FOOD AND DRUG ADMINISTRATION (FDA)

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

DRUG DEVELOPMENT FOR CHRONIC FATIGUE SYNDROME AND MYALGIC ENCEPHALOMYELITIS: PUBLIC WORKSHOP

DAY ONE

Patient-Focused Drug Development Meeting

Thursday, April 25, 2013

1:08 p.m.

Bethesda Marriott

5151 Pooks Hill Road

Bethesda, Maryland 20814

Reported by: Natalia Thomas
Capital Reporting Company

MEETING ROSTER

FDA STAFF

CAPT Laurie Burke, R.Ph., M.P.H.
Associate Director, Study Endpoints and Labeling
Development Team, Office of New Drugs, CDER, FDA

Sara Eggers, Ph.D.
Office of Planning and Analysis, Office of Planning and
Informatics, CDER, FDA

RADM Sandra Kweder, M.D.
Deputy Director, Office of New Drugs, CDER, FDA

Theresa Michele, M.D.
Physician and Clinical Team Leader, Division of
Pulmonary, Allergy, and Rheumatology Products, Office
of New Drugs, FDA.

Theresa Mullin, Ph.D.
Director, Office of Planning and Informatics, CDER, FDA

MEETING ROSTER

(Continued)

FDA STAFF (Continued)

Theresa Toigo, R.Ph., M.B.A.
Associate Director for Drug Safety Operations, CDER, FDA

PUBLIC PARTICIPANTS

James Baraniuk
Diane Bean
Lauren Bean
Jeanette Burmeister
Shannon Cassidy
Dr. Lily Chu
Mary Dimmock
Dr. Derek Enlander
Thomas Equels
Dr. Joan Grobstein
Kathleen Harper

MEETING ROSTER

(Continued)

PUBLIC PARTICIPANTS (Continued)

Karen Hart

Eileen Holderman

Dr. Jon Kaiser

Dr. John Kalns

Natasha Kelemen

Mindy Kitei

Joseph Landson

Dr. Charles Lapp

Patricia LaRosa

Dr. Steven Lempert

Diane Lewis

Denise Lopez-Majano

Kim McCleary

Dr. Judy Mikovits

Robert Miller

Gisela Morales-Barreto

Matina Nicholson

MEETING ROSTER

(Continued)

PUBLIC PARTICIPANTS (Continued)

Carol Olson (ph)

Anita Patton

Dr. Dan Peterson

Mary Schweitzer

Amanda Simpson

Dr. Janet Smith

Jennifer Spotila

Susan Vitka

Charlotte von Salis

Chris Williams

TABLE OF CONTENTS

PAGE

APRIL 25, 2013: PATIENT-FOCUSED DRUG DEVELOPMENT MEETING

Welcome--RADM Sandra Kweder, M.D., Deputy Director, Office of New Drugs, CDER, FDA 10

Overview of FDA's Patient-Focused Drug Development Initiative--Theresa Mullin, Ph.D., Director, Office of Planning and Informatics, CDER, FDA 20

Overview of Discussion Format--
Sara Eggers, Ph.D., Office of Planning and Analysis, Office of Planning and Informatics, CDER, FDA 29

TABLE OF CONTENTS

(Continued)

PAGE

Discussion Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients 37

Moderators: Sara Eggers, Ph.D., and Theresa Toigo, R.Ph., M.B.A., Associate Director for Drug Safety Operations, CDER, FDA

Panel Comments 38

A panel of patients and patient representatives will provide comments to start the discussion on Topic 1.

Large-Group Facilitated Discussion 59

Patients and patient representatives in the audience are invited to add to the dialogue on Topic 1.

Break 93

TABLE OF CONTENTS

(Continued)

PAGE

Discussion Topic 2: Patient Perspective on Treating CFS and ME 93

Moderators: Sara Eggers, Ph.D., and Theresa Toigo, R.Ph., M.B.A.

Panel Comments 95

A panel of patients and patient representatives will provide comments to start the discussion on Topic 2.

Large-Group Facilitated Discussion 119

Patients and patient representatives in the audience are invited to add to the dialogue on Topic 2.

Open Public Comment Period 152

TABLE OF CONTENTS

(Continued)

	PAGE
Closing Remarks--Theresa Mullin Ph.D.	193
Adjourn	195

P R O C E E D I N G S

DR. KWEDER: Good afternoon, everyone. I am delighted to be the person welcoming you to this Part 1 of a two-day workshop. My name is Sandra Kweder, and I am the Deputy Director in the Office of New Drugs at FDA. And again welcome. Welcome to this important meeting on chronic fatigue syndrome and chronic myalgic encephalitis. We are really excited to be here ourselves and we are excited that you're here. As I have kind of looked over the attendance sheet, it's encouraging to see patients, patient caregivers, patient advocates, drug developers, researchers, and other people from the government all in the audience today.

I think the thing that binds us here today is our collective commitment to facilitate development of safe and effective therapies for what we all know is a very debilitating disease. The purpose of this meeting over the next day and a half is to explore important aspects that contribute to our thinking about the drug development for CFS and ME. Our goal is to foster a shared understanding on the important issues regarding

the development of safe and effective therapies. For example, ultimately in identifying things like good measures of outcomes in clinical trials that would test new therapies, how to think about innovative ways to approach development in this disease.

So let me see if I can manage the slides.

I want to focus on what to expect. What we're hoping will come out of today, and tomorrow as well, but particularly today, a better understanding of what are the high impact signs and symptoms of this condition from the perspective of patients and those who care for patients. We would like to gain some collective insight into clinical decision-making by health care providers who take care of these patients and have done so for years. What are their observations and what they see when patients improve or get worse? And how does that match up with the perspective of patients? Where are those points of intersection that really seem to be places that we should focus on in thinking about developing new products? Similarly, some of this we've learned from clinical trials of drugs, large, small trials,

practitioners' experience, and how do we apply those experiences going forward?

Tomorrow we'll also hear some things about tools, whether they're scientific tools or regulatory tools, to apply to drug development in these conditions and how we can merge those with the signs and symptoms that seem to matter most to patients.

The way I see this, we are building a map. There are points on the map where there are pockets of great expertise, really heartfelt positions or views on what matters most, really well-studied, well-thought-out perspectives on how to think about this condition and monitoring it over time and how that would work into clinical development. And then there is the scientific basis and understandings of pathophysiology, clinical response, clinical trial outcomes. How can we create the map that links all of those together?

So in the way of objectives, we're here today on Day One, and so let's start with the focus of that discussion. We're lucky that we have a whole collection of experts here in the room, patients to launch our Patient-Focused Drug Development Initiative.

This initiative goes beyond the particular clinical conditions of CFS and ME, but we are thrilled that we can engage this community in launching this larger initiative of FDA. It's dedicated to engaging patients and patient representatives and dialogue again on the most significant symptoms and negative impacts experienced in their daily lives as a result of the condition. We seek their perspectives on a range of therapies that they've been using or have used in the past to manage that condition. And Dr. Theresa Mullin is going to explain more about that larger initiative shortly right after me.

Tomorrow's discussion will focus on things of a bit more of a technical nature and will explore the broader issues related to drug development. On Day Two, we'll cover topics such as clinical trial design, outcome measures, regulatory issues, and possible pathways to expedite drug development for CFS and ME. But the focus of both days will be on common issues in drug development. Now, it's natural that specific drug products are going to be raised, but they'll be raised in the context of the broader conversation about how to

go forward. We're not here to discuss individual products that would be taken up to go further specifically, although there may be references to that. Those more specifics and detailed discussions of going forward with individual drug products, we have different forums for those discussions, and typically our advisory committee process is used for that where we can bring in just lots and lots of data, but our goal is to move forward.

So to just put us all in the same place, we're talking about chronic fatigue syndrome, or CFS, a serious complex and we all know severely debilitating disease of, for the most part, unknown etiology. It's characterized by profound fatigue lasting 6 months or more by almost any definition one encounters, and that is worsened by physical or intensive mental activity. We know it's a multisystem disorder with a variable symptom complex from patient to patient. There are no uniform diagnostic tests, which makes it a really challenging diagnosis and what clinicians often say is it's a diagnosis of exclusion. And we know that there are no approved therapies. Complicating the picture

further, there is a lack of consensus even among experts in the field on both nomenclature and any specific or exact definition of the disease.

And I want to say a little bit about nomenclature, and we'll talk about two terms. The term "chronic fatigue syndrome" and "myalgic encephalitis" and the term "drug development."

First regarding the name of the disease. We recognize that there is a lot of controversy in this area. Some people call this CFS, some people call it myalgic encephalitis, some people say that the conditions and the terms are referring to the same things, some people say that they're distinctly different. For purposes of this workshop, the terms are likely to be used interchangeably and used really as a frame of reference. We and the people using them we hope will make no judgment on the cause of the different symptom complex their frame of reference.

FDA doesn't endorse any particular definition; however, what we expect is that parties who are engaged in drug development who are submitting clinical trials for our review or new drugs where

clinical trials have been conducted will articulate details about what definition they used for entering patients in the clinical trial so we can all understand who it is that was studied. That's an important aspect that will probably come up more tomorrow into sort of the nuts and bolts of studying and testing drugs in this disease.

Now, again let's go to drug development. For the purposes of this workshop, particularly today, we're using drug development in its broadest sense, the idea of identifying, developing, and evaluating potential therapies that can help patients manage their conditions and get better. We, at FDA, have a narrow role in drug development with a focus on ensuring safety in clinical trials and rendering decisions about whether or not a product's safety and efficacy have been adequately demonstrated for approval.

At this workshop, we're also going to be focusing on the role of other key stakeholders in drug development, including the pharmaceutical industry, academic researchers, clinicians, and our other colleagues in the Department of Health and Human

Services, and in the patient community.

So what's our agenda? Today, the next speaker after me is Dr. Theresa Mullin, who will provide an overview of FDA's Initiative on Patient-Focused Drug Development, and following that, Sara Eggers will go over the format and questions for the key topics being discussed today. During this discussion, today when we hear from patients and their caregivers, a few of my FDA colleagues and myself, we'll be sitting up here, and we may ask you some follow-up questions. They'll be the kind of follow-up questions, like, "Can you tell me more what you meant about what you said in this part of your statement?" And I would like to ask my colleagues who are going to be part of that to introduce themselves.

So why don't we start right here?

MS~~DR~~. TOIGO:Terry Toigo.

DR. KWEDER: And, Terry, where do you work at FDA?

MS~~DR~~. TOIGO:Associate Director for Drug Safety Operations in CDER.

DR. KWEDER: Okay. And Terry, for those of

you who don't know, has a really long history at the Agency. She's a pharmacist, and for a very long time Terry was in charge of all of our patient and patient advocate outreach input and output activities. She has a long track record of excellence in listening and making sure that people get heard.

So Theresa Number 2 is next to her.

Dr. Michele?

DR. MICHELE: All right. I'm Theresa Michele. And I am a physician and clinical team leader in the Division of Pulmonary, Allergy, and Rheumatology Products in the Office of New Drugs at FDA. Our division now is the home at FDA for all of the chronic fatigue syndrome applications. And I am also the Agency representative to the CFSAC.

DR. KWEDER: Okay. Thanks, Terry.

And Theresa Number 3.

DR. MULLIN: Theresa Mullin, and I direct the Office of Planning and Informatics in the Center for Drugs, and I am CDER's lead on the Patient-Focused Drug Development Initiative. You'll hear more about that in a minute. And I have to say I've never been on a panel

with three Theresas before, so it's a little bit unusual for me, too.

(Laughter.)

DR. KWEDER: And they're all spelled the same way, except Terry Toigo's is spelled wrong on her card.

And finally?

DR. BURKE: Laurie Burke, and I direct the Study Endpoints and Labeling Development staff in the Office of New Drugs, and we look at measures of treatment benefit and how to describe the results of clinical studies to demonstrate treatment benefit in the labeling.

DR. KWEDER: So really an important part of this discussion.

So the afternoon is organized as you see here on the slide. You can see that this will be broken up into two topics, and Sara Eggers will explain that to you a little bit more in a few minutes, and Sara is right here.

So what I would like to do, though -- and you know what? Hold off on introducing the whole side of the panel because I know you're going to do that.

At the end of the afternoon, there will be an open public comment period for those who have pre-registered and been confirmed to speak. There is a sign-in sheet at the registration table, so be sure to check in. If you've signed up, make sure your name is on that table, they'll confirm that with you.

And with that, I'm going to turn things over to Theresa Mullin to talk a little bit more about this first day focused on patient input. And again thank you for being here and thank you for your participation. Overview of FDA's Patient-Focused Drug Development Initiative

DR. MULLIN: Okay, well, yes, and hi again. And I'm going to talk and give you a brief overview of this Patient-Focused Drug Development Initiative. This is a particularly special meeting for us in terms of this initiative that we're starting under the Prescription Drug User Fee Act that was reauthorized in 2012.

This is the first such meeting that we'll be having, and I can't imagine a more important place to start in trying to see how well we're able to get

information. We think that this initiative is going to really help FDA because we don't get as much direct engagement and input in a general way from patients as we think would really benefit us.

We thought this initiative would be an important adjunct to our benefit-risk framework effort that we have underway. And our benefit-risk assessments for new drugs involve five key considerations: that's the severity of the condition, the degree of unmet need, how much do current therapies, in other words, ~~treat,~~ how well do they treat the condition?; what clinical benefit is evidenced in the data that's been collected in trials?; what are the risks that are identified in the safety data collected in trials?; and then the question of whether there is a risk management plan that can make sure that the benefits outweigh the risks.

Well, those first two factors comprise what we're calling the clinical context, so the severity of the condition and the degree to which it's not met and taken care of by current therapies. Patients have a unique perspective on this, of course; they are the

ones who experience the disease, they are the ones living with it, they are the ones who are taking the medicines and seeing how well they work or don't, and we realize that we would really benefit from a more systematic approach to gathering that information from patients and not just doing it in the context of a particular drug application where we have to do a great deal of, in fact, conflict of interest screening of people.

We can't get as comprehensive a picture because of the issues around a particular application, so we thought it would be much better if we try to go at this by disease and engage all the key stakeholders. Really, to us, primarily we want to hear from patients and their caregivers if caregiving is a very critical or large part of that experience with the patient and the patient's family, to really get their perspective to help us understand the clinical context from that most direct perspective. And we think that we'll get immediate benefit from hearing about this, capturing it, putting it in a report that we will give to review divisions to reference and use when they're getting

applications or other issues for specific drugs in that disease area.

It may also stimulate the development of other outcome measures that capture more meaningful, patient meaningful, aspects of the disease that could later be used in clinical trials, to look at those aspects of drug performance and see if they are meeting the needs that patients have told us about.

So this initiative under the Prescription Drug User Fee rReauthorization involves a commitment to do ~~at least 20,~~ at least 20 meetings in 20 different disease areas over 5 years, and despite whatever budget constraints we are undergoing right now, we are very committed to doing this initiative in any case, and at least 20, and so these meetings are primarily for patients. We want others to listen. It's an opportunity for patients to talk and, frankly, for everybody else to listen.

And so that's the way we've set it up, but we hope that we get patient advocates to participate, drug companies that are interested in developing drugs in this disease area, FDA reviewers, and caregivers and

other stakeholders we hope will also be there to listen.

We began this process of Patient-Focused Drug Development, well, last summer we started really talking to the review divisions to try to figure out how to get it underway. We realized early on that we wanted additional patient input. We've got other ongoing what we call patient consultation meetings that we've been conducting to try to get their input and perspective on the things we're thinking of doing as part of this initiative, but last September we published a Federal Register Notice with a set of candidate disease areas that our review divisions had identified as a set that they thought these could be good candidates -- there were almost 40 drugs on the list -- and that would be good to elicit public comment to see what the public thought about the drugs that we had identified.

We had a public meeting in October to discuss those candidate disease areas, and we opened a docket, we received about 4,500 comments to the docket, and we've analyzed those comments, taken them back and

talked to the review divisions where the drugs that were identified in the docket would be reviewed to go back and try to identify what would be the best set to start with given that we're only working with about 20 in this first effort. We see this as a long-term project. We don't think we'll be doing it for only 5 years. We think this is something we'll want to continue to do well beyond this 5-year timeframe of PDUFA, but this is almost like a piloting and a good start for us.

And so we identified a set of diseases for the first 3 years, 2013 to 2015, and those are posted on our website, and we can tell you more about those later if you would like. And this, as I said, is our first area, so it's very exciting for us.

Well, how did we come up with the initial list and what kinds of diseases did we think would be particularly good candidates? You see a list of areas. These are our criteria that we had used to develop a set, and you can see why chronic fatigue syndrome is such a good candidate and such a good and appropriate place to focus as, for example, our first disease area.

We were looking in general for diseases that are chronic, symptomatic, and affect functioning and activities of daily living, ones for which these critical aspects for patients are not maybe captured as well as they could be in clinical trials, where there may be no currently very effective therapies and no therapies approved for that disease, where there is a range of severity that patients experience. There may even be identifiable subpopulations that have a particular experience with the disease that would be helpful for us to hear more about, and where there is a fairly broad range of patients that may be affected by it. And as a set of 20, we wanted to try to cover a wide range of disease areas to make sure that we were broadening our perspective and trying to get as many different diseases in there as we could.

And so with that, we picked a set that we think still corresponds to that for the first 3 years, and in planning these specific meetings, we've had sessions, as I mentioned, these patient consultation sessions that we've had, to go over the wording of the questions that we came up with, and patients that had

given us input on our initial questions greatly improved our questions and made them much more meaningful in terms of how they were worded and what we were trying to get at. They were extremely helpful in helping us improve the wording, and yet the same groups told us, "Well, you know, you're going to continue to modify these questions, you're going to have to, for each group that you meet with because every disease is different and they might need slightly different questions, they may have different issues, and you need to be sensitive to that," and so we think that was very good advice, and we have tried to do that as well.

And not only are we needing to maybe modify the questions a little bit to fit the disease context that we'll be doing in a particular meeting, but we also want to be sure that the format of the meeting is tailored to sort of maximize the opportunity to get input from patients and to hear what they have to tell us in the course of a meeting. And so we might vary our format for the meetings across the 20 a little bit for those reasons.

We're hoping that patients will participate

and come to these meetings that we have if they can. We're also making sure that we have remote access available so people can also send in comments electronically. We've heard from patients that they would want to be sure that we heard directly from them and not just be filtered through advocacy groups, so we're trying to make sure we're providing ways for that to happen. We're also looking at whether we can possibly expand, and beyond the 20, maybe we can be collecting information electronically and doing other things for groups that we're not able to meet with face-to-face.

Any of these meetings that we have and the information that we will collect we will be building into a report which reports back what we've heard, we'll be posting those reports on our website, and we see that as the first product of perhaps a series of continuing efforts in each of the disease areas that we'll be looking at. And so if you would like to see more about it, there is a link here to the website where it's almost like the first place to go look. We have a lot of information at this location, and you can

find it by going to this link.

And with that, I really look forward to listening to your input today. And thank you again for coming to the meeting. And I'll turn it over to Sara Eggers now. Overview of Discussion Format

DR. EGGERS: Good afternoon. I'm the only one without a name tent card. And since I put the tent cards out, I don't know how I could have forgotten myself, but I did. It's really great to see you all here. We have been preparing for this for a long time, and I'm so excited that the day has finally come and we get to hear the patients' input directly.

As Theresa said, I'm Sara Eggers. I am one of Theresa Mullin, Dr. Mullin's staff, from the Office of Planning and Informatics within the Center for Drug Evaluation and Research. I will serve as the discussion facilitator today, and my colleague Theresa Toigo will be supporting our discussion as a moderator, making sure that the process runs smoothly, on time, et cetera.

This discussion is rather different from the types of government-sponsored public meetings that

you've participated in, and so I'll be going over that format and the questions before we begin.

We have two main topics today. The first topic is to explore the most significant symptoms of CFS and ME and their impact on daily life. And here we really want to know the most significant symptoms that you experience resulting from your condition, knowing that there are a wide range of symptoms experienced. We also want to explore the negative impacts on your daily life that result from those symptoms, specifically the important activities that you cannot do at all or as fully as you would like because of your symptoms and because of your condition.

And then the second topic is understanding patient perspective on treating CFS and ME. What are you currently doing? What's the range of therapies that you are currently using to treat your condition or its symptoms, and how well do these treatments address your most significant symptoms, and what are the downsides of those treatments?

We have questions that will be coming up at the start of each discussion topic, and that will give

you a good sense.

So now for the format. For each of the Topics 1 and 2, we're first going to hear from a panel of patients and patient representatives, and the purpose here is to set a good foundation for our discussion. There are five panel discussions for each topic, primarily patients, but we do have a patient representative or caretaker, at least one on each of the panels. Each panelist has prepared 2 to 3 minutes of remarks in response to the questions that I'll put up, and after we hear from each of them, we will have some time for some follow-up questions from me and my FDA colleagues up here.

After the panel discussion, we'll broaden the dialogue to include other patients and patient representatives in the audience, and the purpose here really is to build on the experiences shared by the panel and get a sense for what is generally similar and what may be different from what you heard. We'll focus on the key questions for each topic, and I will be asking follow-up questions, inviting participants to raise their hands to speak, and I'll call on you, and

we have some people with microphones who will come to you.

So in a group this size, we will need to rely on the method of raising your hands to speak. I will try to get everyone who wants to speak, knowing that we do have the time limitations, but as much as possible, everyone will have a chance to speak.

Those participating by live webcast can add comments through the webcast comment box, and although they won't be read or summarized today, they will be considered part of the public record. This meeting is being transcribed, and we have people on our team taking detailed notes as well. So even if you don't see me taking notes, which I'm a pretty bad note taker, I can't read my own writing, just know that there are others in the room who are listening very intently and taking notes.

At any point if you have to get up for any reason, please feel free. There are comfortable chairs near the registration, there's a piano there as well, if anyone wants to play or perform during the break, be my guest. There are rest rooms located behind me, if

you go out to the right here and keep going. We'll take a 15-minute break at about 2:40, around 2:40, between Topics 1 and 2.

So in order for this meeting to add the most value to FDA and to the participants, we have a few ground rules for all of us. We are here first and foremost to hear directly from those of you who have this condition. Some of you are here today as caregivers representing someone who could not be here in person, and this is very important because it means that we get to hear a perspective from someone who may be too ill to travel today. We encourage you to contribute to the dialogue as well. Some of you are here as patient advocates, and we encourage your participation as well, again with the intent of speaking on behalf of patients. And we're happy to see participants here who represent research, industry, and government agencies, and we hope that this input is important for you as well and that you will learn something today. We just ask that you stay in listening mode and let the patients and patient representatives contribute to the discussion.

The purpose of the opening panel is to give our discussion a solid foundation; however, the views expressed by the participants speaking first will have no greater weight than any other comments expressed by the participants.

In the large group facilitated discussion -- so after the panel discussion, we'll open it up to the large group, we'll ask participants to focus on the topics that we are currently discussing; for example, a particular symptom. Try to keep responses or comments to a question to 1 or 2 minutes so that we can ensure that everyone can talk and focus on building on what others are saying. I will regularly ask for a show of hands if you generally share a particular view or not, and if you are comfortable, please raise your hand.

We'll try to accommodate everyone who wants to speak. If we don't get your full thoughts on a topic, we strongly encourage you to elaborate on your comments and what you heard today in the docket, which will remain open until August 2nd.

Our discussion will focus on the common ground regarding the symptoms, impacts, and treatments

of CFS and ME, as Dr. Kweder said. There are many important issues to ensuring that people with CFS and ME get the health care treatment and support that they need. For our discussion, though, we want to focus on these topics that I just went over because that's what is critical input for FDA at this time. We may touch upon specific treatments, and that's okay. The discussion of any specific treatments, however, should be done in a way that helps us understand the broader issues.

Again, you are encouraged to elaborate on your perspectives through the docket. And the comments on other topics are welcome at the open public comment for those who have pre-registered and are confirmed to speak during the session.

FDA's staff is here to listen. FDA will have its turn tomorrow to present and discuss in detail various issues related to the drug development process, and they may build on, as will all participants, we hope, on the various topics that will be raised today. Occasionally, as I said, I will turn to them and ask if they have any questions or clarifications.

And we want your feedback from this meeting. What we learn here today will help us continue to design and implement future patient-focused drug development meetings that are useful to FDA and useful to those who contribute to these meetings. There are evaluation forms available, completely voluntary, and at the break, if you go to the back table -- I'll tell you at the break where to go -- you can pick those up and we would be happy to hear your comments.

Above all, courtesy and respect is paramount. Our goal today is to have a fair and open discussion. Therefore, please wait to be acknowledged before speaking. Speak into the microphone and please state your name. I'll try to call on people by name if I can read your name tags, but if you are able and can stand, please stand and state your name. If you are not comfortable or not able to stand, please don't worry, you definitely don't need to.

Avoid any kind of negative or derogatory language, and keep all side conversations to a minimum so that we can focus on the person who is contributing at the moment. Okay? Discussion Topic 1: Disease

Symptoms and Daily Impacts That Matter Most to Patients

DR. EGGERS: And with that, I think we are ready to begin discussion Topic 1. I have asked all the panelists for discussion Topic 1 to join me at the front, and they are here. And I'll go through and say their names and then I'll ask each of you, and we'll go through -- I think we're in alphabetical order -- we'll go through in alphabetical order and ask you to share your remarks, and then, as I said, we'll have follow-up questions.

So we have Dr. Jon Kaiser, we have Mr. Joseph Landson, Ms. Denise Lopez-Majano, Ms. Kim McCleary, and Ms. Charlotte von Salis. I'll say those again. We have Jon Kaiser, Joseph Landson, Denise Lopez-Majano, Kim McCleary, and Charlotte von Salis. Okay? Thank you.

And with that, Jon, I will let you start.

DR. KAISER: From this chair?

DR. EGGERS: From that chair, yes, that's fine. Panel Comments

DR. KAISER: Good afternoon. It's going to be a challenge to condense my experience with this

condition into just a few minutes, but I'll do my best. My name is Dr. Jon Kaiser, and I practice medicine in the San Francisco Bay Area. In 1987, after many stressful years of pre-med, medical school, residency training, and working as a solo doc in a busy emergency room, I developed ME/CFS. I had severe fatigue, recurrent sore throats, chronic pain, and unfreshing sleep. If I exercised just a modest amount, I would experience a devastating crash with an exacerbation of all my symptoms, and I never knew how long a crash would last. Sometimes it would last only a few days and other times it would last several weeks.

My ME/CFS had a significant effect on my work and my personal life. I had to cut down my work hours. I remember lying down on the couch frequently between patients. And if I was able to socialize, I never knew how long it would be before I went up to my wife and said, "We need to leave now." It's like you just hit a wall and you become dizzy and lightheaded and your brain clouds over.

Fortunately, after 5 or 6 years of working really hard to rebuild my health, including taking a

job with much less stress and leaving emergency medicine, I was able to recover to a significant degree; however, I still experience relapses of these symptoms that significantly impact my life. When a relapse occurs I cannot participate fully as a father or a spouse, I need to lie in bed for hours at a time, and I experience total body pain during these relapses.

Now, there are a lot of people who are totally disabled from this condition, bedbound or can't leave their homes, and they're a lot worse off than I am, but I'm not here to speak for them, I'm here to speak for the thousands of people with CFS who are able to work but struggle to make it through each day and each week.

People who are able to work with CFS struggle to get our minds clear enough to function and to be able to think well enough to perform. We struggle to make it into work by 9:00 or 10:00 in the morning and be as productive as everyone else, and we struggle to make it through an 8-hour workday without having to lie down and take a break.

The worst part about this condition, from my

point of view as a person with CFS who is still able to work, is the toll this disease takes on my family. I don't know if I can convey the psychological distress I feel when I'm unable to spend time with my daughters or participate in family activities because I'm in bed on the weekend recovering from all the energy I expended during the week. This for me is the worst part of this condition, the fact that during exacerbations I have no energy left to participate fully in my family and social life.

And one other terrible thing, which I'm sure all of you are familiar with, is that family members and friends just can't understand how I can feel so sick when I'm at home if I'm still able to work and hold a job.

So I want to thank the FDA for holding this meeting and for getting input from patients themselves. I hope they will work to identify treatments that not only help those that are bedbound get out of the house but also help those of us still able to work be able to think more clearly and function at a higher level. And I look forward to hearing other people's perspectives

and having a productive sharing of ideas.

Thank you.

(Applause.)

DR. EGGERS: Thank you very much, Jon.

And I am going to put the discussion questions up here so that you can see the types of questions they were addressing.

And we'll next move on to Joseph Landson.

Thank you, Joseph.

MR. LANDSON: Hello, everyone. I'm Joe Landson. I am a veteran. I am a graduate student sort of, and I have been ill for about 8 years. A little bit about my life today. I live at home with my mom here in the D.C. metro area, and I am on my seventh year of a 2-year master's program. Lots of people take a little bit of extra time to finish a graduate degree, but I'll tell you a little bit about my past so we can put my present situation in perspective.

But first let me answer the central question. The symptom I chose as the most significant for me in my daily life is confusion, which seems an odd choice given the very many different symptoms that are

profoundly disabling for lots of us with this illness.

So why confusion? Several reasons. One, I now have trouble today for longer than 15 or 20 minutes to follow a single conversation with someone I know. My former life as a veteran was as a military linguist. I translated Arabic on the fly. I would typically listen to multiple conversations at once, at least one in each ear of my headphones. I was on a plane, a rattling plane, an old reconnaissance plane, that wasn't very well pressurized, I was trapped in that for up to 10 hours. We would typically get up at 0200, 0400, oh dark 30, as they say, as we know from the movie title now, and go translate whatever our languages were on that plane for a long time, and then we would get up again and do it all the next day.

I now have trouble sitting in a comfortable office translating the same language for more than probably 2 or, at most, 4 hours would be the maximum I could do. And that's why confusion has affected me the most: the loss of my ability as a linguist and hence any possibility of employment in that area, the inability to finish my graduate school program. It's

possible I could work again on a low concentration job, but I have not tried in years, I'm just hoping to finish my thesis.

The confusion probably wouldn't matter as much without another symptom of the illness called post- exertional malaise, and it's not just that we're confused, it's that any sort of effort -- mental, physical, or emotional -- makes us so exhausted that any progress we've made, for instance, on said thesis, I read it the next day, what I've written, and I have to decide. What do I have to decide? It's not making sense to me what I wrote. Now, does that mean I was confused when I wrote it and the writing is actually no good and I can't make sense of it now, or am I confused now and unable to read a perfectly good sentence? In a sense, it doesn't matter because that means the previous day's work is probably wasted.

Thank you.

(Applause.)

DR. EGGERS: Thank you, Joseph.

Denise Lopez-Majano?

MS. LOPEZ-MAJANO: Good afternoon. Thank

you, everyone, for making the effort to be here. Thank you especially to patients who have used scarce energy and financial resources to be here.

I have two children. My son Matthew got sick 2 days after his twelfth birthday. That was over 8 years ago now. He's now 20. My son Alexander got sick over 7 years ago. He's nearly 22. Before they got sick, they were actively engaged in academics, championship level swimming, fencing, theater, family, friends, travel, world affairs. Those are things of the past. They've been housebound since they got sick. They've tried numerous medications but have had virtually no improvement. Since they got sick, I have provided 24/7 care for them. Because they require 24/7 care, I am nearly as housebound as they are. I leave home to get materials from the library, go to the grocery store, I attend my neighborhood book group once every 10 weeks or so.

Usually when I leave home it's to take care of my sons in terms of medically related appointments, driving them to and fro. To be here today, I made arrangements for a full-time caregiver to come in and

stay at my home with my sons with coverage from friends and neighbors as well. However, those plans went up in smoke. The caregiver, 2 weeks ago today, had a heart attack, said caregiver cannot travel at present, said caregiver cannot undergo situations of stress, let alone take care of people 24/7 other than herself.

So I had to punt. I tried my best, I couldn't come up with any other arrangements, so my sons are upstairs in a hotel room with friends and caregivers looking in on them.

Their symptoms run the gamut of post-exertional malaise, immune problems, orthostatic intolerance, neurocognitive problems, autonomic manifestations, myalgias, unfreshing sleep, and more. Both of my sons more than meet the Canadian Consensus Criteria and the International Consensus Criteria for ME, but the symptoms that are most frustrating to them are impaired executive function, impaired reaction times -- keep in mind that in swimming and in fencing they were used to very quick starts and agile movement -- slowed processing speed, impaired working memory, difficulty processing information.

It was said earlier that intensive cognitive exertion triggers post-exertional malaise, but from my experience with my sons, it can be triggered by minimal exertion. For my sons, post-exertional malaise can be triggered by cognitive exertion that lasts more than 20 minutes at a time, about three times a week, meaning they can't study for any extended period of time.

The term "malaise" to the layperson is a misnomer because what they experience and what most patients that I know of experience is much more like a collapse, as was said before. For my sons, a post-exertional malaise or collapse can be brought on by physical or cognitive exertion, and these collapses can last for weeks.

Orthostatic intolerance is also a very significant problem for them. Matthew's resting heart rate when he is sitting down is about 110 beats per minute. Alexander's is about 116. As examples, for the orthostatic intolerance they have tried Florinef, atenolol, propranolol, pindolol, midodrine, and many others, to no avail. Over the years, Alexander and Matthew have repeatedly said that if there were only

one area of function they could improve, they would choose to be able to sustain cognitive function without the payback of post-exertional collapse. Earlier this month, Matthew said to me that he would choose cognitive function because what's made with the mind lasts longer.

Thank you.

(Applause.)

DR. EGGERS: Thank you very much, Denise.

I'll ask Kim McCleary to next go.

MS. McCLEARY: Thank you, Sara. Thank you to the FDA for selecting ME/CFS as the first topic for the series of Patient-Focused Drug Development Initiative workshops. This is a tremendous opportunity for our community and for advancing research and drug discovery.

My comments will be based on the responses that we received over the last 35 days to a survey that we launched on March 18th following the March 11th Federal Register Notice indicating that this would be the first of that series of meetings. We patterned our survey very much after the FDA's questions that

patients can submit answers to directly to the FDA docket.

DR. EGGERS: Kim, may you just say what association you're with?

MS. McCLEARY: Oh, yes, I'm sorry. I'm President and CEO of the CFIDS Association of America.

We patterned the survey questions after those that the FDA published in the Federal Register Notice, and we also augmented the questions with some additional questions that we felt were important in terms of setting the context for this conversation.

And just to recap sort of the demographics of the population that responded to the survey, we had 1,300 survey responses in 35 days. The average age of onset for patients' symptoms was 32, and that broke down to 250 people responded that they became ill at 18 years or younger, so that's quite a significant pediatric population or population of pediatric onset. Between the ages of 19 to 35, there were 500 responses, and again that's the age of onset, and that was the largest group of the four age groups. Ages 36 to 50 was 452, and then onset at age 51 or higher was 157, so

the typical sort of bell curve.

The average number of years since symptoms began at the time the respondent replied was 18 years of illness duration. So this is quite a chronically ill population that responded to the survey, and the range was within the first year they were responding to the survey all the way up to 70 years of illness. So we have quite a range.

Our survey allowed patients to -- or participants, it didn't have to be a patient, it could be anyone who responded to the survey, although 86 percent of the survey respondents reported that they had been diagnosed with ME or CFS or ME/CFS by a health care professional, so I think it's a good study population -- they were able to fill in answers in an open-text format without any guidance or suggestion other than the same language that the FDA used.

We conducted natural language processing analysis of the texts that came in and used principal components analysis to define and distill down the answers. So out of 1,300 responses, there were 700,000 words used in those responses, which then distilled

down to about 970 concept IDs in a unified medical language, and these are some of the topics that came out most highly in the principal components analysis of the data on impact on daily life, "What is the impact of this illness on daily life?"

And there were basically five areas that came out most strongly. The first was a fear of increased risk of death or disease, and that's not something that my fellow panelists have yet brought up. The second feature in terms of impact on life was that, quote/unquote, life is not worth living or life stops, and this translated a little bit more into the loss of friends and a vastly different professional life, and that could mean either the loss of a career or a career that was not the career that the individual was performing before the onset of illness.

The third feature was the lack of effective treatments, and this goes back to what was described earlier as the unmet need, so this condition -- the unmet need and the lack of effective treatments has a major impact on people's everyday lives.

The fourth component was the following: "I

can't work because of sleeplessness, medication side effects, muscle pain, exhaustion, blurred vision, and migraines." So that answer actually responds also to the question about symptoms.

And then the fifth feature that popped out most strongly was the social isolation that comes with this illness, and that would be probably the hardest thing to restore with a drug therapy, but is again another major impact on patients' lives.

I don't have any more time, I'll stop there, but I have lots more comments I could give. We'll submit those to the docket.

DR. EGGERS: Okay. Thank you. Thank you, Kim.

(Applause.)

DR. EGGERS: And I'll ask Charlotte von Salis. And can you get the microphone to where you need it?

MS. VON SALIS: I'm hoping, yeah. Twenty-three years ago --

DR. EGGERS: If you could speak into the microphone as much as possible.

MS. VON SALIS: I can't move to -- okay. Ah, there we go. Okay. Is this better?

DR. EGGERS: There we go.

MS. VON SALIS: Okay. Twenty-three years ago I came down with myalgic encephalomyelitis. I meet the ME International Consensus Criteria as well as the Canadian Consensus Criteria, and I'm only spared gastrointestinal symptoms. With the notable exception of a 20 percent overall improvement that lasted 2 months while on an antiviral prescribed due to low natural killer cell activity and high viral titers, I have not had any significant remission. My most debilitating symptoms fall under the rubric of neurological and cognitive dysfunction.

I'm a lawyer, a graduate of a top 10 law school, used to reading, analyzing, writing, and talking to judges and clients. Within days of getting sick, I could not read a memo I had written myself, it literally looked like hieroglyphics on the page. I cannot think clearly. This includes an inability to process information, be it oral or written. I often cannot communicate properly, struggling to get a

thought together, find a correct word, and then speak coherently. I am no longer able to read or write as I had before and have trouble understanding and remembering. My thinking has slowed down. A QEEG revealed predominant delta wave activity, and I have difficulty prioritizing. My IQ has dropped to 107.

I also have significant problems with light sensitivity -- as you can see, I am wearing dark glasses -- and cannot focus if faced with too much visual or sound stimulation, for example, too many objects in a store, music in a restaurant, busy websites. I get dizzy, spatially disoriented, lose my balance, come down with headaches, and feel nauseated in such environments. Extensive vestibular testing, including computerized dynamic posturography, confirms these symptoms. Sometimes a small amount of anti-seizure medication helps, all too often, though, I must lie down in a quiet room with the drapes drawn.

I can't sustain any mental or physical activity for a significant time without post-exertional exhaustion and exacerbation of all symptoms including low-grade fevers and chills, which lasts for days or

weeks. My activity intolerance is confirmed by abnormal cardiopulmonary exercise testing, also known as CPET. During these times I am unable to do more than go to the bathroom and kitchen as needed.

