FUNCTIONAL GASTROINTESTINAL DISORDERS

PUBLIC MEETING ON

PATIENT-FOCUSED DRUG DEVELOPMENT

Monday, May 11, 2015

Food and Drug Administration

White Oak Campus

10903 New Hampshire Avenue

Silver Springs, MD 20993

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C O N T E N T S

Speaker	Page
Dr. Donna Griebel	5
Dr. Theresa Mullin	11
Dr. Laurie Muldowney	17
Dr. Sara Eggers	25
Tanya Taylor	39
Cynthia Bens	44
Carrie Reily	52
Bettemarie Bond	59
Anne Sirota	111
Lynn Wolfson	117
Julian Chilson	124
Meredith Holt	128
Carol Pasinkoff	131
Tegan Gaekano	175
Marilyn Geller	178
Ellen Komichers	179
Carissa Haston	180
Nancy Ginter	184
Kelly Brezoczky	187

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1 APPEARANCES CONTINUED

2 Ritu Verma 190

3 Mary Berger 192

4 Bruce Zagnit 192

5 Debbie Fisher 196

6 Raymond Panus 197

7 Dr. Andrew Mulberg 199

8

9

10

11

12

13

14

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1 P R O C E E D I N G S
2 DR. EGGERS: Welcome everyone. My name
3 is Sara Eggers and I'm in the Office of Strategic
4 Programs here within the Center for Drug
5 Evaluation and Research here at FDA. I'm going to
6 be the discussion facilitator today and I am
7 delighted that we are finally here at the meeting.
8 I'm especially delighted, since my voice came back
9 on Saturday. This would have been a physically
10 impossible task for me to do, because I lost my
11 voice. So, if I start to lose it in the middle of
12 today, just let me know and I'll try to speak
13 closer to the microphone and someone can bring me
14 some water if they see me struggling.
15 Our meeting today is part of our
16 agency's Patient-Focused Drug Development
17 Initiative, which is focused on gathering patient
18 perspective on functional GI disorders. We'll
19 hear some more background about that in a little
20 bit. And Donna Griebel is going to come up and
21 give some opening remarks in a few minutes, but
22 first I'm going to ask my colleagues at the FDA

1 table to go through and say your name and where
2 you are located within the agency and push the red
3 button to turn the mike on.
4 DR. GRIEBEL: I'm Donna Griebel. I'm
5 the Division Director in the Division of
6 Gastroenterology and Inborn Errors Products.
7 DR. MULBERG: Good afternoon, Andrew
8 Mulberg, Division Deputy in Gastroenterology and
9 Inborn Errors Products.
10 DR. MULDOWNEY: I'm Laurie Muldowney,
11 and I'm a clinical reviewer within the same
12 division.
13 DR. MULLIN: Hi, I'm Theresa Mullin, and
14 I direct the Office of Strategic Programs and and
15 the Center for Drugs.
16 DR. DIMICK: Lara Dimick, and I'm also a
17 Medical Reviewer in the GI Division.
18 DR. VENKATARAMAN: Preeti Venkataraman,
19 also a Clinical Reviewer in the same division.
20 DR. KOVACS: Sarrit Kovacs, Study
21 Endpoints Reviewer in Office of New Drugs.
22 DR. EGGERS: Thank you very much. And

1 we will learn your names in a little bit, as we go
2 through the discussion, so I would like to thank
3 those of you who are in person, and also to the
4 folks that are on the web. We have a very, very
5 strong turnout on our web and participating by web
6 today. There will be every opportunity for those
7 on the web as well.
8 We have a full agenda this afternoon.
9 We'll first spend a little bit of time setting the
10 context and have my FDA colleagues provide some
11 background on our initiative and on the functional
12 GI disorders. And then we're going to get into the
13 whole purpose for our discussion, which is
14 listening to you. I will go over the meeting
15 format and the process before we get into that
16 discussion.
17 Our two main topics are the disease
18 symptoms that matter most to patients, followed by
19 patient perspective on current approaches to
20 treating functional GI disorders. We have time
21 set aside for open public comment this afternoon.
22 While the primary focus of our discussion is

