. I'm out in Nevada
7 and there are ceilings at the Las Vegas pain
8 clinic that I go to, to where -- I take OxyContin
9 10 mg. I am likely to take a higher dose but, you
10 know, I declined it because, like one of the women
11 said before, I'm kind of afraid, where do I turn,
12 you know, 10 or 15 or 20 years from now. I'm 55.

13 And I just wanted to say that they're
14 only allowed to dispense four pills a day,
15 regardless of the medication. You know, I think
16 if you have a patent -- I take tramadol. I take
17 Cymbalta and I take the Oxy. And this medicine is
18 only rated to last, you know, four to five hours.
19 But we're expected to make it stretch over a 24-
20 hour period, which his pretty distressing because,
21 you know, if you do a simple multiplier, you know,
22 it's four hours a piece, you know, four pills and

1 that's 16 hours. I mean, what do you do with the
2 rest of the day? And that's one of the dilemmas
3 that I've had and a lot of people have had with
4 the DEA crackdown.

5 And I just would like to see opioids --
6 a conversation about opioids open up because, you
7 know, I don't get high off of it. I'm in severe
8 pain. I have sensory neuropathy in my feet and it
9 just affects the pain and it makes it, you know --
10 makes me able to go about my daily business.

11 MS. GIAMBONE: Thank you so much. Thank
12 you. Graham, we'll take one more caller. So
13 Operator, one more caller, please.

14 OPERATOR: The next comment in the queue
15 is from Janet Metapol [ph]. Your line is now
16 open.

17 JANET: Hello?

18 MS. GIAMBONE: Yeah, we can hear you,
19 Janet.

20 JANET: Hi. Yes. I have neuropathy --

21 MS. GIAMBONE: So now we can't hear you,
22 Janet. So can you --

1 JANET: Hello?

2 MS. GIAMBONE: Yeah. Can you maybe
3 speak a little bit louder into the phone?

4 JANET: Okay. I'm sorry about that.
5 Okay. Yes. I was diagnosed with -- [off mic] --
6 but I've been suffering from it for a few years
7 back and forth. I was suffering from it. It was
8 called -- [off mic] -- I traveled from different
9 states to find out what was -- what I had. And
10 finally, here in Florida, they -- the doctors, the
11 neurologists told me it was neuropathy. But it
12 was hard to find out what it was because I didn't
13 have diabetes. So it was harder for the
14 neurologists to find out what it was.

15 MS. GIAMBONE: And Janet, can you tell
16 us very quickly what you would look for in an
17 ideal treatment?

18 JANET: Ideal treatment? Right now, I
19 am doing therapy at home. I am thinking about
20 doing -- I can't really walk that much. I am -- I
21 am taking medication because I am taking
22 Trivantin, which is Neurontin, 3,600 mg. I'm

1 taking Topamax. I'm taking Topamax, Lyrica and
2 I'm taking --

3 MS. GIAMBONE: Okay.

4 JANET: -- I'm taking Cymbalta. I'm
5 taking -- what is the other medication -- I am
6 taking a whole bunch of other medications that I
7 can't really remember right now.

8 MS. GIAMBONE: That's okay. Thank you
9 so much, Janet. Thank you for sharing those
10 comments. We appreciate it. Okay. So I'm going
11 to stop in just a minute here. I just want to
12 thank everybody for all of your comments. Again,
13 I know we didn't get to everything. But please go
14 to the public docket. Please enter your comments
15 there. They're very, very important and that's a
16 way to continue the discussion. At this point --
17 and again, thank you all for being here. It was
18 so important to us and wonderful to hear
19 everything that you've had to say. So I'm going
20 to turn it over to my colleague, Meghna, for the
21 open public comment period now. Meghna?

22 OPEN PUBLIC COMMENT

1 MS. CHALASANI: Yeah. Hi, everyone. I
2 want to thank you all again for coming today and
3 staying with us until Friday, at 5 p.m. And thank
4 you so much for sharing all your wonderful stories
5 with us. They've been very insightful and
6 informative. We're now going to be moving on to
7 the open public comment session. And for those of
8 you that are not aware, the purpose of this
9 session is to allow an opportunity for those who
10 have not had a chance to speak on issues that are
11 not related necessarily to our two main discussion
12 topics.

13 This is also an opportunity for
14 participants who are not patients or patients'
15 representatives to comment as well. Please keep
16 in mind that we will not be responding to your
17 comments. But they will be transcribed and be a
18 part of the public record. Since we would like to
19 be transparent, we would encourage you to note any
20 financial interests that you have that are related
21 to your comment. If you do not have such
22 interests, you may state that for the record as

1 well. And if you prefer not to provide this
2 information, you may still provide your comments.