The impact of this illness on my life has been significant. I've had to give up my law career. I can't work. Due to my light and sound sensitivity and my activity limitations, I have to pay to have groceries delivered, laundry washed, and my home cleaned. Socializing is difficult, as I can't predict how I will feel at a given time, and I must avoid overly stimulating environments. The latter often includes the internet, something many people with my disease turn to for social contact. I must limit my TV viewing and I am rarely able to listen to music. Phone calls must be limited as well. I've had to give up one of my greatest pleasures, reading, relying instead on a special audio book player that allows me to slow down the reader's voice and change the tone.

I have moved to a quieter neighborhood and adjusted to a life spent mainly housebound and lying on a couch or bed. As I can't walk much more than a mile

on a good day, I've had to enjoy the outdoors through views from my windows or balcony.

I've lost almost half my life to this illness and still wait for appropriate treatment. And I am able to participate in this workshop only because I live 5 minutes from its location.

Thank you.

(Applause.)

DR. EGGERS: Thank you very much, Charlotte.

So in order to make sure that we have enough time for the facilitated discussion, I'm just going to ask my colleagues at FDA if they have any burning questions for any of the discussants up here.

Dr. Kweder?

DR. KWEDER: I want to ask, Mr. Landson, you talked about confusion, and I found that really intriguing, and I wanted to ask you -- you said a few things and I'm trying to tease out your description of being confused, and particularly your experience when you're trying to read something you wrote the day before. Is it a sense of a cognitive confusion or is it more like a fog? Can you differentiate?

MR. LANDSON: It's difficult, but, yes, I can differentiate, I think, between cognitive confusion and a fog. I think I've experienced both. I'm trying to sort out which I experienced when.

DR. KWEDER: Okay. And so do you see words that you don't understand? Is it like, "I don't know that word"?

MR. LANDSON: Yes.

DR. KWEDER: Okay.

MR. LANDSON: For instance, I was just reading something about someone with the last name of "Ishere," but then it was actually a comment that someone is here?

(Laughter.)

DR. KWEDER: Okay. Yeah.

MR. LANDSON: Didn't get that.

DR. KWEDER: Yeah. Okay.

MR. LANDSON: That's a strange experience for a linguist.

DR. KWEDER: Right. Okay. Yeah, I bet. Thank you.

DR. EGGERS: Yes, Terry, Theresa. Dr.

Michele.

(Laughter.)

DR. MICHELE: Too many Theresas.

So I would ask any of you to respond to this, but many of you have talked about the post-exertional malaise, and I'll use that term for want of a better one, but you've all mentioned that this can occur both secondary to cognitive exercise or due to physical exercise. Can you differentiate? Do you have different symptoms with your crash if you were exerting yourself mentally versus exerting yourself physically? And do you find one to be a greater trigger than the other?

MS. VON SALIS: Okay, I'll take that, I guess. Yeah, I think they are different. For me, the stimulation, I think the cognitive, actually having to mentally exert myself, talk to people or read or try to write or something, does cause a crash that is somewhat different from the physical in the sense that my head feels like it's going to explode, I don't know how else to explain it than that. And I really have to have total silence, total darkness. The physical exertion

crash, well, they both are the same in the sense that I guess with the mental, everything -- basically all of my symptoms are exacerbated, and that's why "exhaustion" to me isn't even the correct word because, yes, I am more tired than healthy people, but that is only one of my symptoms. It's basically an exacerbation of absolutely everything.

DR. KAISER: If I could make a comment on that. Jon Kaiser. One of the post-exertional symptoms that is the strangest to me is a post-exertional sore throat, and it can be physical exertion or it can be just working too many hours straight, within 24 hours I'll have a sore throat, and it's not like I have become infected with a virus, it doesn't follow the normal course of a 7- to 10-day viral illness, it doesn't become a strep throat, but it's more of an inflammatory response. And so I've learned that if I'm in the midst of exerting myself either physically or at work for an extended period of time, I don't wait for the sore throat, I just take anti-inflammatories to try and prevent it, and that seems to help me somewhat, but I can break through that, I can break through the anti-

inflammatories if either I go on too long or I don't take them soon enough. So I wanted to make that comment.

DR. EGGERS: Any other final burning questions?

(No audible response.) Large-Group Facilitated Discussion

DR. EGGERS: Okay, let's move this conversation to engage everyone. And if I can, let's see, Murphy's law is going to come into play. Does this come off? Yeah. Okay, it came off. And now the second thing, let's see if I can come down into the front so that I can speak closer to you.

Terry, how much time do we get to have for this? Do we have a few minutes left over?

DR. TOIGO: Yes. You have 40 minutes, and you have 10 minutes for each of the top three symptoms that you're going to identify.

DR. EGGERS: But we can go a little bit over to the break?

DR. TOIGO: Yeah. Well, we're about 10 minutes behind.

DR. EGGERS: Okay. So we get our 40 minutes for this. Great.

Okay. My first question that I want to -- do you have a question?

UNIDENTIFIED FEMALE SPEAKER: I wanted to comment.

DR. EGGERS: Okay. Let me ask, I want to ask one general question first, and that is, we heard five experiences, and I thank you for those experiences, I know it can be difficult. It's difficult for me to stand up here and ask questions; I'm sure it's very difficult to share your experiences.

But what I want to know from the patients and those who have loved ones with the condition is, how many of you related with some person's story up here? Did you generally relate? If you feel comfortable, can you show a raise of hands?

(Show of a lot of hands.)

DR. EGGERS: Okay. So we're pretty reflective of experiences. And at the end we'll talk a little bit about some of the differences that you might feel, but I want to focus first on the similarities.

And we're going to go through some of the key symptoms and sets of symptoms that we heard today. We heard a lot about cognitive functioning. I'm just going to use that as a catch-all. We heard a lot about the collapse. We heard about sensoral sensitivities to light and sound. We heard about problems related to blood pressure and orthostatic intolerance. And then we heard a lot about the impacts.

But let's focus on the symptoms first. And I would like to start with the cognitive functioning ones. So we heard each of you, I believe, mentioned cognitive functioning. We heard brain clouds over, confusion, and where you have significant time limitations, and I would just like to see if anyone would like to build upon and share their experience about the cognitive functioning limitations that they would feel comfortable sharing.

Okay. And that's right, I don't have to go to you. Microphones will come to you.

MS. NICHOLSON: I have significant --

DR. EGGERS: Can you state your name?

MS. NICHOLSON: Oh, yes. I'm Matina

Nicholson. I've had ME for almost 7 years. I have significant cognitive dysfunction, and partly it turns -- just minimally if I just read something, I can't retain, short-term memory loss. My body just shuts down. It's hard to concentrate. I can't focus. Word-finding, talking is difficult, so I have to kind of be quiet because I have to talk on the next panel. Otherwise, I will start stuttering or I can't get words out. So those are the most common. I have a lot more, but that's briefly.

DR. EGGERS: Can I just, before we go on to the next person, if you feel comfortable raising your hands, for who has problems with finding words or getting words out and speaking.

(Show of some hands.)

DR. EGGERS: Okay. Any other types?

(Show of hands.)

DR. EGGERS: Yes.

DR. SMITH: Dr. Janet Smith. I'm one of those working sick. And I find that decision-making is very stressful and I have more problems with decision-making. And getting to the question about whether

mental fatigue versus physical fatigue, they are both extremely fatiguing. The mental fatigue, I'm just totally wiped out. The physical fatigue has more muscle pain associated with it.

DR. EGGERS: Okay. So the challenges with decision-making or decision-making becomes harder, slower, more troubling, more anxiety about decision-making, if you feel comfortable raising your hand to say that you have that general experience.

(Show of a couple of hands.)

DR. EGGERS: Okay. Okay. Anyone else?

(Show of hands.)

DR. EGGERS: We're on this side of the room, so let's go with Mary first, and then I'll come to you.

MS. SCHWEITZER: I'm on the next panel, so I'm going to talk about me in the next panel. Right now I want to talk about the people up here, who I know almost all of you. I know many of the people in this room because I see you at CFSAC meetings, and what people here don't know -- I do better because I'm on treatment -- what people here don't know is how much effort it took for these people to talk, and after

people get up and testify, for one thing, sometimes you'll hear them testify, "You're going to be cut off in 3 minutes," "You're going to be cut off in 5 minutes," and they speak very slowly because it's hard to remember or read what it is that you're reading because you have cognitive dysfunction.

And then once when I was very sick and I was testifying, as soon as I was through, I passed out on the floor, and my friends knew what was happening, they saw me slipping from the chair, they got up, they got me, they brought me back, they brought me back and let me lie down in the back of the room, and somebody brought me something to drink.

This happened to another friend of mine, I could tell she was about to crash because she started shouting suddenly and getting more incoherent and louder, and I knew she was about to go, and she did, boom, down she went, and we had to take her in the bathroom, and she was sitting on the floor, and we were giving her something to drink, and it took people quite some time to get her settled again. I ended up driving her home. She was incoherent the whole way home. She

has no memory of that. And I had her spend the night in my house instead of driving home because obviously she couldn't drive.

So what a lot of you people don't know -- and we know because we take care of each other, there is someone else who is here, Carol is the back here somewhere, when I crashed once, Carol and her husband took care of both me -- and I was with someone else who was a patient, we had come on the train, the patient, I had taken care of her and brought her, she didn't know how to get back on the train, so Ken, the husband, had to take the other patient back to Union Station to get her on the train because she didn't know how to do it by herself while Carol took care of me and Ken came back and got me and Carol, and they took me home, and I laid down on a sofa while they called my husband, and he drove down to pick me up from Delaware. We met at BWI.

So the thing that I want everybody here to understand is that the patients who are speaking are generally speaking at a great cost to what they are going to be like after this. And I wish some of you

could see what we are like afterwards, what they are like afterwards, because then you might understand this disease a lot better. Okay.

DR. EGGERS: Thank you very much, Mary.

(Applause.)

DR. EGGERS: Before going back to the next person, let me just get a show of hands if you're comfortable, how many of you would put as a significant symptom for you the idea of confusion that is so bad that it scares you, that you don't know what you've done, that it causes anxiety?

(Show of a few hands.)

DR. EGGERS: Okay. Okay. So we have -- and I'm sorry I can't see your name. Yeah, in the --

MS. WILLIAMS: Chris.

DR. EGGERS: Chris. Thank you, Chris.

MS. WILLIAMS: I'm Chris Williams, and I'm patient, and I'm going to be on a panel tomorrow. I just wanted to pick up on something that Jon was saying as someone working. I am no longer working, but I did work for 2-1/2 years after I got sick, and I also had a very demanding job working in Federal Government doing

health policy, and I was used to supervising about 70 people, running multiple activities, et cetera, and when I was diagnosed, I was diagnosed on the, quote/unquote, mild end of the spectrum.

One of the things that I was no longer able to do, and am no longer able to do, is multitask, and those of us who have demanding professional jobs understand what that means. Even though my husband has been very, very supportive over the almost 5 years I've been sick, he does not really get the no multitasking idea. When I tell him that I have to finish what I'm doing first before I can get on to the next thing, he really does not get that even though he lives with me and he's seen it.

So I think that there is a sort of a slippery slope going from what we were able to do as high-functioning professionals to the impact of this illness.

I also had another comment on something Jon said. Could I?

DR. EGGERS: Sure.

MS. WILLIAMS: You were talking about the

crash and the physical versus the cognitive, and I, both as a professional and personally, was somebody used to doing a lot of public speaking, and one of the things, while I fortunately don't have the most serious of the cognitive issues, when I speak, whether it's publicly or going to talk to my therapist about how depressed I am that I'm sick, I get a sore throat, and the sore throat comes on, I know it's going to come on, I know it's just a price I pay to be on a phone call, to be in a public venue, or even at a social venue, and I did not know about the anti-inflammatories, but I'm going to follow up on that.

Thank you.

(Laughter.)

DR. EGGERS: Okay. We've heard a lot about cognitive limitations. First, does anyone on this side have a comment, any that they want to share an experience? I just want to make sure I don't always look over on this side.

Yes? Yes, Tasha.

MS. KELEMEN: Hi. My name is Tasha. I'm going to be talking later. I just wanted to respond to

what I thought was an interesting question about the different way we react to overexertion mentally versus physically, and I have noticed a difference. When it's too much physical activity, I find that the sensation, the response, is very much one of the whole body throbbing, sort of a sensation of some kind of inflammation as well as the muscle pain. With the overexertion mentally, I get nauseous feeling with that, and it's a little bit strange to explain, but it's sensations that's a lot more focused in the head and the neck.

DR. EGGERS: I will at this point ask if any of my FDA colleagues want to ask a follow-up question about anything they've heard so far.

(No audible response.)

DR. EGGERS: No? Okay. Okay.

Does anyone have a real pressing cognitive one that they want to talk about?

(Show of hands.)

DR. EGGERS: Okay. We had a comment right there in the back.

DR. GROBSTEIN: My name is Joan Grobstein.

I'm a physician. I've had ME for 13 years. I'm not going to stand up because I really can't. I would just like to comment that I think when you use the term "anxiety," that is not really correct.

DR. EGGERS: Okay.

DR. GROBSTEIN: What people experience is fear, not anxiety. Anxiety is something that you're worried about that might not happen. Fear is when you know that something bad is going to happen and so you pull back from doing whatever you're doing in order to avoid it. So I think it's very important to make it clear that this group of patients is not anxious. We have a severe condition that causes huge impacts in our lives, and we have a very legitimate fear of what happens when we overexert ourselves because we have experienced it.

(Applause.)

DR. EGGERS: Thank you, Joan, for the clarification. I was going to say I saw a lot of head nods, and your claps reaffirm that.

I know that there are others who want to talk about maybe cognitive, but I do want to make sure that

we move on to talk about the crashes that come on from either the cognitive exertion or the physical exertion, and if we have time, we'll come back and ask any other questions.

We have talked a lot about what triggers it, what triggers those crashes, is what I'll call them for lack of any other term. And how many of you, when you've heard other people talking, like Tasha and John talking, say, "Yes, I experience -- those are similar to what I experience"?

(Show of a few hands.)

DR. EGGERS: Anyone who has something completely different that happens to them when a crash is about to happen that they want to share?

MS. LOPEZ-MAJANO: There are times that you have no idea when a crash will happen.

DR. EGGERS: Okay. Can you elaborate, please? And if you could state your name.

MS. LOPEZ-MAJANO: Denise Lopez-Majano. There are times that you have no idea when a crash will happen, when something that you can normally undertake suddenly produces a collapse.

MR. LANDSON: I just want to echo that. Joe Landson, sorry. One thing could be the straw that breaks the camel's back. You try to measure out your limited life as best you can, and you overstep sometimes.

MS. VON SALIS: Yeah, I agree. It's the unpredictability of this that's really, really quite difficult to live with.

DR. EGGERS: Does anyone want to share about, follow up, build on what they're saying?

(Show of hands.)

DR. EGGERS: Yes?

MS. NICHOLSON: Yeah. Crashes are unpredictable. For instance, for me, I have to go 2 hours to see my doctor in New York, no one will treat me where I live in Delaware, and one time just to drive 30 minutes to a train, get on a train, get off the train, and then I went to go get a cab, I actually blacked out, and I started walking across the street, and the bus started honking and just nudged me. Thank God it went from a red to a green, and I just looked up, people were yelling, and I was just, "Oh, wow." And

it can just happen at any time, and it's hard to manage that for me.

DR. EGGERS: And are there times when you -- are there ways that you have found that you can make it more predictable in a sense?

(Show of hands.)

DR. EGGERS: Yes? And if you could just state your name?

MS. BEAN: Hi. I am Diane Bean, and I am a caretaker for my daughter Lauren, who is here with me. And I just want to make the point that obviously the symptoms that everyone else has talked about are things that she has experienced. She used to be also an honor student and an athlete, got sick at age 15. But one thing that we have noticed that hasn't really been emphasized I think yet is how interrelated they all are. So when you talk about the crash, you know, it's not just the physical pain or it's not just the head pain, it's also more cognitive impairment, more orthostatic intolerance, more neurological issues. So they're very interrelated, and I do think it's important to tease it apart, but we've been in search

of the treatment that's going to sort of get at the core problem for the 15 years that she's been ill, and without success, because it's been our experience that when some of it is better, it's all better. And if there is any predictability at all, the one thing that Lauren has noticed -- and this is more a negative predictability -- is that the worse sleep she gets, the worse she's going to feel during the day across the board in every way, the more lightheaded she'll be. And so sleep for her is something that we suspect is a major symptom. She has had two separate sleep studies, which shows that she gets zero slow-wave sleep, and this is even with sleep medications.

DR. EGGERS: Okay. We have someone in the back?

MS~~DR~~. TOIGO:Sara, you have 20 minutes.

DR. KWEDER: Can you ask about the sleep?

DR. EGGERS: Oh, sure. Before we go there, Dr. Kweder, would you like to --

DR. KWEDER: Yeah, I would like to know -- several people did mention them. I would like to see in the room for how many people lack of sleep or poor

quality sleep seems to be a trigger for these crashes.

(Show of a lot of hands.)

DR. KWEDER: Yes. Thank you.

DR. EGGERS: Okay. Yes, let's go --

MS. CASSIDY: Hi. I am Shannon Cassidy. I'm a patient. I just wanted to address the question of whether you can predict a crash and if there are any signs. I think there probably aren't in terms of the way I start feeling, to say, "Oh, I'm going to crash." I think there are things that I know that will make me crash, which is pushing it too hard, having been physically overexerted, having had to think real hard, and so I kind of know that it's going to come, whereas there are other times where I haven't done that and there is no warning, there is nothing I have done, there is nothing I can attribute it to, and for me literally it's an eye movement, like I'm looking here, I look over there, and, boom, I know I'm going to have a crash because I can feel my whole body changing, it's like an instantaneous knowledge.

DR. EGGERS: And how long will that crash last? Let me just follow up a little bit.

MS. CASSIDY: That crash can last anywhere from a day to weeks.

DR. EGGERS: Thank you.

Yes, we have a question.

MS~~DR~~. TOIGO:Just to clarify, when Sandy asked the crash/sleep/sleeplessness connection, I think people were responding to the sleeplessness but maybe not the connection.

DR. KWEDER: Right.

DR. TOIGO:So can we ask the question again 11 --

DR. EGGERS: Sure.

DR. KWEDER: Yes.

MS~~DR~~. TOIGO:-- the way you wanted to ask, Sandy, and make sure that you get the right --

DR. KWEDER: Okay, right. I'm sorry, I don't want to interrupt the flow here.

DR. EGGERS: No, no.

DR. KWEDER: But my question is, how many of you would say that when you know you've had poor sleep or when you've had a poor night's sleep, that that is likely to trigger a crash?

(Show of some hands.)

DR. KWEDER: Okay.

MS. HARPER: We're looking at each other like we always have poor sleep.

DR. KWEDER: All right. But if it's particularly problematic, particularly, because the mom said she knows when her daughter has a particularly difficult night that it's going to be a problem.

DR. CHU: Hi. My name is Lily. I'm a patient. I'm also a physician. And I will be on the panel tomorrow. But I just wanted to comment about sleep. So there is always this concern that maybe people with CFS, if they only slept better or slept a longer number of hours, that they would feel better, and I want to dispel that notion. For me, I could sleep 10 to 12 hours a night, and I do, and I still don't feel good in the morning. Of course, if I get less than 10 to 12 or if I have a bad night for whatever reason, I feel even worse.

DR. KWEDER: Right, and that's what I was asking.

DR. EGGERS: I see a lot of heads. Is that

generally shared? Okay. Okay.

MS. BEAN: If I could just clarify. Hi. I'm Lauren Bean. I just wanted to clarify, it's not necessarily that an especially poor night's sleep will make me crash, but that if I have had an especially poor night's sleep and I do something that I would have normally done on a day when I got better sleep, I'm much more likely to crash, and I know that going in usually.

DR. KWEDER: Thank you.

DR. EGGERS: Just to stay on -- oh, let's let Dr. Michele ask a question.

DR. MICHELE: Actually two questions. One is by show of hands, if you could just tell me how many of you find that the onset of your crashes are always rapid, like within minutes to an hour or so?

(Show of one to two hands.)

DR. MICHELE: So that's not necessarily the case, it may come on more slowly.

The second question is with regard to duration of crashes. If anyone could comment on if you have a more mild event that set off your crash, are you

likely to have a shorter duration of your crash, whereas if you did more exertion prior to the crash, are you going to have a longer crash? Is there anything predictable about that?

DR. EGGERS: Okay, I see head noddings. Let's let Ms. LaRosa.

MS. LaROSA: Pat LaRosa. For me, I don't know when I'm going to crash. And I'm trying to remember what you just asked in that question. Could I ask you --

DR. MICHELE: Duration.

MS. LaROSA: That's right, duration. The duration of the crash? No, it doesn't seem to correlate at all, and it may be that it was a lot of very little things over the preceding days or weeks that you're not aware of, or it just could be that you did too much in one day or had poor sleep. It's just sometimes it's there and sometimes it's not. When you feel good, you feel good, and you pay for it. We will all pay for this, this weekend, but we appreciate the chance to share it.

DR. EGGERS: Thank you. Okay. Anything else

about this? And then I'll move on to another set of topics. Someone who hasn't --

Mr. Miller?

MR. MILLER: So Robert Miller, a patient since 1982. So this is a great question because I literally got in yesterday and had a pretty good evening. Got up this morning, I've had a pretty good morning. I just went to the business center and my crash just started. So I don't know why I went to the business center. You know, I got there, sat down, logged into the computer, and I was like, "Why am I here?"

Now, there will be days when I can go outside, function with my kids, and exert energy and will not have anything set me off, there will be no crash. So just like Pat just said, it's just like when it's coming, it comes, and sometimes it's not that you've done some major expenditure of energy. So that was it.

DR. EGGERS: So generally I see a lot of head nodding in agreement with this.

Before we move on, Dr. Burke?

DR. BURKE: It sounds like there are many times of crashes actually, I mean, that there is the kind of crash where you are blacking out, like crossing the road and blacking out, and then there is the crash where you have a click and there's a loss of cognition or memory. And I just think there's a lot that we could explore here. I don't think we could possibly get to the end of this in one afternoon.

DR. KWEDER: That's okay. That's okay.

DR. BURKE: But I think if we could hear more about what we're defining as a crash or a collapse, that would be really useful, and the range of that.

DR. EGGERS: Okay. Sure. So can someone say where they -- let's go with someone over there next to Mr. Miller?

DR. SMITH: Dr. Janet Smith. There are two types of crashes. There is the mental one, that Bob just described, and that's actually what I sought treatment for, is because I was finding myself going down a one-way road the wrong way and over a bridge with no sight, and it could have been deadly. Another time I was in the hospital and I knew -- I had been to

the hospital thousands of times, and I got out the elevator and couldn't remember where to go. The physical crash is like if you run a marathon and you bonk. I mean, I can barely put one foot in front of the other, I can barely lift my arm, I jerk.

UNIDENTIFIED FEMALE SPEAKER: (Off mic.)

DR. SMITH: No, no, I jerk, too. So that's different crashes.

DR. EGGERS: And when you say you jerk, can you just explain just so we all know what you're talking about?

DR. SMITH: All of a sudden --

DR. EGGERS: Your body is jerking.

DR. SMITH: Yes. I almost knocked a table over one time because I had my legs crossed, and my foot jerked, and set the table over.

DR. EGGERS: Okay. Is this a type --

DR. BURKE: And then something more about the duration. Oh, I'm sorry. And then the range of duration. We're seeing that all of the symptoms improve at once for some people, and I heard one person say that it could last for weeks or it can last a day.

And so can we qualify those crashes by time, length of time?

DR. CHU: The reason why I'm waving here is because this is a basic question I don't think has been really well answered, and I've actually reviewed the studies on this, the few studies, and what they find is that people can crash within a few minutes of an activity or even days after, and it's like a moving target.

In terms of duration, similarly, some people can crash and it will last for a few days, but it can last for weeks or months depending on the type of thing they were doing before.

DR. EGGERS: Okay. So, let's see, let's go with -- and then we'll get Amanda and then we'll get over here. Okay?

MS. HARPER: Hi. My name is Kathleen Harper. I'm a registered nurse. And I've had several types of crashes, but the worst ones were after I had like minor skin surgery and pneumonia. After the pneumonia, I had a 2-year crash. After the skin surgery, it was about 6 months. And just this October, I had to go -- I went

to the supermarket, I was feeling okay, I was with my daughter, which helps to be with someone, and they had no water. I needed to go -- so we had to go to another supermarket. Well, that did it. I was disoriented and everything, but I got home and I got into bed. That night I had to -- I woke up with heart beating out of my chest, and I couldn't breathe, and I called the ambulance, and they said I was in atrial fibrillation, and that was the first time that ever happened to me. So I apparently pushed myself where my heart just -- it's a muscle and it went just -- it went berserk.

And ever since then I've been trying to recover from that where now I can't go to the store the way I used to, like which was once or twice a week I was able to do that. And I just got driven here. And I've been sick for 22 years, and it all started with my teenage daughter getting mono, and she's still sick, and I'm still sick, and we really desperately need help. It's getting worse. Now my heart is being affected, I'm on medication that actually makes me more tired, so I'm trying to beg the doctors, "Give me something else," I'm like so sleepy. So anyway, it's

nice to be here and have a place to be heard.

Thank you.

DR. EGGERS: Thank you very much for the feedback.

Shall we let Ms. Simpson talk? And then we'll come over here.

Right here in the front?

MS. SIMPSON: Hi. I'm Amanda Simpson, and I'm a patient. And I would just say -- maybe I'll help explain -- I have my symptoms all the time, it's just a matter of whether or not I can function, how bad those symptoms are. For me, a crash is when my symptoms get to the point where I just can't go anymore, I don't have any cognitive function left to focus, to be able to speak coherently, or my body just simply won't go anymore. And I haven't had the blackouts or anything like that, and they'll last anywhere from a day to I've had one where I was in bed for 3-1/2 months and struggled to make it from my bed to the bathroom. And yet here I am now. So it's just, I think, one of the most frustrating parts about the illness itself, is that you have no way to plan your life, it's definitely

difficult.

DR. EGGERS: Thank you.

And here?

MS. HART: Thank you. My name is Karen Hart. I would like to speak to the crash as well. I know where my social envelope is, and that's about 1 hour and 45 minutes. If I exceed that, I pay that price. So 2 weeks ago I had tea with my lady friends, which is probably easy for you to do, but because I went to about 2 hours and 30 minutes because someone else was driving, that was 5 days for me in the house because of an extra 45 minutes of social interaction, and that means 5 days of avoiding conversation, of not leaving my home, of not answering the telephone, of e-mail, all that stuff, it's just too much, because of that 45 minutes. What is this going to cost us? Weeks. I don't have anything on my calendar for 2 weeks. Do you? Because what is this going to cost me? There is no way for me to predict that.

DR. EGGERS: Thank you.

MS. McCLEARY: Sara?

DR. EGGERS: Yes. Yes. Go ahead. Kim?

MS. McCLEARY: So there were three themes that came out that weren't necessarily just words that popped out of our survey in answering this question, and the three themes were "restriction," "dependency," and "adaptation," and that's what I'm hearing a lot of in the comments also.

And if I could just read five quick quotes that are direct quotes from the survey. "My day is structured around my illness." "Every aspect of my life has been adjusted, my job, my role as mother and wife." "I call myself in jail, a prisoner of this disease." "I have a very small life." "I'm living a life of lowered expectation and I feel like this is a living death."

DR. EGGERS: Can I just ask, how many of you saw your own experiences reflected in those quotes?

(Show of some hands.)

DR. EGGERS: Okay. Dr. Kaiser.

DR. KAISER: Yeah. I would like to try and just put into pseudo-medical terms what I think we're all trying to describe about these crashes, and that is, it's almost like your nervous system at any given

point just completely runs out of energy and you just fall off a cliff, and it's then followed by sometimes an inflammatory cascade.

And as someone who has recovered to a good extent from this, when I finish a workweek, my Saturday and my Sunday are completely different experiences. I spend the entire day Saturday in the midst of recovery and fog and pain and exhaustion. And fortunately that recharges my nervous system enough so when I wake up Sunday, I often feel completely normal. And so for me, the recharge occurs to a significant extent with a full day of bed rest, but I think for many people who are speaking who have the condition more serious at this point, that when your nervous system runs out of gas, it can take weeks to recharge it.

MS. VON SALIS: Or months.

DR. KAISER: Or months.

DR. EGGERS: Okay. I just want to do -- looking at the time, we have about 3 to 5 minutes left, and I know that we aren't going to be able to cover everything, but what I wanted to get -- and let's see if we get to this -- is there anything that you have

had in your experience that you haven't heard anyone on the panel mention, you haven't heard it in anyone else's comments -- okay -- that you want to make sure is important to say. Now, we only have 3 minutes. I know everything is important, but we'll try to get as many as we can.

MS. BURMEISTER: My name is Jeannette Burmeister. And this is something that I think is very important and hasn't been brought up, and that is that my crashes pretty much correlate with very low NK cell function and very high viral titers, so that's pretty much something that my doctor, Dr. Peterson, and I have figured out, so my NK cell function could be as low as 1, which is basically no functioning NK cells at all. So this is something that's measurable, it's not just a subjective, "Oh, I feel lousy today," kind of thing. We do have the science already to measure this, and I think it's very important that people know about that.

(Applause.)

DR. EGGERS: Okay. Are there any follow-up questions to that one on the table? Okay. Anyone? Okay. So we'll -- let's see, yes, we'll go there, and

then we'll go over --

MS. HART: I simply want to say that I have blurred vision and double vision. You all have four eyes. That's really disconcerting to look at.

(Laughter.)

DR. EGGERS: Okay. Ms. Spotila.

MS. SPOTILA: My name is Jenny Spotila. I'm a patient and I'll be on a panel tomorrow. No one has mentioned gut problems, irritable bowel syndrome and other gut symptoms, and how those flare up also in reaction to activity and crashes and may have their own cycle. Even on good days your gut can still be out of whack.

DR. EGGERS: Okay. Any follow-up questions about those problems?

(Show of hands.)

DR. EGGERS: Okay. I think we have time for one more. Okay. We'll do two more because we haven't heard from you in the back.

So first in the purple shirt. I can't -- sorry.

DR. GROBSTEIN: Hi. Joan Grobstein. I just

want to comment that I think we're hearing varying descriptions of a single phenomenon, and I would like to point out that if we did not know that people with diabetes had high blood sugar and we just listened to them describe their experience when they have high blood sugar, we would have a similar variability in what we heard. So I want to make the point that there is probably a single underlying thing that is happening to all of us patients that we have not yet identified.

DR. EGGERS: Very good point. And finally in the -- oh, yes, in the back there. Yes. I'm sorry. Raise your hand.

MS. VITKA: Oh, okay. Hi. I am Susan Vitka and I'm a mom of a patient, and I just wanted to say there is one other measurable symptom that always comes along with a crash, which is the sore throat, that's been mentioned, but then also a fever. So something is happening that's measurable in a certain sense.

DR. EGGERS: Okay. And I guess we have one more in the back.

MS. PATTON: Hello. Anita Patton, 26 years. Anyways, there are two things. One, if you're not

sick, you might understand. Like you're working on the computer and all of a sudden it says, "Not responding." That's like all of a sudden you have nothing to draw from. So this is a scientific situation. Like there is always a "Why? Why is this happening?" A lot of times -- and this hasn't been mentioned -- is a trigger would be a viral or a bacterial infection. Instant nothing, no output of energy. So you say output of energy, it's ATP, just a basic science, biology, whatever high school class where, why is your body not making ATP? So those are like the questions that help us maybe find answers.

DR. EGGERS: Okay. Thank you. Okay. I want to sincerely thank all of you for your input into the first discussion on behalf of my colleagues up here at the table. We are going to take a 15-minute break, so we will be back at 3:05. And at that time, I would like for the people who have been identified for the second panel to work their way up at that break. Again, the rest rooms are located behind us here, and there are some chairs in the lobby. And if there are any questions, let me know. Thank you very much.

Oh, I'm sorry, one thing. Graham is telling me there are some evaluation forms, completely voluntary, if you would like to fill them out and return them at the end of the day.

(Break.)

DR. EGGERS: Can we have everyone start to take their seats? And if as you're taking your seats, if you are a patient or a patient representative, and in particular if you want to participate in the facilitated discussion, can you move up to the front? My eyesight is hard enough to see in the front row, I have a challenging time seeing in the back. Discussion Topic 2: Patient Perspective on Treating CFS and ME

DR. EGGERS: Okay, I'm going to get started with the second discussion topic, and again the format of this discussion topic will be identical to the last discussion topic, which I thought was truly such a good discussion, and we look forward to the discussion to the next topic, which is really focusing on patients' perspective on treatment approaches. And we have again five people who will present their comments first to set a good foundation for our broader discussion. We

have Mary Dimmock, Tasha Kelemen, Matina Nicholson, Mary Schweitzer, and Amanda Simpson, and they will share their experiences. They each have prepared a couple, 2 to 3, minutes of remarks. We'll go through their comments and then ask a few follow-up questions for them, of them, and then broaden it to the rest of the participants in the audience. Okay?

The questions that we're looking at are focused on understanding the treatment approaches that you take as patients to help treat your condition or its symptoms, including prescription medicines, over-the-counter products, non-drug therapies, such as activity limitations, et cetera. And what we're really looking for is what specific symptoms your treatments address, or how do you feel after you take those treatments? And then we're also looking to see, what are the downsides of those treatments, for example, the side effects?

Now, there are a number of treatments. We're going to hear from up here and we're going to hear from through our discussion, and we're just going to try to do exactly what we did for the first topic and cover

whatever we can knowing that the docket is available and we want to hear your full perspectives through there. Okay?

With that, I will turn it over to Mary Dimmock to begin. And Mary -- just so everyone knows, Mary is a caretaker of someone with CFS and ME. Panel Comments

MS. DIMMOCK: Thank you, Sara, and thank you to the FDA and to everybody for being here today. I'm speaking for my 25-year-old son, who woke up one day with myalgic encephalomyelitis after contracting Giardia while backpacking across Asia. Three years later, he is largely housebound, often unable to read or write more than a few sentences, sit or stand for long periods of time, watch TV, listen to music without exacerbating his symptoms. He spends his day, most of his day, lying flat listening to audio books.

In the years before he found an ME specialist, doctors were dismissive or gave him ineffectual or harmful recommendations. One, exercise at a gym landed him in bed for a couple days. After reaching an ME specialist, he was prescribed Imunovir

to address low natural killer cell function and high inflammatory cytokines, Florinef for orthostatic intolerance demonstrated by a tilt table test, mirtazapine to alleviate non-refreshing sleep, Equilibrant to deal with various viruses, antifungals for Candidas, supplements to treat low neurotransmitters and low cortisol, and an activity program to try to address the post-exertional malaise. He uses sleep hygiene, strict pacing, and an avoidance of sugar, alcohol, and coffee, and he was also on a long regimen of treatments, antibiotics for Lyme disease.

Of all these treatments, Florinef, the antifungals, the dietary avoidance, and the strict pacing have had an effect either on specific symptoms or on helping him to avoid relapses, but there are only two drugs that have made a difference, two treatments that have provided a big difference, the azithromycin-doxycycline combination for Lyme led to an amazing increase in his ability to get around. He would be out of the house for 5 hours at a time. He was able to read entire books. He read 1,000 pages of books in 6

weeks. He was able to walk a couple of miles. But it only lasted 6 weeks, and in spite of another year of IV, IM, and oral antibiotic treatment, it never came back.

The second drug, Kineret, was prescribed for high IL-1. It decreased his inflammatory cytokines significantly and normalized his neurotransmitters, but it produced limited functional change.

He is slightly better. He wakes up feeling slightly better in the morning. He is able to do about an hour of activity every other day instead of every fourth day. He is able to tolerate sitting up for a little bit longer periods of time, and he has a slight decrease is cognitive issues. We would barely notice it. The healthy people in this room would not think it was important to them at all. To him, it's like a miracle, but it is not the dream he has of regaining his life. Because of his immunological markers and Kineret's lack of clinical effect, his doctors have prescribed rituximab. It's not FDA approved for this disease, so if he is going to go onto it, he's going to have to pay for it out of pocket.

He has access to one of the best doctors in the country, he has good insurance, and he is well supported by his family and his wife, but in spite of this, over all this time, he remains in bed sick with little quality of life and little hope that he will ever get better. He is willing to accept significant risk in new treatments and trying anything to give him back his life and to escape this hellish debility of this disease.

Thank you.

(Applause.)

DR. EGGERS: Thank you, Mary.

I'll ask Tasha Kelemen to go next.

MS. KELEMEN: My name is Tasha Kelemen. I developed CFS in 1996 following a tropical illness I had while working in Angola in Africa. I believe I can provide a unique perspective on the treatment of CFS since I have been diagnosed and treated for the illness in three different countries: in Belgium, in the U.K., and in the U.S. Treatments have included everything from antibiotics, azithromycin, doxycycline, antivirals, Valtrex, famciclovir, to supplements, B-12

injections and others, graded exercise therapy, CBT, and pacing. I'm currently on famciclovir, 500 milligrams, and low doses of Savella, 25 milligrams, and amitriptyline, 10 milligrams.

Other than in the U.K., I have been lucky to live in locations where I had access to a CFS specialist covered through my insurance. This is not the case for many patients. The main reason I wish to comment today is to caution against what I see as a possible harmful trend to uncritically adopt the treatment approaches favored in the U.K.

I will provide a brief background to my illness for context. My illness started suddenly in April 1996 when I was working in Angola. I developed very sore muscles, fever, severe fatigue, and lost approximately 20 pounds over 2 months. I had a rash on my arms. I returned to Belgium and during the following years had recurrent bouts of throat infections with swollen glands, fever, and muscle ache. I also developed headache and dizziness.

I felt increasingly persistently fatigued and found it a struggle to keep up with the demands of a

full-time job. (Becomes emotional.) I found that my symptoms got worse after exercise.

I was diagnosed with CFS in January 1999. I moved to work part-time. I moved to the U.S. in 1999. During the following 2 years, my symptoms became cyclical. I would have 4- to 8-week bouts of severe fatigue with sore throat, muscle ache, headaches, joint aches, followed by relatively good periods. From October 2000 to May 2001, following testing revealing a Rickettsia conorii infection most likely contracted in Angola, I was treated with antibiotics. I can't say for certain whether this treatment helped, but I was consistently well until June 2003. I was able to work full-time and to be fully active outside of work including doing physical activities. However, in June 2003, around 3 months after the birth of my daughter, I became very sick with CFS again. (Becomes emotional.)

DR. EGGERS: Tasha, we can come back. Why don't we go to the others and we'll come back and you can finish?

MS. KELEMEN: I'll be fine. I'll hurry up. Sorry.

DR. EGGERS: Oh, don't worry. No worries.

MS. KELEMEN: For the next few years I grew very sick, worse than previously. I had to spend a whole year in bed and was mostly housebound for 2 years. I felt that it was my great misfortune to be living in the U.K. at this time. I was not offered any kind of treatment other than a referral to a CBT program, for which there was a 2-year waiting period. I saw several general practitioners, primary care physicians, who generally treated the illness with much skepticism.