1 really dialog with patients living with functional
2 GI disorders, open public comment gives anyone a
3 chance to offer a perspective or experience or a
4 comment at the end of the meeting. So, anyone can
5 comment. And to participate, you'll sign up at
6 the registration desk, if you haven't already.
7 We'll close that registration sign-up at the
8 break, and it's a first come, first served. The
9 time allotment will probably be on the order of
10 two minutes.
11 There is a kiosk with food and
12 beverages, and restrooms are located behind the
13 kiosk toward the back wall in that lobby and then
14 all the way to the right. We're going to take a
15 15-minute break somewhere between 2:45 and three
16 o'clock. It says 2:45 on your agenda, but I think
17 our first discussion is going to be jam packed,
18 and so we'll let it slip a bit into that. So, by
19 three o'clock we'll be taking a break, but please
20 feel free at any time -- this is a very informal
21 setting and informal meeting. Get up when you
22 need to, do whatever you need to and make

1 yourselves comfortable, and let us know if there's
2 anything that you need. The meeting is being
3 transcribed and a live webcast is being recorded
4 and will be archived on our website. And with
5 that, I would like to turn it over to Donna who
6 will give some welcoming remarks.
7 DR. GRIEBEL: Good afternoon. And I
8 welcome you as well to this Patient-Focused Drug
9 Development meeting on functional GI disorders.
10 You've already heard that I'm Donna Griebel. I'm
11 the Division Director in the Division of
12 Gastroenterology and Inborn Errors Products. Our
13 division is the division in the Office of New
14 Drugs that reviews drugs that are intended to
15 treat functional GI disorders. We're grateful to
16 all of you patients and patient advocates who came
17 to the White Oak Campus to be here with us today
18 in the audience. And as well, I understand that
19 we are joined by many, many more via web.
20 Today's meeting is one in a series of
21 what we're calling FDA's Patient-Focused Drug
22 Development Meetings. Theresa Mullin will be

1 talking a bit more about this initiative in a few
2 minutes. Functional GI disorders are common
3 disorders. They're characterized by persistent
4 and recurrent GI symptoms and occur as a result of
5 abnormal functioning of the upper and lower GI
6 tract. Disorders within this group include
7 irritable bowel syndrome, gastroparesis, chronic
8 persistent symptomatic gastroesophageal reflux
9 disease that persists despite standard therapeutic
10 interventions, and chronic idiopathic
11 constipation. Dr. Laurie Muldowney from our
12 division will be providing a bit more background
13 information on these disorders in a few minutes.
14 This is a very important meeting to us.
15 We fully understand that functional GI disorders
16 are serious conditions and that there is a great
17 need for treatments for these disorders. It's
18 FDA's responsibility to ensure that the benefits
19 of a drug outweighs its risks. Therefore, having
20 this kind of dialog is extremely valuable for us.
21 What we hear from you today can help us understand
22 how patients view benefits and how they view the

1 risk of treatments for these disorders. We want
2 to hear from you today about the different ways
3 your symptoms affect your daily life. It's also
4 important to hear from you what you value in a
5 treatment for functional GI disorders and what you
6 would like to see in future treatments.
7 It's important to remember that FDA is
8 just one part of the drug development process. We
9 do not represent the boots on the ground who are
10 actually doing the drug development or conducting
11 the clinical trials. Drug companies working with
12 researchers and patient communities are the ones
13 who conduct the trials and submit applications for
14 new drugs to the FDA. We at FDA work closely with
15 drug companies throughout the drug development
16 process. We have frequent meetings with
17 companies. We discuss early clinical trial
18 designs. We discuss the results of those early
19 clinical trials to give input on what the designs
20 for the so-called pivotal trials that will be
21 submitted to support the application for approval.
22 We also look at the safety results from those

1 trials and early safety information from animal
2 data.
3 I know there are a lot of
4 representatives from industry, academia, and
5 others in the room and on the web. We thank you
6 all for being here and being a part of this
7 meeting as well. We believe this meeting will be
8 a valuable source of information for you, too.
9 So, again, welcome everyone. I'll now
10 turn it over to Theresa Mullin who will talk about
11 our broader efforts in Patient-Focused Drug
12 Development.
13 DR. MULLIN: Thank you, Donna. And good
14 afternoon again. And as Donna said, I'm going to
15 just tell you a little bit more about this
16 initiative that we've undertaken, that this
17 functional GI disease meeting is a part of this
18 initiative for us. As Donna was saying, you know,
19 FDA's job is to assess whether the benefits
20 outweigh the risks for a given application, a
21 given new drug and a disease. And we get the
22 evidence submitted to us by the sponsor, the so-