3 We have collected six folks who are
4 interested in providing their comments and we have
5 about 10 minutes. So if we could have about two
6 minutes per speaker, that would be great. And I
7 am going to be a little strict with time as well.
8 If you start approaching the two- minute time
9 limit, I will ask you to start wrapping up. So
10 first, we have James Yadlon. I apologize if I'm
11 mispronouncing anyone's name. If we could get a
12 mic to James, please?

13 MR. YADLON: First of all, I want to
14 thank the FDA for doing this. This is an
15 incredible afternoon, very educational.

16 [Applause.]

17 MR. YADLON: Second, the panel, the
18 ladies and gentlemen on the panel, with your
19 courage and your incredible stories are just mind-
20 boggling and I commend you and wish you the very
21 best in the future. I'm on the board of directors
22 of the GBS Foundation and I had GBS 42 years ago.

1 I was totally paralyzed. For the last 42 years,
2 I've had very sore feet. And they hurt. But what
3 I'd like to take a minute or so to do is read a
4 couple of the comments from our members who sent -
5 - who I solicited -- I said please put in one
6 sentence a description of your pain. So I'm going
7 to read a couple. You just stop me when you want
8 to stop me.

9 It feels like I put my feet into
10 scalding water and dealing with the after-effects
11 of that burn 24/7, while simultaneously having
12 them in a washing machine with the vibration
13 coming up from the soles of my feet, up through to
14 my calves. It is like walking on a board barefoot
15 full of 16-pennynails, 24/7. The only thing I can
16 say is it feels like a toothache in my arms and
17 legs. That's the only way I can describe my pain.
18 Without pain management -- these are all from
19 different people, by the way. These are all
20 individual ones.

21 Without pain management, I would be
22 unable to get out of bed. The pain feels like

1 lightning bolts, severe sunburn and numbness all
2 at once and in levels. When I'm asking about my
3 pain, my answer is simple. My legs feel like
4 telephone poles filled with razor blades. If that
5 doesn't get the message across, nothing will. My
6 nerve pain is like being constantly rolled on a
7 bed of red-hot nails, burning, prickling,
8 stinging, stabbing. The mere touch of my child's
9 hand on mine can feel like a 12,000-volt electric
10 shock. I don't know if you want to let me do a
11 couple more --

12 MS. CHALASANI: How about two more?

13 MR. YADLON: Two more. All right. I
14 think you've got the idea. One more. I live with
15 pain, burning, hot, cold, numb, tingly feet 24/7,
16 365, trying to concentrate and live life.

17 MS. CHALASANI: Thank you, James. And I
18 know Soujanya and other folks have mentioned this,
19 but please submit your comments to the public
20 docket so that they'll be a part of the public
21 record and this summary report as well. Next, we
22 have Tim Murphy.

1 MR. MURPHY: I'll pass.

2 MS. CHALASANI: Okay. Thanks, Tim.
3 Gary? Gary Shrout?

4 MR. SHROUT: I'll be quite quick because
5 I've had plenty of chance to comment. But I didn't
6 know signing up, so I signed up. One, I'd
7 encourage you to look for the cure. Yeah, you've
8 got to treat pain. Totally agree with you. You
9 know, folks that are that bad off, you've got to
10 treat them. But please look for the cure and I
11 think there's some things coming out -- and again,
12 what I said before, what drove me up here, please
13 each out to the Elysium Health guys. I've got a
14 couple of articles I'm going to leave with you
15 all, Scientific American and Fast Company
16 Magazine. It's where I found out about them.
17 Help them -- keep them honest.

18 I have no financial association with
19 them. I'm a completely surprised, caught off-
20 guard customer that wound up being positively
21 affected. My life is an uncontrolled multivariate
22 experiment. Is this going to help others? I have

1 no idea. But it sure helped me. And if you guys
2 can help it to help others and things like that
3 and get the cost down, that's awesome. And thank
4 you. I'm impressed. This is an impressive
5 function. Thank you for taking time and you're
6 telling us thanks for staying here until 5 o'clock
7 on a Friday. You guys work here. You've been
8 here all week. Thank you very much.

9 [Applause.]

10 MS. CHALASANI: Thank you, Gary. Next,
11 we have Pam Schlemmon.

12 MS. SCHLEMON: Thanks. Hi. I'm Pam
13 Schlemmon. I'm the president of the Foundation for
14 Peripheral Neuropathy, and I do want to echo what
15 everybody said here today. Thank you. I applaud
16 you for selecting peripheral neuropathy as part of
17 the patient-focused drug development initiative.
18 I think we all know the impact that peripheral
19 neuropathy has, not only with the patients here,
20 but there are families, the economy, the
21 healthcare economy. So I do want to say thank
22 you.