In 2005, I was provided the opportunity to enroll in the PACE trial in Oxford, for which I could choose GET, graded exercise therapy, or CBT. I chose GET, as it provided an opportunity to get physical therapy. I found the opportunity to see a physical therapist weekly to work on gentle stretches very helpful. I was able to increase the distance I could walk slightly but remained very limited in my mobility. GET helped only to a limited point. It was in no way a cure.

The GET program included a patient manual.

The manual tried to explain how CFS symptoms, not including symptoms like headaches, dizziness, twitching muscles, were the result of deconditioning. I was referred to CBT in 2006, when my name came up on the waiting list. I went to a few sessions before leaving for the U.S. I did not find it helpful. By the end of 2006, I had started to improve. I had started weekly B-12 injections in 2005 and think that these did help with muscle pain and concentration.

I moved back to the U.S. in 2007 and started on Valtrex in line with the results of EBV and herpesvirus tests. Since then I've been on and off Valtrex and I'm now on famciclovir. I went back to work in 2007 starting part-time at 10 to 15 hours and have gradually been able to move to 25, 28, 32, and now 35 hours per week. I believe that the antiviral treatment has really helped me.

Of course, it's hard for a patient to know what works with CFS because the symptoms themselves shift over time. Though I am much better today than I was for most of the past decade, nothing I have tried is a cure. Of the many different treatments I've tried

over the years, I believe that the following have been particularly helpful at particular points in time: Valtrex, famciclovir, vitamin B-12 injections, Savella, and pacing. I don't see evidence for any of the others in my case.

I believe all CFS patients should be provided with access to a trained physical therapist to work on stretching and exercises that meet their individual capacity. I believe this is a simple missing piece that could benefit many of us. For me, pacing is the number one most effective strategy without which I would never have been able to go back to work.

I now have an exciting job as the executive director of a small nonprofit organization. I still can't walk more than 3 blocks, I can't stand more than a few minutes, but I am lucky to have seen significant improvements in my mental concentration. I spend a lot of time in bed, need to rest after work and on the weekend, but being able to work has been very important to my health.

I believe that the U.K. does not apply the same criteria to the diagnosis of CFS that the U.S. and

other countries do. I don't remember being asked about symptoms outside of fatigue when joining the PACE trial. I therefore think the results of the PACE trial are not generalizable to those who meet the narrow definition of CFS outlined by the Canadian Criteria. I never had access to a trained CFS specialist, as claimed by the study authors. I also think the U.K.

approach is harmful to patients. The idea that all CFS symptoms come from deconditioning that could simply be avoided by overcoming negative thought patterns is ridiculous and offensive.

The U.S. should think very carefully and look a bit more closely at the GET and CB PACE trials before promoting similar approaches in the U.S.

(Applause.)

DR. EGGERS: Thank you very much, Tasha.

Matina Nicholson?

MS. NICHOLSON: Can you hear me? Okay. Hi. I'm Matina Nicholson. I've had myelitis (sic) encephalitis for over 6 years. Prior to that, I had a successful career. I was moving into senior management at a top pharmaceutical company in marketing. So now

due to the time, I will address the treatments that are for my most significant symptoms because my list of symptoms is very long.

First, I have a lot of significant cognitive and neurological symptoms, but at this time there are no treatments that are working for me. I need to really go back to a neurologist.

Next is post-exertional malaise, PME (sic), or penny (ph). I take -- just to be here today, I take a high dose, within label, of Adderall, therefore, I do that if I have to go to doctor point meetings or advocate, but sometimes I take up to 60 milligrams of Adderall, and I'm still sleeping at that time, I listen to my body.

For autoimmune, I do Myers' cocktail. I can't get to my doctor's in New York, 2 hours or 3 hours, so I can only get that bimonthly. I self-inject. I get gammaglobulin shots once a month, self-inject B-12, and glutathione. I am also on levocarnitine and Vitamin D shot or pill. For sleep abnormalties (sic), I use Ambien and Xanax most likely when I'm on the Adderall because I take so much

Adderall, it's hard for my body to unwind, but again I kind of watch what I take because I don't like using something up and coming down, so I'm very careful. So like last night I only got 2 hours of sleep. Pain due to fibromyalgia, I use Cymbalta, Vicodin, or a heating pad.

My treatment regime has changed a multitude of times due to new abnormalties (sic) and disease progression. To date, no treatment works well for me. They aim just at symptom control or mask the symptom. By masking the symptoms is what exasperate my symptoms, and I crash. This could last several days, weeks, or months. Currently, I'm trying to get approval for Medicare to try IVIG. Otherwise, due to the expense, I will not be able to afford it. The same with some of the other drugs in clinical trials.

My current treatments don't improve my daily life. It allows me to get to an appointment or hopefully see a friend or family, but I never know, it depends on that day, so people have to be patient with me. For me, any minimal mental or physical activity makes me very sick, leaving me a prisoner to my

bedroom.

I have many abnormalties (sic) with so far no treatments. To date, I have no treatment options at this time in terms of low natural killer cells, low growth hormone. I have very high titers of EBV, HHV-6, CMV. I tried all the antivirals. They didn't work for me and actually one antiviral I used I broke out in hives. I have high interleukin 6 and 2. I have very bad cognitive dysfunction, so I would like to really focus on some research about cognitive rehabilitation therapy that's done for MS, encephalitis, and Lyme and lupus.

The neurological issues I need treated are balance, weakness of limbs, blackouts, fainting, twitches. My one leg drags. I don't know if it's a neurotransmitter problem. Sleep abnormalties (sic), you always don't get refreshing sleep, so I think you really need to do more sleep studies in terms of any CFS patients with and without their drugs to stay awake. And then nothing is working on my GI issues. I tried everything.

So the most significant downsides of my

treatment is the use of amphetamine salts. I'm not talking about this drug, it's just for me. It causes severe dry mouth, jitters, high pulse rate, and then I can't sleep at night. After the use of Adderall, I need to take Ambien, but I can only take 10 milligrams because Ambien makes me -- over 10 milligrams, I will drive and I don't know it, I'll eat, I'll wake up somewhere doing some weird thing, so 10 milligrams is my limit.

Adderall gets me through the day, but that's just today and hopefully tomorrow. I may look happy and healthy to you, but I am suffering greatly, but I'm in a survivor mode. I am fortunate enough to attend this meeting while many patients cannot.

At this time, I am mostly bedbound, homebound, for 80 percent of the time suffering terribly with poor quality of life and no hope that I'll ever get better. I am willing to accept significant risk to escape from this disease that imposes this miserable debility and leaves so little for which to live. All my work and career aspirations went down the drain. I think I'm just waiting my turn

for heaven, but thank God for my friends and the incredible group of patients. ME/CFS patients are incredibly strong and have a lot of courage.

We look forward to partnering with you, the FDA, to find more new ways to allow us to fast-track drug approval outlined by your special drug approval process. Also, we want to look for a way to fast-track an FDA compassionate care program for this disease and this illness must be given at least equal consideration for drug development as HIV, Alzheimer's, cancer, et cetera. Our federal approval process needs to be customized for a complex, serious, and debilitating disease, and I think this is a start.

Thank you.

(Applause.)

DR. EGGERS: Thank you very much, Matina.

I'll ask Dr. Mary Schweitzer.

MS. SCHWEITZER: Hi. My name is Mary Schweitzer. I have been on Ampligen most of the time for over 14 years. I was a 44-year-old tenured professor of history at Villanova when I suffered a blackout in my office on October 24th, 1994. From that

point on, I was very sick. I suffered from blackouts, absence seizures, ataxia, expressive dysphasia, disorientation, short-term memory loss, dyslexia, tinnitus, sensitivity to light and sound, massive confusion to the extent that I once poured an entire pot of coffee into a silverware drawer, convinced it was a cup. I had intense pain behind my eyes and in the back of my neck, suffered intense headaches, and had constant muscle pain. I could not pass a Romberg test.

I practiced the enveloped theory of pacing. We treated hypothyroidism with Cytomel and Levothroid, NMH bouts with Florinef, but it didn't work, and sleep with Flexeril, Ambien, and Klonopin. This made me more comfortable, but nevertheless, my condition got worse and worse. My world grew smaller and smaller. I couldn't drive a car. By the summer of 1996, I was falling every time I tried to walk, so we had to get a wheelchair. In 1997, we added a riser to the toilet and a shower chair. Finally, in the fall of 1998, I was confined to bed, able only to make it to the bathroom and back by holding onto furniture, and walls,

and my Golden Retriever. By the end of 1998, I couldn't even brush my own teeth.

It was at this point that Dr. Dharam Ablashi found me positive for HHV-6 variant A in a study, we also found I was positive for the 37-kDa RNase L defect, both predictors of success with Ampligen, which is why my family decided to pay the expense that Ampligen was both in terms of money and time.

I began Ampligen on February 4th, 1999. In 2 months, I could walk without a cane. In 5 months, I could drive again. The most remarkable moment was when I realized that for the first time in 4-1/2 years I did not feel sick. After 6 months, the defective RNase L was gone and HHV-6A was dormant. I also read an entire book. In September, I danced with my son at his wedding and I walked barefoot on a beach. Ampligen took care of my encephalitic and neurological symptoms such as described here in this handout.

After that, it became a matter of stamina. It took a lot longer, more years, to work back up to stamina like a normal person. I continued to improve on Ampligen, and after 20 months, I thought I had been

cured, but 1 year later -- so I stopped treatment because it's expensive. One year later, I had a blackout and HHV-6A was back. It took 7 months to get back on Ampligen in Philadelphia. We decided to stay on it indefinitely and just put the cost into our current income. I remained on Ampligen for over 5 years before I lost it again. At that point, I was doing so well I could go hiking for a half hour with my brother, but in January 2008, the head of my practice died, and we lost permission to continue receiving Ampligen.

Seven months later, I crashed again. I saw my new specialist, Dr. Dan Peterson, at Lake Tahoe. I was running a fever and had active cases of Epstein-Barr and cytomegalovirus. My natural killer cell function was 3 percent. I had abnormal SPECT scan and cytokine patterns, and my VO2 max score was so low it fit Social Security's definition for permanent disability from a heart condition.

In July 2009, a spinal tap revealed that my spinal fluid contained active HHV-6 and CMV as well as the defective RNase L. We concluded I had to get back

on Ampligen, so I moved to Nevada, 3,000 miles away from my home and my husband of 25 years. I started Ampligen once again on -- (Becomes emotional.) -- excuse me -- on March 10th, 2010. After 2 months, I no longer needed a cane. By the summer, I was walking along the lake. And in August my husband sent my car out to me because I was well enough to drive again. I had to spend over a year in Nevada separated from my husband. Then in the spring of 2011, I heard that Dr. Derek Enlander would be starting Ampligen treatment in New York City, and I came home.

Today I get Ampligen by going to New York City twice a week. It's a 12-hour day. I have to take a local train to Wilmington, I take Metro -- I take Amtrak to New York, and a Metro bus out to Dr. Enlander's. I take 3 hours because now I get a liter IV saline twice a week instead of the Florinef, that works for the NMH, and I get Ampligen. Then I turn around, the other direction, 3 hours, and then I'm home.

It's that important that I remain on Ampligen. Without Ampligen, I could not be here talking

to you.

Without Ampligen, I don't have a life. I can take care of myself. I have very little stamina. It takes longer to work the stamina up, but my husband has a very aggressive form of bladder cancer, and he has to be cared for. I got 5 hours of sleep last night because we had a family crisis, and my son and my daughter both turned out to be leaving on the same time tomorrow. I am stuck in a Hobbesian choice: I can only get Ampligen by moving away or by leaving home for 12 hours twice a week, but without Ampligen, I couldn't care for my husband, and my family would have to care for me. And my son and my daughter have talked about how they would have to do that, how they would care for the two of us. Right now, it's enough trying to take care of Bob. Please don't take Ampligen away from me again. It is that important.

Thank you.

(Applause.)

DR. EGGERS: Thank you very much, Mary.

And finally we have Amanda Simpson. Can you reach the microphone?

MS. SIMPSON: Yeah. I'm good. Thank you.

Hi. And thank you so much for having me. I am so grateful for the opportunity and I am so grateful to be able to be here today. A little over 3 years ago I had to put my 15-year-old dog to sleep on Christmas Eve. Three weeks later my dad was diagnosed with cancer. And that same night my husband was killed in a car accident on his way home from the gym. As you might imagine, it was a difficult and stressful time. And 4-1/2 months later, I woke up feeling like I had the flu. Two days later I was in the emergency room. Thirteen months, 30 doctors, across Dallas, Houston, L.A., and New York later I was finally diagnosed with ME/CFS.

My life had changed dramatically in 15 months, but I simply refused to believe that my life was over at the age of 44, and so I have pursued the most aggressive treatment options that I've had available to me. I take 16 pills each day. I used to do well to remember to take my multivitamin, and I take 2 injections each week. I've been on 100 milligrams of Savella two times a day since August of 2010 for pain

management and increased energy levels, and quite simply, I believe it's the only reason that I've been able to remain on my own and that I haven't been completely bedridden. I also use Tylenol and rarely hydrocodone for pain management. I take Bystolic and diltiazem to help with my heart rate and blood pressure, both of which were fine before I got sick. It took a while to find the right sleep medication, but I now take zolpidem CR, 12.5 milligrams, and can usually get 7 to 8 hours of sleep a night. To help bolster my immune system, I take hepapressin and Nexavir injections, Immunoprop and Immunoprop Plus from Dr. Enlander, a multivitamin, fish oil, resveratrol, Vitamin C and Vitamin D supplements.

In October of last year, I began taking GcMAF, and I've had a significant decrease in the number of symptoms, including weakness, pain, brain fog, sore throat, nausea, and sensitivity to light and sound, and I have experienced a significant increase in energy and functionality. My EBV, HHV-6, and CMV levels have all decreased.

I have also embraced some helpful non-drug

therapies, including acupuncture and chiropractic care, to help treat headaches, sleep disturbance, and pain, and I believe that they've made a significant difference for me.

I changed my diet. I have eliminated almost all processed foods. I drink at least 80 to 100 ounces of water a day. I have eliminated aspartame completely from my diet, and I am in the process of converting over to the Super Immunity Diet by Dr. Furhman. I use Lumosity.com to help with my memory and concentration issues, I try to play that every day.

I rely heavily on my faith, my family, my friends, and my two sweet dogs to help me maintain a positive attitude. And I think depression is maybe one of the things that is such a misunderstanding about this disease, you know, it's easy when you feel like your life is over because of the way you feel, but I think that the positive attitude and believing that somewhere, someday out there, there is hope has helped a whole lot. And I also severely limit my stress and activity levels.

There are certainly downsides to all of this.

The drugs have competing side effects. The Savella gives me energy, the diltiazem makes me tired, the zolpidem I have to take to help sleep, and it goes on and on. And then there are the more humiliating side effects that are of a more personal nature, and I won't go there, but finally there is the exorbitant cost. My medical care can cost as much as $2,500 a month.

It was really important to me after those initial 15 months to find a way to still matter. It's hard to do that when you're cooped up in a bedroom. And I can say that although I am not as well as I would like to be, these treatments have restored a great deal of purpose and meaning to my life, enough so that I am in the process of trying to start a nonprofit organization to help speak up for those with this illness who can't speak for themselves.

DR. EGGERS: Thank you very much.

(Applause.)

DR. EGGERS: And thank you to all the panelists. I want to see -- now, I don't want to limit the time for the broad discussion, so we'll bring you guys back in. But before I go to the broad discussion,

I just want to see if any of my colleagues at FDA have any burning questions that they want to ask as a follow-up to the panelists.

(No audible response.) Large-Group Facilitated Discussion

DR. EGGERS: Okay. Well, let's go down -- and did this to myself again, I put it back. It could make a loud noise. Okay.

Now let's see if can do the same thing. Excuse me. I'll come down here. I feel much more comfortable down here. And I do again want to thank the people who have come up here today and speak. It is difficult, and we sincerely thank you for sharing your experiences, and I hope that we can build on the experiences. So I want to ask the same question I asked at the start of the last discussion, which is how many of you saw your experiences reflected in at least one of the panel members who spoke today?

(Show of a lot of hands.)

DR. EGGERS: Okay. I know there are differences, and at the end we will try to get into those differences again, but for now I would like to

focus on the general types of treatment approaches that we heard and build up a little bit more on what we heard from the panel members.

So we heard a lot about treatments that are an attempt to treat the underlying source of the condition, the immune modulators, the immunosuppressants, and the antimicrobials, antibiotics, and antivirals. I would like to spend some time on that. We'll spend -- let's see, how much -- we have -- Terry, can you just -- I should have -- MS. TOIGO:3:40. So you have until about 12 4:15.

DR. EGGERS: 4:15. Okay. So we'll spend some time on that, and then we'll move on to the ones that really are targeted to treat the symptoms, the more symptomatic components. Okay?

So would anyone like to start? We heard about Ampligen, we heard about Rituxan, we heard about Kineret, and then we heard about some antimicrobials. Would anyone like to build on what they've heard? Let's start with Ampligen. Does anyone want to build on what they heard from Ampligen?

(Show of hands.)

DR. EGGERS: Yes.

MS. BURMEISTER: Jeannette Burmeister. I'm going to make it real quick. I had a treadmill test about 3 weeks ago, and I had two horrible days after that, the typical symptom flare-ups, I didn't sleep, my digestive system was completely messed up, pain. It was pretty horrible. Two days later I went into the office to get my Ampligen infusion, barely made it to the office. After my infusion, I was bouncing out of the office. So it was an immediate huge improvement.

I also have in the last 2-1/2 weeks gone through two moves, two because I live in Incline Village, like Mary was, and my 2-year-old daughter and my husband live in the Bay Area, and so we just happened to have to have two moves, and I've gotten through them and here I am today. And this would not have been possible without Ampligen. I am so much more functional because of the drug, it's like I'm an entirely new person.

DR. EGGERS: So can I just ask, so everyone takes different treatments, so if you feel comfortable

raising your hand that you have had an experience like what Jeannette -- right? -- Jeannette has shared with this sort of instant -- okay, we've got -- okay, some in the back?

(Show of a couple of hands.)

DR. EGGERS: Okay. How about sharing experiences like what Mary talked about?

(Show of a couple of hands.)

DR. EGGERS: Okay. Would anyone else like to add upon this?

(Show of hands.)

DR. EGGERS: Okay, we'll go with both of you.

DR. SMITH: Janet Smith, Sioux Falls, South Dakota. In 1998, I was diagnosed with an actual IgG deficiency, so I was started on gammaglobulin, which helped for 3 years, but then it was either retire or disability or do something drastic, and that drastic was that I've been commuting to Incline Village from Sioux Falls, South Dakota, weekly to get Ampligen. At first, I couldn't even walk up the jetway. The first time I tried to blow out a candle after I started Ampligen, the wax went all over the table.

(Laughter.)

DR. SMITH: So I have been commuting. Now it's every other week because I'm starting a practice out in Incline Village, Nevada. So I have two practices going. And I wouldn't be here today if it wasn't for Ampligen.

DR. EGGERS: Okay. Mr. Miller?

MR. MILLER: Robert Miller, patient since 1982. So I want to build on my previous statement of my crash has started. Because of Ampligen, I will bounce back. I've already started to feel better just from sitting and resting, but had I not been on Ampligen for this trip, I would not have made it here. Before Ampligen, I was literally bedbound. When people talk about being bedbound, I mean, we're like bricks, we can't be moved. My wife would come in and check on me to see if I was breathing because I would sleep for days at a time. I didn't get up to eat, I didn't get up to go to the rest room.

My doctor, Dr. Dan Peterson, who is here, enrolled me into the Ampligen 516 clinical trial in 1998. At the end of that, Hemispherx, the drug

sponsor, gave everybody 6 months of drug for free. Within that span of time, it was like -- it's hard to describe. When people ask you about your energy level and cognition, for me, it was this like little glimmer of light that I could feel and see again, and I kind of built off of that. Prior to Ampligen, I had been placed on Famvir, Valtrex, Valcyte, antibiotics such as Zithromax, Levaquin, Ceftin, amoxicillin. I was put on Prozac, Pamelor, Desyrel, several other antidepressants, Lyrica, Cymbalta, Flexeril, did acupuncture.

When we're talking about symptoms, it's difficult for us to say that -- and Jeannette did a great job earlier explaining that when my energy level is low and I'm tested, my natural killer cell numbers will be down to zero, my natural killer cell function will be down. Prior to Ampligen, my total T cell count was 285. On Ampligen, it's five times that.

What Mary described is very much a mirror of what I've experienced. I've been on and off Ampligen. I did so well on it, and my wife had a chance to move from the Reno area to D.C. for a promotion, that we

talked to Dr. Peterson, my health was doing pretty well, we talked about what the percentages would be if I went off of Ampligen, whether I would maintain my health, whether it would improve or whether I would slide back. There was about a 66 percent chance that I would at least maintain it.

We moved to Northern Virginia. I was there for 2 years and went into a slide and went right back to where I was when I very first started. So in the midst of the housing crisis, we sold everything we owned, we moved back to Reno, Nevada, so I could be close to Dr. Peterson and get back on Ampligen.

It's different for every patient, just like every medication is. It's not a cure for me. I am one of, you know, the most severe type patients, and you can certain confirm that with Dr. Peterson, and for any medication to get me up and allow me to think clearly, allow me to function, allow me to make my own meals, allow me to outside with my boys, is a miracle drug.

Thank you.

(Applause.)

DR. EGGERS: Okay. I want to make sure that

we touch the range, and I think if you agree that your experiences on that particular drug are reflected and shared by the experiences that we've just heard, then we'll move on and talk about other treatments that you're taking to really try to deal with the underlying condition.

DR. CHU: Hi. My name is Lily. A lot of the treatments that people are talking about other than symptomatic treatments I think are limited to a very small population of CFS patients. I see Dr. Klimas and I see Dr. Montoya, but I have enough insurance, money, knowledge, and a supportive family to help me get to those places, and a lot of patients don't. So this is a somewhat selective group already who are able to come here, and try some of these treatments.

(Applause.)

DR. EGGERS: Okay. Yes?

MS. OLSON: Hi. I'm Carol Olson (ph). I have been sick for 28 years, getting sick in Denver when there was an outbreak. I have done many things that many of you have done, but one thing that's most significant for me that no one has mentioned was

Vistide with Dr. Peterson. That's also cidofovir. It's a very potent AIDS drug. It had tremendous effects. I looked differently, I lost a lot of weight, my weight had been going up and down, I had always been kind of thin, but I wasn't. And that seems to happen to a lot of CFIDS people, but the most important thing was that I could think quite clearly. And at any rate, I don't respond well to toxic medicines, this is a toxic medicine, which most HIV/AIDS doctors will tell you, and a lot of them have had experience with. It also seems to treat viruses that nothing else touches.

So I think in fairness -- and another reason, you can also see this as a biological disease that has physical causes when something affects it so profoundly.

So I think both for that reason and for the reason that it helped many people so significantly, and I believe Dr. Peterson has just had a study with it, I think that's something else you ought to throw out. I am also doing -- I'm doing GcMAF now, and I think it's helpful, I'm not really sure, but Vistide is something that had a very powerful effect with me for 7 months.

Thank you.

(Applause.)

DR. EGGERS: Any questions from -- oh.

MS. NICHOLSON: I think when we look at treatments moving forward -- and this is just my opinion -- I think it's great. These drugs are not going to work in all people, so we really have to look at that because I think of it as cancer. If you have chemotherapy, it's not going to cure all cancer. You can go even smaller to brain cancer. One type of chemotherapy is not going to help a different type of cancer. So it's great to see like a lot of these drugs that are working on people, and we need to put that into some type of measurement because we are unique, to allow these people to have drugs that work for them, that works in a subset group versus if we're going to use a big case definition such as Fukuda -- did I say it right? -- no drug is going to have the efficacy for that entire group.

(Applause.)

DR. EGGERS: Okay. Anyone else want to talk about -- we haven't -- let's see, both Mary Dimmock and

Tasha talked about azithromycin. Does anyone want to share anything with that?

(No audible response.)

DR. EGGERS: Okay. Any other -- I'm going to look to Dr. Michele and see if there are other treatments that you would like us to follow up on.

DR. MICHELE: Yeah. I would like to move to the pain management category, and if folks could talk about their experiences with some of the products that are approved for fibromyalgia, I think I heard a couple of them. I heard people mention Savella, I heard people mention Cymbalta.

DR. EGGERS: Okay. Would anyone like -- okay. Yes?

MS. HART: My name is Karen Hart. I am having very good luck with this compounded formula LDM. I just started on that, and it's very nice.

DR. EGGERS: Anyone else?

MS. NICHOLSON: I have one.

DR. EGGERS: Oh, yeah.

MS. NICHOLSON: Cymbalta works well. I tried Savella and Lyrica. With those drugs, they have a lot

of different side effects that work differently on each person, so basically it's either going -- like an antidepressant, it's either going to work for you or not and you try a different antidepressant, and it's in the same class as SSRI, in my opinion, so you just have to find a pain killer that's going to work for you. I don't want to talk bad about it, but it just didn't work for me.

DR. EGGERS: And can I ask, how long would you try, generally try, something before you would decide that that wasn't going to work for you?

MS. NICHOLSON: Well, one of the drugs I don't want to mention, I knew in the first 2 days because I had significant serious side effects. With Cymbalta, usually that takes -- because that's also an antidepressant, that usually takes 2 to 3 months, so I would give it like 2 or 3 months, depending on if it's -- if I still have significant pain, it will be shorter, but I try to allow the drug to work based on whatever the indication says, in the prescribing information.

DR. EGGERS: Okay. Is this resonating, this

discussion about pain and pain management? Is it resonating?

Well, go with Joe.

MR. LANDSON: Hi. Yes, Joe Landson. Just to add, Cymbalta does have some marginal pain benefit, pain management benefit, for me, but it also had side effects, including intermittent loss of vision. I lost access to it when I lost insurance. I'm now in the VA Health System, which only does generics, nothing that's still on patent. Cymbalta should be off of patent shortly, so we may see it in the VA pharmaceutical system or not. Who knows? We'll see. Thank you.

DR. EGGERS: Yes?

MS. SPOTILA: Jennie Spotila. I've been on pretty much every antidepressant for pain management and not a single one has worked, so we had to go to codeine, Flexeril, gabapentin, which no one has mentioned yet.

And the time period for trying a drug, I'll give it 8 weeks at least before abandoning it, and over time, I've been sick 18 years, the pain management process has evolved substantially during that time.

I've probably tried at least 25 drugs, maybe more, and over time they lose effectiveness, I have to switch it up. It's probably the biggest part of my treatment regimen, is managing the pain.

DR. EGGERS: I see a lot of head nods. Your experiences match with what Jennie is saying? Okay. Okay.

Yes, Amanda.

MS. SIMPSON: Just real quickly, I wanted to say when my Savella hasn't worked, and I've needed to take pain medication, I think one of the most frustrating things is that once you get out of that realm and into the kinds of things you're talking about, for me, it does nothing but contribute to my brain fog and the memory and concentration. It makes that so much worse and it makes so much harder to come out because you've got all of the narcotics in your system, and that for me is very frustrating.

DR. EGGERS: And, Amanda, can I follow up with that and say, how do you make those choices? How do you weigh the benefits that you think you'll get with one drug with the downsides that you think you

might get? And let's stay with this example that you're talking about, the pain management versus the brain fog.

MS. SIMPSON: I have gotten to the point where the only time I will take the pain medication beyond the Savella is if basically I'm laying in bed and trying not to move because I hurt that badly. It has to get to the point where I can't sleep, I can't find a comfortable position to rest in, to the point where I can't function anyway, and getting rid of the pain becomes most important.

DR. EGGERS: Okay. Let me just see, is this a shared experience? It's the last hope, when the pain is so bad?

Okay, yes, Matina.

MS. NICHOLSON: I would also like to ask people, like a lot of us have major stomach issues, and we have to really watch what pain management we have to take because it's like give-or-take. So I wanted to see what people have done with that. And also I think I wanted to reach out to researchers and look at medical marijuana because there are a lot of good

studies that it doesn't affect the gut and it also works on sleep as well as pain because it works on different neurotransmitters. So that's something.

DR. EGGERS: Does anyone want to take Matina's, about managing the side effects of the intestinal side effects?

Yes, Ms. LaRosa.

MS. LaROSA: I have serious gastric issues, and most of the pain medicines have a basis, they're NSAIDs, can't do them. So I use Voltaren Gel on my joints. I don't know if it works or whether the rubbing it in works, I'm not sure which. And I have a TENS unit, which is transcutaneous electric stimulation. And it sort of just deadens the nerves, and I do that when I'm laying in bed and can't sleep because it hurts so much.

MS. SCHWEITZER: Can I say something?

DR. EGGERS: Yes.

MS. SCHWEITZER: I just want to mention, you talked about this is terms of fibromyalgia. Not everybody with this disease has fibromyalgia, and they are not the same thing. There is an unusually large

number of people who have both, but at least half of us don't, and probably more than half. That doesn't mean I don't have pain issues, I do, partly because I gained a lot of -- I was in really good shape before I got sick, I was a skier, but 6 months after I got sick, "pfttt," my metabolism was bad and I gained weight, and that's part of the problem. Part of the problem is that I fell so many times. You learn you can't walk because you fall, and I've fallen so many times, I've had three back surgeries, two knee surgeries, I'm going to have to have a knee replacement. So I have pain issues, but it's not fibromyalgia. I have muscle pain issues, and it's not fibromyalgia either.

So there are other -- and irony of ironies, when you talk about bad side effects, the one drug I can't take anything that has Tylenol in it. Anything with Tylenol in it makes my liver markers skyrocket, which is ironic because of all the other drugs I'm taking, which are serious, but I did try -- I tried Cymbalta and in combination with an antibiotic, I ended up passing out, and that's how come I had one of my back surgeries.

But the main thing I wanted to say is we don't all have fibro, so when you talk about pain and people with this condition, it's not necessarily fibromyalgia.

DR. EGGERS: That's a good point.

DR. MICHELE: Yeah. If I might just clarify, my question was not meant to imply that people with chronic fatigue syndrome all have fibromyalgia, that's not what I was getting at, I just was grouping those medications together since they all have an indication for fibromyalgia and pain specifically related to that.

DR. EGGERS: So we'll go -- we haven't -- sorry.

KATHLEEN HARPER: I just wanted to say that since this illness is so long term, which we didn't know in the beginning, but my daughter was 14 when she got ill, and by 18, doctors had put her on oxycodone and Percocet, and she had to take a lot of Advil, and she wound up with esophageal ulcers after a few years of that, and now she would have -- I mean, she needs to go into a rehab or something to get off these medications. So, I mean, I am very angry that she was

ever put on them.

They wouldn't let me in on the decision. When I called the doctor and said why -- questioned what they were doing, they just told me I had no right, that she was an adult. But I'm her caretaker, she has to live with me because she is completely disabled, couldn't even be here, and it's just a nightmare.

Twenty-two years of pain medication does a lot of bad things, and I'm getting older, I'm in my sixties now, I don't want to take anything that is going to affect my cognition, which is already, you know, poor from the brain fog.

DR. EGGERS: And I think you're making a really good point that I just want to make sure that we're all capturing up here, is that I think what I'm hearing is that since the diagnosis wasn't made, wasn't easily made, that you and your daughter were trying a number of other things that in the end, if you knew what you knew now, you wouldn't have tried that.

KATHLEEN HARPER: If I knew it was going to be 22 years, I would have never have --

DR. EGGERS: Is this a shared experience with

them? I see a lot of head nodding. Yeah.

KATHLEEN HARPER: And like I said, she actually had hemorrhaging esophageal ulcers at like 30, and her health is now -- she doesn't just have chronic fatigue syndrome or ME, she has ulcers and, you know, just -- it's a nightmare, it's a nightmare. Sorry.

DR. EGGERS: If I can take -- okay, we'll go with --

DR. CHU: I just wanted to add to Mary's point earlier. Besides fibromyalgia, there are different types of pain in CFS, and even though the definition, the Fukuda definition, includes muscle and joint pain, there hasn't been a lot of research into different -- into the pain in CFS. Like, for example, some people have nerve pain that's related to like a reactivation of herpesviruses, and some people have reported that they get better when they take antivirals for that, but there is also stomach pain, you know, and other types of pain that haven't really been explored.

DR. EGGERS: I think Diane has a -- Diane, right? --

MS. LEWIS: Yes.

DR. EGGERS: -- had her hand up.

MS. LEWIS: I'm not on any pain medication at this time, although I certainly would like to have some.

(Laughter.)

MS. LEWIS: But one thing that I -- you know, I'm a social worker, I'm not a doctor, but I attribute a lot of my pain to the fact that I'm not getting enough oxygen, and therefore my muscles are really hurting, and so, you know, my lack of ability to deep breathe, you know, my sleep issues, there are a lot of -- I think there are a lot of reasons that cause the body to be depleted of oxygen, and there is just no way, if a doctor doesn't even believe, you know, that there is anything wrong with you.

I am on an extreme amount, $400 a month in copays, for medications, and none of it's working, it's all palliative care, and it doesn't even get to the core of the problem because I'm hearing antivirals, pain medications, a lot of medications here, nobody has mentioned Provigil. Provigil is the one thing that does keep me alert and it does really help. And I also

use Vyvanse instead of the Adderall. But as far as the pain goes, I really think a lot of that pain comes from a lack of oxygen, and your body is just not -- there is nothing there for it to draw on.

DR. EGGERS: Can I -- I'm going to ask one question, and then if we don't -- if we have -- I caught up on something, and I didn't write down which of you said it, but I would like to probe a bit deeper into the idea of masking symptoms and causing -- by taking one medication to mask symptoms, and I think I -- I'm sorry, I don't know which one -- and the idea that you maybe push yourself a little bit more than you should, then you would have, if you weren't on the medications that make you feel good right now. Is that an --

MS. NICHOLSON: I thought about that for a while. I think when I'm on it -- and I can't speak in terms of the pharmacology of it -- I just think my body is on overdrive. Even if I try to even pace myself, it's very hard to pace because you're just full of jitters. I find myself, I can just feel my body running when I'm -- and not turning off. I feel like

I'm a car and the wheels are turning and I'm not moving, and that's even if I'm just laying in bed, and that's just my side effect. Like she mentioned Provigil. I tried Provigil and that made me jump out of my skin.

So, again, I think different people respond to these different medicines, you have to find one that works for you, but in terms of what you said, it's usually because it's a medication and it keeps working. It lasts in my body longer. It says it has a short half-life, but not for me.

MS. KELEMEN: I wanted to make one comment, too, it's not actually related to your question.

DR. EGGERS: That's fine.

MS. KELEMEN: My own personal perspective -- and not to go contrary to the purpose of this workshop, we need medicines to help people with CFS and ME -- but my philosophy is to try to take as few medicines as possible, and I can do that maybe because I've had this illness for 16 years, so I feel like I have a good sense, and I've tried things and they haven't worked, but then I discontinue them. And I think we really, as

patients -- I hear people are taking a lot of medicine, and probably a lot of it isn't working.

DR. EGGERS: Yeah. I think Dr. Kweder has a follow-up to that.

DR. KWEDER: Yeah. You had mentioned actually that you thought one of the adjunctive treatments that helped you the most was physical therapy and the stretching. Can you say a little more about what it was that helped? How did it help you specifically?

MS. KELEMEN: Yeah. I only did that for a short while, and I have to say that was really probably the only thing that was good about the treatment that I had in the U.K. I think it was having a trained professional who knew through conversations with me what the limits were, basically that at that time I could really only do lying and sitting exercises but was able within that framework to give me very limited exercises that I could do every day. And I think having that guidance -- you know, none of us are kind of specialists in this, so we often don't know what to do. We want to increase our capacity as much as we

can, and we just don't know the best way to go about it.

I mean, the other thing I would say again, going back to pacing, I disagree with some of what, just from my own experience, others have said. I feel like I can tell when I'm overdoing things, when I'm getting to a point where it's going to be too much. And so my life is on a daily basis a very carefully collaborated system, you know, and I have a mat I lie on at work. I have arranged all kinds of complicated work arrangements. You know, I don't work a full day from the office, I work from home much of the time.

So I think we really have to figure out kind of by monitoring ourselves carefully what works, what doesn't work, and, of course, some of us -- you know, I have a wonderful husband who is there to help, and some people don't have that kind of care and help at home, but I think we can do things ourselves that will help.

DR. EGGERS: Let me just go on and see if anyone wants to follow up on that and build on that.

Dr. Kaiser?

MS. TOIGO: Sara, 10 minutes.

DR. EGGERS: Okay. Thank you.

DR. KAISER: Yeah, just quickly to build on what Tasha was saying. I maintain a yoga practice, which is kind of California physical therapy.

(Laughter.)

DR. KAISER: But what stretching, what daily or every other day stretching, does is it releases endorphins, and so there is a natural release of -- there is a natural pain control that comes from developing a practice like that, and when you first start you can barely do a stretch or a posture, but that's why I think Tasha's point, that having access to a trained professional, they can help you build and develop that so that it can have some effect.

DR. EGGERS: Thank you.

I'm going to turn and see if my FDA colleagues have any other questions about particular treatment approaches, things that you haven't heard about that you want to probe a bit deeper.

Dr. Michele.

DR. MICHELE: One thing that's been mentioned only in passing but has come up in the course of

discussion of clinical trials is IV saline, and I'm just wondering how many of you have used that and if you find it to be beneficial.

UNIDENTIFIED FEMALE SPEAKER: What?

UNIDENTIFIED FEMALE SPEAKER: IV saline.

UNIDENTIFIED FEMALE SPEAKER: Oh, I use it.

(Show of some hands.)

DR. EGGERS: Let's go next to Dr. Kaiser.

UNIDENTIFIED FEMALE SPEAKER: Well, I'll tell you the abbreviated story. I flew down to Puerto Rico with my grandson, who didn't have the right papers to get on the cruise ship, and after many stressful hours, we finally got him on, and I had a total, total crash. The next morning when I woke up, I said I've got to go to the infirmary. I went in the infirmary, my blood pressure went down to like 65, and I fainted, and the Belgian doctor, who understood what chronic fatigue syndrome was, said, "I can either send you home or give you a bag of saline." He gave me the saline drip, I got up and went shopping.

(Laughter and applause.)

DR. EGGERS: We had one in the -- if one of

you can work your way in the back to Ms. Patton. Did you want to add to that? Did you raise your hand? No? Okay, come back up. Did you see someone else back there?

UNIDENTIFIED FEMALE SPEAKER: Yeah. IV saline helps. I consider it a treatment and a relatively cheap one. It helps with the lightheadedness. And I also tend to get a little bit dehydrated when I have a crash, and it obviously helps with that.

DR. EGGERS: Yes?

DR. GROBSTEIN: My name is Joan Grobstein. I would like to say that you can also just use oral salt and water. That can be very effective in an emergency.

DR. EGGERS: Any other burning questions?

(No audible response.)

DR. EGGERS: So we have 5 minutes left, and I just want to do what we did for the first topic, which is see, does anyone else have anything that they want to share, a perspective or something that they want to share that they haven't heard shared by the comments from the panel or by others?