1 called sponsor, the company sponsoring that
2 application. And they collect that information in
3 the clinical trials that they run. But what's
4 very critical for us to understand is the context
5 of this disease, and really, the severity of this
6 disease and the degree to which there's an unmet
7 medical need. That the treatments that are
8 currently available and on the market already, how
9 well do they meet that need? How well do they
10 treat that disease and that severity? And what we
11 realized is that patients -- well, you might think
12 this is kind of a, why did it take the lightbulb
13 this long to go on, but, you know, the patients
14 are in a very unique position to inform that,
15 because patients are the ones who experience the
16 disease. They are the ones who are going to use
17 the treatment. Any benefits to be gained, they
18 will be experiencing any risks they will
19 experience, and they're uniquely positioned to
20 tell us about the severity of the disease and
21 what's the most impactful aspects of the disease
22 for them, and whether or not the treatments that

1 are available, if any, are effective.
2 And so, we wanted a more systematic way
3 to get this kind of information. We have a very
4 good patient representative program, but we can
5 only -- we involve patients as individuals
6 representing the whole community of patients. And
7 they are helping us in looking at particular drug
8 applications, particular matters, as the
9 government calls it. And we also have to do some
10 conflict of interest screening for that because of
11 that particularity. We wanted to get a more
12 widespread input from patients experiencing a
13 disease, and that's why we set up these meetings.
14 And so, getting the information in this kind of by
15 disease and not by particular drug enables us to
16 have a larger meeting like the one we're having
17 today. And those of you who have come -- and
18 thank you very much for coming to this meeting and
19 being in the room and for joining us on the
20 webcast. Your perspective on this disease really
21 helps us to understand the context and make those
22 better-informed decisions both in the development

1 programs and companies coming in to talk about
2 drugs in development, and when we're looking at
3 applications.
4 So, we set this up, this Patient-Focused
5 Drug Development, that's the name we use to refer
6 to these meetings as a way to kind of pilot this
7 idea of trying to get information in, you know, in
8 the context of the disease, not in the context of
9 a particular drug application. And we're
10 committed to do at least 20 of these meetings,
11 each in a different disease area over the five
12 years of this program or the reauthorized PDUFA
13 program that goes from fiscal year 2013 to 2017.
14 And so, we started in September of 2012 right
15 before our new fiscal year, '13 was to start. Put
16 out a list of diseases, got public comment, got a
17 lot of comment on that. And the first 16 of the
18 diseases we're covering in the first three years
19 were in response to that process of getting public
20 input on our list revising it and putting it out
21 there. And this is the list that we had for the
22 first three years. And as you can see, we're

1 working our way through the lists that we had to
2 date, and here we are today covering our
3 functional GI disorders meeting. And so, as I
4 said, we really focus on the severity and what's
5 it like to live with this disease? What are the
6 most important impacts? And what are your
7 experiences with current treatments? And Sara
8 showed you that our two sessions are organized
9 around those two themes. We start out with that,
10 but we also ask the review division when our
11 office is trying to help coordinate these meetings
12 and setting them up, what other questions do you
13 want to ask? It's a very special and unique
14 opportunity for us to hear from patients with a
15 disease about other aspects, maybe clinical trial
16 participation, trade-offs that they think --
17 questions that the review division would like
18 answers to, like to hear from patients about.
19 This is a golden opportunity to ask questions like
20 that as well. So, we tailor the meetings a little
21 bit to the particular aspects of the disease and
22 treatments associated with that disease. And we

1 find that patient advocacy groups and others have
2 -- and actively helping us get the word out about
3 the meetings ahead of time has helped us to really
4 make them a success because of the increased
5 participation.
6 And finally, what do we produce? At the
7 end of these meetings, which we have the meeting,
8 we have the webcast, we have a wonderful
9 discussion here. We hear from a very rich set of
10 panelists and their perspectives. We also have
11 our docket. We leave open an electronic docket,
12 so any documents or other information that people
13 want to submit to us during or after the meeting,
14 we leave that open for at least a month or so, so
15 we can get that information in. We put all that
16 together in what we call the Voice of the Patient
17 Report. And if you go to our website, you'll see
18 the reports that we have posted there to date for
19 the meetings we've already had. And we think
20 these reports are helpful to our review divisions
21 as a sort of a reference set they can go back and
22 look at later, especially as applications come in