1 The foundation focuses its efforts on
2 education, funding research. We have a peripheral
3 neuropathy research registry that's going to
4 address hopefully some of the very things that
5 everybody has been talking about today. What are
6 the underlying mechanisms that are causing
7 peripheral neuropathy and then most importantly
8 trying to identify and deliver new therapies
9 specifically for peripheral neuropathy that will
10 help these patients because, as we know today,
11 we've heard a lot today that much of the drugs
12 that people are taking are not very effective?
13 And I also want to let you know that we did a
14 survey as well. We had over a thousand
15 responders. We have put some of them, about 590
16 of the -- what I want to say is we did an analysis
17 of the 590 responders and that information and the
18 results of that survey is on the public docket.
19 So again, thank you very much.

20 MS. CHALASANI: Thank you, Pam. Next,
21 we have Larry Silverburg.

22 DR. SILVERBURG: I will be quick. As a

1 family physician, retired for 43 years, a
2 professor of family medicine teaching, teaching
3 medical ethics of professionalism at a college
4 medical school in Philadelphia, what I would like
5 to say is as patients, you have a right to expect
6 your doctor to communicate with you and to be
7 kind, to be gentle. There is no inconsistency
8 between being highly intelligent and also being
9 very nice. A lot of times, doctors, even today,
10 do not handle their patients and listen to their
11 patients. We were talking -- Dr. Hertz and I were
12 talking about the patient narrative. It's a very
13 difficult narrative.

14 And so, I just want to say you should be
15 expecting of your doctors to be kind, to be open-
16 minded. It's okay if you make a mistake with them
17 or they make a mistake with you. If you can't work
18 with your physician, find another physician. But
19 also, work with them. Tell them what bothers you.
20 They are human. They may not have the time.
21 They're under a lot of pressure. Things in
22 healthcare are changing. Learn to communicate and

1 be prepared with your doctors. And thank you
2 again.

3 MS. CHALASANI: Thank you, Larry. And
4 last, we have Leslie Levine.

5 MS. LEVINE: I will also be very brief.
6 It was estimated that there are over a hundred
7 types and causes of neuropathy. And it's really a
8 challenge to approve a new drug for neuropathy for
9 anything other than diabetic neuropathy because
10 clinical trials, by their nature, need a
11 homogenous population of subjects that is of a
12 certain size. And most forms of neuropathy are
13 rare.

14 As a person who's being treated with
15 IVIG, which is only approved for three types of
16 neuropathy -- and mine isn't one of them -- it can
17 be a very -- a real struggle for people with
18 neuropathy since the drug choices are so limited
19 and so many are not on-label. Insurance companies
20 are very reluctant to pay for expensive drugs off-
21 label. So I know this is not something that the
22 FDA has a whole lot of control over, but I just

1 wanted to voice the issue that when things come up
2 for -- that might be expanded in their label, that
3 it would be great if you can do what you can to
4 enlarge the indications. Thank you.

5 MS. CHALASANI: Thank you, Leslie.
6 Exactly 10 minutes. I didn't even need to bother
7 anyone today. Now, I would like to call Dr.
8 Sharon Hertz to the stand for closing remarks.

9 CLOSING REMARKS

10 DR. HERTZ: Well, this was our second
11 patient-focused drug development experience. And
12 I am glad that we have as an agency embarked on
13 this because this has been another extremely
14 valuable experience. It's always interesting to
15 get responses that you don't expect, which is of
16 course the value because I don't need to hear what
17 I already know. We need to hear what we don't
18 know. And I think that we've gotten some very
19 good information from everyone here in terms of
20 not just the personal experience, but what's
21 important and some areas of need. And so, I
22 appreciate that and I thank you all for taking the

1 time out of your busy lives, in spite of your
2 pain, to come and participate. We appreciate it.

3 We will go over the discussions from
4 today and we will go over the docket submissions
5 very carefully, trying to get as much information
6 as we can to help move forward the development of
7 products to treat painful neuropathies as much as
8 possible. If you have any comments, please send
9 them to the docket. Down the road, if you have
10 comments, you can always find us here at FDA and
11 we're always interested to hear what you're
12 thinking. Thank you [Applause.]

13 [WHEREUPON, the foregoing adjourned at 4:57 p.m.]

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CERTIFICATE OF NOTARY PUBLIC

I, ERICK MCNAIR, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



ERICK MCNAIR

Notary Public in and for the
STATE OF MARYLAND

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I, BENJAMIN GRAHAM, hereby certify that I am not the Court Reporter who reported the following proceeding and that I have typed the transcript of this proceeding using the Court Reporter's notes and recordings. The foregoing/attached transcript is a true, correct, and complete transcription of said proceeding.

06/20/2016

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