DR. GROBSTEIN: Joan Grobstein again. I would like to just say that in terms of pain management, if somebody has a broken leg, it will be very painful, and it will be less painful as the leg heals. If you break that leg repeatedly, it will get more and more difficult to control that pain. So we have the equivalent situation here. We don't know what the underlying cause of the pain is, and so therefore we cannot probably adequately treat many people's pain.

So I know that this is an FDA meeting, but I also know that there are members of other agencies in the government here, and I would like to put in a big pitch for the fact that we need more research, more money, to look at the underlying causes of this illness. Until we find that, people are going to be taking drugs, having side effects from the drugs, watching the drugs' effects dissipate over time because we are not treating the disease. I am not saying that we should not treat symptoms, because we should. We need to make everybody comfortable and we need clinical trials of palliative measures, but what we really need is research.

(Applause.)

DR. EGGERS: Here.

MS. HART: I have a topic pain medication, so therefore it does not affect my cognitive abilities, thank God, but what's in it is gabapentin, Lidocaine, cyclobenzaprine, baclofen, diclofenac, I don't know how that's pronounced, but if anybody is interested in those percentages, they can see me. It's a compounded prescription, it works beautifully.

MS. PATTON: Hello. Anita Patton. May you please ask the question of the audience like you asked us to raise our hand, may you please how many people represented here today are from any sort of pharmaceutical company that could help us in drug development?

DR. EGGERS: Would anyone care to volunteer themselves as being from there?

(Show of five hands.)

DR. EGGERS: Okay.

(Applause.)

DR. EGGERS: Any other final thoughts? I think we have time for two more people.

MS. BURMEISTER: Jeannette Burmeister. I just want to -- well, obviously, what we really need is some approved drug treatment, and that's why we're all here, and I think that's the most important thing, but I want to give a big shout-out to the research of Staci Stevens and Chris Snell. I wear this heart rate monitor all the time because I know what my aerobic threshold is, and I know when I go over I will crash. So when I brush my teeth, I sit down, so I know I won't go over. I think that's very valuable, and I think that's something that's maybe underutilized at this point.

DR. EGGERS: Okay. Good. Oh, more one, and then we'll come with your question.

Yes.

MS. SMITH: One other thing that hasn't --

DR. EGGERS: And your name?

MS. SMITH: Janet Smith.

DR. EGGERS: Thank you.

MS. SMITH: One other thing that hasn't been mentioned that goes along with physical therapy and the heart rate monitor is I've always asked myself why am I

better than a lot of patients as far as physically? And I think it's because the adaptation has come naturally for me. Like the shower chair, sitting down to shower, I sit down whenever there is a chair available. I've had a handicapped sticker since 1994. And so if by using the handicapped sticker I can do one more stop at the store or see one more patient because I'm using those aids that come naturally for me, but other people, they don't think about sitting down and how to reserve energy.

DR. EGGERS: Okay. Thank you.

Well, we have more question from Dr. Kweder.

DR. KWEDER: Actually, it's not a question, but it's a comment because I wanted to pick up on something that Joan said, which is -- and someone said it, it might have been you, Joan, in the last session about getting at the underlying cause. And I don't want people to think, though, that hearing about the symptoms and the varied experiences of patients, even if it's a common underlying cause and everyone experiences it differently, is not a worthwhile endeavor. And I do think it is worthwhile in that it

helps us develop research pathways to explore where we see some of the commonalities, where we get hints about potentially some of the common pathophysiology that particular agents that are helpful are addressing, and that's one of the reasons why we wanted other researchers here. And one of our goals is to stimulate more conversations, people smarter than me thinking about, so how could we tie this all together pathophysiologically and really begin to target therapy development? So, yeah, we're helping symptoms, which may be first on our plate, but ultimately getting to the bottom of this and understanding what that common root is so that we can actually cure it.

So your point is absolutely well taken, and we're hoping that ultimately this kind of exercise is one way to contribute to building the map.

DR. EGGERS: Thank you.

(Applause.)

DR. EGGERS: And I think that that is a good place to stop with Discussion 2. Again, a fabulous discussion, and there are evaluation forms, and if you can't find them -- I think they're in the back -- come

find me or one of my colleagues and we'll find them. They're completely voluntary, if you want to take one in. And if you want to take it tonight and think about it, we'll be here tomorrow.

With that, I'm going to turn it over to Theresa Toigo, who is going to close with the Open Public Comment Session.

I will ask the panel members up here, you guys are free to go down. Thank you again so much.

(Applause.) Open Public Comment Period

MS. TOIGO: So I hope the panel will indulge me here and maybe we'll change our plan for our session a little bit because it seems like we can maybe do a lot of this from people sitting if they don't want to get up. So we'll try something a little different here.

But this is the Open Public Comment Session, and both FDA and the public believe in a transparent process for information gathering, so we need to do a little bit of the formality here to ensure that we take care of the process, the requirements. So we're going to invite the stakeholders that are pre-registered and

confirmed to share their perspective with us during this part of the meeting.

And to ensure the transparency, we think it's important to understand the context of an individual's presentation, so you are encouraged to disclose at the beginning of your presentation whether or not any organization paid for your expenses to attend this meeting. And if you choose to not address that, then that's fine as well. But that's an important part of our open public process, that we explain that.

So how is this session going to work? We had originally intended to use a timer, but if the speakers are willing to work with me, we have 2 minutes for each person to speak, and instead of the timer, I've got my timer, and if you're willing, as I'm going to watch it, and as you're getting close to the 2 minutes, then I'll let you know, I'm going to put my hand up, and then that way we can ensure that we get to everybody, that everybody is able to get their allotted time, and that everybody else gets out of here at the time that they want, but I think we've heard enough today that it's not easy for people to stand, so to make people come to

the middle, to the center, to do it in the timed process is probably not ideal.

So are you all willing to work with me who are going to be speaking in the Open Public Session, and when I go like this, know that you've got to get close to wrapping it up? Okay, well, then that's how we're going to do it.

So what's important here, too, is that we know that not all patients speak with one voice, and we certainly heard that today, that people are at different stages of the disease and therefore things that matter to them are going to be different, but the insights that you can provide us are going to be helpful as to the sessions tomorrow, and they are also going to be important as we think about the challenging issues related to drug development in this particular disease area.

And so we want this, like I said, to be fair. So you're willing to work with me, and I am willing to change the system, and hopefully my panel here is going to allow me that. They'll give me some daggers if I let the time go too long, but let's give it a try.

So our first speaker -- it's not on there yet. Okay. So the first speaker that I have on the list is Ms. Courtney Alexander? Is Ms. Alexander here?

UNIDENTIFIED FEMALE SPEAKER: Michael --

MS. TOIGO: Changed. Okay. So Mr. Michael Walzer?

(No audible response.)

MS. TOIGO: Okay. How about Ms. Anita Patton? Okay. Anita, do you want to come up the microphone, or are you going to -- okay.

And so Steven Chilinski is next. So if you're going to be -- just so you're ready.

MS. PATTON: Hello. Thank you. Sorry, there were a lot of cords over there, I didn't want to fall.

MS. TOIGO: Okay.

MS. PATTON: Thank you for having this drug development meeting. I think it is incredibly valuable and a pleasure to be here.

I would say so similar, so many things, about what so many patients have talked about today except that I think it naturally falls into several different subsets, like some people have sudden onset, slow

onset, some people have low NK cells, low IgG, high viral titers, high cytokines. Those type of things our doctors could get together, just an idea, get together a subset and really put their research, their science, their experience with patients, and over like some of them decades, to identify which people might most likely respond to much treatments.

And my question about the pharmaceutical companies is, how can we draw them in if there is not a whole lot of representation here today? How can we get that and how can we facilitate faster treatments to help more people?

MS. TOIGO: To that point, I would bet there are a lot of them watching through webcasts, so they are certainly probably hearing the input, and there are some of them here.

MS. PATTON: And the last thing, of course, is just that I'm an Ampligen responder, huge response, 15 years, long time on it, and I'm disappointed that it wasn't approved, and hoping like, is there any way we can put some sort of another trial or another type of investigation to say that the people who did respond,

why did they? And how can we help? I mean, there would be hundreds, maybe thousands, of people who could have a response if there was some sort of global trial, another one, that would be done.

MS. TOIGO: Okay. Thank you for those comments.

(Applause.)

MS. TOIGO: The point of this is not for us to be responding, this is the Open Public Session and we're taking your comments.

MS. PATTON: Thank you.

MS. TOIGO: So next on our list -- thank you -- is Steven Chilinski?

UNIDENTIFIED FEMALE SPEAKER: Courtney Alexander.

MS. TOIGO: Courtney Alexander. Okay. I'm sorry. I've got a different list here, and I better look at the screen. It's been revised three times. I'm sorry. Courtney, please go ahead.

DR. SMITH: I'm not Courtney.

MS. TOIGO: That's right.

DR. SMITH: I know. But I'm standing in for

Courtney. I am Dr. Janet Smith, and I am on the board of Simmaron Research, which is Dr. Daniel Peterson's foundation that he founded, and what we are trying to do is scientifically redefined CFS/ME. So we are strictly trying to do the science part. But today what I would like to do is plead with the FDA and with this panel to go along with the guidelines that just came out with the Alzheimer's, with the looser rules on approving Alzheimer's drugs, I would like to plead that that would go along with looser rules for approving drugs for CFS/ME since there are no approved drugs.

Thank you.

(Applause.)

MS. TOIGO: Thank you. Okay. We'll try one more time. Steven Chilinski?

(No audible response.)

MS. TOIGO: No? Okay. So next we have Judy Mikovits. I know Judy is here because I talked to Judy.

DR. MIKOVITS: You did. I'm Dr. Judy Mikovits, and my travel expenses have been covered by several physicians and several patients. So I'm just

going to read because I want to make it quick and I could talk forever.

We do not know the causes of multiple sclerosis, Parkinson's disease, Alzheimer's disease, lupus, or ME/CFS. All of these serious debilitating diseases have abnormalities of the immune system and inflammation in common, if not central, components.

We made a handout, and many of you have it today, the people who sponsored my travel, of just a few of those biological abnormalities, the clinical lab tests, and the drugs with potential for repurposing. The FDA has just approved dimethyl fumarate as an immune modulator, an antioxidant for treatment of multiple sclerosis. The bright focus in Alzheimer's drug discovery foundations just announced a Phase I clinical trial of bexarotene, an FDA-approved cancer drug which acts on retinoid receptors like Vitamin D and thyroid receptors, which are both abnormalities on this list, known abnormalities tested in ME/CFS.

In Norway, oncologists Drs. Fluga and Mellan just completed last year a small clinical trial of FDA-approved cancer drug Rituxan with success in about 30

percent of the patients. The logical next step to do in this trial and with the Ampligen responders and non-responders is gene expression, in fact, profiling, and, in fact, immune profiling to determine the difference between responders and non-responders at the molecular level.

The FDA has demonstrated its commitment by holding this unprecedented meeting, and we thank you. Drugs which are FDA approved are generally safe in humans. And, of course, everything has its risks. In serious diseases without treatments, a classification FDA recently gave ME/CFS, the benefits far outweigh the risks.

For advocacy groups here today and those listening, I encourage you to fund these clinical trials with the drug companies, fund these follow-up studies profiling responders and non-responders to divide patients that exhibit different levels of disease activity, prognostication and possibly insights into pathophysiology as these MS and Alzheimer's disease foundations have done. The technology and expertise exists. The absence of a causative agent

should not leave this field floundering any longer. It's a new era for ME/CFS treatment.

Thank you.

MS. TOIGO: Thank you, Judy. And I think we got those documents, but it would be good if you would submit those to the public docket so that they're officially then included in the record as part of your presentation.

DR. MIKOVITS: We will.

MS. TOIGO: Okay. Thank you.

Next we have Derek Enlander.

DR. ENLANDER: Good afternoon. I am from the Mount Sinai Medical School in New York. About a year or so ago, we actually received a million dollar grant from one of my patients, and the dean of the medical school said, "Oh, that's very generous of you. Let's actually form an ME/CFS Center," and indeed actually we formed an ME/CFS Center at Sinai, and our first project was to prove whether GET, graded exercise therapy, was appropriate in this disease. We actually have got undergoing the research in post-exertional malaise, and we actually expect to look at 150 controls and 150

patients in this disease. We are actually going to look at the usual array of cytokines, the usual array of immune markers, but we are also going to include genetic studies with a geneticist, Eric Schadt. Eric Schadt seems to be actually well known amongst all the genetic people that I've ever spoken to. We've got actually a series of 39 pages of the genome study on our first patients. It is a most remarkable genetic study. And we are not actually going to look at whether in fact graded exercise therapy is the correct method or approach and we will actually prove or disprove the PACE idea.

Thank you.

(Applause.)

MS. TOIGO: Thank you, Dr. Enlander. If there is any additional information related to your talk that you want to submit to the docket as well, we would welcome you to do that. Thank you.

Next, Gisela Morales-Barreto. And I'm not sure if I got that right. I tried to catch people whose names I wasn't sure of before.

DR. MORALES-BARRETO: No, you didn't, but you

tried very well.

(Laughter.)

DR. MORALES-BARRETO: And thank you for acknowledging that because not everybody, as I said, takes the time to ask, you know, the question.

First and foremost, thank you very much for putting this and making this happen in such a compassionate way today. I am very pleased and happy to be here.

I am Dr. Gisela Morales-Barreto. And I am here today as a caregiver of an individual that I love dearly and has been sick for the last 6 years. I am not going to bother you with the symptoms because they are pretty much what has been said all afternoon. She has suffered a lot, and we were blessed at some point in time to be -- I was driving to work and I heard it on NPR, the voice of Dr. Peterson. So she moved a year ago -- well, over a year ago, to Incline Village, and she came back a couple of months ago, but she also came back herself again in many, many ways.

Being an active observer of all those symptoms that she has had has not been easy, and

watching a person that moved literally at the speed of light to be limited for a long time to bed for days, months, and years really has been demoralizing and emotionally draining.

I am a cancer survivor, and when I had cancer, I had options for treatment. This population has really options that are not really approved by anybody and guaranteed that you are going to get cured. Here, after almost 12 years, and I know that if I get sick again, God forbid, I can go back and find treatments that have been approved. For me, the big elephant in the room after everything that has been said is the fact that we need the pharmaceutical companies, FDA cannot do it alone, and we need the pharmaceutical companies to come and play the game. The only way I honestly think, as a psychologist, is to also invite them with your approval. I think the FDA approval will open up the doors for the pharmaceuticals to say, "Yes, we can. Yes, we can help."

So I already saw the hand, but I really implore you to look into this from that point of view. If you approve any drug with whatever the name is --

Ampligen will be nice, but if it's not Ampligen, anything -- that will support the patients, it will open the door for more research and more pharmaceutical people coming into this.

Thank you very much.

(Applause.)

MS. TOIGO: Thank you, Dr. Morales-Barreto.

MS. MORALES-BARRETO: Good.

(Laughter.)

MS. TOIGO: And I skipped Mr. Thomas Equels? Close?

MR. EQUELS: That's it.

MS. TOIGO: Okay. My apologies. These don't work for up here, and that one I'm obviously not very good at either. So --

(Laughter.)

MR. EQUELS: I'm a little tall for this one, too.

First of all, I want to thank everybody, Admiral Kweder, the FDA staff, and most of all, all of the patients and clinicians that have taken the time to come here today.

I am the Executive Vice Chairman of Hemispherx Biopharma, and we have an experimental drug that you've heard about, Ampligen. I would like to just share a few words about how Hemispherx and Ampligen got involved with CFS. We were actually, over 30 years ago, asked by the FDA to get with I believe it was with Dr. Peterson and Dr. Lapp with an unusual thing that they had out there called the Tahoe flu and to provide our drug on an experimental basis for a female subject who had a remarkable recovery. And I believe there were about 12 additional subjects that were approved that did extremely well. That was over 30 years ago, and we're here today, and it's been a long and difficult journey for a small company such as ours, but we're participating in this process because we know that there are thousands of Americans that are disabled, seriously disabled, we know from the research that we've reviewed that these people have their lives shortened probably due to the medication that they're on and the disease by decades. And we believe we can contribute to that process. And we responded when you asked us 30 years ago to come to the table and work,

and we've toiled in this vineyard for many years, and we make our commitment that we will be 110 percent with you, and with you, to make this happen.

Now, we know from the HIV/AIDS epidemic that when there are no drugs, the results are dire, and we believe that where subsets can be identified where a drug can be effective, whether it be Ampligen or some of the other drugs, that where there is an unmet medical need, there should be some form of expedited approval applied.

I would like to mention --

MS. TOIGO: You've got about 30 seconds. Okay?

MR. EQUELS: Okay -- three articles that I think warrant a lot of study, causes of death among patients with chronic fatigue, which deals with cardiac death increases, and shortening of mortality, cardiac toxicity in chronic fatigue syndrome, which deals with the effect of all of these -- you've heard about probably 35 or 40 different medications, all of which have severe -- not all of which -- some of which have severe side effects and the impact, and then a double-

blind, placebo-controlled randomized clinical trial of the TLR3 agonist, that study has to do with the exercise issues, and how that may have an effect.

Now, we have expended a great deal of time and a great deal of money to get to where we are today, and I just want to say that we are prepared to enter into not a legal partnership, but a real partnership, with the FDA, with the clinicians, and with the patients to bring relief for these people who so desperately need it.

Thank you.

(Applause.)

MS. TOIGO: Thank you, and thank you for paying attention to the hand signals.

(Laughter.)

MS. TOIGO: Mr. David Strayer.

UNIDENTIFIED MALE SPEAKER: He'll be here. So save 2 minutes.

MS. TOIGO: Ah, see? Okay.

So Dr. Dan Peterson.

DR. PETERSON: Thank you. I am here today representing myself as a caregiver but of approximately

9,000 patients over the last 30 years --

(Applause.)

DR. PETERSON: -- which has given me a bit of experience on the front of the disease, the front lines, as they say. And on behalf of these patients, their families, and really even their physicians, I implore this esteemed gathering and committee to not only devise, but to execute a therapeutic strategy, which is much needed.

The federal diagnostic criteria were established more than 25 years ago, even though they were revised a few times. The CDC has identified, counted, surveyed, and queried an estimated 1 million people in this country suffering from the disorder. The attended disability and poor prognosis has been documented worldwide by families, physicians, and the patients. The estimated cost hit to our country is $9 billion a year, a diagnostic marker would yield a company $250 million a year, a therapy probably in the billions of dollars, yet 25 years later we have no FDA approved drug for this indication, or therapy.

So the heterogeneous nature of the disorder

has been a problem, obviously, and I see that as an invitation or a beg to study subsets in this disease that have the same pathogenic mechanisms. Over this 25-year period of therapeutic stagnation, there have been thousands of peer-reviewed articles published with respect to pathogenesis, but it's difficult to connect the dots. I'll just mention a few. Worldwide, the number one immunological marker is low NK cell function. MRI scans are abnormal by everyone who has looked at them. SPECT scans are abnormal. Low VO2 max and stress testing is a universal finding. Many clinicians are already utilizing these markers and endpoints in their own practices as they treat these patients to document efficacy or to teach us more about the disease.

Symptomatic therapy, unfortunately, I think is useful in quality of life, but I have not seen it return patients to full functional physical nor cognitive conditions. I think targeted immunological therapy has a possibility to do that.

On behalf of clinicians worldwide -- you may not know this -- we already have established

consortiums and collaborations worldwide with multicenter primary care clinics that are ready and willing to do pilot projects, Phase I, II, and III clinical trials, and more, and I know we're all committed to doing this.

So I implore again this committee to take some action to support the private sector, to use the resources of the Federal Government, its science, its personnel, its computing capacity, et cetera, to develop safe and effective therapies.

Thank you.

(Applause.)

MS. TOIGO: Thank you.

Mary Silvey?

(No audible response.)

MS. TOIGO: Eileen Holderman?

(No audible response.)

MS. TOIGO: James Baraniuk?

Oh, I'm sorry. Eileen? Okay.

MS. HOLDERMAN: Good afternoon. My name is Eileen Holderman. I'm an independent advocate for ME. Thanks to the FDA for hosting this conference and

giving me the opportunity to speak. I would like to address a concern, and that is the concern of the name of the conference, which doesn't really distinguish between myalgic encephalomyelitis and chronic fatigue syndrome. There are 1 million American men, women, and children suffering with ME, 17 million worldwide, and unfortunately in 1988, the CDC renamed it chronic fatigue syndrome, which is unscientific and dismissive, and it was further compounded by definitions that included the empirical Oxford definition which just states one symptom, fatigue, to have it, and today you heard multitudes of symptoms that really describe this disease.

The results of the faulty definitions have caused muddied research, the inability to replicate findings, no universal biomarkers, drug development without target audience, erroneous medical information on websites, bad media and press, skewed public perception, and, most importantly, neglect and harm inflicted on patients who truly have ME. The disease costs the nation billions in lost productivity, tax revenue, and medical benefits. The funding for this

disease has been abysmally low and it needs to be commensurate with the disease burden.

The solution is that all the government agencies, the scientific, medical, academic, legal, advocate, and patient communities must come together and adopt the Canadian Consensus Criteria and to dismantle the use of CFS and move research and treatment forward to help the over 1 million Americans with this disease.

Thank you.

(Applause.)

MS. TOIGO: Thank you.

Okay. Dr. Barraniuk?

DR. BARRANIUK: Thank you very much for letting me speak. I'm Jim Barraniuk. I'm from Georgetown. I wanted to applaud Badrul Chowdhury and his crew for taking on this very great challenge. All the best.

I also wanted to tell you that it's not all doom and gloom. We have started publishing the results of our studies from Gulf War illness patients who also meet chronic fatigue syndrome criteria, only about half

met fibromyalgia criteria. We have identified three separate dimensions of exercise-induced FMRI changes that we believe we may be able to apply to chronic fatigue syndrome.

First off, we have identified a white matter abnormality that separates the GWI CFS people from healthy controls. We have two mutually exclusive bold blood flow responses to exercise that subdivide into four mutually exclusive groups and I think begins to address the issue of heterogeneity, and with these, they're purely objective. You can't use any subjective criteria to define them in advance.

So the simple message is all of these subjective criteria that we're using for these subjective syndromes we're going to get rid of, we're going to have objective diseases, we're going to have objective diseases that will end up in Harrison's Textbook of Medicine.

(Laughter.)

DR. BARANIUK: A little bit, since I have 30 seconds, my complex message here is that what we identified is a problem in the right inferior fronto-

occipital fasciculus, a white matter tract that connects the pre-frontal lobe here that deals with fatigue and valuation of pain. It moves and connects with the insula, which deals with phantom pain, the emotional link of how much pain means to you. And it tracks posteriorly to involve the working memory, the default network, which is your mind wandering or daydreaming that all of a sudden breaks up your thoughts. It also connects your dorsal and ventral attention networks, which are the systems for maintaining your focus. And if you think about the cognitive dysfunction, the exercise-induced exertional exhaustion, that's what are model is demonstrating abnormalities in, and based on this, we're hoping we don't get sequestered --

(Laughter.)

DR. BARANIUK: -- and we actually get some funds to keep going.

Thank you very much.

(Applause.)

MS. TOIGO: Thank you.

And again just a reminder to you and to

anyone else, anything that you want to submit to supplement your public comments, please submit them in writing to the docket.

So next we go to Mr. Charles Lapp.

So, see, you're all proving me wrong, nobody has sat down, so everybody has come up to the podium.

(Laughter.)

DR. LAPP: Thank you for this opportunity. I'm Charles Lapp. I'm a physician from Charlotte, North Carolina, and I've been treating patients with chronic fatigue syndrome since 1985, and I've been using Ampligen since 1988. My expenses today will be kindly reimbursed by Hemispherx, but I am not here to speak for them, I'm here to speak for the patients and say that in the 28 years -- or 25 years that I've been using Ampligen, we've had excellent success. I reviewed our records recently, and it shows that over 50 percent of our patients have responded very nicely to Ampligen and about 30 percent have very significant improvements, which is sort of a disconnect from the data. You know, we chose the endpoints from the Ampligen studies many, many years ago, and there seems

to be a disconnect from the endpoints that we are using to measure the effect compared to the patients' global impression of change and the physicians' global impression of change. We see patients who are treated with Ampligen, as you've heard here today, who have seen remarkable improvements and have been able to return to gainful occupations, school, and work.

I guess the most important thing that I can say -- there are two points that I would make today. One is that in all of the years that I have been administering Ampligen, we have not had a serious side effect from this drug. There are not many drugs that you can say that about.

And the second thing is that I think history will show that when a new drug is brought into a field, for example, when AZT was approved for AIDS or when interferon was approved for multiple sclerosis, there were many other players, many other pharmaceutical houses, that got into the field, and it really opened up the treatment of these two illnesses. We hope that perhaps Ampligen will do that for chronic fatigue syndrome.

Thank you for your time.

(Applause.)

MS. TOIGO: Thank you, Dr. Lapp.

Steven Lempert.

DR. LEMPERT: I'm Dr. Steven Lempert. I have no financial interests.

Approximately 70 percent of patients tested in a 1994 study of chronic fatigue syndrome were positive by culture for HHV-6. There is a subgroup of CFS patients with active HHV-6 infection on culture. Characterization by nested polymerase chain reaction has indicated predominantly HHV-6A more frequently than HHV-6B. In the paper by Dr. Ablashi entitled, "Ampligen Inhibits Human Herpesvirus 6 In Vitro," viral replication was inhibited by 46 to 98 percent. The in vitro antiviral effects reported by Dr. Ablashi for Ampligen appears to translate clinically to being effective in vivo in severely sick CFS patients. Mary Schweitzer was HHV-6A positive before Ampligen and negative on Ampligen three times.

Ampligen converts an active HHV-6 infection into a quiescent or latent herpesvirus with marked

recovery of both the patient's health and functioning. Patients severely afflicted with a neurovirulent human herpesvirus 6A, as occurs in subgroups with chronic fatigue syndrome and progressive multiple sclerosis, have died without an effective antiviral such as Ampligen.

Ampligen infusions target a presumptive viral trigger in a subgroup of patients with CFS. Antiviral Ampligen needs to be transferred to the FDA antiviral division and reevaluated now rather than wait another 10 to 20 years.

Thank you.

(Applause.)

MS. TOIGO: Thank you, Dr. Lempert.

Mr. Dwight Merriman?

(No audible response.)

MS. TOIGO: Joan Grobstein? I know she's here. Grobstein, I'm sorry, Grobstein.

DR. GROBSTEIN: I would like to sit.

MS. TOIGO: Okay.

DR. GROBSTEIN: Thank you. Hello. I'm Dr. Joan Grobstein. I'm a physician. I've had ME for 14

years. I think I might have said 13 earlier, but I've lost count.

FDA is faced with a great responsibility to encourage rapid development of treatments for this serious disease. There are several important issues to keep in mind in this process. It's extremely important when evaluating drugs to make sure that this patient population is well defined. I strongly suggest that the FDA require the use of the Canadian Consensus Criteria for all studies.

In order to better define the patient population, FDA should also make the validation of biomarkers a very high priority. As you have heard today, patients have many measurable abnormalities. It's important to distinguish between therapeutic agents that treat symptoms versus agents that treat the underlying cause of ME. Although the underlying cause is still unknown, it's very possible to treat symptoms. It's also possible to treat associated infections even if the infection is not the sole cause of the disease. It's very likely that multiple agents will have to be used concomitantly to treat this multisystem disease.

This reality should be addressed in the design and evaluation of drug trials. Outcome measures must reflect the impact of ME on patients' lives. Small improvements in function are extremely important to patients, and we're willing to tolerate risks to get those improvements.

Finally, the FDA should demonstrate a sense of great urgency to evaluate therapies for ME. As you know, there are currently no approved treatments. Patients are paying for expensive efficacious treatments like Ampligen and Rituxan out of pocket, causing financial harm on top of physical disability. It is FDA's responsibility to remedy this situation.

Thank you.

(Applause.)

MS. TOIGO: Thank you, Dr. Grobstein.

Jeannette Burmeister.

MS. BURMEISTER: My name is Jeanette Burmeister, and nobody has paid for my expenses to be here. I'm here to urge the FDA to play a more proactive role in working with Hemispherx towards the accelerated approval of Ampligen. Quite obviously, a

subgroup of ME patients has been identified as a result of being Ampligen responders, and a tremendous amount can be learned from that, yet one gets the impression that the Agency is not all that interested in the drug. Ampligen is not even a topic at this drug development workshop.

Dr. Peterson, the physician with the most experience and success in administering the drug, and many other treatments as well, has not even been invited to one of tomorrow's panels. I'm happy to see that he got at least a two-minute slot today.

At the Ampligen FDA Advisory Committee meeting, the FDA stated that there is no path for an Ampligen approval on an accelerated approval process. No explanation was given for that. In contrast, the FDA has recently developed new guidelines for an accelerated approval process for Alzheimer's drugs for patients who are not even sick yet. Why the drastically different standard? I wonder.

Looking back at the approval of AZT as the first drug to treat HIV and AIDS, it becomes clear that the FDA does indeed have discretion to adopt looser

rules if the circumstances warrant it. At the end of last year, the FDA approved, again under accelerated approval program, Sirturo, a drug to treat tuberculosis, that is five times more likely to kill patients than the standard drug treatment for the disease without proof of increased efficacy.

I am not so convinced that the FDA's hands are bound when it comes to an accelerated approval of Ampligen. Instead, it seems that an unfortunate double standard applied by the FDA to ME and Ampligen compared to other diseases and other drugs has Ampligen headed straight towards the cliff as Hemispherx as running out of money and the drug is going away potentially forever.

Thank you.

(Applause.)

MS. TOIGO: Thank you, Ms. Burmeister.

And I have three more names that are not on the slide, but Mindy Kitei, K-I-T-E-I? I'm sorry, I don't know if I got that even close.

MS. KITEI: Kitei.

MS. TOIGO: Kitei, okay, Kitei.

MS. KITEI: My name is Mindy Kitei, and I'm a science reporter and blogger at CFS Central. In 1994, I wrote an investigative piece for Philadelphia Magazine called "The AIDS Drug No One Can Have," about the experimental drug Ampligen. But I'm here today to say that it's vital that the FDA understands one thing, much of the data on this disease is useless because CDC, and before that the NIH, have not been studying patients with ME. They are not studying patients with natural killer cell defects, VO2 max abnormalities, or abnormal tilt table tests. They are not studying patients who meet the Canadian Consensus Criteria for the disease or the International Consensus Criteria.

(Applause.)

MS. KITEI: While the different definitions can get incredibly confusing, you need to know one thing, the Fukuda and the revised Fukuda, also known as the empirical definition, as well as the Oxford definition, and the Holmes definition of this disease are not accurate, yet CDC uses these definitions instead of the Canadian Consensus and the International Consensus, which are accurate.

Dr. Leonard Jason, of DePaul University, has shown in published studies that CDC, in employing the empirical definition, is studying patients with major depressive disorder, not patients with ME. That's like doing an HIV trial and none of the people are HIV-positive.

As a result of studying the wrong cohort, doctors are misinformed. Dr. Lisa Corbin said recently that she tells her patients that, "Monday is for mending, Tuesday is ironing." I found her advice to be, in a word, clueless, but typical of the help ME patients receive. Imagine giving this hokey advice to patients with HIV or MS. ME patients want and need treatment, not patronizing bromides.

Five of the patients I interviewed in 1994 for the article on Ampligen have died, one of them a good friend of mine, three of them in their forties and fifties. Do you really think that these patients would be alive today if only they had done their mending on Monday?

Thank you.

(Applause.)

MS. TOIGO: Thank you.

Next is Mr. John Kalns, K-A-L-N-S?

DR. KALNS: Hi. I'm an owner of a small company called Hyperion Biotechnology. I am not really a CFS or ME person. We had this audacious idea in 2004 that we could measure fatigue by evaluating changes in the composition of saliva. The Army was very interested in this topic because a lot of folks that were fighting over there were profoundly fatigued. Since then, we published a number of papers about the use of this biomarker. There are several small peptides that are found in saliva that are quite informative.

More recently, we have published or given a paper at the American Association of Clinical Chemistry describing application of the technology to CFS patients. I have to caution that these were archival saliva samples. The providence was not absolutely certain, but the poster presentation, as presented, got an award at this annual meeting, and it's a pretty well-attended meeting.

I guess why I'm here ultimately is to pose a

question. I need spit.

(Laughter.)

DR. KALNS: I need spit from CFS patients, I need spit from control patients or control people. There are a lot of flaws, and I'll be the first to admit that there are some serious flaws with the small cohort that we looked at in CFS patients. And I don't want to step on any toes or get anybody ruffled, and I am very cognizant of the XMRV debacle.

I would say that if there are investigators out there that have protocols that are ongoing, please talk to me. I want to get that saliva. I would require that the saliva samples, if sent to me, are blinded; I don't want to have any bias, I don't want to -- if it doesn't pan out, it doesn't pan out. The big market for us is in assessment of fatigue in healthy people, not in sick people, but I really think that this technology might have a lot of applications in terms of evaluating new drugs, in terms of efficacy, maybe in predicting crashes. There could be a lot of potential here. But come talk to me. I'll be here tomorrow as well.

(Applause.)

MS. TOIGO: Thank you.

And, Ms. Diane Lewis? Do you want a microphone, Diane?

MS. LEWIS: I hope I can do this because my laptop hasn't been working all day. I am Diane Lewis. I'm a licensed certified social work clinical therapist. I'm here to tell you, as a professional, this disease does not benefit well from CBT. But from a personal note, I want to say that the distance between life and death is but one step, but the difference between living a daily death is a life sentence with this chronic disease. The experience robs you of who you are, destroys your integrity, personality, and the stigma and discrimination that comes with this disease is uncalled for.

For every attempt to step forward, the slow dying nature is no longer a step forward but stepping backwards with each passing day. No having medical parity means that we are nonexistent in life. I spend most of 75 to 80 percent of most days in bed at rest, and it was easier for me as a single parent working two

and three jobs and earning my two master's degrees than to be sitting on the beside.

So today is a choice, and I know that I will suffer from this, and I want to let you know that when I work, I do four clinical hours of work because I stay within my boundaries. That's really taxing me. In order to do that, I have to stay completely in bed rest with no contact at all possible on Sundays. I will work my 4 hours on Monday. It will take me a long time to do my notes, but then when I do come home, I am in bed Tuesday and Wednesday unless I have appointments, and if that means I have appointments, that extends that week.

So I actually am living to be able to help people, but I am on a palliative care plan. Medications that I get I've been told by our hospital administrator that, "We don't treat that disease here." You know, none of the doctors will consider this disease, and so every single doctor I see or get referred to will only treat just the symptoms that I would come in and say that was most disturbing.

I invest a lot of my energy and my time and

efforts into energy conservation, knowing myself, trying to find out ways where I can actually achieve something, but know that if I have to use the cane -- if anybody has ever seen a social worker in hospital, you know we're on the fast draw. I have to have the cane to slow me down; otherwise, I am going to burn out. I can eat a meal and my body will just drain of energy.

MS. TOIGO: So you've got about 10 seconds left. Do you want to wrap it up for us?

MS. LEWIS: Okay. But I do use a lot of hydrotherapy. I benefit from soaks. But other than that, my medical interventions is a mockery. I have been told to do so many things, and the best treatment that I've gotten is because I have taken studies from Dr. Peterson, Dr. Lapp, Dr. Klimas, and I've taken them to the doctors, and if those doctors will respect that research, then they will give me the medication I need. Otherwise, I am waiting for the last stage.

MS. TOIGO: Thank you for your comments --

(Applause.)

MS. TOIGO: -- and for agreeing to be the

last speaker, unless I think we covered everybody who didn't get on this list but had signed up. Is there anybody who thought they were going to speak in the Open Public Session and didn't get a chance to?

(No audible response.)

MS. TOIGO: We haven't gone over our time, so if there is anybody who didn't get an opportunity and has a comment that takes less than 2 minutes? One minute. Okay. That's it.

MR. MILLER: So I also would like to thank the FDA for agreeing to this meeting. I would also like to thank the advocates who helped to put this meeting together.

What I would like to kind of reaffirm and reconfirm is that FDA was willing in the days of HIV and AIDS to work with companies and bend the rules, change the rules, alter policy, try to figure out how to get a medication to people to save their lives. We now have what I'm referring to as the Alzheimer's plan, which I would ask the FDA to allow for Ampligen. It's changing policy for patients who aren't patients yet. It is willing to give people who are not actually

confirmed with Alzheimer's who knows what potent drugs that are going to be coming out to treat these people, but FDA is willing to bend.

It was mentioned that Sitro (sic) -- Situro, excuse me, was fast-tracked December the 31st of this past year, and that this drug kills five times more patients than placebo does, but somehow policy was altered because there is an unmet medical need. There is an unmet medical need right here and there has been for a very long time.

And so FDA is here and Ampligen's sponsor is here. There's a gap. We've got to figure out how to bridge that gap. We need to get the right people in the room and figure out how to do that. How do we bridge it? FDA, the sponsor, the expert clinicians that you heard today, and there are other expert clinicians who have given Ampligen that certainly can sit down and help.

So thank you.

(Applause.)

MS. TOIGO: Thank you. Okay. I think that closes the Open Public Session. You already spoke

during the open -- we need to be fair here, so I think it's time now that I turn it over to Dr. Mullin to close the meeting. And if there are comments that didn't get into the Open Public Session or if you gave your presentation and neglected to add something that you thought about later, please submit your comments in writing to the docket. And I really applaud the speakers for working with me, and doing this without our timer. This session facilitated that. We can't always do that in open public meetings, but it was the right thing to do here, and you proved it, and you worked with me. So thank you very much.

(Applause.) Closing Remarks

DR. MULLIN: Okay, well, I just want to close by thanking you again for being here today. Thank you for sharing your experiences with what life is like living with ME and CFS, you know, the terrible cognitive and physical impacts you have been telling us about, the crashes you experience, and the fear of crashing and the consequences of your just trying to engage in daily life the way the disease has constricted your life, and managing physical pain and

other problems and challenges you've told us about today.

And thank you for sharing your experience with what you've been trying to do to treat the condition as best you can and the range of therapies that you've described and the things that have worked well and what has worked better than other things.

I also want to finally thank you for being so generous with your time, and after spending a few hours with you today, having a much better -- I know I have a much better appreciation of what a sacrifice you've made and really how courageous you are to have come to this meeting today, knowing full well, as I now understand, that you're going to have some consequences for even expending the energy to be here and tell us about how you're doing. And so I think that that is just a tremendous courageous contribution that you're making on behalf of this disease and other patients who couldn't be here, and I want to thank you so much.

And on behalf of this Patient-Focused Initiative, I think you've really set us off to a very challenging start because we have to do our best to try

to meet the level of contribution that you've made to us. This is, as I said, a first meeting, and this is, I think, a first effort for us in this area to be trying to do better with trying to capture and describe these quality of life and life impacts. As I said, we'll have that docket open to receive more comments until August. We'll be producing a summary report capturing the information and having available in fact the transcripts and the raw materials so people --

(Loud noise.)