1 associated with that disease. Industry sponsors
2 have told us it's useful. And actually, we've
3 heard from patients who have had the diseases that
4 we've already had meetings about. And they have
5 said the reports have actually been very helpful
6 to them as well. We see them as maybe also a
7 kickoff of a way to look at more systematic
8 collection of this information that might even be
9 done during clinical trials and used as part of
10 that evidence base for deciding about whether the
11 benefits exceed the risks.
12 And with that, I'd like to turn the mike
13 over to Laurie to tell you more about the
14 background on the disease, thank you.
15 DR. MULDOWNEY: My name is Laurie
16 Muldowney, again, and I'm a Clinical Reviewer
17 within the Division of Gastroenterology and Inborn
18 Error Products. And I want to thank everybody for
19 coming today to provide us with really helpful and
20 important insights as to what it's like to live
21 day to day with a functional gastrointestinal
22 disorder. Before we turn the floor over to you

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1 all, I was asked to just provide some brief
2 background on some of the disorders that are
3 represented today.
4 So, functional GI disorders is really a
5 term used to describe a group of chronic GI
6 disorders in which patients experience symptoms,
7 but there's generally no anatomic or structural
8 abnormality. So, these diseases can affect
9 anywhere from the esophagus to the rectum, and
10 they're typically characterized by a chronic
11 course, and often with very unpredictable symptoms
12 that can be disabling to patients. There's still
13 a lot to learn about the underlying cause of
14 functional GI disorders. These are not
15 psychological disorders. The signs and symptoms
16 are thought to relate to a number of issues,
17 including abnormal intestinal motility, abnormal
18 intestinal perception, or abnormal brain/gut
19 communication. Because there are no objective
20 measures, though, for example, generally no
21 abnormalities on a colonoscopy, the diagnosis is
22 really based on patient signs and symptoms.

1 There are approximately 45 functional
2 gastrointestinal disorders. And this is based on
3 the Rome III criteria. So, the Rome criteria were
4 established by an international group of experts
5 in order to standardize the diagnosis and the
6 classification for functional GI disorders. I've
7 listed some of them here. Of course, this is not
8 an inclusive list, and Donna mentioned several of
9 these before. Irritable bowel syndrome, which can
10 further be subdivided into constipation or
11 diarrhea predominant or a mixed subtype. Chronic
12 idiopathic constipation, functional dyspepsia,
13 gastroparesis, and and functional abdominal pain,
14 again, are just some examples. Importantly, there
15 is a lot of overlap between these conditions and
16 many, many patients we know suffer from two or
17 more functional GI disorders.
18 They're incredibly common, so some
19 estimates suggest that at any one time, two out of
20 every five people in the United States are
21 affected by a functional GI disorder. And
22 importantly, they impact across every demographic

1 category. So, across age, gender, race,
2 ethnicity, and socio-economic status. I've
3 included some prevalence numbers here for some of
4 the disorders that I believe are represented
5 today, but as you can see, particularly irritable
6 bowel syndrome, functional dyspepsia, and
7 functional constipation, which we also call
8 chronic idiopathic constipation, are very, very
9 common.
10 So, I mentioned before that some of the
11 symptoms are thought to relate to abnormal
12 intestinal perception and abnormal brain/gut
13 communication, so this slide just really shows
14 sort of that brain/gut communication that I
15 mentioned. When we talk about abnormal intestinal
16 perception, we're basically just implying that
17 normal activities of the GI tract, so intestinal
18 contractions, normal things that we expect to
19 happen, cause pain or discomfort, whereas a
20 patient who is not suffering from a functional
21 gastrointestinal disorder would not perceive that
22 as painful.