DR. MULLIN: Am I doing that? Maybe.

And we'll be posting that and sharing that with the reviewers and others. And so this has been a very rich and challenging start for us.

So thank you again. And I hope -- I know you'll have a very good day tomorrow as well if you're able to be there. And I hope you have a good night.

(Applause.) (Whereupon, at 5:10 p.m., Day One of the Drug Development for Chronic Fatigue Syndrome and Myalgic Encephalomyelitis: Public Workshop, Patient-Focused Drug Development Meeting, was adjourned.)

CERTIFICATE OF COURT REPORTER

I, NATALIA THOMAS, the Court Reporter before whomm the foregoing proceeding was taken, do hereby certify that the proceeding was recorded by me; that the proceeding was thereafter reduced to typewriting under my direction; that said transcript is a true and accurate record of the proceeding; that I am neither related to nor employed by any of the parties to this proceeding; and, further, that I have no financial interest in this proceeding.

_____
NATALIA THOMAS
Digital Court Reporter

CERTIFICATE OF TRANSCRIPTION

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

_____ _____
Date DEBORAH ARBOGAST
Transcriptionist

$

$2,500 118:7

$250 169:19

$400 139:16

$9 169:17

0

0200 42:11

0400 42:11

1

1 7:4,14,19 10:3 31:3 33:3 34:11 36:22 37:3,4 86:6 89:14 112:1 169:13 172:5 173:8

1,000 96:22

1,300 48:14 49:21

1:08 1:14

10 6:6 42:10 44:18 52:15 59:17,21 77:16,18 99:4 102:14 108:5,6,8 143:22 179:11 190:9

10:00 39:18

100 115:21 117:6

107 53:6

10-day 58:15

10th 113:4

110 46:17 167:2

116 46:18

119 8:15

11th 47:19

12 77:16,18 114:11 164:9 166:11

12.5 116:9

12-hour 113:13

13 70:1 180:1

14 109:20 136:16 179:22

15 42:3 73:14 74:2 102:14 115:15 118:9 156:19

150 161:22

152 8:20

157 48:22

15-minute 33:2 92:16

15-year-old 115:5

16 115:19 141:20

17 172:6

18 48:16 49:3 131:21 136:17

18th 47:19

19 48:19

193 9:5

195 9:7

1982 80:5 123:9

1985 176:11

1987 38:3

1988 172:7 176:12

1994 109:22 150:5 178:8 184:2 185:15

1996 98:15 99:14 110:17

1997 110:19

1998 110:20 111:1 122:14 123:22

1999 100:3,4 111:9

2

2 8:4,13,18 18:7 31:3,9 33:3 34:11 42:18 44:5 45:3 52:9 72:14 86:8,10,17 93:13 94:4 99:16 100:5 101:4 105:16 106:4 107:8 111:9 113:4 115:21 125:8 130:13,16,17 151:20 153:13,16 168:18 191:8

2:40 33:2

20 6:11 23:11,15 25:4 26:13 27:20 28:9 42:3 44:6 46:5 52:9 74:16 99:16 111:22 179:11

2000 100:9

2001 100:9

2003 100:13,16

2004 186:5

2005 101:12 102:8

2006 102:4,7

2007 102:10,14

2008 112:9

2009 112:20

2010 113:4 115:22

2011 113:9

2012 20:19

2013 1:13 6:3 25:12

2015 25:12

20814 1:18

2-1/2 66:21 121:12

22 44:7 84:16 137:21

24 58:12

24/7 44:14 45:6

24th 109:22

25 1:13 6:3 99:3 102:15 113:2 132:1 169:11,20 176:15

250 48:16

25-year 170:4

25-year-old 95:10

26 91:21

28 102:15 126:19 176:15

285 124:18

29 6:16

2nd 34:20

2-year 41:15 83:21 101:8

2-year-old 121:14

3

3 18:17 25:12 26:18 31:9 64:3 88:19 89:4 94:4 100:16 103:15 105:16 112:16 113:16,19 115:4 121:5 122:16 130:16,17

3,000 113:1

3:05 92:17

3:40 120:11

30 42:12 72:17

86:10 115:12 138:3 159:22 166:6,13,22 167:12 169:1 174:20 176:19

3-1/2 85:18

31st 192:5

32 48:15 102:15

35 47:18 48:14,19 102:16 167:20

36 48:21

37 7:5

37-kDa 111:5

38 7:11

39 162:7

4

4 42:18 100:6 189:9

4,500 24:21

4:15 120:12,13

40 24:15 59:16 60:1 167:20

4-1/2 111:12 115:10

44 115:17

44-year-old 109:20

45 86:7,12,15

452 48:22

46 178:15

4th 111:9

5

5 23:12 25:6 38:21 55:6 64:3 67:9 86:11,13 88:19 96:21 111:10 112:6 114:6 146:17

5:10 195:18

50 48:21 176:18

500 48:19 99:2

51 48:22

5151 1:17

516 123:21

59 7:16

5-year 25:8

6

6 14:14 38:21 83:21 96:22 97:2 104:20 107:8 111:13 124:1 135:5 163:12 178:14

60 105:12

65 145:16

66 125:5

6A 179:3

7

7 44:7 58:15 62:1 112:3 116:10 127:22

70 49:7 67:1 178:7

700,000 49:21

75 188:21

8

8 41:12 44:5 116:10 131:20

80 108:16 117:6 188:21

86 49:11

8-hour 39:20

8-week 100:6

9

9,000 169:1

9:00 39:18

93 7:21 8:5

95 8:10

970 50:1

98 178:15

A

abandoning 131:20

abbreviated 145:10

abilities 148:4

ability 42:20 96:20 139:10

Ablashi 111:3 178:13,16

able 20:22 28:11 36:15,17 38:16 39:2,12,15,17 40:1,14,20 47:2 49:15 53:2 54:15 55:5 67:5,6,16 84:15 85:14 88:20 96:21 97:1,10,12 100:13 101:18 102:15 103:12,19 106:15 110:21 115:4 116:3 126:14 142:18 153:19 174:3 177:6 189:14 195:17

abnormal 54:2 112:16 170:9,10 184:11

abnormalities 159:6,10,18,19 175:14 180:14 184:10

abnormality 174:6

abnormalties 105:21 106:8 107:2,16

absence 110:2 160:22

absolutely 58:7 151:14 186:18

abysmally 173:1

academic 16:21 173:4

academics 44:8

accelerated 181:22 182:14,17 183:2,8

accept 98:6 108:18

access 28:2 98:1 99:6 103:7 104:6 131:8 144:12

accident 115:8

accommodate 34:16

accurate 184:20,22 196:7

ache 99:19 100:7

aches 100:8

achieve 190:2

acknowledged 36:12

acknowledging

163:4
across 27:20 72:19 74:8 95:12 115:12
Act 20:18
action 171:7
active 100:14 112:14,21 163:21 178:10,21
actively 44:8
activities 18:4 26:3 30:11 40:5 67:2 100:15
activity 14:16 52:11 53:5,20 54:1,8 69:4 83:8 90:11 94:13 96:7 97:11 106:21 117:21 160:19
acts 159:17
actual 122:14
actually 43:13 51:3 56:12 57:16 72:18 78:13 81:2,18 83:5 84:20 107:7 138:3 141:13 142:6 150:13 151:13 161:14,17,20,22 162:1,5,7,9,11 166:5 175:17 189:14 190:2 191:22
acupuncture 117:1 124:11
adaptation 87:5 150:2
add 7:18 8:17 32:8 33:4 122:10 131:5 138:9 146:2 193:5
added 110:19
Adderall 105:10,13,22 106:1 108:4,10 140:1
additional 24:7 48:10 162:16 166:11
address 30:18 75:6 94:15 96:1,8 105:1 153:8 172:2 174:10
addressed 181:1
addressing 41:7 151:4
adequately 16:17 147:9
Adjourn 9:7
adjourned 195:22
adjunct 21:6
adjunctive 142:6
adjusted 54:21 87:10
administering 177:11 182:8
ADMINISTRATION 1:4
administrator 189:16
Admiral 165:20
admit 187:6
adopt 99:10 173:6 182:22
adult 137:5
advance 174:12
advancing 47:15
advice 27:12 185:10,12
Advil 136:18
advisory 14:7 182:12
advocacy 28:6 160:14
advocate 18:4 105:12 171:21 173:5
advocates 10:12 23:20 33:14 191:12
aerobic 149:7
affairs 44:10
affect 26:2 134:1 137:11 148:4
affected 26:12 42:19 84:20
affects 127:14
afflicted 179:2
afford 106:15
Africa 98:16
afternoon 10:2 19:15 20:1 29:6 37:21 43:22 81:8 161:12 163:14 171:20
afterwards 66:1,2
against 99:9
age 48:14,20,21,22 73:14 115:17
agencies 33:18 147:11 173:4
Agency 18:2,15 182:4
agenda 17:2
agent 160:22
agents 151:4 180:16,21
ages 48:19,21
aggressive 114:5 115:18
agile 45:20
ago 44:6,7 45:3 51:20 52:4 86:8 115:5 121:5 161:14 163:18,19 166:6,13,22 169:11 176:22
agonist 168:2
agreeing 190:22 191:11
agreement 80:21
Ah 52:1 168:19
ahead 86:22 157:19
aids 127:2 150:8 177:16 182:21 184:4 191:16
aim 106:10
alcohol 96:10
alert 139:22
Alexander 44:6 46:21 155:3 157:15,16
Alexander's 46:18
alive 185:19
Allergy 2:18 18:11
alleviate 96:4
allotted 153:19

allow 109:5 125:17,18,19 128:15 130:19 154:21 191:20

allowed 49:9

allows 54:18 106:18

alone 45:6 164:14

alphabetical 37:7,8

already 89:17 123:11 126:14 137:11 164:20 170:12,22 192:22

alter 191:17

altered 192:8

Alzheimer's 109:10 158:8,9 159:4,14 160:20 182:17 191:19 192:1

am 10:2,5 18:10,14,20 29:13 39:11 41:5,11,14 43:14 44:15 53:2,8 54:3,15 55:4 58:5 66:20 67:6 68:7 73:9 75:5 80:11 85:20 91:13 102:20 103:16 105:19 108:12,13,15,18 114:9 115:3 117:8 118:11,13 121:17,18 125:14 127:20 129:15 136:22 139:16 147:18 149:22 154:19 158:1 161:12 163:8,10,12 164:5 166:1 168:21 176:13 183:7 186:4 187:9 188:6 189:10,14,15 190:6,19 195:11 196:7 197:3

Amanda 5:9 83:15 85:8 94:2 114:21 132:8,19

amazing 96:19

Ambien 105:21 108:5,6 110:14

ambulance 84:8

America 48:6

American 172:5 186:15

Americans 166:16 173:8

amitriptyline 99:4

among 15:1 167:15

amongst 162:5

amount 38:8 53:16 139:16 182:2

amoxicillin 124:8

amphetamine 108:1

Ampligen 109:19 111:6,8,9,16,22 112:4,6,11 113:1,3,10,12,18 ,22 114:2,10,11,16 120:18,21,22 121:9,18 122:19,22 123:6,10,13,14,2 1 124:6,17,18,20 125:3,12 156:18 160:2 165:1 166:3,5 167:7 176:12,16,19,22 177:5,11,21 178:14,17,19,20, 21 179:6,7,9 181:11,22 182:2,5,12,14 183:9,10,11 184:5 185:16 191:20 192:17

Ampligen's 192:11

Amtrak 113:15

analysis 2:10 6:15 49:19,20 50:3

analyzed 24:22

analyzing 52:16

Angola 98:16 99:14 100:11

angry 136:22

Anita 5:6 91:21 148:10 155:8,9

announced 159:15

annual 186:20

answer 41:19 51:3

answered 83:5

answering 86:14 87:3

answers 48:1 49:15,21 92:12

anti 53:16 58:22

antibiotic 97:3 135:20

antibiotics 96:11 98:21 100:11 120:8 124:7

antidepressant 130:3,4,16 131:15

antidepressants 124:10

antifungals 96:5,14

anti-inflammatories 58:20 68:11

antimicrobials 120:7,19

antioxidant 159:13

antiviral 52:10 102:16 107:7 178:16 179:5,8,9

antivirals 98:22 107:6 120:8 138:17 139:19

anxiety 63:7 66:11 70:4,7

anxious 70:12

anybody 148:7 164:8 187:8 190:4 191:3,7

anymore 85:13,16

anyone 32:21 49:11 61:14 63:11 68:16 69:17 71:12 72:9 78:21 89:1,2,21 120:17,20,21 122:9 128:21 129:1,13,18 134:4 143:20 146:19 148:16 176:1

anything 69:14 79:4,22 80:15 85:16 86:17

88:22 98:7 129:2 135:16 137:10 139:15 146:19 165:2 176:1

anyway 84:22 133:10

Anyways 91:22

anywhere 76:1 85:17

apart 73:22

apologies 165:13

apparently 84:10

appears 178:17

applaud 173:16 193:7

applause 41:3 43:19 47:8 51:15 55:8 66:5 70:17 89:19 98:11 104:15 109:15 114:19 118:18 125:21 126:16 128:2,20 145:21 148:1,20 151:18 152:10 157:7 158:13 162:14 165:6 168:12 169:2 171:12 173:11 175:20 178:2 179:13 181:15 183:16 184:14 185:22 188:1 190:21 192:20 193:13 195:18

application 22:7,11 186:16

applications 18:14 23:1 187:18

applied 167:10 183:10

apply 12:1,5 103:21 174:3

appointment 106:18

appointments 44:20 189:11,12

appreciate 79:20

appreciation 194:11

approach 11:5 22:5 104:8 162:11

approaches 93:20 94:9 99:11 104:14 120:1 144:18

appropriate 25:21 55:4 161:20

approval 16:17 106:13 109:6,11 164:17,18 167:10 181:22 182:14,17,20 183:3,8

approve 164:22

approved 14:22 26:7 97:20 129:10 149:3 156:20 158:11 159:12,22 160:9 164:7,11 166:12 169:21 177:16,17 181:9 183:2

approving 158:9,10

approximately 99:16 168:22 178:7

April 1:13 6:3 99:14

Arabic 42:6

ARBOGAST 197:3,12

archival 186:17

area 15:10 23:2,22 25:15,22 38:3 41:14 42:21 47:1 121:15 124:22 154:17 195:3

areas 23:12 24:13,20 25:18 26:14 28:18 50:6

aren't 75:8 88:20 191:21

arm 82:5

arms 99:17

Army 186:7

arranged 143:10

arrangements 44:22 45:8 143:11

array 162:2

article 185:16

articles 167:14 170:5

articulate 16:1

Asia 95:12

aspartame 117:7

aspect 16:4 87:9

aspects 10:20 23:5,7 26:4

aspirations 108:21

assessment 187:16

assessments 21:8

Associate 2:6 3:7 7:8 17:20

associated 63:4 180:19

association 48:4,6 186:15

ataxia 110:2

atenolol 46:20

athlete 73:14

ATP 92:9,11

atrial 84:8

attack 45:4

attempt 120:5 188:17

attend 44:17 108:13 153:7

attendance 10:10

attended 169:15

attention 168:14 175:10

attitude 117:14,18

attribute 75:16 139:7

audacious 186:5

audible 59:6 69:15 119:4 129:3 146:16 155:7 158:16 171:15,17 179:16 191:5

audience 7:18 8:17 10:13 31:16 94:7 148:11 172:17

audio 54:18 95:17

augmented 48:9

August 34:20 113:6 115:22 195:7

authors 104:7
autoimmune 105:15
autonomic 45:13
avail 46:21
available 28:3 36:6 95:1 115:19 150:4 195:8
average 48:14 49:2
avoid 36:19 54:11 70:11 96:16
avoidance 96:9,14
avoided 104:10
avoiding 86:13
awake 107:20
award 186:20
aware 79:16
away 113:1 114:10,16 183:13
azithromycin 96:18 98:21 129:1
AZT 177:16 182:20

B

B-12 98:22 102:8 103:3 105:19
background 99:12
backpacking 95:12
backwards 188:19
baclofen 148:6
bacterial 92:7
bad 32:14 66:9 70:9 77:18 85:11 107:9 130:7 133:14 135:6,15 137:9 172:18
badly 133:7
Badrul 173:16
bag 145:19
balance 53:13 107:14
balcony 55:2
Baraniuk 3:12 171:18 174:20 175:17
barefoot 111:16
barely 82:4,5 97:14 121:9 144:11
Barr 112:15
Barraniuk 173:13,14,15
based 47:17 130:19 175:14
basic 83:4 92:9
basically 50:6 58:2,6 89:14 130:2 133:6 142:16
basis 12:15 134:9 143:8 166:9
bathroom 54:4 64:19 85:19 110:22
bation 58:7
Bay 38:3 121:15
beach 111:16
Bean 3:13,14 73:9 78:2,3
beating 84:6
beats 46:17
beautifully 148:9
became 48:16 100:5,17 111:19
become 38:19 58:14,16
becomes 63:6 100:1,17 113:3 133:11 182:21
bed 39:6 40:5 54:22 84:5 85:18,19 88:12 95:21 98:4 101:4 103:18 110:21 133:6 134:15 141:2 164:2 188:21 189:7,11
bedbound 39:9 40:19 108:15 123:14,15
bedridden 116:4
bedroom 107:1 118:10
beg 84:21 170:2
begin 30:2 37:3 95:5 151:9
beginning 136:16 153:6
begins 174:9
behalf 33:16 92:15 169:5 170:21 194:18,20
behind 32:22 59:22 92:20 110:7
Belgian 145:17
Belgium 98:19 99:17
believe 61:11 98:16 102:16 103:1,6,9,21 115:16 116:2 117:3 127:18 139:14 152:18 166:6,11,20 167:6 174:3
believing 117:18
bell 49:1
bend 191:16 192:3
beneficial 145:3
benefit 19:10,11 21:4,12 22:4,20 103:10 131:5,6 188:9 190:12
benefit-risk 21:6,7
benefits 21:17 132:21 160:12 172:22
berserk 84:11
beside 189:2
Besides 138:10
best 25:3 38:1 45:7 72:4 98:1 143:1 173:18 190:14 194:5,22
bet 56:20 156:13
Bethesda 1:16,18
better 11:9 16:13 22:12 52:2 57:6 63:20 66:3 74:4 77:13,14 78:7 97:9,10 98:6 102:20 108:18 123:11 138:17 150:1 157:17 180:11

194:7,10,11 195:4
bexarotene 159:16
beyond 13:1 25:8 28:9 133:6
bias 187:14
biggest 132:3
billion 169:18
billions 169:20 172:21
bimonthly 105:17
binds 10:15
biological 127:13 159:10
biology 92:9
biomarker 186:11
biomarkers 172:16 180:13
Biopharma 166:2
Biotechnology 186:4
birth 100:16
birthday 44:5
bit 13:14 15:4 19:1,18 20:8 27:14,20 41:13,16,17 50:12 59:19 60:21 69:9 75:22 97:13 104:13 120:2 140:8,12 144:19 146:8 152:13,20 169:3 174:20
blacked 72:19
blacking 81:3,4
blackout 109:22
112:3
blackouts 85:16 107:14 110:1
bladder 114:5
blessed 163:15
blind 168:1
blinded 187:14
blocks 103:15
blogger 184:2
blood 61:7 91:4,6 116:6 145:15 174:8
blow 122:21
blurred 51:2 90:3
board 74:9 158:1
Bob 81:17 114:16
body 39:7 62:4 69:5 75:19 82:13 85:15 92:10 105:14 106:1 139:13 140:3,18,21 141:10 190:7
bold 174:7
bolster 116:10
bolts 16:6
bonk 82:4
book 44:17 54:18 111:15
books 95:17 96:22
boom 64:18 75:18
bother 163:13
bottom 151:12
bounce 123:11
bouncing 121:10
bound 183:8
boundaries 189:6
bouts 99:18 100:6 110:13
bowel 90:9
box 32:9
boys 125:19
brain 38:20 61:12 116:17 128:10 132:15 133:3 137:12
break 7:21 32:21 33:2 36:7,8 39:21 58:22 59:20 92:16,19 93:5 147:5
breaks 72:3 175:8
breathe 84:7 139:11
breathing 123:17
bricks 123:15
bridge 81:20 192:13,15
brief 20:14 99:12
briefly 62:10
bright 159:14
bring 14:8 118:21 168:9
broad 26:12 118:21,22
broaden 31:14 94:6
broadening 26:15
broader 13:15,22 35:9 93:22
broadest 16:10
broke 48:15 107:7
broken 19:16
147:3
bromides 185:14
brother 112:9
brought 46:12 50:9 64:11,13 65:10 89:9 177:15
brush 111:2 149:9
budget 23:12
build 31:17 35:19 61:15 72:10 119:14 120:2,20,21 123:9 143:20 144:2,13
building 12:8 28:14 34:12 151:16
built 124:6
burden 173:2
Burke 2:5 19:7 80:22 81:1,10 82:18
Burmeister 3:15 89:7,8 121:3 149:1 181:17,18,19 183:17
burn 190:6
burning 55:12 59:4 119:2 146:15
bus 72:20 113:15
business 80:8,10
busy 38:5 53:11
BWI 65:18
Bystolic 116:5

C

cab 72:18
calendar 86:17
California 144:4
camel's 72:3
Canadian 45:15 52:7 104:5 173:6 180:9 184:12,21
cancer 109:10 114:5 115:7 128:8,9,10,12 159:16,22 164:5,6
Candidas 96:6
candidate 24:13,20 25:21
candidates 24:15 25:18
candle 122:21
cane 111:10 113:5 190:3,6
capacity 103:9 142:22 171:9
Capital 1:22
CAPT 2:5
capture 23:4 195:4
captured 26:4
capturing 22:20 137:15 195:8
car 110:17 113:6 115:8 141:1
card 19:5 29:7
cardiac 167:16,17
cardiopulmonary 54:2
cards 29:8
care 11:12,14 21:21 35:3 44:14,15,19 45:6 49:14 65:5,8,10,14 101:9 109:8 111:17 114:3,12,14,16 117:1 118:7 139:18 143:17 148:16 152:21 171:2 189:15
cared 114:6
career 50:14,15 54:6 104:21 108:21
careful 106:3
carefully 104:12 143:8,14
caregiver 44:22 45:3,4,5 163:11 168:22
caregivers 10:11 17:9 22:15 23:22 33:9 45:10
caregiving 22:15
caretaker 31:8 73:10 95:6 137:5
Carol 5:5 65:6,7,14,15 126:18
Carolina 176:10
cascade 88:3
case 23:14 78:19 99:8 103:5 128:17
cases 112:14
Cassidy 3:16 75:5 76:1
catch 162:20
catch-all 61:4
category 129:8
caught 140:7
causative 160:22
cause 15:17 57:18 139:12 147:8 150:17,20 180:17,20
caused 172:15
causes 66:11 70:13 108:2 127:14 147:14 159:3 167:15
causing 140:9 181:12
caution 99:9 186:17
CB 104:13
CBT 99:1 101:7,14 102:4 188:9
CDC 169:12 172:7 184:8,20 185:2
CDER 1:5 2:7,11,14,22 3:7 6:6,11,16 7:9 17:21
CDER's 18:20
Ceftin 124:8
cell 52:11 89:10,13 96:1 112:15 124:15,16,17 170:8 184:10
cells 89:14 107:4 156:1
center 1:5 18:19 29:15 80:8,10 154:1 161:17,18
central 41:19 159:7 184:2
CEO 48:6
certain 91:18 100:12 125:16 186:19
certainly 117:22 139:3 154:10 156:15 192:17
CERTIFICATE 196:1 197:1
certified 188:7
certify 196:3 197:3
cetera 29:20 67:2 94:13 109:11 171:9
CFIDS 48:6 127:6
CFS 8:5 10:21 13:2,18 14:11 15:10 30:5,15 35:1,2 39:12,15 40:1 49:13 77:13 93:13 95:6 98:15,17 99:6 100:3,17 102:1,19 103:6,22 104:5,6,9 107:19 126:10 138:11,14 141:17 166:5 173:7 174:6 178:10,18 179:8 184:2 186:5,16 187:3,7 193:17
CFS/ME 158:4,11
CFSAC 18:15 63:19
chain 178:11

chair 37:18,19 64:10 110:20 150:3,4
Chairman 166:1
chairs 32:19 92:21
challenge 37:22 173:17
challenges 63:5 194:1
challenging 14:20 93:12 154:15 194:22 195:14
championship 44:9
chance 32:7 79:21 124:21 125:5 191:4
change 54:19 97:8 152:12 154:20 177:3,4 191:17
changed 106:7 115:15 117:5 155:5
changes 174:2 186:6
changing 75:19 191:21
Characterization 178:11
characterized 14:14
charge 18:3
Charles 4:12 176:4,9
Charlotte 5:13 37:13,15 51:16 55:9 176:9
cheap 146:7
check 20:5 123:16
Chemistry 186:15
chemotherapy 128:9,11
chest 84:7
children 44:4 172:6
Chilinski 155:11 157:13 158:15
chills 53:22
chiropractic 117:1
choice 41:21 114:9 189:3
choices 132:20
choose 47:2,4 101:14 153:8
chose 41:20 101:14 176:21
Chowdhury 173:16
Chris 5:14 66:15,16,17 149:6
Christmas 115:6
chronic 1:7 10:7 14:11 15:6 18:13 25:20 26:2 38:7 136:8 138:4 145:17 167:16,18 172:4,7 173:22 174:3 176:11 177:21 178:8 179:3 188:13 195:19
chronically 49:4
Chu 3:17 77:9 83:3 126:7 138:9
cidofovir 127:1
circumstances 183:1
City 113:11,13
claimed 104:7
claps 70:20
clarification 70:19
clarifications 35:22
clarify 76:5 78:2,3 136:6
class 92:10 130:5
classification 160:11
cleaned 54:10
clear 39:16 70:12 182:21
clearly 40:21 52:20 125:17 127:7
click 81:5
clients 52:17
cliff 88:2 183:12
clinical 2:17 11:3,13,22 12:14,16 13:1,16 15:22 16:1,3,15 18:10 19:11 21:12,19 22:18 23:6 26:5 97:19 106:16 123:21 145:1 147:20 159:10,16,21 160:15 168:1 171:4 186:15 188:7 189:5
clinically 178:17
clinicians 14:20 16:21 165:21 168:8 170:12,21 192:15,17
clinics 171:2
close 125:12 152:6 153:16 154:6 165:11 183:20 193:3,14
closely 104:13
closer 59:13
closes 192:22
Closing 9:5 193:13
clouds 38:20 61:12
clueless 185:11
CMV 107:6 112:21 116:20
cocktail 105:15
codeine 131:17
coffee 96:10 110:6
cognition 81:5 124:4 137:11
cognitive 46:1,5,13 47:2,5 52:14 55:21 56:2 57:8,16 61:3,10,12,16 62:2 64:6 68:1,5,16 69:17 70:22 71:2 73:19 85:14 97:14 105:4 107:9,10 148:4 170:19 175:12 193:18
cognizant 187:9
coherently 53:2 85:15
cohort 185:7 187:7
collaborated 143:9

collaborations 171:1
collapse 46:11,12 47:3 61:5 71:22 81:11
collapses 46:13
colleague 29:17
colleagues 16:22 17:9,14 31:13 55:12 69:13 92:15 119:1 144:17 152:1
collect 28:14
collected 21:13,15
collecting 28:10
collection 12:21
collective 10:16 11:13
combination 96:19 135:20
comes 51:6 68:8 80:17 91:15 140:2 144:9 183:8 188:16
comfortable 32:19 34:15 36:17 42:16 60:16 61:17 62:12 63:8 66:8 110:15 119:11 121:22 133:9 147:20
coming 29:4 30:21 80:17 106:3 165:4 192:2
commensurate 173:2
comment 8:20 20:2 24:16 32:9 35:13 56:12 58:8 59:3 60:6 67:19 68:17 69:20 70:3 77:11 78:21 91:1 99:9 141:12 150:14 152:7,10,17 191:8
comments 7:11,13 8:10,12 24:21,22 28:3 32:9 34:4,10,19 35:12 36:9 37:20 47:17 51:11 87:6 89:3 93:21 94:5 95:7 146:21 157:6,10 176:2 190:20 193:3,6 195:6
commitment 10:16 23:10 160:7 167:2
committed 23:14 171:5
committee 14:7 169:7 171:6 182:12
common 13:19 34:21 62:9 150:20 151:3,12 159:7
commonalities 151:2
communicate 52:22
communities 173:5
community 13:3 17:1 47:15
commuting 122:18 123:2
companies 23:21 156:9 160:16 164:14,15 191:16
company 1:22 104:22 148:14 166:14 169:19 186:4
compared 177:2 183:10
compassionate 109:8 163:8
competing 118:1
complete 197:8
completed 159:21
completely 36:6 71:13 88:1,6,10 93:2 116:4 117:7 121:7 137:6 152:2 189:7
complex 14:12,18 15:18 109:12 174:21
complicated 143:10
Complicating 14:22
component 50:22
components 49:20 50:3 120:16 159:7
composition 186:7
compounded 129:16 148:8 172:9
comprehensive 22:10
comprise 21:18
computer 80:11 92:2
computerized 53:15
computing 171:9
concentrate 62:5
concentration 43:1 102:9 103:17 117:10 132:15
concept 50:1
concern 77:12 172:2
concluded 112:22
concomitantly 180:22
condense 37:22
condition 11:11 12:12 13:8,10 21:9,12,20 30:7,13,17 33:8 38:1 39:9,22 40:8 50:19 60:14 70:13 88:13 94:10 110:15 112:19 120:6 126:6 136:3 194:5
conditions 12:5 13:2 15:12 16:13 170:19
conducted 16:1 49:18
conducting 24:9
conference 171:22 172:3
confined 110:21
confirm 20:6 125:16
confirmed 20:3 35:14 54:1 153:1

192:1
confirms 53:15
conflict 22:8
confused 43:7,13,14 55:19
confusing 184:16
confusion 41:21 42:2,19 43:4 55:16,21 56:2 61:13 66:9 110:5
connect 170:6
connection 76:6,8
connects 175:2,3,9
conorii 100:10
consensus 15:1 45:15,16 52:6,7 173:6 180:9 184:12,13,21,22
consequences 193:20 194:14
conservation 190:1
consider 146:6 189:18
consideration 109:9
considerations 21:9
considered 32:11
consistently 100:13
consortiums 171:1
constant 110:9
constraints 23:13
constricted 193:22
consultation 24:8 26:20
contact 54:14 189:8
contained 112:21
CONTENTS 6:1 7:1 8:1 9:1
context 13:22 21:19 22:6,18 27:14 48:11 99:13 153:4
continue 25:8 27:6 36:2 112:10
continued 3:2,4 4:2,4 5:2,4 7:2 8:2 9:2 111:21
continuing 28:18
contracted 100:10
contracting 95:11
contrary 141:16
contrast 182:15
contribute 10:20 33:13,22 36:5 132:14 151:16 166:21
contributing 36:21
contribution 194:17 195:1
control 106:10 144:9 147:6 187:4
controls 161:22 174:7
controversy 15:9
conversation 13:22 42:4 48:11 59:9 86:13
conversations 36:20 42:7 142:15 151:7
converting 117:8
converts 178:21
convey 40:3
convinced 110:6 183:7
cooped 118:10
copays 139:17
Corbin 185:8
cords 155:14
core 74:2 139:19
correct 53:1 58:4 70:4 162:10 197:8
correlate 79:14 89:10
corresponds 26:18
cortisol 96:7
cost 65:21 86:16,18 112:5 118:6,7 169:17
costs 172:21
couch 38:15 54:22
count 124:17 180:2
counted 169:13
countries 98:19 104:1
country 98:2 169:14,17
couple 63:10 94:4 95:21 97:1 122:5,8 129:10 163:19
courage 109:3
courageous 194:12,17
course 21:22 27:19 58:15 77:17 102:18 143:15 144:22 156:17 160:10
Court 196:1,2,14 197:4,6
courtesy 36:10
Courtney 155:3 157:14,16,19,20 158:1
cover 13:16 26:13 88:20 94:22
coverage 45:1
covered 99:7 158:21 191:1
CPET 54:3
CR 116:9
crash 38:9,10 57:10,18 58:1 64:15 68:1 71:13,16,20 73:17 75:7,9,11,19,21 76:1,22 78:5,8,22 79:1,2,3,8,13 80:9,16 81:3,4,11 82:3 83:7,11,21 85:12 86:5 91:16 106:12 123:10 145:13 146:9 149:8
crash/sleep/ sleeplessness 76:6
crashed 65:7 112:12

crashes 71:1,6 72:13 75:1 78:15,21 81:2,17 82:8 83:1,19 87:21 89:10 90:11 187:20 193:19

crashing 193:20

create 12:17

crew 173:17

crisis 114:7 125:10

criteria 25:19 45:16 52:6,7 103:22 104:5 169:10 173:6,22 174:1,12,14 180:10 184:12,13

critical 22:15 26:4 35:6

crossed 82:15

crossing 81:3

cruise 145:12

culture 178:9,10

cup 110:7

cure 101:21 102:22 125:14 128:9 151:13

cured 112:1 164:8

current 21:10,21 106:17 112:6

currently 26:6 30:16,17 34:9 99:2 106:13 181:9

curve 49:1

customized 109:12

cut 38:14 64:2,3

cycle 90:12

cyclical 100:6

cyclobenzaprine 148:6

Cymbalta 106:5 124:10 129:12,21 130:15 131:5,10 135:20

cytokine 112:17

cytokines 96:2 97:6 156:2 162:2

cytomegalovirus 112:15

Cytomel 110:12

D

D.C 41:14 124:22

dad 115:6

daggers 154:21

daily 7:5 13:7 26:3 30:5,9 37:1 41:21 50:4,5 106:17 143:8 144:6 188:12 193:21

Dakota 122:14,19

Dallas 115:12

Dan 5:7 112:13 123:20 168:20

danced 111:15

Daniel 158:2

dark 42:12 53:8

darkness 57:22

data 14:8 21:13,15 50:4 176:21 184:7

date 106:9 107:3 197:12

daughter 73:10 77:7 84:2,17 100:16 114:8,13 121:14 136:16 137:17

daughters 40:4

David 168:16

day 1:9 10:19 12:19 13:15 20:9 29:11 39:13 42:15 43:10 55:1,20 74:8 76:2 78:7 79:17 82:22 85:17 87:8 88:7,12 93:4 95:10,16,17 97:11,12 106:20 108:10 113:13 115:19,22 117:7,11 142:19 143:11 144:7 188:6,19 195:16,18

daydreaming 175:8

days 13:19 38:11 44:5 47:18 48:14 52:17 53:22 79:15 80:13 83:8,11 86:11,13 90:12 95:21 106:12 115:11 121:5,8 123:18 130:13 164:2 188:21 191:15

day's 43:17

deadens 134:14

deadly 81:21

deal 22:8 96:5 118:12 126:5 168:4,5

deals 167:16,18 175:2,4

dean 161:15

dearly 163:12

death 50:8 87:14 167:15,17 188:11,12

debacle 187:9

debilitating 10:18 14:12 52:13 109:12 159:5

debility 98:8 108:20

DEBORAH 197:3,12

decade 102:21

decades 156:6 166:20

December 192:5

decide 43:11 130:11

decided 111:7 112:4

decision 62:21 63:7 137:2

decision-making 11:13 62:20 63:6

decisions 16:15

deconditioning 102:3 104:9

decrease 97:14 116:16

decreased 97:6 116:21

dedicated 13:4

deep 139:10

deeper 140:8 144:19
default 175:7
defect 111:6
defective 111:13 112:22
defects 184:10
deficiency 122:15
define 49:20 174:12 180:11
defined 180:8
defining 81:11
definitely 36:18 85:22
definition 14:15 15:3,20 16:2 104:5 112:18 128:17 138:12 172:10 184:18,19 185:3
definitions 172:9,14 184:15,20
degree 21:10,20 39:3 41:16
degrees 189:1
dehydrated 146:9
Delaware 65:17 72:16
delighted 10:3
delivered 54:9
delta 53:5
demanding 66:22 67:7
demands 99:22
demographics 48:12
demonstrate 19:11 181:7
demonstrated 16:17 96:3 160:7
demonstrating 175:13
demoralizing 164:3
Denise 4:16 37:12,14 43:21 47:9 71:19
Denver 126:19
Department 16:22
DePaul 185:1
dependency 87:4
depending 83:12 130:17
depends 106:20
depleted 139:13
depressed 68:7
depression 117:14
depressive 185:4
Deputy 2:14 6:5 10:5
Derek 3:19 113:10 161:11
derogatory 36:19
describe 19:10 87:21 91:5 124:3 172:12 195:4
described 50:18 81:18 111:18 124:19 194:6
describing 186:16
description 55:18
descriptions 91:2
design 13:16 36:3 181:1
desperately 84:18 168:10
despite 23:12
destroys 188:14
Desyrel 124:9
detail 35:17
detailed 14:4 32:13
details 16:2
determine 160:4
devastating 38:9
develop 25:19 144:14 151:1 171:10
developed 38:6 98:15 99:14,20 182:16
developers 10:12
developing 11:20 16:11 23:21 144:10
development 1:7,11 2:7 6:4,9 10:16,21 11:1,5 12:5,14,22 13:15,18,20 15:7,21 16:8,10,14,20 17:5 18:21 19:8 20:12,15 23:3 24:4 35:18 36:4 47:13 109:10 148:15 151:10 154:16 155:17 172:16 180:4 182:5 195:19,22
devise 169:8
Dharam 111:3
diabetes 91:4
diagnosed 49:13 67:3 98:18 100:3 115:6,13 122:14
diagnosis 14:20,21 103:22 137:16
diagnostic 14:19 169:10,18
dialogue 7:19 8:18 13:5 31:15 33:13
Diane 3:13 4:15 73:9 138:20 188:3,4,6
diclofenac 148:6
died 112:10 179:5 185:16
diet 117:5,8,9
dietary 96:14
difference 69:3 96:17,18 117:4 160:4 188:12
differences 60:21 119:21,22
different 14:6 15:14,18 23:11 26:16 27:9,10 29:21 31:19 41:22 50:13 57:10,15,19 69:2 71:13 82:8 88:6 98:19 102:22 121:22 125:13 128:11 130:1,4 134:3 138:11,14 141:6,7 152:15 154:11,12 155:21 157:17 160:18 167:20 182:19 184:15
differentiate 55:22

56:2 57:9
differently 127:3 130:1 150:21
difficult 54:10 56:1 60:10,12 62:6 72:8 77:8 86:1 115:9 119:13 124:13 147:6 166:14 170:6
difficulty 45:22 53:6
digestive 121:7
Digital 196:14
diltiazem 116:6 118:2
dimensions 174:2
dimethyl 159:12
Dimmock 3:18 94:1 95:5,8 128:22
dire 167:5
direct 18:18 19:7 21:2 22:19 87:8
direction 113:19 196:6
directly 28:5 29:12 33:7 48:1
director 2:6,14,22 3:7 6:6,10 7:9 10:5 17:20 103:14
disability 112:19 122:17 169:15 181:12
disabled 39:9 137:6 166:17
disabling 42:1
disagree 143:4
disappointed 156:19
disclose 153:5
disconcerting 90:4
disconnect 176:20 177:1
discontinue 141:22
discovery 47:16 159:15
discretion 182:22
discrimination 188:15
discuss 14:1 24:19 35:17
discussants 55:13
discussed 17:7
discussing 34:9
discussion 6:13 7:4,14,16 8:4,13,15 12:20 13:13 17:8 19:14 29:5,17,18,21 30:22 31:6,14 33:22 34:2,6,7,21 35:4,8 36:11,22 37:3,4 41:5 55:11 59:7 92:15 93:10,12,15,16,17,18,22 94:21 118:21,22 119:5,16 131:1 145:1 151:20,21
discussions 14:4,6 31:6
disease 7:4 10:18 11:5 14:13 15:3,8 16:7 22:1,13 23:2,5,12,22 24:13,20 25:22 26:7,10,14 27:8,14 28:18 36:22 40:2 50:8 54:14 66:3 87:12 96:12 97:21 98:9 106:8 108:19 109:8,13 117:16 127:13 134:21 147:18 154:11,17 159:4 160:19,21 161:20 162:1 166:20 169:4 170:2,15 172:13,20 173:1,2,9 180:5,20,22 183:6 184:7,13,19 188:9,13,16 189:17,18 193:21 194:18
diseases 25:11,17 26:1,16 159:6 160:11 174:16,17 183:11
dismantle 173:7
dismissive 95:19 172:8
disorder 14:17 169:14,22 185:4
disorientation 110:3
disoriented 53:12 84:4
dispel 77:15
disprove 162:12
dissipate 147:17
distance 101:18 188:10
distill 49:20
distilled 49:22
distinctly 15:13
distinguish 172:3 180:15
distress 40:3
disturbance 117:2
disturbing 189:21
divide 160:18
division 2:17 18:11,13 179:10
divisions 22:22 24:5,13 25:1
dizziness 99:20 102:2
dizzy 38:19 53:12
doc 38:5
docket 24:20,21 25:2 34:19 35:12 48:2 51:12 95:1 161:6 162:17 176:3 193:7 195:6
doctor 72:15 89:12 105:11 123:20 137:3 139:7,14 145:17 189:19
doctors 84:21 95:19 97:19 98:1 115:12 127:9 136:17 156:3 185:8 189:18 190:17
doctor's 105:16
document 170:14

documented 169:16
documents 161:5
dog 115:5
dogs 117:13
dollar 161:14
dollars 169:20
done 11:15 35:9 66:11 75:14,15 78:7 80:18 107:11 126:20,21 133:20 157:4 160:21 185:19
doom 173:20
door 165:3
doors 164:18
dormant 111:14
dorsal 175:9
dose 105:10
doses 99:3
dots 170:7
double 90:3 167:22 183:9
downsides 30:20 94:17 107:22 117:22 132:22
doxycycline 96:19 98:21
Dr 3:17,19,21 4:7,8,12,14,18 5:7,10 10:2 13:10 17:3,17,18,20,22 18:8,9,16,18 19:4,7,13 20:13 29:6,14 35:1 37:2,11,18,19,21 38:2 41:4 43:20 47:9 48:3 51:13,16,21 52:3 55:9,14,15 56:5,9,15,17,20, 22 57:3 58:8 59:4,8,16,19,21 60:1,7,19 61:21 62:11,16,18,19 63:5,11,13 66:4,6,13,16 67:21 68:15 69:12,16,20,22 70:5,6,18 71:12,17 72:9,12 73:3,7 74:14,16,17,18,1 9,20 75:3,4,21 76:3,5,9,10,12,1 3,14,16,18,19 77:2,5,9,20,22 78:10,11,12,13,1 8 79:5,11,22 80:20,22 81:1,9,10,13,16 82:7,9,12,13,14, 17,18 83:3,14 85:3 86:2,20,22 87:15,18,19 88:17,18 89:12,20 90:6,14,17,22 91:10,19 92:13 93:6,14 98:12 100:18 101:1 104:16 109:16,17 111:3 112:13 113:9,15 114:20 116:12 117:9 118:17,19 119:6,20 120:13 121:2,21 122:6,9,12,13 123:2,7,20 125:1,12,16,22 126:7,10,11,17 127:1,18 128:3,21 129:4,5,7,13,18, 20 130:9,22 131:13 132:5,19 133:12 134:4,18 136:5,6,12 137:13,22 138:7,9,20 139:1 140:5 141:14 142:3,5 143:19,21 144:1,2,6,15,20, 21 145:8,22 146:11,12,15,17 147:1 148:2,16,19,21 149:13,17,19 150:11,12,13 151:17,19 157:20,22 158:1,2,20 161:9,12 162:15,22 163:3,10,17 165:7 166:7 168:20,21 169:3 173:13,14 174:20 175:17 176:8 178:3,5,13,16 179:14,19,21 181:16 182:7 185:1,8 186:3 187:3 190:16 193:2,14 195:11
drags 107:15
drain 108:22 190:7
draining 164:4
dramatically 115:15
drapes 53:18
drastic 122:17
drastically 182:19
draw 92:3 140:4 156:9 190:5
drawer 110:6
drawn 53:18
dream 97:17
drink 64:13,20 117:6
drip 145:19
drive 65:3 72:16 108:7 110:17 111:11 113:7
driven 84:15
driving 44:21 64:21 65:2 86:11 163:16
dropped 53:6
drove 65:17
Drs 159:20
drug 1:4,5,7,11 3:7 6:3,8 7:9 10:12,20 12:5,22 13:15,18,20 14:5 15:7,21 16:8,10,14,19 17:5,20 18:20 20:11,15,18 22:7 23:7,10,20 24:3 29:15 35:18 36:3 47:13,15 51:8 97:5 108:2 109:6,10 121:19 123:22 124:1 125:19 126:2 127:2 128:18 130:19 131:19 132:22 135:15

148:14 149:3 154:16 155:16 159:15,17,22 160:16 164:22 166:2,9 167:7 169:21 172:16 177:12,15 181:2 182:4,5,8,21 183:3,5,13 184:4,5 192:6 195:19,22

drugs 2:7,14,19 6:6 10:5 11:22 15:22 16:6 18:12,20 19:9 21:8 23:1,21 24:15,17 25:1 96:17 106:16 107:19 118:1 128:6,12,15 129:22 130:12 132:1 135:18 147:16,17 158:9,11 159:11 160:9 167:5,8 177:12 180:7 182:17 183:11 187:19 192:1

dry 108:3

due 52:10 54:7 57:8 105:1 106:4,8,14 166:19

duration 49:4 78:21 79:1,11,12,13 82:19,20 83:10

during 17:7 32:21 35:15 39:7 40:7,8 54:3 74:8 99:17 100:5 131:22 153:1 193:1

Dwight 179:15

dying 188:18

dynamic 53:15

dysfunction 52:14 62:2 64:6 107:9 175:12

dyslexia 110:3

dysphasia 110:2

E

ear 42:8

earlier 46:1 47:3 50:19 124:14 138:10 180:1

early 24:6

earning 189:1

easier 188:22

easily 137:17

easy 86:9 117:16 153:22 163:22

eat 108:7 123:18 190:7

EBV 102:11 107:5 116:20

echo 72:1

effect 38:13 96:15 97:19 127:22 141:3 144:14 167:19 168:3 177:2,12

effective 10:17 11:1 26:6 50:17,20 103:11 146:14 167:7 171:10 178:18 179:5

effectiveness 132:2

effects 51:2 94:18 118:1,5 127:2 130:1,14 131:7 134:5,6 135:15 147:16,17 167:22 178:16

efficacious 181:10

efficacy 16:16 128:18 170:14 183:6 187:19

effort 21:6 25:5 43:7 44:1 63:22 195:3

efforts 28:18 190:1

Eggers 2:9 6:14 7:7 8:7 17:6 19:17 29:5,6,13 37:2,19 41:4 43:20 47:9 48:3 51:13,16,21 52:3 55:9 56:22 59:4,8,19 60:1,7,19 61:21 62:11,16,18 63:5,11,13 66:4,6,13,16 67:21 68:15 69:12,16,20 70:5,18 71:12,17 72:9,12 73:3,7 74:14,18 75:4,21 76:3,12,18 77:22 78:11 79:5,22 80:20 81:13 82:9,13,17 83:14 85:3 86:2,20,22 87:15,18 88:18 89:20 90:6,14,17 91:10,19 92:13 93:6,14 98:12 100:18 101:1 104:16 109:16 114:20 118:17,19 119:6,20 120:13 121:2,21 122:6,9,12 123:7 125:22 126:17 128:3,21 129:4,13,18,20 130:9,22 131:13 132:5,19 133:12 134:4,18 136:5,12 137:13,22 138:7,20 139:1 140:5 141:14 142:3 143:19 144:1,15 145:8,22 146:11,15,17 148:2,16,19,21 149:13,17,19 150:11 151:17,19

Eileen 4:6 171:16,19,21

either 50:14 58:18 59:1 71:2 96:15 122:16 130:2,3 135:13 145:18 165:15

elaborate 34:18 35:11 71:17

electric 134:13

electronically 28:4,10

elephant 164:12

elevator 82:2

elicit 24:16

eliminated 117:5,7

else 23:18 39:19 57:20 63:11 65:6,8 73:12 79:22 84:22

86:10 122:9 127:11,19 128:21 129:18 146:3,19 153:20 176:1
else's 89:3
e-mail 86:14
embraced 116:22
emergency 38:5 39:1 115:11 146:14
emotional 43:8 100:1,17 113:3 175:5
emotionally 164:4
emphasized 73:16
empirical 172:10 184:18 185:3
employed 196:8
employing 185:2
employment 42:21
encephalitic 111:17
encephalitis 10:8 15:6,11 104:20 107:11
encephalomyelitis 1:8 52:5 95:11 172:4 195:21
encounters 14:15
encourage 33:12,14 34:18 160:15 180:4
encouraged 35:11 153:5
encouraging 10:11
endeavor 150:22
endorphins 144:8
endorse 15:19
endpoints 2:6 19:8 170:13 176:21 177:1
energy 40:6,9 44:2 80:14,18 88:1 92:8,9 116:1,20 118:2 124:3,14 150:10 189:22 190:1,8 194:15
engage 13:3 22:13 59:9 193:21
engaged 15:21 44:8
engagement 21:3
engaging 13:4
enjoy 55:1
Enlander 3:19 113:10 116:13 161:11,12 162:15
Enlander's 113:16
enroll 101:13
enrolled 123:21
ensure 34:11 152:20 153:3,18
ensuring 16:14 35:2
enter 168:6
entering 16:2
entire 88:7 96:22 110:5 111:14 128:19
entirely 121:20
entitled 178:13
envelope 86:6
enveloped 110:11
environments 53:14 54:12
epidemic 167:4
Epstein 112:14
equal 109:9
Equels 3:20 165:10,12,17 167:14
Equilibrant 96:5
equivalent 147:7
era 161:2
Eric 162:4
erroneous 172:17
escape 98:8 108:19
esophageal 136:19 138:3
especially 44:2 78:4,5
established 169:11 170:22
esteemed 169:7
estimated 169:13,17
et 29:19 67:2 94:13 109:10 171:9
etiology 14:13
evaluate 181:8
evaluating 16:11 180:7 186:6 187:19
evaluation 1:5 29:16 36:6 93:2 151:21 181:2
Eve 115:6
evening 80:7
event 78:22
everybody 23:18 65:19 95:9 124:1 134:21 147:20 153:18,19,20 163:4 165:19 176:6 191:1
everyday 50:21
everyone 10:2 32:5,7 34:12,16 39:19 41:10 44:1 59:9 73:12 93:6 95:5 121:21 150:20 170:9
everything 58:2,7 84:5 88:21 89:5 98:20 107:21 125:10 160:10 164:12
evidence 103:4
evidenced 21:13
evolved 131:22
exacer 58:6
exacerbated 58:3
exacerbating 95:16
exacerbation 38:9 53:21
exacerbations 40:8
exact 15:3
exactly 94:22
example 11:2 25:22 34:9 53:10 94:17 133:1 138:14 177:16
examples 46:18
exasperate 106:11

exceed 86:7
excellence 18:5
excellent 176:16
except 19:5 155:20
exception 52:8
excited 10:8,9 29:11
exciting 25:15 103:13
exclusion 14:21
exclusive 174:7,9
excuse 113:4 119:10 192:5
execute 169:8
executive 45:18 103:13 166:1
exercise 54:2 57:8,9 95:20 99:1 100:2 101:14 151:15 161:19 162:10 168:3 174:8
exercised 38:8
exercise-induced 174:2 175:12
exercises 103:8 142:17,19
exert 57:17 80:14
exerting 57:10,11 58:18
exertion 46:2,4,5,13 57:22 58:11 71:2 79:2
exertional 43:6 45:12 46:12 175:12
exhausted 43:8
exhaustion 51:2 53:21 58:4 88:8 175:13
exhibit 160:18
exists 160:22
exorbitant 118:6
expand 28:9
expect 11:7 15:20 161:22
expectation 87:13
expedite 13:18
expedited 167:9
expended 40:6 168:4
expending 194:15
expenditure 80:18
expense 106:14 111:7
expenses 153:7 158:21 176:12 181:19
expensive 112:2 181:10
experience 12:1 22:1,16 26:8,10 30:7 37:22 38:9 39:3,7 46:3,9,10 55:19 56:18 61:15 63:9 68:18 70:6 71:9,10 74:3 89:1 91:5 122:1 127:10 133:13 137:22 143:5 156:5 169:4 182:8 188:13 193:19 194:3
experienced 13:7 30:8 56:3,4 70:16 73:13 116:19 124:20
experiences 12:2 31:17 60:9,12,20 87:16 88:6 94:3 119:14,15,17 122:7 126:2,3 129:9 132:6 150:19,21 193:16
experimental 166:2,9 184:5
expert 192:15,16
expertise 12:10 160:22
experts 12:21 15:2
explain 13:11 19:17 57:21 69:9 82:10 85:10 102:1 153:10
explaining 124:14
explanation 182:15
explode 57:20
explore 10:19 13:14 30:4,9 81:7 151:1
explored 138:19
expressed 34:3,4
expression 160:3
expressive 110:2
extended 46:7 58:19
extends 189:12
Extensive 53:14
extent 88:5,11 110:5
extra 41:16 86:12
extreme 139:16
extremely 27:4 63:2 166:12 180:6 181:4
eye 75:17
eyes 90:4 110:7
eyesight 93:11

F

fabulous 151:20
faced 53:9 180:3
face-to-face 28:12
facilitate 10:16 156:11
facilitated 7:16 8:15 34:6 55:11 59:7 93:10 119:5 193:9
facilitator 29:17
fact 22:8 40:8 139:8 147:13 160:3,4 162:10 164:13 195:8
factors 21:18
fainted 145:16
fainting 107:14
fair 36:11 154:18 193:1
fairly 26:12
fairness 127:12
faith 117:12
fall 52:13 88:2 110:20 135:9 155:14
fallen 135:9
falling 110:18

falls 122:13,19 155:21
famciclovir 98:22 99:2 102:13 103:3
familiar 40:12
families 169:6,16
family 22:17 40:2,5,9,12 44:9 98:3 106:19 111:7 114:7,12 117:12 126:12
Famvir 124:7
fasciculus 175:1
fast 190:5
faster 156:11
fast-track 109:5,7
fast-tracked 192:5
father 39:5
fatigue 1:7 10:7 14:11,14 15:6 18:14 25:20 38:6 63:1,2,3 99:15 100:7 104:2 136:8 138:5 145:17 167:16,18 172:4,8,11 173:22 174:4 175:3 176:11 177:21 178:8 179:4 186:6 187:16 195:20
fatigued 99:21 186:9
fatiguing 63:2
faulty 172:14
favored 99:11
FDA 1:4 2:3,7,11,14,19,22 3:4,8 6:6,11,16 7:9 10:6 13:4 15:19 16:13 17:9,19 18:12,13 21:2 23:22 31:13 33:5 35:6,16 36:4 40:16 47:12 48:1,8 49:17 55:12 69:13 95:9 97:20 109:5,8 119:1 144:16 147:10 152:18 158:6 159:12,21 160:7,9,12 164:14,17 165:20 166:6 168:8 169:20 171:22 179:9 180:3,9,12 181:7,20 182:12,13,16,22 183:2,10 184:6 191:11,15,20 192:3,11,15
FDA-approved 159:16
FDA's 6:8 17:4 20:11 35:16 47:22 181:13 183:7
fear 50:7 70:7,8,14 193:19
feature 50:10,17 51:5
February 111:9
federal 24:12 47:20 48:8 66:22 109:11 169:10 171:8
Fee 20:18 23:10
feedback 36:1 85:4
feel 32:19 40:4,13 53:13 54:11 60:16,22 61:17 62:12 63:8 74:8 75:19 77:14,17,19 79:19 87:13 88:10 89:16 94:15 111:13 117:16,17 119:10 121:22 123:11 124:5 140:14,21,22 141:20 143:5
feeling 69:8 75:9 84:1 97:9 115:10
feels 57:20
fell 135:8
fellow 50:9
felt 48:10 99:21 101:5
female 60:5 82:6 145:4,5,6,9 146:5 155:4 157:14 166:10
fencing 44:9 45:19
fever 91:17 99:15,19 112:14
fevers 53:22
fibrillation 84:8
fibro 136:2
fibromyalgia 106:5 129:10 134:20,21 135:12,13 136:4,8,11 138:10 174:1
field 15:2 161:1 177:15,19
fifth 51:5
fifties 185:18
fighting 186:9
figure 24:5 143:13 191:17 192:12,14
figured 89:13
fill 49:15 93:3
filtered 28:6
final 59:4 148:21
finally 19:6 29:11 91:10 110:20 114:21 115:13 118:6 145:13 181:7 194:8
financial 44:3 178:6 181:12 196:9
finding 62:6,13 81:19 170:11
findings 172:16
fine 37:20 100:21 116:7 141:14 153:9
finish 41:16 42:22 43:3 67:11 88:5 100:20
first 15:8 20:9,20 21:18 25:5,12,15,22 26:18 28:17,21 30:3 31:3 33:6 34:3 41:19 47:12,21 49:6 50:7 60:3,8,22 61:9 63:14 67:12 68:16 84:9 90:20 92:15 93:21

94:22 105:4 111:12 122:20 125:9 130:13 144:10 146:18 151:11 155:1,2 161:18 162:8 163:6 165:19 174:5 182:21 187:5 195:2,3

fish 116:13

fit 27:14 112:18

five 21:8 31:6 50:6 60:8 87:7 93:21 124:18 148:18 183:4 185:15 192:6

flare 90:10

flare-ups 121:6

flat 95:17

flaws 187:5,6

flew 145:10

Flexeril 110:14 124:10 131:17

floor 64:9,19

Florinef 46:19 96:2,13 110:13 113:17

floundering 161:1

flow 76:17 174:8

flu 115:11 166:8

Fluga 159:20

fluid 112:21

fly 42:6

FMRI 174:2

focus 11:7,20 12:19 13:13,19 16:14 25:22 31:19 34:8,12,21 35:4 36:21 53:9 60:22 61:9 62:5 85:14 107:10 120:1 159:14 175:11

focused 17:5 20:9 69:10 94:9 195:22

focusing 16:19 93:19

fog 55:22 56:3 88:8 116:18 132:15 133:3 137:12

folks 129:8 186:8

follow-up 17:11 31:12,21 37:9 69:13 89:20 90:14 94:5 119:3 142:4 160:16

FOOD 1:4

foods 117:6

foot 82:4,16

forbid 164:10

foregoing 196:3

foregoing/ attached 197:7

foremost 33:7 163:6

forever 159:2 183:14

forgotten 29:8

form 114:5 161:17 167:9

formality 152:20

format 6:13 17:6 27:16,20 29:5 30:2 31:2 49:16 93:15

formed 161:18

former 42:5

forms 36:6 93:2 151:21

formula 129:16

forties 185:17

fortunate 108:13

fortunately 38:21 68:4 88:8

forums 14:6

forward 12:2 14:1,5,9 29:2 40:22 93:18 109:4 128:5 173:8 188:17,18

foster 10:21

foundation 31:5 34:2 93:22 158:3

foundations 159:15 160:21

founded 158:3

fourth 50:22 97:12

frame 15:16,18

framework 21:6 142:18

Francisco 38:3

frankly 23:17

free 32:19 124:1 152:9

frequently 38:15 178:12

friend 64:14 106:19 185:17

friends 40:13 44:10 45:1,9 50:13 64:9 86:8 109:1 117:13

fro 44:21

front 37:5 59:13 82:4 85:7 93:10,11 169:4

fronto 174:22

frustrating 45:17 85:21 132:12,18

Fukuda 128:17 138:12 184:17

full 34:17 88:11 95:2 140:20 143:11 170:18 194:13

full-time 44:22 100:1,14

fully 30:12 39:5 40:9 100:14

fumarate 159:12

function 39:16 40:21 45:18 47:1,2,5 80:14 85:11,14 89:11,13 96:1 112:16 124:16 125:18 133:10 170:9 181:4

functional 97:8 121:19 170:18

functionality 116:20

functioning 26:2 61:3,10,12,16 67:17 89:14 179:1

fund 160:15,16

funding 172:22

funds 175:18

Furhman 117:9
furniture 110:22
future 36:3

G

gabapentin 131:17 148:5
gain 11:12
gained 135:3,6
gainful 177:7
game 164:15
gammaglobulin 105:18 122:15
gamut 45:11
gap 192:12,13
gas 88:14
gastric 134:8
gastrointestinal 52:8
gathering 22:5 152:19 169:7
GcMAF 116:16 127:20
Gel 134:10
gene 160:3
general 21:3 26:1 60:8 63:9 101:9 120:1
generalizable 104:4
generally 31:18 34:14 60:16 65:21 78:1 80:20 101:10 130:10 160:9
generics 131:9
generous 161:16 194:9
genetic 162:4,6,8
geneticist 162:4
genome 162:7
gentle 101:17
Georgetown 173:16
gets 74:7,12 108:10 153:20 182:3
getting 22:22 40:17 52:17 62:14,22 64:16 84:17,19 126:19 133:10 136:9 137:9 139:8 143:7 150:17 151:11 153:16
GI 107:20
Giardia 95:12
Gisela 4:20 162:19 163:10
given 25:4 27:1 41:22 54:11 87:22 109:9 169:3 182:15 186:14 192:17
give-or-take 133:19
gives 118:2
giving 64:20 172:1 185:12
glands 99:19
glasses 53:9
glimmer 124:4
global 157:3 177:2,3
gloom 173:20
glutathione 105:19
goal 10:21 14:9 36:11
goals 151:6
God 72:21 109:1 148:5 164:10
Golden 111:1
gone 111:14 121:12 191:6
gotten 121:16 133:4 190:15
government 10:13 33:18 66:22 147:12 171:8 173:3
government-sponsored 29:22
graded 99:1 101:14 161:19 162:10
gradually 102:15
graduate 41:11,16 42:22 52:15
Graham 93:1
grandson 145:11
grant 161:14
grateful 115:3,4
great 12:10 22:7 29:9 60:2 65:21 80:5 101:5 118:12 124:14 128:6,12 168:4,5 173:17 180:3 181:8
greater 34:4 57:12
greatest 54:17
greatly 27:1 108:12
green 72:21
grew 101:2 110:16
Grobstein 3:21 69:22 70:6 90:22 146:12 147:1 179:17,18,19,21, 22 181:16
groceries 54:9
grocery 44:17
ground 33:6 34:22
group 27:8 32:3 34:6,8 44:17 48:21 70:12 109:2 126:14 128:16,19
grouping 136:9
groups 27:5 28:6,11 48:21 160:14 174:9
growth 107:5
guaranteed 164:8
guess 57:15 58:2 91:19 177:8 186:22
guest 32:22
guidance 49:16 142:20
guidelines 158:7 182:16
Gulf 173:21
gut 90:9,10,12 134:1
guys 118:22 152:9
GWI 174:6
gym 95:21 115:8

H

half 10:19 55:3 112:8 135:1,2 173:22

half-life 141:11

hand 34:15 63:8 91:12 122:1 139:1 146:2 148:12 153:17 164:20 168:14

handicapped 150:5,6

handout 111:18 159:8

hands 31:22 32:4 34:14 60:17,18 62:13,15,17 63:10,12 66:7,12 69:19 71:11 72:11 73:6 75:2 77:1 78:14,17 87:17 90:16 119:19 121:1 122:5,8,11 145:7 148:18 183:7

happen 28:8 70:8,9 71:14,16,21 73:1 127:5 163:7 167:3

happened 64:14 84:9 121:16

happens 70:15 71:13

happy 33:16 36:9 108:11 163:8 182:10

hard 38:22 62:5 64:4 73:1 75:11,12 93:11 102:18 106:1 118:10 124:2 140:20

harder 63:6 132:16

hardest 51:7

harm 172:19 181:12

harmful 95:20 99:10 104:8

Harper 3:22 77:3 83:17 136:14 137:20 138:2

Harrison's 174:17

Hart 4:5 86:4 90:2 129:15 148:3

haven't 75:14 85:16 89:1,2 90:18 116:3 128:22 136:12 138:19 141:21 144:18 146:21 191:6

having 20:21 39:20 41:1 57:16 75:11,12 115:2 129:16 142:14,20 144:12 147:16 155:16 188:19 194:10 195:8

head 57:19 69:10 70:19 73:18 79:5 80:20 112:9 132:5 138:1

headache 99:20

headaches 53:13 100:7 102:2 110:8 117:2

headed 183:11

headphones 42:8

heads 77:22

heals 147:5

health 11:14 16:22 35:3 38:22 49:13 67:1 103:20 125:1,4 131:9 138:4 179:1

healthy 58:5 97:15 108:12 174:7 187:16

hear 12:3 17:8 18:21 22:14 26:11 27:18 29:12 31:3,11 33:7,11 36:9 64:2 81:10 94:20 95:2 104:18 142:1

heard 18:6 28:4,5,15 31:19 34:19 60:8 61:2,4,5,6,8,11,12 68:15 69:14 71:8 82:21 85:1 89:1,2 90:19 91:7 113:9 120:2,3,4,17,18,19,20,22 126:3 129:10,11 144:18 146:21 153:21 154:10 163:16 166:3 167:19 172:12 177:5 180:13 192:16

hearing 22:20 40:22 87:5 91:1 137:16 139:19 150:18 156:15

heart 45:3 46:16 84:6,10,19 112:19 116:6 149:6,22

heartfelt 12:10

heating 106:5

heaven 109:1

heavily 117:12

He'll 168:17

hellish 98:8

Hello 41:10 91:21 148:10 155:13 179:21

help 16:12 21:2 22:18 36:2 40:19,20 58:21 84:19 85:9 92:11 94:10 102:8 116:6,10 117:2,10,13 118:3,15 126:12 128:11 139:22 141:17 142:9 143:16,17,18 144:13 148:14 156:12 157:1 164:19 173:8 185:11 189:14 192:18

helped 100:12 101:20 102:17 117:19 122:16 127:17 142:7,9 191:12

helpful 26:11 27:4 101:18 102:6 103:2 116:22 127:21 151:4 154:14

helping 27:5 96:16 151:10

helps 35:9 53:17

84:2 146:6,7,9 151:1
Hemispherx 123:22 166:2,4 176:13 181:21 183:12
hemorrhaging 138:3
hence 42:20
hepapressin 116:11
hereby 196:3 197:3
herpesvirus 102:12 178:14,22 179:3
herpesviruses 138:16
herself 45:6 65:14 163:20
he's 44:6,7 67:14 97:21
heterogeneity 174:10
heterogeneous 169:22
HHV-6 107:5 111:4 112:21 116:20 178:9,10,21
HHV-6A 111:14 112:3 178:12,19
HHV-6B 178:13
hi 20:13 68:21 73:9 75:5 77:9 78:2 83:17 85:8 90:22 91:13 104:18 109:18 115:2 126:7,18 131:4 186:3
hieroglyphics 52:19
high 11:10 52:11 67:16 89:11 91:4,5 92:10 96:1 97:6 105:10 107:5,8 108:3 156:1,2 180:13
higher 40:21 48:22
highly 50:3
hiking 112:8
Hill 1:17
hints 151:2
history 18:1 109:21 177:14
hit 38:18 169:17
HIV 109:10 182:21 185:5,13 191:15
HIV/AIDS 127:9 167:4
hives 107:8
Hobbesian 114:9
hokey 185:12
hold 19:21 40:15
Holderman 4:6 171:16,20,21
holding 40:16 110:22 160:8
Holmes 184:19
home 18:13 40:14 41:13 44:16,19 45:1 54:9 64:22 65:2,15 84:5 86:14 113:2,11,20 114:10 115:8 143:12,17 145:18 189:10
homebound 108:16
homes 39:10
honestly 164:16
honking 72:20
honor 73:13
hope 15:17 23:20 24:1 33:18 35:20 40:18 98:5 108:17 117:19 119:14 133:13 152:11 177:20 188:5 195:15,17
hopefully 106:19 108:11 154:20
hoping 11:8 27:22 43:2 51:19 151:15 156:20 175:14
hormone 107:5
horrible 121:5,8
hospital 81:22 82:1 189:16 190:4
hosting 171:22
hotel 45:9
hour 78:16 86:6 97:11 112:8
hours 38:14 39:6 42:11,18 58:12 72:15 77:14,16 86:10 96:21 102:14,16 105:16,17 106:4 113:16,19 114:6,11 116:10 145:12 189:5,9 194:9
house 40:19 65:2 86:11 96:21
housebound 44:11,15 54:21 95:13 101:4
houses 177:19
housing 125:10
Houston 115:12
huge 70:13 121:11 156:18
human 16:22 178:14 179:2
humans 160:10
humiliating 118:4
hundreds 157:2
hurry 100:21
hurt 133:7
hurting 139:10
hurts 134:16
husband 65:7,11,16 67:8 113:2,6,9 114:4,12 115:7 121:15 143:16
hydrocodone 116:5
hydrotherapy 190:12
hygiene 96:9
Hyperion 186:4
hypothyroidism 110:12

I

idea 16:11 66:9 67:11 71:16,20

104:8 140:9,11 156:3 162:12 186:5

ideal 154:2

ideas 41:1

identical 93:16

identifiable 26:9

identified 21:14 24:14,18 25:2,11 91:9 92:18 167:6 169:12 174:1,5,22 182:1

identify 25:3 40:18 59:18 156:6

identifying 11:2 16:11

IDs 50:1

IgG 122:14 156:1

II 171:3

III 171:3

IL-1 97:6

ill 33:12 41:12 48:16 49:5 74:2 136:17

I'll 29:4 30:1 31:10,22 36:7,14 37:5,6,13 38:1 41:17 47:10 51:10,16 57:6,14 58:13 63:14 71:6 80:1 85:9 90:8 98:13 100:21 108:7,18 109:17 119:10 131:19 145:9 153:16 170:7 187:5,21

illness 42:1 43:5 49:4,7 50:5,16 51:7 54:5 55:3 58:15 67:18 85:21 87:9 98:15,18 99:13 101:10 109:9 118:16 136:15 141:20 147:15 173:21

illnesses 177:20

I'm 18:9 20:7,14 29:6,11,13 32:14 39:11 40:4,5,11,14 41:10 43:2 48:5 51:19 52:7,15 55:11,18 56:3 58:17 60:11 61:3,22 62:19 63:2,15,16,20 66:14,17,18 67:11 68:7,11,21 70:1 75:5,9,17,18 76:16 77:9,10 78:2,7 79:8 82:19 83:3,18 84:18,20,21,22 85:8,9 87:5,12 90:7 91:11,14 93:1,14 95:9 99:2 102:13 104:19 105:13,22 106:3,13 108:1,12,22 113:19 115:1 121:3,19 123:3 124:15 126:18 127:20,21 129:4 131:8 133:6 134:12,15 135:10,18 137:5,9,15 139:2,7,8,19 140:5,11,17,22 141:1,2 143:6 144:16 145:1 150:7 152:5 153:15,17 156:18,19 157:16,18,20,22 158:20,22 162:19 165:14,17 171:19,21 173:15 176:9,14 178:5 179:18,21,22 181:20 182:10 183:19 184:1,5 186:3,22 188:7,8 191:19

IM 97:3

imagine 20:21 115:9 185:12

immediate 22:20 121:11

immune 45:12 116:11 120:6 159:6,13 160:4 162:3

Immunity 117:9

immunological 97:18 170:8,19

Immunoprop 116:12

immunosuppressants 120:7

impact 11:10 30:5 39:4 50:4,10,21 51:9 54:5 67:17 167:22 181:3

impacts 7:5 13:6 30:9 34:22 37:1 61:8 70:13 193:18 195:5

impaired 45:18,21

impairment 73:19

implement 36:3

implore 164:21 169:7 171:6

imply 136:7

important 10:6,19,22 16:4 19:13 20:21 21:6 30:11 33:10,19 35:2 48:10 70:11 73:22 89:4,5,9,18 97:16 103:19 113:21 114:17 118:8 127:6 133:11 149:4 153:4,9 154:8,15 177:8 180:5,6,15 181:4

importantly 172:19

imposes 108:20

impression 177:3,4 182:3

improve 11:16 27:5 47:1 82:21 102:7 106:17 111:21 125:4

improved 27:2

improvement 44:13 52:9 121:11

improvements 103:17 176:20 177:6 181:4,6

Imunovir 95:22

inability 42:22 52:20 172:15

Incline 121:13 122:18 123:4 163:18
include 31:15 162:3
included 98:20 101:22 161:7 172:10
includes 52:20 54:13 138:12
including 16:20 38:22 53:15,21 94:11 100:15 102:2 116:17 117:1 131:7
incoherent 64:16,22
income 112:6
increase 96:20 101:18 116:19 142:22
increased 50:7 116:1 183:6
increases 167:17
increasingly 99:21
incredible 109:2
incredibly 109:3 155:17 184:16
indeed 161:17 182:22
indefinitely 112:5
independent 171:21
indicated 178:12
indicating 47:20
indication 130:20 136:10 169:21
individual 14:1,5 50:15 103:8 163:11
individual's 153:4
indulge 152:11
industry 16:20 33:17
ineffectual 95:20
infected 58:14
infection 92:7 100:10 178:10,21 180:20
infections 99:19 180:19
inferior 174:22
infirmary 145:15
inflammation 69:7 159:7
inflammatories 59:1
inflammatory 58:17 88:3 96:2 97:6
inflicted 172:20
Informatics 2:11,22 6:11,16 18:19 29:15
information 21:1 22:5 28:10,14,22 45:22 52:21 130:21 152:19 162:16 172:17 195:8
informative 186:13
infusion 121:9,10
infusions 179:7
inhibited 178:15
Inhibits 178:14
initial 25:16 27:1 118:9
initiative 12:22 13:1,4,11 17:4 18:21 20:12,15,17 21:1,5 23:9,14 24:11 47:13 194:21
Initiative--Theresa 6:9
inject 105:18,19
injections 99:1 102:8 103:3 115:21 116:12
innovative 11:4
input 18:4 20:9 21:3 24:7,9 27:1,18 29:3,12 33:18 35:6 40:17 92:14 156:15
insight 11:13
insights 154:13 160:19
instance 43:9 56:10 72:14
instant 92:7 122:3
instantaneous 75:20
instead 54:17 65:2 97:11 113:17 140:1 153:14 183:9 184:21
insula 175:4
insurance 98:2 99:7 126:11 131:8
integrity 188:14
intended 153:12
intense 110:7,8
intensive 14:16 46:1
intent 33:15
intently 32:16
interaction 86:12
interchangeably 15:15
interest 22:8 196:10
interested 23:21 148:7 182:4 186:8
interesting 69:1
interests 178:6
interferon 177:17
interleukin 107:8
intermittent 131:7
International 45:16 52:6 184:13,21
internet 54:13
interrelated 73:16,21
interrupt 76:17
intersection 11:19
interventions 190:13
interviewed 185:15
intestinal 134:6
intolerance 45:13 46:15,19 54:1 61:7 73:20 96:3
intriguing 55:17

introduce 17:15
introducing 19:21
invest 189:22
investigation 156:22
investigative 184:3
investigators 187:10
invitation 170:2
invite 152:22 164:17
invited 7:18 8:17 182:10
inviting 31:21
involve 21:8 175:6
involved 166:5
involves 23:10
IQ 53:6
ironic 135:18
ironies 135:14
ironing 185:10
irony 135:14
irritable 90:9
Ishere 56:12
isn't 58:4 142:2
isolation 51:6
issue 174:10
issues 10:22 13:15,17,19 22:11 23:1 27:10 35:2,10,18 68:5 73:20 97:14 107:13,20 117:11 133:17 134:8 135:3,12,13 139:11 154:16 168:3 180:5
it's 10:10 13:4,20 14:13,17,21 19:1 21:20 23:16 25:15 28:21 29:9 37:21 38:18 42:22 43:6,7,11 44:19 49:14 56:1 57:20 58:6,13,16 60:10,11 62:5 64:4 68:5,8,9 69:3,9,10 70:11 72:6 73:1,17,18,19,21 74:3,4 75:13,17,19 77:5,8 78:3 79:17,18 80:16,17 83:8 84:11,19,22 85:10,20,22 86:15 87:22 88:2 89:15,18 92:9 97:16,20 102:18 106:1 107:15 108:2 112:2 113:13,21 114:15 116:2 117:16 118:9 121:19 123:3 124:2,12,18 125:13,14 127:1,20 128:6,9,12 129:17 130:2,3,4,17 132:3 133:13,19 135:12,13 136:3 137:7 138:6 139:17 140:20 141:8,9,13 143:7 148:8 150:2,13,14,20 153:3,21 155:1 157:18 161:2 165:1 166:13 170:6 173:19 180:6,15,18,19,21 184:6 186:20 191:20 193:2
IV 97:3 113:17 145:1,5 146:5
I've 18:22 43:10 54:6,16 55:1,3 56:3 58:17 62:1 67:9 70:1 80:7 83:5,18 84:12,16 85:17 102:12,22 104:19 115:18,21 116:2,16 121:16 122:18 123:11 124:20 131:14,21 132:1,10 135:9 141:19,21 145:14 149:22 150:4 153:14 157:17 162:6 176:10,11,15 179:22 180:1 189:16 190:15,16
IVIG 106:14

J

jail 87:11
James 3:12 171:18
Janet 5:10 62:19 81:16 122:13 149:18 158:1
January 100:3 112:9
Jason 185:1
Jeanette 3:15 181:18
Jeannette 89:7 121:3 122:2 124:13 149:1 181:17
Jennie 131:14 132:6
Jennifer 5:11
Jenny 90:7
jerk 82:5,7,9
jerked 82:16
jerking 82:13
jetway 122:20
Jim 173:15
jitters 108:3 140:21
Joan 3:21 69:22 70:18 90:22 146:12 147:1 150:15,16 179:17,22
job 39:1 40:15 43:1 66:22 87:10 100:1 103:13 124:14
jobs 67:7 189:1
Joe 41:10 72:1 131:3,4
John 4:8 71:8 186:2
join 37:4
joining 104:2
joint 100:7 138:13
joints 134:11
Jon 4:7 37:11,14,17 38:2 41:4 58:9 66:19

67:19
Joseph 4:11 37:11,14 41:8,9 43:20
journey 166:14
judges 52:17
judgment 15:17
Judy 4:18 158:17,18,19,20 161:4
July 112:20
jump 141:4
June 100:13,15

K

Kaiser 4:7 37:11,14,18,21 38:2 58:8,9 87:18,19 88:17 143:21 144:2,6 145:8
Kalns 4:8 186:2,3 187:3
K-A-L-N-S 186:2
Karen 4:5 86:4 129:15
Kathleen 3:22 83:17 136:14 137:20 138:2
Kelemen 4:9 68:21 94:1 98:13,14 100:21 101:2 141:12,15 142:11
Ken 65:11,14
key 16:19 17:7 21:8 22:13 31:20 61:1
kids 80:14
kill 183:4
killed 115:7
killer 52:11 96:1 107:4 112:15 124:15,16 130:6 184:10
kills 192:6
Kim 4:17 37:12,15 47:10 48:3 51:14 86:22
kindly 176:13
kinds 25:17 132:13 143:10
Kineret 97:5 120:19
Kineret's 97:19
kitchen 54:4
Kitei 4:10 183:19,21,22 184:1,15
K-I-T-E-I 183:19
Klimas 126:10 190:16
Klonopin 110:14
knee 135:10,11
knew 38:10,16 64:9,17 81:22 130:13 137:18,19,20 142:15
knocked 82:14
knowledge 75:20 126:12
known 54:2 159:19 162:5 184:17
Kweder 2:13 6:5 10:2,4 17:18,22 18:16 19:4,13 35:1 55:14,15 56:5,9,15,17,20 74:17,19,20 75:3 76:9,13,16,19 77:2,5,20 78:10 81:9 142:3,5 150:12,13 165:20

L

L.A 115:13
lab 159:10
label 2:6 105:10
labeling 19:8,12
lack 15:1 50:17,20 71:7 74:22 97:19 139:10 140:3
lady 86:8
laid 65:16
lake 112:13 113:6
landed 95:21
Landson 4:11 37:12,14 41:8,10,11 55:15 56:1,8,10,16,18 72:1,2 131:4
language 36:20 42:17 49:17,18 50:2
languages 42:13
Lapp 4:12 166:7 176:4,8,9 178:3 190:16
laptop 188:6
large 11:22 22:16 34:6,8 134:22
Large-Group 7:16 8:15 59:6 119:4
largely 95:13
larger 13:3,11
largest 48:21
larosa 79:7,12 134:8
LaRosa 4:13 79:6,7 134:7
last 24:4,11 38:11,12 46:14 47:18 56:11 75:22 76:1 82:22 83:11,12 85:17 93:16 106:4,12 114:6 116:15 119:16 121:12 133:13 150:16 156:17 159:21 163:12 169:1 183:2 190:19 191:1
lasted 52:9 97:2
lasting 14:14
lasts 46:5 47:6 53:22 141:10
latent 178:22
later 23:6 25:14 68:22 95:13 112:1,2,12 115:6,10,11,13 121:8 169:20 193:6
latter 54:12
Laughter 19:3 56:14 57:2 68:14 90:5 123:1 139:5 144:5 145:21 163:2 165:9,16 168:15 174:19 175:16 176:7

187:2
launch 12:22
launched 47:19
launching 13:3
laundry 54:9
Lauren 3:14 73:10 74:6 78:3
Laurie 2:5 19:7
law 52:15 54:6 59:10
lawyer 52:15
laying 133:6 134:15 141:2
layperson 46:8
LDM 129:16
lead 18:20
leader 2:17 18:10
learn 33:19 36:2 135:8
learned 11:21 58:17 182:3
least 23:11,15 31:8 42:7 109:9 117:6 119:17 125:6 131:20 132:1 135:1 182:11
leave 38:18 39:10 44:15,19 161:1
leaves 108:20
leaving 39:1 86:13 102:5 106:22 114:8,10
led 96:19
leg 107:15 147:3,4,5
legal 168:7 173:4
legitimate 70:14
legs 82:15
Lempert 4:14 178:4,5 179:14
length 83:1
Leonard 185:1
less 39:1 77:18 147:4 191:8
let's 12:19 16:8 59:8,9,12 61:9 63:14 75:4 78:11 79:6 81:14 83:14 88:21 89:22 119:6,9 120:9,20 128:22 133:1 145:8 154:22 161:16
letting 173:15
Levaquin 124:8
level 40:21 44:9 124:3,14 160:6 195:1
levels 116:1,21 117:21 160:18
levocarnitine 105:20
Levothroid 110:12
Lewis 4:15 138:22 139:2,6 188:3,5,6 190:11
library 44:16
licensed 188:7
Lidocaine 148:5
lie 39:6,20 53:18 64:12 143:9
life 30:5,10 38:14 39:4 40:10 41:13,21 42:5 50:4,5,10,11,13 54:5,21 55:3 72:4 85:22 87:10,12,13 97:18 98:5,8 106:18 108:17 114:2 115:15,16 117:17 118:13 143:8 170:17 188:11,12,20 193:16,21,22 195:5
lift 82:5
light 53:7 54:7 61:6 110:4 116:18 124:5 164:2
lightheaded 38:19 74:9
lightheadedness 146:8
likely 15:15 76:22 78:8 79:1 100:10 105:21 156:7 180:21 183:4
Lily 3:17 77:9 126:7
limbs 107:14
limit 54:14 108:9 117:20 118:20
limitations 32:6 54:8 61:14,16 68:16 94:13
limited 54:16 72:4 97:8 101:19,20 126:9 142:18 164:2
limits 142:16
line 102:11
lines 169:5
linguist 42:5,20 56:19
link 28:20 29:1 175:5
links 12:17
Lisa 185:8
list 24:16 25:17,18 102:5 105:2 155:3 157:12,17 159:19 191:2
listen 23:16,18 24:2 35:16 42:6 54:15 95:15 105:13
listened 91:4
listening 18:5 29:3 32:16 33:21 95:17 160:15
liter 113:16
literally 52:19 75:17 80:6 123:14 164:1
little 15:4 19:1,18 20:8 27:14,20 41:12,16,17 50:12 59:19 60:21 69:9 75:22 79:15 97:13 98:5 108:20 114:3 115:4 120:2 124:4 140:12 142:8 146:8 152:13,15,20 165:17 174:20
live 32:8 41:13 55:6 72:8,16 99:6 108:21 121:13,15 137:6
liver 135:17
lives 13:7 50:21

51:9 67:13 70:14 166:18 181:3 191:18

living 22:2 26:3 50:11 87:12,14 101:6 188:12 189:14 193:17

lobby 92:21

lobe 175:2

local 113:14

located 32:22 92:20

location 28:22 55:6

locations 99:6

logged 80:11

logical 160:1

long 18:1,2,5 29:10 38:10,17 42:14 59:1 75:21 95:15 96:11 105:3 130:9 136:15 154:22 156:19 164:2 166:14 189:9 192:10

longer 42:3 47:6 53:2 66:20 67:5,6 77:14 79:3 97:13 111:20 113:5 114:4 141:10 161:1 188:18

long-term 25:5

looser 158:8,10 182:22

Lopez-Majano 4:16 37:12,14 43:21,22

71:15,19

lose 53:12 132:2

loss 42:20 50:12,14 62:4 81:5 110:3 131:7

lost 55:3 99:15 112:7,10 127:3 131:7,8 172:21 180:2

lot 15:9 28:22 39:8,10 60:18 61:3,4,8 62:9 65:4 66:3 68:3,15 69:10 70:19 71:5 75:2 77:22 79:14 80:20 81:6 87:5 92:5 103:17 105:4 109:3 111:20 117:20 119:19 120:4 126:7,13 127:3,5,10 128:12 129:22 132:5 133:17,22 135:4 136:18 137:9 138:1,13 139:8,11,12,20 140:2 142:1,2 150:1 152:14 155:14 156:10,14 163:15 167:15 186:8 187:5,18,20 189:22 190:11

lots 14:8 41:15 42:1 51:11

loud 119:8 195:10

louder 64:17

lousy 89:16

love 163:11

loved 60:14

low 43:1 52:10 89:10,13 96:1,6,7 99:3 107:4 112:17 124:15 156:1 170:8,10 173:1

lowered 87:13

low-grade 53:22

luck 129:16

lucky 12:20 99:5 103:16

Lumosity.com 117:10

lupus 107:12 159:5

lying 38:15 54:21 95:17 142:17

Lyme 96:11,19 107:11

Lyrica 124:10 129:22

M

M.B.A 3:6 7:8 8:8

M.D 2:13,16 6:5

M.P.H 2:5

Magazine 184:4

main 30:3 99:8 136:1

mainly 54:21

maintain 117:13 125:3,6 144:3

maintaining 175:11

major 50:21 51:9 74:11 80:18

133:17 185:3

malaise 43:6 45:12 46:2,4,8,12 57:6 96:8 105:8 161:21

MALE 168:17

manage 11:6 13:10 16:12 73:1

management 21:16 104:21 116:1,5 129:8 131:1,6,15,21 133:2,18 147:3

managing 132:4 134:5 193:22

manifestations 45:14

manual 101:22 102:1

map 12:8,9,17 151:16

marathon 82:3

March 47:19 113:4

marginal 131:5

marijuana 133:22

marked 178:22

marker 169:18 170:8

markers 97:18 135:17 162:3 170:12

market 187:16

marketing 104:22

Marriott 1:16

Mary 3:18 5:8 63:14 66:4 94:1,2 95:4,5,6

98:12 109:17,18 114:20 121:14 122:7 124:19 128:22 171:14 178:18

Maryland 1:18

Mary's 138:9

mask 106:10 140:10

masking 106:11 140:9

massive 110:4

master's 41:15 189:1

mat 143:9

match 11:17 132:6

materials 44:16 195:9

Matina 4:21 61:22 94:1 104:17,19 109:16 133:15

Matina's 134:5

matter 7:5 12:7 37:1 43:4,16 85:11 111:19 118:9 154:12 174:5 175:1

matters 12:11

Matthew 44:4 46:22 47:4

Matthew's 46:16

max 112:17 170:10 184:10

maximize 27:17

maximum 42:18

may 14:3 17:10 23:3 26:6,8,12 27:10 31:19 33:11 35:6,19 48:3 78:19 79:14 90:11 100:9 108:11 131:11 148:10,12 151:11 168:3 170:21 174:3

maybe 26:4 27:13 28:9 70:22 76:7 77:12 85:9 92:12 117:14 132:1 140:12 141:19 149:11 152:12,13 157:2 187:20 195:11

mccleary 47:11 48:5 86:21 87:1

McCleary 4:17 37:12,15 47:10

ME/CFS 38:6,13 47:12 49:13 109:2 115:14 159:5,19 160:12 161:2,17,18

meal 190:7

meals 125:18

mean 43:12 50:14 81:2 82:4 123:15 135:2 136:20,22 143:3 157:1

meaning 46:6 118:13

meaningful 23:4,5 27:3

means 33:10 43:16 67:8 86:13 175:5 188:20 189:12

meant 17:12 136:7

measurable 89:15 91:15,18 180:14

measure 72:3 89:17 177:2 186:6

measurement 128:14

measures 11:3 13:17 19:9 23:4 147:21 181:2

mechanisms 170:3

media 172:18

medical 38:4 50:1 118:7 133:22 161:13,15 167:9 172:17,22 173:4 188:19 190:13 192:8,9

medically 44:20

Medicare 106:14

medication 51:1 53:17 84:20 116:8 125:14,17 132:11 133:5 137:8 139:2 140:10 141:9 148:3 166:19 190:18 191:18

medications 44:12 74:13 136:10,22 139:17,20 140:14 167:20 189:15

medicine 38:2 39:2 127:9 142:1 174:18

medicines 22:3 94:11 127:8 134:9 141:7,17,18

meet 27:8 28:11 45:15 52:5 103:8 104:4 173:22 184:12 195:1

meeting 1:11 2:1 3:1 4:1 5:1 6:4 10:7,18 20:16,20 23:7 24:19 27:15,16,19 29:4 32:11 33:4 36:1 40:17 108:14 147:10 153:2,8 155:17 160:8 182:13 186:20,21 191:11,13 193:3 194:13 195:2,22

meetings 23:11,15 24:8 26:19 27:20 28:1,13 29:22 36:4,5 47:21 63:19 105:11 193:10

Mellan 159:20

members 40:12 119:18 120:3 147:11 152:8

memo 52:18

memory 45:21 62:4 65:1 81:6 110:3 117:10 132:15 175:6

men 172:5

mending 185:10,19

mental 14:16 43:7 53:19 58:2 63:1,2 81:17 103:17 106:21

mentally 57:11,17 69:2,8

mention 74:21 89:2 129:11,12

130:13 134:19 167:11 170:7
mentioned 26:20 57:7 61:11 90:9 91:17 92:6 126:22 131:18 139:21 141:3 142:5 144:21 149:21 192:4
merge 12:6
Merriman 179:15
message 174:13,21
messed 121:7
met 21:20 65:17 174:1
metabolism 135:6
method 32:4 162:11
metro 41:14 113:14,15
mic 82:6
Michael 155:4,5
Michele 2:16 18:8,9,10 57:1,3 78:12,13,18 79:11 129:5,7 136:6 144:20,21
microphone 36:13 51:17,22 114:22 155:10 188:4
microphones 32:1 61:19
middle 154:1
midodrine 46:20
midst 58:18 88:7 125:10
migraines 51:3
Mikovits 4:18
158:18,20,21 161:9
mild 67:4 78:22
mile 54:22
miles 97:1 113:1
military 42:5
Miller 4:19 80:3,4 81:15 123:7,8 191:10
milligrams 99:3,4 105:12 108:5,6,8 115:21 116:9
million 161:14 169:13,19 172:5,6 173:8
mind 45:19 47:5 175:7 180:6
minds 39:16
Mindy 4:10 183:19 184:1
mine 64:14 185:17
minimal 46:3 106:21
minimally 62:3
minimum 36:20
minor 83:19
minute 18:22 46:18 191:9
minutes 19:18 31:9 34:11 38:1 42:3 46:6 55:6 59:15,16,17,22 60:1 64:3,4 72:17 74:16 78:16 83:7 86:7,10,12,16 88:19 89:4 94:4 103:16 143:22 146:17
153:13,16 168:18 191:8
miracle 97:17 125:19
mirror 124:19
mirtazapine 96:4
miserable 108:20
misfortune 101:5
misinformed 185:8
misnomer 46:9
missing 103:9
misunderstanding 117:15
mobility 101:19
mockery 190:13
mode 33:21 108:13
model 175:13
moderator 29:18
Moderators 7:7 8:7
modest 38:8
modify 27:7,13
modulator 159:13
modulators 120:6
molecular 160:5
mom 41:13 77:6 91:14
moment 36:22 111:11
Monday 185:9,20 189:9
money 111:8 126:11 147:14 168:5 183:13
monitor 149:7,22
monitoring 12:13 143:14
mono 84:17
month 47:4 105:18 118:7 139:16
months 14:14 52:10 83:12,22 85:18 88:16,17 99:16 100:16 106:13 111:10,13,22 112:3,12 113:4 115:10,12,16 118:9 124:1 127:22 130:16,17 135:5 163:19 164:3
Montoya 126:11
Morales-Barreto 4:20 162:19,22 163:3,10 165:7,8
morning 39:18 77:17 80:7,8 97:10 145:14
mortality 167:17
mostly 101:4 108:15
mother 87:10
Mount 161:13
mouth 108:3
move 14:9 41:8 52:1 59:8 71:1 80:1,22 93:10 102:15 120:14 124:21 126:4 129:7 133:7 173:7
moved 54:20 100:4 102:10

113:1 123:16 125:7,11 163:17 164:1

movement 45:20 75:17

moves 121:13,16 175:3

movie 42:12

moving 83:8 104:21 114:10 128:5 141:2

MRI 170:9

muddied 172:15

Mullin 2:21 6:9 9:5 13:10 17:3 18:18 20:8,13 29:14 193:2,14 195:11

Mullin's 29:14

multicenter 171:2

multiple 42:7 67:2 159:3,14 177:17 179:4 180:21

multisystem 14:17 180:22

multitask 67:6

multitasking 67:10

multitude 106:7

multitudes 172:12

multivitamin 115:20 116:13

Murphy's 59:10

muscle 51:2 63:4 69:7 84:11 99:19 100:7 102:9 110:9 135:12 138:12

muscles 99:15 102:3 139:9

music 53:11 54:15 95:15

mutually 174:7,9

myalgias 45:14

myalgic 1:8 10:7 15:6,11 52:5 95:11 172:4 195:20

myelitis 104:19

Myers 105:15

myself 17:9 29:9 52:18 57:17 58:18 81:19 84:10 87:11 114:3 119:7 140:19,21 149:22 168:22 190:1

N

narcotics 132:17

narrow 16:13 104:4

Natalia 1:21 196:2,13

Natasha 4:9

nation 172:21

natural 13:20 49:18 52:11 96:1 107:4 112:15 124:15,16 144:8,9 184:10

naturally 150:2,8 155:21

nature 13:14 118:5 169:22 188:18

nausea 116:18

nauseated 53:13

nauseous 69:8

nearly 44:7,15

necessarily 78:4,18 87:2 136:3

neck 69:11 110:8

negative 13:6 30:9 36:19 74:6 104:10 178:20

neglect 172:19

neglected 193:5

neighborhood 44:17 54:20

neighbors 45:2

neither 196:7

nerve 138:15

nerves 134:14

nervous 87:22 88:9,14

nested 178:11

network 175:7

networks 175:10

neurocognitive 45:13

neurological 52:14 73:20 105:5 107:13 111:17

neurologist 105:7

neurotransmitter 107:16

neurotransmitters 96:7 97:7 134:3

neurovirulent 179:2

Nevada 113:1,8 123:4 125:11

nevertheless 110:15

Nexavir 116:11

nice 85:1 129:17 165:1

nicely 176:18

Nicholson 4:21 61:20,22 62:1 72:13 94:1 104:17,18,19 128:4 129:19,21 130:12 133:16 140:16

night 65:1 77:8,16,18 84:6 106:4 108:4 114:6 115:7 116:10 195:17

nightmare 137:7 138:6

night's 76:21 78:4,6

NIH 184:8

NK 89:10,13,14 156:1 170:8

NMH 110:13 113:18

nobody 139:20 176:5 181:19

nodding 80:21 138:1

noddings 79:5

nods 70:20 132:5

noise 119:8 195:10

nomenclature 15:2,5

non 160:2
non-drug 94:12 116:22
none 139:17 142:20 185:5 189:18
nonexistent 188:20
nonprofit 103:14 118:14
non-refreshing 96:4
non-responders 160:5,17
nor 170:18 196:8
normal 58:15 88:10 111:21
normalized 97:7
normally 71:21 78:7
North 176:10
Northern 125:7
Norway 159:20
notable 52:8
note 32:14 188:10
notes 32:13,14,17 189:10 197:6
nothing 75:15,16 92:3,8 102:21 107:20 127:11 131:9 132:14 140:4
notice 24:12 47:20 48:8 97:14
noticed 69:3 73:15 74:6
notion 77:15
NPR 163:17
NSAIDs 134:10
nudged 72:20
numerous 44:12
nurse 83:18
nuts 16:6

O

objective 174:11,16,17
objectives 12:18
objects 53:11
observations 11:16
observer 163:21
obviously 65:2 73:11 146:9 149:2 165:14 170:1 181:22
Occasionally 35:21
occipital 175:1
occupations 177:7
occur 57:7
occurs 39:5 88:11 179:3
October 24:19 83:22 100:9 109:22 116:15
odd 41:21
offensive 104:11
offered 101:6
office 2:7,10,14,18,22 6:6,10,14,15 10:5 18:12,19 19:9 29:14 42:17 109:22 121:9,10,11 143:12
officially 161:7
oh 42:11 48:5 61:22 72:22 74:18 75:9 78:11 82:19 89:16 91:11,13 93:1 101:1 128:3 129:20 145:6 149:13 161:16 171:19
oil 116:13
okay 17:22 18:16 20:13 35:7 36:22 37:15 51:13 52:1,2,4 56:5,9,15,17,20 57:14 59:8,11 60:1,3,7,19 61:18 62:16 63:5,11 66:3,13 68:15 69:16,20 70:5 71:17 74:14 75:4 76:16 77:2 78:1 79:5,22 81:9,13 82:17 83:14,16 84:1 87:18 88:18 89:3,20,21,22 90:6,14,17,18 91:13,19 92:13 93:14 94:7 95:3 104:18 119:6,8,20 120:13,16 122:3,6,9,12 123:7 125:22 126:17 128:21 129:4,13,14 130:22 132:6,7 133:12,15 138:7 144:1 146:3 148:19 149:13 150:11 154:6 155:2,5,8,9,10,15 157:5,16 158:14,17 161:10 165:13 167:13,14 168:19 171:19 173:13 179:20 183:22 190:11 191:9 192:21 193:14
old 42:9
older 137:9
Olson 5:5 126:18
oncologists 159:20
ones 22:1,2 26:3 60:14 61:11 83:19 120:14
one-way 81:20
ongoing 24:8 187:11
onset 48:15,18,20,22 50:16 78:15 155:22 156:1
onto 97:21 110:22
open 8:20 20:2 34:7,20 35:13 36:11 152:6,10,17 153:10 154:4 157:9 164:18 165:3 191:4 192:22 193:1,4,10 195:6
opened 24:20 177:19
opening 34:1

open-text 49:16
Operations 3:7 7:9 17:21
opinion 128:6 130:5
opportunity 23:17 27:17 47:14 101:12,15,16 115:3 172:1 176:8 191:7
options 107:3 115:18 164:6,7
oral 52:21 97:3 146:13
order 33:4 37:7,8 55:10 70:10 180:11 189:7
organization 103:14 118:15 153:7
organized 19:15
originally 153:12
orthostatic 45:12 46:15,19 61:7 73:20 96:2
others 23:16 32:16 34:13 46:21 70:21 99:1 100:19 103:4 143:5 146:22 195:13
otherwise 62:8 106:14 190:6,19
ought 127:19
ounces 117:6
ours 166:15
ourselves 10:9 70:15 143:14,18
outbreak 126:20
outcome 13:17 23:4 181:2
outcomes 11:3 12:16
outdoors 55:1
outlined 104:5 109:6
output 18:4 92:8
outreach 18:4
outside 80:14 100:14 104:2 125:19
outweigh 21:17 160:12
overall 52:9
overcoming 104:10
overdoing 143:6
overdrive 140:19
overexert 70:15
overexerted 75:12
overexertion 69:2,8
overly 54:12
overstep 72:4
overview 6:8,13 17:4 20:11,14 29:5
owned 125:11
owner 186:3
Oxford 101:13 172:10 184:18
oxycodone 136:17
oxygen 139:9,13 140:3

P

p.m 1:14 195:18
pace 101:13 104:2,3,13 140:19,20 162:12
pacing 96:9,15 99:2 103:4,10 110:11 143:4
pad 106:6
page 6:2 7:3 8:3 9:3 52:19
pages 96:22 162:7
paid 153:7 181:19
pain 38:7 39:7 51:2 63:4 69:7 73:18,19 88:8 102:9 106:4 110:7,9 115:22 116:5,17 117:2 121:7 129:8 130:6,18 131:1,5,6,15,21 132:4,11 133:2,5,11,13,18 134:2,9 135:3,11,12 136:2,11 137:8 138:11,13,14,15, 18,19 139:2,8,20 140:2 144:9 147:2,6,8,9 148:3 175:3,4,5 193:22
painful 147:4
palliative 139:18 147:21 189:15
Pamelor 124:9
pan 187:15
panel 7:11,12 8:10,11 18:22 19:22 31:3,6,14,18 34:1,7 37:20 62:7 63:15,16 66:18 77:11 89:2 90:8 92:19 95:6 119:18 120:3 146:22 152:8,11 154:20 158:7
panelist 31:9
panelists 37:4 50:9 118:20 119:3
panels 31:9 182:10
paper 178:13 186:15
papers 145:11 186:10
paramount 36:10
parent 188:22
parity 188:20
Parkinson's 159:4
participants 3:10 4:4 5:4 31:21 33:5,17 34:3,5,8 35:19 49:10 94:7
participate 23:20 27:22 39:5 40:5,9 55:5 93:9
participated 30:1
participating 32:8 166:15
participation 20:11 33:15
particular 13:1 15:19 22:7,11 26:10 27:15 34:10,14 93:9

103:2 126:2 144:17 151:4 154:16

particularly 11:9 16:9 20:16 25:18 55:19 77:6,7 103:2

parties 15:20 196:8

partly 62:2 135:3

partnering 109:4

partnership 168:7

part-time 100:4 102:14

pass 110:9

passed 64:8

passing 135:21 144:22 188:19

past 13:10 41:17 44:11 102:21 192:6

Pat 79:7 80:16

patent 131:10

path 182:13

pathogenesis 170:6

pathogenic 170:3

pathophysiologically 151:9

pathophysiology 12:15 151:3 160:20

pathways 13:18 151:1

patient 7:12,17 8:4,11,16 10:11,12 13:5 14:18 17:1,4 18:3 20:9 22:16 23:5,20 24:7,8 26:20 30:15 31:4,7,15 33:14,21 49:10 65:9,12 66:18 75:6 77:10 80:4 85:9 90:8 91:14 93:8,13 101:22 102:18 106:20 123:8 125:13 150:7 173:5 180:7,11 195:21

patient-focused 1:11 6:3,8 12:22 18:20 20:11,15 24:3 36:3 47:13 194:20

patients 7:12 8:11 10:11 11:11,12,14,16,18 12:7,21 13:4 16:3,12 17:8 21:3 22:6,14 23:8,16,17 26:4,8,12,22 27:18,22 28:4 29:12 31:4,7,15 33:16,21 38:16 40:17 44:2 46:10 48:1,15 49:9 51:9 60:13 65:20 70:12 91:9 93:19 94:10 99:8 103:6 104:8 107:19 108:14 109:2 125:15 126:10,13 142:1 150:1,19 154:9 155:20 156:5 158:22 160:1,18 161:15 162:1,8 165:2,21 167:16 168:9 169:1,5,17 170:14,18 172:20 173:21 176:10,14,18 177:2,4 178:7,10,18 179:8 180:14 181:3,5 182:1,18 183:5 184:9,12 185:3,4,9,12,13, 15,18 186:17 187:3,4,7 191:21 192:7 194:18

patient's 22:17 179:1

Patients 7:5,17 8:16 21:21 37:1 179:2 181:10

Patricia 4:13

patronizing 185:14

patterned 47:21 48:7

patterns 104:11 112:17

Patton 5:6 91:21 146:1 148:10 155:9,13,16 156:17 157:11

pay 54:8 68:9 79:19,20 86:7 97:22 111:7

payback 47:3

paying 168:14 181:10

PDUFA 25:9

pediatric 48:18

peer-reviewed 170:5

penny 105:9

people 10:13 15:10,11,13,16 18:6 22:9 28:3 32:1,12 35:2 36:14 39:8,12,15 41:15 45:6 48:16 54:13 57:17 58:5 63:17,18,20,21,22 64:1,20 65:4 67:2 70:6 71:8 72:22 74:21,22 76:7 77:13 82:21 83:7,10 88:12 89:18 91:3 92:18 93:21 97:15 106:20 119:12 123:14 124:3 126:8 127:6,17 128:7,13,15 129:11,12 133:17,20 135:1 136:3,7 138:15,16 141:6,17 142:1 143:17 147:15 148:12,22 150:9,18 151:7 152:14 153:22 154:10 155:22 156:1,6,12,22 157:2 159:9 162:6,20 165:4 166:18 168:9 169:14 174:6 185:5 187:4,17 189:15 191:18,22 192:2,13 195:9

people's 40:22 50:21 147:9

peptides 186:12

per 46:17 102:16

percent 49:12 52:9

108:16 112:16 125:5 160:1 167:2 176:18,19 178:7,15 188:21

percentages 125:2 148:8

perception 172:19

Percocet 136:18

perfectly 43:15

perform 32:21 39:17

performance 23:7

performing 50:16

perhaps 28:17 177:21

period 8:20 20:2 46:7 58:19 101:8 131:19 152:10 170:4

periods 95:15 97:13 100:8

permanent 112:18

permission 112:10

persistently 99:21

person 10:3 33:10 36:21 40:1 62:12 66:7 82:21 111:21 121:20 130:2 153:14 164:1 186:5

personal 38:14 118:5 141:15 188:10

personality 188:15

personally 68:2

personnel 171:9

person's 60:15

perspective 8:4 11:11,18 21:22 22:17,19 24:10 26:15 30:15 33:11 41:18 93:13,20 98:17 141:15 146:20 153:1

perspectives 12:12 13:8 35:12 40:22 95:2

Peterson 5:7 89:12 112:13 123:20 125:1,12,16 127:1,18 163:17 166:7 168:20,21 169:3 182:7 190:16

Peterson's 158:2

pfttt 135:6

ph 5:5 105:9 126:18

Ph.D 2:9,21 6:10,14 7:7 8:7 9:5

phantom 175:4

pharmaceutical 16:20 104:22 131:11 148:14 156:8 164:13,15 165:3 177:18

pharmaceuticals 164:18

pharmacist 18:2

pharmacology 140:18

Phase 159:15 171:3

phenomenon 91:2

Philadelphia 112:4 184:3

philosophy 141:18

phone 54:15 68:9

physical 14:16 43:8 46:13 53:19 57:8,19,22 58:11 63:1,3 68:1 69:4 71:2 73:18 82:3 100:15 101:15,16 103:7 106:21 127:14 142:7 144:4 149:21 170:18 181:12 193:18,22

physically 57:11 58:18 69:3 75:12 150:1

physician 2:17 18:10 70:1 77:10 176:9 179:22 182:7

physicians 101:10 158:22 169:6,16 177:3

piano 32:20

pick 36:8 65:17 66:19 150:14

picked 26:17

picture 14:22 22:10

piece 103:9 184:3

pill 105:20

pills 115:19

pilot 171:3

piloting 25:9

pindolol 46:20

pitch 147:13

placebo 192:7

placebo-controlled 168:1

placed 124:7

places 11:19 126:13

plan 21:16 85:22 152:12 189:15 191:19

plane 42:8,9,14

planning 2:10,22 6:10,14,15 18:19 26:19 29:15

plans 45:2

plate 151:11

play 32:21 59:10 117:11 164:15 181:20

player 54:18

players 177:18

plead 158:6,9

please 32:19 34:15 36:12,13,16,17 71:18 114:16 148:11,12 157:19 176:2 187:11 193:6

pleased 163:8

pleasure 155:18

pleasures 54:17

Plus 116:12

PME 105:8

pneumonia 83:20

pocket 97:22 181:11

pockets 12:9

podium 176:6

point 32:18 40:1 69:12 73:11 85:13 88:1,14 91:3,7,10 101:20 105:11 110:1 111:3 112:7 133:4,8,9 136:5 137:14 138:10 143:7 144:12 149:12 151:14 156:13 157:8 163:15 164:21

points 11:18 12:9 103:2 177:9

policy 67:1 191:17,21 192:7

polymerase 178:11

Pooks 1:17

poor 74:22 76:20,21 77:4 78:4,6 79:17 108:17 137:12 169:15

popped 51:5 87:3

population 48:13,18 49:5,15 126:10 164:6 180:8,12

pose 186:22

position 133:9

positions 12:10

positive 111:4,5 117:14,18 178:9,19 185:6

possibility 42:21 170:20

possible 13:17 32:6 43:1 51:22 99:10 121:18 141:19 180:18,19 189:8

possibly 28:9 81:7 160:19

post 43:6 45:11 46:11

posted 25:12

poster 186:19

posteriorly 175:6

post-exertional 46:2,4 47:3 53:20 57:5 58:9,10 96:8 105:8 161:21

posting 28:16 195:12

posture 144:11

posturography 53:15

pot 110:6

potent 127:2 192:1

potential 16:12 159:11 187:21

potentially 151:3 183:13

pounds 99:16

poured 110:5

powerful 127:22

practice 38:2 112:9 123:3 144:3,10

practiced 110:11

practices 123:5 170:13

practitioners 12:1 101:9

pre 20:2

preceding 79:15

predict 54:10 75:7 86:19

predictability 74:5,7

predictable 73:5 79:4

predicting 187:20

predictors 111:6

predominant 53:5

predominantly 178:12

pre-frontal 175:2

pre-med 38:4

prepared 31:9 94:3 168:6

preparing 29:10

pre-registered 35:14 152:22

prescribed 52:10 95:22 97:5,20

prescribing 130:20

prescription 20:18 23:9 94:11 148:9

present 35:17 41:18 45:4 93:21

presentation 153:5,6 161:8 186:19 193:5

presented 186:19

President 48:6

press 172:18

pressing 69:17

pressure 61:7 116:7 145:16

pressurized 42:10

presumptive 179:7

pretty 32:14 60:19 80:6,7 89:10,11 121:8 125:1 131:15 163:14 186:20

prevent 58:21

previous 43:17 123:9

previously 101:3

price 68:9 86:7

primarily 22:14 23:15 31:7

primary 101:9 171:2

principal 49:19 50:3

prior 79:2 104:20 124:6,17

prioritizing 53:6

priority 180:13

prisoner 87:11 106:22

private 171:7

proactive 181:21

probably 16:5 42:18 43:4,17 51:7 75:8 86:9 91:8 132:1,3 135:2 142:2,12 147:9 154:2 156:15 166:19 167:20 169:19

probe 140:8 144:19

problem 46:16 74:2 77:8 107:16

135:7 139:19 170:1 174:22
problematic 77:6
problems 45:12,13 53:7 61:6 62:13,21 90:9,15 194:1
proceeding 196:3,4,5,7,9,10 197:4,6
proceedings 197:9
process 14:7 24:3 29:19 35:18 52:21 109:7,11 117:8 118:14 131:22 152:19,21 153:10 154:2 166:15,21 180:6 182:14,17
processed 117:6
processing 45:21,22 49:18
produced 97:8
produces 71:22
producing 195:7
product 28:17
productive 39:19 41:1
productivity 172:21
products 11:21 13:21 14:2,5 94:12 129:9
product's 16:16
Products 2:18 18:12
professional 49:14 50:13 67:7 68:2 142:15 144:13 188:8
professionals 67:17
professor 109:21
profiling 160:3,4,17
profound 14:14
profoundly 42:1 127:15 186:9
prognosis 169:15
prognostication 160:19
program 41:15 42:22 96:8 101:8,22 109:8 183:3
progress 43:9
progression 106:9
progressive 179:4
project 25:6 161:18
projects 171:3
promoting 104:14
promotion 124:22
pronounced 148:7
proof 183:6
properly 52:22
propranolol 46:20
protocols 187:11
prove 161:19 162:11
proved 193:11
provide 7:13 8:12 17:4 98:17 99:12 154:13 166:9
provided 44:14 96:18 101:12,15 103:6
providence 186:18
providers 11:14
providing 28:7
Provigil 139:21 141:4
proving 176:5
Prozac 124:9
pseudo-medical 87:20
psychological 40:3
psychologist 164:16
public 1:8 3:10 4:4 5:4 8:20 20:2 24:16,17,19 29:22 32:11 35:13 68:3,10 152:7,10,17,18 153:10 154:4 157:9 161:6 172:18 176:2 191:4 192:22 193:4,10 195:21
publicly 68:6
published 24:12 48:8 170:5 185:2 186:10,14
publishing 173:20
Puerto 145:10
pull 70:10
Pulmonary 2:18 18:11
pulse 108:3
punt 45:7
purely 174:11
purple 90:20
purpose 10:18 31:5,16 34:1 118:13 141:16
purposes 15:14 16:9
pursued 115:17
push 140:12
pushed 84:10
pushing 75:11
putting 22:21 163:7

Q

QEEG 53:4
qualify 83:1
quality 75:1 98:5 108:17 170:17 195:5
queried 169:13
question 21:15 34:11 41:19 51:4 60:3,4,8 62:22 69:1,13 75:6 76:4,10,19 78:12,20 79:9 80:5 83:4 87:3 119:15 136:7 140:6 141:13 148:11 149:14 150:12,13 156:8 163:5 187:1
questioned 137:3
questions 17:6,11,12 26:22 27:1,2,7,10,14 30:2,21 31:10,12,20,21 35:22 37:10 41:6,7 47:22

48:7,9,10 55:13 59:5 60:11 71:4 78:13 89:21 90:14 92:11,22 94:5,8 119:2 128:3 144:17 146:15

quick 45:20 87:7 121:4 159:1

quickly 132:9 144:2

quiescent 178:22

quiet 53:18 62:7

quieter 54:20

quite 48:17 49:4,8 64:20 72:7 116:1 127:7 181:22 186:12

quote/unquote 50:11 67:4

quotes 87:7,8,16

R

R.Ph 2:5 3:6 7:8 8:8

RADM 2:13

raise 31:22 34:15 60:17 91:12 146:2 148:12

raised 13:21 35:20

raising 32:4 62:12 63:8 122:1

randomized 168:1

range 13:8 26:8,12,14 30:8,16 49:6,8 81:12 82:19 126:1 194:5

rapid 78:16 180:4

rarely 54:15 116:4

rash 99:16

rate 46:17 108:3 116:6 127:7 149:6,22

rather 29:21 179:10

rattling 42:8

raw 195:9

reach 114:22 133:21

reaching 95:22

react 69:2

reaction 45:18 90:11 178:11

reactivation 138:16

reader's 54:19

reading 52:16 54:17 56:11 64:5

ready 37:3 155:12 171:2

reaffirm 70:20 191:14

real 69:17 75:12 121:4 132:9 168:7

reality 181:1

realize 22:4

realized 24:6 111:12

really 10:8 11:19 12:10,11 14:19 15:15 18:1 19:13 21:2,4 22:4,14,17 24:4 29:2,9 30:6 31:17 38:22 55:16 57:21 67:10,13 70:2,4 72:7 73:15 81:12 83:5 84:18 90:4 93:19 94:13 102:17 105:7 107:9,18 118:8 120:15 126:5 127:21 128:7 133:18 135:4 137:14 138:19 139:9,22 140:2 141:22 142:12,17 143:13 147:21 149:2 151:9 156:4 164:3,7,20 169:6 172:3,12 177:19 185:18 186:4 187:17 189:6 193:7 194:12,21

realm 132:13

reason 32:19 77:19 83:3 99:8 116:2 127:12,16,17

reasons 27:21 42:2 139:12 151:5

Reauthorization 23:10

reauthorized 20:18

rebuild 38:22

recap 48:12

receive 185:12 195:6

received 24:21 47:18 161:14

receiving 112:10

recently 160:12 176:17 182:16 185:8 186:14

receptors 159:17,18

recharge 88:11,15

recharges 88:9

recognize 15:9

recommendations 95:20

reconfirm 191:15

reconnaissance 42:9

record 18:5 32:11 161:7 196:7

recorded 196:4

recordings 197:7

records 176:17

recover 39:2 84:13

recovered 88:4

recovering 40:6

recovery 88:7 166:10 179:1

recurrent 38:7 99:18

red 72:21

redefined 158:4

reduced 196:5

reevaluated 179:10

reference 15:16,18 22:22

references 14:3

referral 101:7

referred 102:4 189:19

referring 15:12

191:19
reflect 181:3
reflected 87:16 119:17 126:2
reflective 60:20
refreshing 107:17
refused 115:16
regaining 97:17
regard 78:20
regarding 10:22 15:8 34:22
regime 106:7
regimen 96:11 132:4
Register 24:12 47:20 48:8
registered 20:3 83:18
registration 20:4 32:20
regularly 34:13
regulatory 12:4 13:17
rehab 136:21
rehabilitation 107:10
reimbursed 176:13
relapse 39:5
relapses 39:3,7 96:16
relate 60:16
related 13:15 35:18 44:20 60:15 61:6 136:11 138:15 141:13 154:16
162:16 196:8
relatively 100:8 146:7
release 144:8
releases 144:7
relief 168:9
rely 32:3 117:12
relying 54:17
remain 34:20 113:21 116:3
remained 101:19 112:6
remains 98:4
remarkable 111:11 162:8 166:10 177:6
remarks 31:10 37:9 94:4 193:13
Remarks-- Theresa 9:5
remedy 181:13
remember 38:15 64:5 79:9 82:2 104:1 115:20
remembering 53:4
reminder 175:22
remission 52:12
remote 28:2
renamed 172:7
rendering 16:15
Reno 124:22 125:11
repeatedly 46:22 147:5
replacement 135:11
replicate 172:15
replication 178:15
replied 49:3
report 22:21 28:15 195:7
reported 1:21 49:12 138:17 178:16 197:4
reporter 184:2 196:1,2,14 197:4
Reporter's 197:6
Reporting 1:22
reports 28:15,16
represent 33:17
representation 156:10
representative 18:15 31:8 93:8
representatives 7:13,17 8:12,16 13:5 31:4,16 33:22
represented 148:13
representing 33:9 168:22
repurposing 159:11
require 44:14 180:9 187:13
requirements 152:21
research 1:5 29:16 33:17 47:15 107:10 138:13 147:13,22 149:5 151:1 156:4 158:2 161:21
165:3 166:17 172:15 173:7 190:18
researchers 10:12 16:21 133:21 151:6
reserve 150:10
residency 38:4
resonating 130:22 131:2
resources 44:3 171:8
respect 36:10 170:6 190:17
respond 57:4 68:22 127:8 141:6 156:7,22
responded 48:13,16 49:5,11 166:21 176:18
respondent 49:3
respondents 49:12
responder 156:18
responders 160:2,3,5,17 182:2
responding 49:6 76:7 92:2 157:9
responds 51:3
response 12:16 31:10 58:17 59:6 69:5,15 119:4 129:3 146:16 155:7 156:18 157:3 158:16 171:15,17 179:16 191:5
responses 34:10 47:17 48:14,19

49:21,22 174:8
responsibility 180:3 181:13
rest 32:22 88:12 92:20 94:6 103:18 123:19 133:9 188:21 189:7
restaurant 53:11
resting 46:16 123:12
restore 51:8
restored 118:12
restriction 87:4
result 13:7 30:10 102:3 182:1 185:7
resulting 30:7
results 19:10 102:11 104:3 167:5 172:14 173:20
resveratrol 116:13
retain 62:4
retinoid 159:17
retire 122:16
Retriever 111:1
return 93:4 170:18 177:7
returned 99:17
revealed 53:5 112:20
revealing 100:9
revenue 172:22
review 15:22 22:21 24:5,13 25:1
reviewed 25:2 83:5 166:18 176:17
reviewers 23:22 195:13
revised 157:18 169:12 184:17
Rheumatology 2:18 18:11
rich 195:14
Rickettsia 100:10
Rico 145:10
rid 133:10 174:15
ridiculous 104:11
riser 110:19
risk 21:16 50:8 98:7 108:19
risks 21:14,17 160:10,13 181:5
Rituxan 120:18 159:22 181:11
rituximab 97:20
RNase 111:5,13 112:22
road 1:17 81:4,20
Robert 4:19 80:4 123:8
robs 188:14
role 16:14,19 87:10 181:21
Romberg 110:9
room 12:21 32:16 38:6 45:9 53:18 63:13,19 64:12 74:22 97:15 115:11 123:19 164:12 192:14
rooms 32:22 92:20
root 151:13
ROSTER 2:1 3:1 4:1 5:1
row 93:11
rubbing 134:12
rubric 52:13
ruffled 187:8
rules 33:6 158:8,10 183:1 191:16,17
run 45:11 82:3
running 67:2 112:14 140:22 183:12
runs 29:19 88:1,14

S

sacrifice 194:11
safe 10:17 11:1 160:9 171:10
safety 3:7 7:9 16:15,16 17:21 21:14
saline 113:17 145:1,5,19 146:6
Salis 5:13 37:13,15 51:17,19 52:1,4 57:14 72:6 88:16
saliva 186:7,12,18 187:12,13
salt 146:13
salts 108:1
samples 186:18 187:13
San 38:3
Sandra 2:13 6:5 10:4
Sandy 76:5,15
Sara 2:9 6:14 7:7 8:7 17:5 19:17,18 29:4,13 47:11 74:16 86:21 95:8 143:22
sat 80:10 176:6
Saturday 88:5,7
save 168:18 191:18
Savella 99:3 103:3 115:22 118:1 129:11,22 132:10 133:6
saw 64:10 70:19 87:16 101:9 112:12 119:17 164:20
scan 112:16
scans 170:9,10
scarce 44:2
scares 66:10
Schadt 162:4,5
school 38:4 42:22 52:16 92:10 161:13,16 177:7
Schweitzer 5:8 63:15 94:2 109:17,18,19 134:17,19 178:19
science 89:17 92:9 156:4 158:5 171:8 184:2
scientific 12:4,15 92:4 173:4
scientifically

158:4
sclerosis 159:4,14 177:17 179:4
score 112:17
screen 157:18
screening 22:8
search 73:22
seats 93:7
second 30:14 50:9 59:12 78:20 92:19 93:15 97:5 177:14
secondary 57:8
seconds 167:12 174:21 190:9
sector 171:7
Security's 112:18
seeing 22:3 82:20 93:12
seek 13:8
seem 11:19 12:7 79:13
seems 41:21 58:21 75:1 127:5,11 152:13 162:5 176:22 183:9
seen 67:14 103:16 170:17 177:6 190:4
seizure 53:17
seizures 110:2
selecting 47:12
selective 126:14
self 105:17,18
send 28:3 145:18
senior 104:21
sensation 69:4,6
sensations 69:10
sense 16:10 31:1,18 43:12,14,16 55:21 57:19 58:1 73:5 91:18 141:21 181:7
sensitive 27:11
sensitivities 61:5
sensitivity 53:8 54:7 110:4 116:18
sensoral 61:5
sent 113:6 187:13
sentence 43:15 188:13
sentences 95:14
separate 74:11 174:2
separated 113:8
separates 174:6
September 24:11 111:15
sequestered 175:15
series 28:17 47:13,21 162:7
serious 14:12 68:4 88:13 109:12 130:14 134:8 135:19 159:5 160:11 177:11 180:5 187:6
seriously 166:17
serve 29:16
Services 17:1
session 35:15 150:16 152:7,12,17 153:11 154:4 157:9 191:4 192:22 193:4,9
sessions 26:20,21 102:5 154:14
sets 61:2
setting 48:11
settled 64:21
Seven 112:12
seventh 41:14
several 38:12 42:2 74:21 83:18 101:9 106:12 124:9 155:21 158:22 180:5 186:11
severe 38:6 70:13 99:15 100:6 108:3 125:15 167:21,22
severely 14:12 117:20 178:18 179:2
severity 21:9,19 26:8
Shannon 3:16 75:5
shape 135:4
share 34:14 37:8 60:12 61:15 68:17 71:14 72:9 79:21 94:3 129:2 146:20,21 153:1 166:4
shared 10:22 31:17 78:1 122:2 126:3 133:13 137:22 146:21
sharing 41:1 61:17 119:13 122:6 193:16 194:3 195:12
sheet 10:10 20:4
she'll 74:9
she's 18:2 74:2,8 84:17 179:17
shift 102:20
ship 145:12
shirt 90:20
shopping 145:20
short 141:10 142:12
shortened 166:19
shortening 167:17
shorter 79:1 130:19
shortly 13:12 131:11
short-term 62:4 110:3
shot 105:20
shots 105:18
shouting 64:16
shout-out 149:5
shower 110:20 150:3
shown 185:2
shows 74:12 176:17
shuts 62:4
sic 104:19 105:8,21 106:8 107:2,16 192:4
sick 40:14 44:4,6,8,11,13

52:18 62:20 64:7 66:21 67:10 68:7 73:14 84:16,17,18 92:1 98:4 100:17 101:3 106:22 110:1 111:13 116:7 126:19 131:21 135:5 163:12 164:10 178:18 182:18 187:17

sight 81:21

signals 168:14

signed 20:5 191:2

significant 13:6 30:4,6,19 38:13 39:2 41:20 46:16 48:17 52:12 53:7,20 54:6 61:13,20 62:2 66:8 88:11 98:6 103:16 105:2,4 107:22 108:19 116:16,19 117:3 126:22 130:14,18 176:19

significantly 39:4 97:7 127:17

sign-in 20:4

signs 11:10 12:6 75:8

silence 57:22

silverware 110:6

Silvey 171:14

similar 31:18 71:9 91:6 104:14 155:19

similarities 60:22

similarly 11:21 83:10

Simmaron 158:2

simple 103:9 174:13

simply 85:15 90:2 104:10 115:16 116:2

Simpson 5:9 85:5,8 94:2 114:21 115:1 132:9 133:4

Sinai 161:13,18

sincerely 92:14 119:13

single 42:4 91:2,8 131:16 188:22 189:19

Sioux 122:13,19

Sirturo 183:3

sit 95:14 149:9 150:4 179:19 192:18

Sitro 192:4

sitting 17:10 42:16 46:17 64:19 97:12 123:12 142:17 150:3,9 152:14 189:2

situation 41:18 92:4 147:7 181:13

situations 45:5

Situro 192:4

sixties 137:10

size 32:3

skepticism 101:11

skewed 172:18

skier 135:5

skin 83:20,21 141:5

skipped 165:10

skyrocket 135:17

sleep 38:8 45:14 74:7,10,11,12,13,17,22 75:1 76:20,21 77:4,12,16 78:4,6,7 79:17 96:4,9 105:20 106:4 107:16,17,18 108:4 110:13 114:6 115:5 116:8,10 117:2 118:3 121:6 123:17 133:8 134:2,15 139:11

sleeping 105:13

sleeplessness 51:1 76:7

sleepy 84:22

slept 77:13

slide 19:16 125:5,8 183:19

slides 11:6

slight 97:13

slightly 27:9 97:9,10 101:19

slippery 67:15

slipping 64:10

slope 67:16

slot 182:11

slow 54:18 155:22 188:17 190:6

slowed 45:21 53:4

slower 63:7

slowly 64:4 78:19

slow-wave 74:12

small 11:22 53:16 87:12 103:14 126:10 159:21 166:14 181:3 186:3,11 187:6

smaller 110:16 128:10

smarter 151:7

Smith 5:10 62:19 81:16 82:7,12,14 122:13 123:2 149:16,18,20 157:20,22 158:1

smoke 45:3

smoothly 29:19

Snell 149:6

soaks 190:12

social 40:10 51:6 54:14 68:10 86:6,12 112:18 139:7 188:7 190:4

socialize 38:16

Socializing 54:10

sofa 65:16

sold 125:10

sole 180:20

solid 34:2

solo 38:5

solution 173:3

somebody 64:12 68:2 147:3

someday 117:19

somehow 192:7

someone 33:9,11 42:4 56:11,13 65:6,8 66:20 74:14 80:2 81:13,14 84:2 86:10 88:4 95:6 146:3 150:15

somewhat 57:18 58:21 126:14

somewhere 65:7 108:8 117:19

son 44:4,6 95:10 111:15 114:7,13

sons 44:20 45:1,9,15 46:3,4,11

sore 38:7 58:10,13,20 68:7,8 91:16 99:15 100:7 116:18

sorry 48:5 66:14 72:2 76:16 82:19 90:21 91:11 93:1 100:22 136:13 138:6 140:11 155:13 157:17,19 171:19 179:18 183:19

sort 16:5 27:17 41:11 43:7 48:12 49:1 56:4 67:15 69:6 74:1 122:3 134:14 148:13 156:21 157:3 176:20

sought 81:18

sound 53:10 54:7 61:6 110:4 116:19

sounds 81:1

source 120:5

South 122:13,19

span 124:2

spared 52:7

spatially 53:12

speak 20:3 31:22 32:4,5,7 34:17 35:15 36:13 39:11,12 51:21 53:1 59:13 64:4 68:5 85:15 86:5 118:15,16 119:12 140:17 153:14 154:9 172:1 173:15 176:14 191:3

speaker 17:3 60:5 82:6 145:4,5,6,9 146:5 155:1,2,4 157:14 168:17 191:1

speakers 153:12 193:8

speaking 33:16 34:3 36:13 62:14 65:20,21 68:3 88:13 95:10 154:4

special 20:16 54:18 109:6

specialist 95:19,22 99:7 104:6 112:13

specialists 142:21

specific 13:20 15:3 23:1 26:19 35:7,8 94:14 96:15

specifically 14:3 30:10 136:11 142:10

specifics 14:4

SPECT 112:16 170:10

spectrum 67:4

speed 45:21 164:1

spelled 19:4,5

spend 40:4 65:1 88:7 101:3 103:17 113:8 120:8,9,13 188:20

spending 194:9

spends 95:16

spent 54:21

spinal 112:20,21

spit 187:1,3,4

spite 97:2 98:3

spoke 119:18 192:22

spoken 162:6

sponsor 124:1 192:11,15

sponsored 159:9

Spotila 5:11 90:6,7 131:14

spouse 39:6

spring 113:9

SSRI 130:5

Staci 149:5

staff 2:3 3:4 19:8 29:14 35:16 165:20

stage 190:19

stages 154:11

stagnation 170:4

stakeholders 16:19 22:13 24:1 152:22

stamina 111:19,21 114:3,4

stand 36:15,16,17 60:11 70:2 95:14 103:15 153:22

standard 182:19 183:5,10

standing 157:22

start 7:14 8:13 12:19 17:16 20:22 25:4,10 30:22 37:17 61:10 62:8 75:9 93:6 109:13 118:14 119:16 120:17,21 144:11 194:22 195:14

started 24:4 64:15 72:19,20 80:9 84:16 93:14 99:13 102:7,10 113:2 122:15,21 123:10,11 125:9 129:17 173:20

starting 20:17 102:14 113:10 123:3

starts 45:20

state 36:13,16 61:21 71:18 73:8

stated 182:13

statement 17:13 123:9

states 172:11

Station 65:12
stay 33:20 45:1 78:11 107:19 112:4 133:1 189:5,7
step 160:1 187:8 188:11,17,18
stepping 188:18
Steven 4:14 155:11 157:13 158:15 178:4,5
Stevens 149:6
sticker 150:5,6
stigma 188:15
stimulate 23:3 151:6
stimulating 54:12
stimulation 53:10 57:16 134:14
stomach 133:17 138:18
stop 51:10 150:6 151:20
stopped 112:1
stops 50:11
store 44:17 53:11 84:13 150:7
story 60:15 145:10
straight 58:12 183:12
strange 56:18 69:9
strangest 58:10
strategy 103:11 169:8
straw 72:2
Strayer 168:16
street 72:19
strep 58:16
stress 39:1 45:5 117:20 170:11
stressful 38:4 62:21 115:9 145:12
stretch 144:11
stretches 101:17
stretching 103:8 142:8 144:6,7
strict 96:9,14
strictly 158:5
strong 109:3
strongly 34:18 50:7 51:6 180:8
structured 87:9
struggle 39:13,15,17,19 99:22
struggled 85:19
struggling 52:22
stuck 114:9
student 41:11 73:14
studied 16:4
studies 19:11 74:11 83:6 107:18 134:1 160:17 162:4 173:21 176:22 180:10 185:2 190:15
studying 16:6 184:8,9,11 185:3,7
stuff 86:15
stuttering 62:8
subdivide 174:8
subgroup 178:9 179:8 182:1
subgroups 179:3
subject 166:10
subjective 89:16 174:11,14,15
subjects 166:11
submit 48:1 51:12 161:6 162:17 176:1,2 193:6
submitting 15:21
subpopulations 26:9
subset 128:16 156:4
subsets 155:22 167:6 170:2
substantially 131:22
success 74:3 111:6 159:22 176:16 182:8
successful 104:21
sudden 82:12 92:2,3 155:22 175:8
suddenly 64:16 71:22 99:13
suffer 189:4
suffered 109:21 110:1,8 163:15
suffering 108:12,16 169:14 172:6
sugar 91:4,6 96:10
suggest 180:8
suggestion 49:16
summarized 32:10
summary 195:7
summer 24:4 110:17 113:5
Sunday 88:6,10
Sundays 189:8
Super 117:9
supermarket 84:1,4
supervising 67:1
supplement 176:2
supplements 96:6 98:22 116:14
support 35:3 165:2 171:7
supported 98:3
supporting 29:18
supportive 67:9 126:12
sure 18:6 20:4,5 21:17 26:14 27:16 28:2,5,7 29:19 40:11 55:10 60:11 67:21 68:18 70:22 74:18 76:12,15 81:13 89:3 125:22 127:21 134:12 137:14 162:20,21 180:7
surgeries 135:10,22
surgery 83:20,21
survey 47:18,22 48:7,13,14

49:5,7,9,11,12 87:3,8
surveyed 169:13
survivor 108:13 164:5
Susan 5:12 91:13
suspect 74:10
sustain 47:2 53:19
sweet 117:13
swimming 44:9 45:19
switch 132:2
swollen 99:19
symptom 14:18 15:18 34:10 41:20 43:5 66:9 74:11 91:15 106:10 121:6 172:11
symptomatic 26:2 120:16 126:9 170:16
symptoms 7:4 11:10 12:6 13:6 30:4,6,8,10,12,18,19 34:22 37:1 38:10 39:4 41:22 45:11,17 48:15 49:2 51:4 52:8,13 53:16,21 57:10 58:3,6,9 59:17 61:1,2,9 73:12 82:20 85:10,12 90:10 94:11,14 95:16 96:15 100:2,5 102:1,2,19 104:2,9 105:2,3,5 106:11 111:17 116:17 120:15 124:12 140:9,10 147:19 150:19 151:10 163:13,22 172:12 180:16,18 189:20
syndrome 1:7 10:7 14:11 15:6 18:14 25:20 90:9 136:8 138:5 145:18 167:18 172:5,8 173:22 174:4 176:11 177:22 178:8 179:4 195:20
syndromes 174:15
system 87:22 88:9,14 116:11 121:7 131:9,12 132:18 143:9 154:20 159:6
systematic 22:5
systems 175:10

T

table 6:1 7:1 8:1 9:1 20:4,6 36:7 82:14,16 89:21 92:16 96:3 122:22 166:22 184:11
tags 36:15
Tahoe 112:13 166:8
tailored 27:17
taker 32:14
taking 22:2 32:13,14,17 38:22 93:7 116:15 126:5 135:19 140:10 142:1 147:16 157:10 173:17
talk 15:5 20:8,14 23:17 34:12 57:17 60:20 62:7 63:16,17,22 68:6 69:18 70:21 71:1 73:17 85:5 123:15 126:4 128:21 129:8 130:7 135:15 136:2 159:2 162:17 187:12,21
talked 25:1 55:16 57:5 71:5 73:12 114:13 122:7 125:1,2 129:1 134:20 155:20 158:18
talking 14:11 24:5 52:17 62:6 67:22 68:22 71:8,9 82:11 108:2 113:22 124:12 126:8 132:13 133:2
tall 165:17
tap 112:20
target 83:9 151:9 172:17 179:7
targeted 120:15 170:19
Tasha 68:20,21 71:8 94:1 98:13,14 100:18 104:16 129:1 144:3
Tasha's 144:12
tax 172:21
taxing 189:6
tea 86:8
teach 170:14
team 2:7,17 18:10 32:12
tease 55:18 73:22
technical 13:14
technology 160:21 186:16 187:18
teenage 84:17
teeth 111:2 149:9
telephone 86:14
tend 146:8
TENS 134:13
tent 29:7
tenured 109:20
term 15:5,7 46:8 57:6 70:3 71:7 136:15
terms 15:5,12,14 20:16 27:3 44:20 48:11 50:10 75:8 83:10 87:20 107:4,18 111:8 134:20 140:18 141:8 147:2 187:19
terrible 40:11 193:17
terribly 108:17
Terry 17:17,18,22 18:3,16 19:5 56:22 59:14 120:10
test 11:3 96:3 110:10 121:4
tested 124:15

159:19 178:7
testify 64:1,2
testifying 64:8
testing 16:6 53:14 54:2 100:9 170:11
tests 14:19 102:12 159:11 184:11
Textbook 174:18
texts 49:19
thank 20:9,10 29:3 37:15 40:16 41:2,4,9 43:18,20,22 44:1 47:7,9,11 51:13 55:7,9 56:21 60:9 66:4,16 68:13 70:18 72:20 75:3 76:3 78:10 79:22 85:2,3 86:2,4,20 92:13,14,22 95:8 98:10,12 104:16 109:1,14,16 114:18,20 115:1,2 118:17,19 119:11,13 125:20 128:1 131:12 144:1,15 148:5 149:19 150:11 151:17 152:9 155:13,16 157:5,11,12 158:12,14 160:8 161:3,4,10 162:13,15,18 163:3,6 165:5,7,19 168:11,13,21 171:11,13 173:10,12,14 175:19,21 176:8 178:1,3 179:12,14,21 181:14,16 183:15,17 185:21 186:1 188:2 190:20 191:10,12 192:19,21 193:12,15 194:3,8,19 195:15
thanking 193:15
Thanks 18:16 171:22
that's 16:4 21:9,13 23:19 35:5,7 37:19 42:19 48:17,20 50:8 56:18 58:3 61:18 62:10 69:10 72:7 74:1 77:20 78:18 79:12 81:9,18 82:7 86:6 87:5 89:11,15 90:4 91:16,18 92:3 107:11 108:10 126:21 127:1,19 130:6,15 131:9 134:3 135:7,21 136:5,8 138:15 141:2,3,14 144:12,21 148:7 149:3,4,10,11 151:5 153:9 154:6 157:21 161:16 165:12 175:13 185:4 189:6 191:9
theater 44:9
the-counter 94:12
themes 87:1,4
themselves 17:15 40:17 102:19 118:16 148:17
theory 110:11
therapeutic 169:8 170:4 180:15
therapies 10:17 11:1,4 13:9 14:22 16:12 21:11,21 26:6,7 30:16 94:12 117:1 171:10 181:8 194:5
therapist 68:6 101:17 103:7 188:8
therapy 51:8 99:1 101:14,16 107:11 142:8 144:4 149:21 151:9 161:19 162:10 169:19,21 170:16,20
thereafter 196:5
therefore 36:12 104:3 105:10 139:9 147:8 148:4 154:11
there's 32:20 81:5,6 192:12
Theresa 2:16,21 3:6 7:8 8:8 13:10 17:3 18:7,9,17,18 20:8 29:13,14,17 56:22 152:6
Theresas 19:1 57:3
thesis 43:3,9
they'll 13:21 17:11 20:6 85:17 154:21
they're 12:4 15:13 19:4 22:22 39:10 72:10 73:21 134:9 151:22 152:2 161:6 166:19 174:11
they've 13:9 44:11,12 69:14 117:3 120:20
thin 127:5
third 50:17
Thirteen 115:12
Thomas 1:21 3:20 165:10 196:2,13
thoughts 34:17 148:21 175:9
thousands 39:12 82:1 157:2 166:16 170:5
threshold 149:8
thrilled 13:2
throat 58:11,13,16,20 68:7,8 91:16 99:18 100:7 116:18
throats 38:7
throbbing 69:6
throw 127:19
Thursday 1:13
thyroid 159:18
tie 151:8
tilt 96:3 184:11
timeframe 25:8
timer 153:12,14,15

193:9
tinnitus 110:4
tired 58:5 84:21 118:2
titers 52:11 89:11 107:5 156:2
title 42:12
TLR3 168:2
today 10:14,15 11:8,9 12:18 16:9 17:2,7,8 29:3,17 30:3 32:10 33:8,12,20 34:19 35:20 36:2,11 41:13 42:3 44:21 45:3 61:2 89:16 95:9 99:9 102:20 105:9 108:11 113:12 115:4 119:12,18 121:17 123:5 148:13 153:21 154:10 155:20 156:10 158:5 159:9 160:14 163:8,11 165:22 166:13 168:5,21 172:11 176:12 177:5,9 180:14 182:11 184:5 185:19 189:3 192:16 193:15 194:2,10,13
toes 187:8
Toigo 3:6 7:8 8:8 17:17,20 29:18 59:16,21 74:16 76:5,10,14 120:11 143:22 152:6,11 155:5,8,15 156:13 157:5,8,12,16,21 158:14,17 161:4,10 162:15 165:7,10,13 167:12 168:13,16,19 171:13,16,18 173:12 175:21 178:3 179:14,17,20 181:16 183:17,22 186:1 188:2 190:9,20,22 191:6 192:21
Toigo's 19:5
toiled 167:1
toilet 110:19
tolerate 97:12 181:5
toll 40:2
tomorrow 11:8 12:3 16:5 35:17 66:18 77:11 90:8 108:11 114:9 152:4 154:14 187:22 195:16
tomorrow's 13:13 182:10
tone 54:19
tonight 152:3
tools 12:4,5
top 52:15 59:17 104:22 181:12
topic 7:4,14,19 8:4,13,18 30:4,14,22 31:7,20 34:18 36:22 37:3,4 47:12 93:13,15,16,17,19 94:22 146:18 148:3 182:5 186:8
topics 13:16 17:7 19:17 30:3 31:3 33:3 34:9 35:5,13,20 50:2 80:2
total 39:7 57:22 124:17 145:13
totally 39:9 63:3
touch 35:6 126:1
touches 127:11
towards 181:21 183:12
toxic 127:8
toxicity 167:18
track 18:5
tracks 175:6
tract 175:1
train 65:9,11,13 72:17,18 113:14
trained 103:7 104:6 142:14 144:13
training 38:5
transcribed 32:12
transcript 196:6 197:5,7
transcription 197:1,8
Transcriptionist 197:13
transcripts 195:9
transcutaneous 134:13
transferred 179:9
translate 42:13 178:17
translated 42:6 50:12
translating 42:17
transparency 153:3
transparent 152:18
trapped 42:10
travel 33:12 44:10 45:4 158:21 159:9
treadmill 121:4
treat 21:11,12 30:17 72:15 94:10 96:6 117:2 120:5,15 127:11 147:9,19 170:13 180:16,18,19,22 182:21 183:3 189:17,20 192:2 194:4
treated 98:18 100:11 101:10 107:13 110:12 177:4
treating 8:5 30:15 93:13 147:18 176:10
treatment 19:10,11 35:3 55:4 63:21 74:1 81:19 93:20 94:9 97:3 98:17 99:11 100:12 101:7 102:17 106:7,9 107:3 108:1

112:1 113:10 115:18 120:1 132:3 142:13 144:18 146:6 149:3 159:13 161:2 164:6 173:8 177:20 183:5 185:14 190:14

treatments 30:18,20 34:22 35:7,8 40:18 50:18,20 94:14,16,17,19 96:11,13,17 98:7,20 102:22 105:1,6 106:17 107:3 118:12 120:4 121:22 126:4,8,9,15 128:5 129:6 142:7 156:7,11 160:11 164:11 180:4 181:9,11 182:9

tremendous 47:14 127:2 182:2 194:17

trend 99:10

trial 12:16 13:16 16:3 101:13 104:3 123:21 156:21 157:3 159:16,21 160:2 168:1 185:5

trials 11:3,22 15:22 16:1,15 21:13,15 23:6 26:5 104:13 106:16 145:1 147:21 160:16 171:4 181:2

tried 27:12 43:2 44:12 45:7 46:19 102:1,21,22 107:6,21 110:18 122:21 129:21 132:1 135:19 137:19 141:4,21 162:20 163:1

trigger 57:12 75:1 76:22 92:6 179:8

triggered 46:3,5

triggers 46:2 71:5,6

trip 123:13

tropical 98:15

trouble 42:3,16 53:3

troubling 63:7

true 196:6 197:8

truly 93:17 172:20

try 22:12 24:5,9 25:3 26:13 32:5 34:10,16 36:14 57:17 58:20 72:3 87:19 89:5 94:21 96:8 106:14 117:11 119:21 126:5,15 130:4,10,19 135:19 140:19 141:18 152:15 154:22 158:14 191:17 194:22

trying 20:22 26:15 27:4 28:7 55:18,20 56:3 79:8 84:12,21 87:21 98:7 106:13 114:15 118:14 131:19 133:7 137:17 158:3,5 190:2 193:20 194:4 195:4

tuberculosis 183:4

Tuesday 185:10 189:11

turn 20:7 29:4 35:17,21 54:14 95:4 108:22 113:18 144:16 152:5 193:2

turned 114:8

turning 140:22 141:1

turns 62:2

TV 54:14 95:15

twelfth 44:5

Twenty 51:19

Twenty-three 52:4

Twenty-two 137:8

twice 84:14 113:13,17 114:11

twitches 107:15

twitching 102:2

two-day 10:4

two-minute 182:11

Tylenol 116:4 135:16,17

type 82:17 83:12 125:15 128:10,11,14 156:2,21

typed 197:5

types 29:22 41:6 62:16 81:17 83:18 120:1 138:11,19

typewriting 196:5

typical 49:1 121:6 185:11

typically 14:6 42:6,11

U

U.K 98:19 99:5,11 101:6 103:21 104:7 142:14

U.S 98:20 100:4 102:6,10 103:22 104:12,14

ulcers 136:19 138:3,5

ultimately 11:2 151:11,15 186:22

unable 40:4 43:15 54:3 95:13

uncalled 188:16

uncritically 99:10

undergo 45:5

undergoing 23:13 161:21

underlying 91:8 120:5 126:5 147:8,14 150:17,20 180:17

understand 16:3 22:18 35:9 40:13 56:6 65:20 66:2 67:8 92:1 153:4 194:14

understanding 10:22 11:9 30:14 53:3 94:9 151:12

understandings 12:15
understands 184:6
understood 145:17
undertake 71:21
underutilized 149:11
underway 21:7 24:6
unfortunate 183:9
unfortunately 170:16 172:7
unfreshing 38:7 45:14
UNIDENTIFIED 60:5 82:6 145:4,5,6,9 146:5 155:4 157:14 168:17
unified 50:1
uniform 14:19
Union 65:12
unique 21:22 98:17 128:14
unit 134:13
universal 170:11 172:16
University 185:1
unknown 14:13 180:18
unless 189:11 191:1
unmet 21:10 50:19,20 167:8 192:8,9
unprecedented 160:8
unpredictability 72:7
unpredictable 72:14
unscientific 172:8
unusual 19:2 166:7
unusually 134:22
unwind 106:1
upon 35:7 61:15 122:10
upstairs 45:9
urge 181:20
urgency 181:8
useful 36:4 81:12 170:17
useless 184:7
User 20:18 23:10
usual 162:2
usually 44:19 78:9 116:9 130:15,16 141:9
utilizing 170:12

V

VA 131:8,11
Valcyte 124:7
validation 180:12
Valtrex 98:22 102:11,13 103:3 124:7
valuable 149:10 155:17
valuation 175:3
value 33:5
variability 91:6
variable 14:17
variant 111:4
varied 150:19
various 35:18,20 96:5
vary 27:19
varying 91:1
vastly 50:13
ventral 175:9
venue 68:10
versus 57:11 63:1 68:1 69:2 128:16 133:2 180:16
vestibular 53:14
veteran 41:11 42:5
Vice 166:1
Vicodin 106:5
view 34:14 40:1 164:21
viewing 54:15
views 12:10 34:2 55:2
Village 121:14 122:18 123:4 163:18
Villanova 109:21
vineyard 167:1
viral 52:11 58:15 89:11 92:7 156:2 178:14 179:7
Virginia 125:7
virtually 44:13
virus 58:14
viruses 96:5 127:11
vision 51:2 90:3 131:7
Vistide 127:1,21
visual 53:10
vital 184:6
vitamin 103:3 105:20 116:14 159:17
Vitka 5:12 91:13
vitro 178:14,16
vivo 178:18
VO2 112:17 170:10 184:10
voice 54:19 154:9 163:17
Voltaren 134:10
voluntary 36:6 93:3 152:2
volunteer 148:16
von 5:13 37:13,15 51:16,19 52:1,4 57:14 72:6 88:16
Vyvanse 140:1

W

wait 36:12 55:4 58:19 179:10
waiting 101:8 102:5 108:22 190:19
wake 88:9 108:7
wakes 97:9
walk 54:22 97:1 101:19 103:15 110:18 111:10 122:20 135:8
walked 111:16

walking 72:19 113:5
wall 38:19
walls 110:22
Walzer 155:6
wandering 175:7
War 173:21
warning 75:15
warrant 167:15 183:1
washed 54:9
wasn't 42:9 123:6 127:5 130:11 137:16 156:20 162:21
wasted 43:17
watch 95:15 106:2 133:18 153:15
watching 147:17 156:14 164:1
water 84:3 117:7 146:14
wave 53:5
waving 83:3
wax 122:22
ways 11:4 28:7 73:4 109:5 163:20 190:2
weakness 107:14 116:17
wear 149:6
wearing 53:8
webcast 32:8,9
webcasts 156:14
website 25:13 28:16,20
websites 53:12 172:18
wedding 111:16
Wednesday 189:11
week 39:14 40:7 46:6 84:14 102:16 113:13,17 114:11 115:21 123:3 189:13
weekend 40:6 79:20 103:19
weekly 101:17 102:7 122:19
weeks 38:12 44:18 45:3 46:14 54:1 76:2 79:15 82:22 83:12 86:8,16,17 88:15 97:1,2 106:12 115:6 121:5,12 131:20
weigh 132:21
weight 34:4 127:3 135:6
weird 108:8
welcome 10:6 35:13 162:18
Welcome--RADM 6:5
welcoming 10:3
we'll 12:3 13:16 15:5 17:10 20:20 22:19 25:6,7 27:15 28:16,19 31:14,19 33:1 34:7,8,16 37:6,7,9 41:8 51:11 60:20 71:3 83:15 85:6 89:5,22 90:1,18 94:4 100:19 118:21 120:9,13,14 122:12 126:4 131:12 136:12 138:7 149:14 152:1,4,12,15 158:14 195:6,7,12
well-attended 186:21
well-studied 12:11
well-thought 12:11
we're 11:8 12:18,20 14:1,11 16:10,18 20:17,22 21:19 24:10 25:4 27:22 28:2,7,8,11 31:3 33:16 37:7 43:6 59:21 60:19 61:1 63:13 77:3 81:11 82:20 87:20 91:1 94:8,13,16,19,20 ,21 123:15 124:12 128:16 137:15 149:3 151:10,15 152:21 154:7 157:10 166:13,15 171:4 174:14,15,16 175:14 181:5 190:5
we've 11:21 23:19 24:7,9,22 26:19,21 28:4,15 43:9 68:15 73:22 122:3 126:3 153:21 162:6 166:18 167:1 176:16 192:12
whack 90:13
whatever 23:12 42:13 70:10 77:19 92:10 95:1 130:20 164:22
wheelchair 110:19
wheels 141:1
whenever 150:4
whereas 75:13 79:2
Whereupon 195:18
whether 12:4 16:16 21:16 28:8 62:22 68:5 75:7 85:11 100:12 125:3,4 134:11 153:6 161:19 162:10 167:7
white 174:5 175:1
whole 12:20 19:21 64:22 69:5 75:19 101:4 117:20 156:10
whomm 196:2
whose 162:21
wide 26:14 30:8
wife 38:17 87:11 98:3 123:16 124:21
Williams 5:14 66:15,17 67:22
willing 98:6 108:18 153:13,15 154:3,19 171:3 181:5 191:15,22 192:3

Wilmington 113:14
windows 55:2
wiped 63:3
wish 65:22 99:8
woke 84:6 95:10 115:10 145:14
women 172:5
wonder 182:19
wonderful 143:16
wondering 145:2
worded 27:3
wording 26:21 27:5
work 12:13 17:18 22:3 38:13,14 39:13,15,18 40:2,14,18,20 43:1,17 51:1 54:7 58:19 66:21 92:19 100:4,13,14 101:17 102:14 103:7,12,18,19 107:6 108:21 110:13 111:20 114:4 128:7,15 130:1,3,6,8,11,19 143:10,11,12,15 146:1 153:11,13 154:3,19 163:16 165:14 166:22 177:7 188:7 189:5,9 191:16
workday 39:20
worked 131:16 132:10 141:21 193:12 194:6,7
worker 139:7 190:4
working 25:4 38:5,21 45:21 58:12 62:20 66:20,22 92:1 98:16 99:14 105:6 107:20 128:13 139:17 141:9 142:2 175:6 181:21 188:6,22 193:8
works 102:19 106:9 113:18 128:16 129:21 134:2,11,12 141:8 143:14 148:9
workshop 1:8 10:4 15:14 16:9,18 55:5 141:16 182:6 195:21
workshops 47:14
workweek 88:5
world 44:10 110:16
worldwide 169:16 170:7,21 171:1 172:6
worried 70:8
worries 101:1
worry 36:17 101:1
worse 11:17 39:10 74:7,8 77:19 84:19 100:2 101:3 110:15,16 132:16
worsened 14:16
worst 39:22 40:7 83:19
worth 50:11
worthwhile 150:21,22
wound 136:19
wow 72:22
wrap 190:10
wrapping 154:6
write 53:2 57:18 95:14 140:7
writing 32:15 43:13 52:16 176:3 193:7
written 43:10 52:18,21
wrong 19:5 81:20 139:15 176:5 185:7
wrote 43:12,13 55:20 184:3

X

Xanax 105:21
XMRV 187:9

Y

yelling 72:22
yesterday 80:6
yet 27:5 50:9 73:16 85:20 91:9 131:18 155:2 169:20 182:3,18 184:20 191:21
yield 169:18
yoga 144:3
York 72:15 105:16 113:11,12,15 115:13 161:13
you'll 18:21 64:2 132:21 195:16
younger 48:17
yourself 57:11 140:12
you've 20:5 30:1 57:7 66:10 71:8 76:20,21 80:18 132:17 154:5 166:3 167:12,19 177:5 190:9 194:1,4,6,11,21 195:1

Z

zero 74:12 124:16
Zithromax 124:8
zolpidem 116:9 118:3