1 Abnormal brain/gut communication is
2 referring to what we call the enteric nervous
3 system or the little brain in the gut. And this
4 is really just a set of nerves throughout the GI
5 tract that send signals to the central nervous
6 system and vice versa. So, in patients with
7 functional gastrointestinal disorders, these
8 interactions are impaired and patients experience
9 pain, nausea, and other symptoms when they
10 shouldn't.
11 So, some of the common signs and
12 symptoms that you all are very well familiar with,
13 pain, heartburn, abdominal distention and
14 bloating, nausea and vomiting, constipation and
15 diarrhea. We also see urgency, decreased
16 appetite, swallowing difficulties and
17 incontinence. And again, I know that's not an
18 inclusive list, but just some of the common signs
19 and symptoms that are seen.
20 So, we understand that these conditions
21 can have a significant impact on an individual's
22 quality of life. Patients are impacted, not only

1 physically, but socially and emotionally as well.
2 And misunderstanding, even in the medical
3 community, can lead to misdiagnosis, unnecessary
4 testing, incorrect procedures or treatments, and
5 worse outcomes for patients.
6 So, what are the costs for functional
7 gastrointestinal disorders? It's difficult to
8 estimate the costs, because a lot of what is seen
9 is done in an outpatient basis. But I've seen
10 numbers ranging from one and a half to ten billion
11 for direct costs. And when we think about direct
12 costs, we're basically talking about costs for
13 doctors' visits, for hospitalizations and
14 surgeries, and for medications, so things that are
15 directly related to that diagnosis. But indirect
16 costs are really even more astounding with
17 estimates of up to 20 billion. So, that's
18 including the cost of lost work days, lost school
19 days, those types of things, in addition to the
20 costs of actually seeing your doctor and taking
21 your medications.
22 It's difficult to cover the full

1 spectrum of treatments when we're talking about
2 such an array of disorders, but I was asked to
3 provide sort of an overview of some treatment
4 options. In general, dietary management is
5 commonly used for these conditions, and there are
6 a number of over-the-counter drugs that are
7 commonly used. Antidiarrheals or promotility
8 agents can be used to treat the diarrhea or
9 constipation associated with some of these
10 disorders. Proton pump inhibitors and H2 blockers
11 are classes that are often used to treat
12 heartburn-related symptoms. There are
13 prescription therapies available for some. We
14 understand that it is limited and there's a need
15 for new and more options for these disorders, but
16 lubiprostone and linaclotide are both indicated to
17 treat irritable bowel syndrome with constipation
18 as well as chronic idiopathic constipation.
19 Metoclopramde, of course, is indicated for
20 gastroparesis, and alosetron is indicated for
21 irritable bowel syndrome with diarrhea, but is
22 limited in that it's only actually indicated for

1 women and it has some restrictions because of some
2 safety concerns.
3 Off-label medication use, of course,
4 patients are sometimes prescribed antidepressants.
5 And there are also a few therapies such as
6 Zelnorm, domperidone, and cisapride, to name a
7 few, which are not approved therapies for a
8 variety of reasons, but which can be accessed
9 through special programs for patients who have
10 failed other treatment options. And finally, in
11 gastroparesis, specifically, gastric electrical
12 stimulation has been used and sometimes feeding
13 tubes are necessary.
14 So, patient-reported outcomes for
15 conditions like functional GI disorders where
16 there's no structural or biochemical abnormality
17 that we're necessarily tracking, input from
18 patients is really particularly important.
19 Patient-reported outcomes can, for us, represent a
20 direct measure of treatment benefits. So, if we
21 can demonstrate that a therapy improves how
22 patients feel or function in their daily life,

1 which, of course, has to come directly from the
2 patient, then that's a way that we can assess
3 whether or not one of these treatments is
4 providing benefit. These measurements need to be
5 well understood and evaluated in what we call
6 adequate and well-controlled trials. So, when
7 you're comparing against patients who are not on
8 the same treatment so that we can see how that
9 would compare. So, really, you know, these
10 meetings are always very important and it's always
11 really helpful for us to get insights from
12 patients and caregivers, but in a disease -- in a
13 group of disorders, like functional GI disorders
14 where we're really relying on that input to
15 determine if drugs are working or not, I think
16 it's really even more important. So, we very much
17 appreciate your time and your thoughts today. And
18 that's it, thank you.
19 DR. EGGERS: So, I'm the last FDA person
20 to speak for a while and then we'll move to the
21 patients. I just want to go over the format and
22 how this works. This meeting is quite different in

1 format and style than what you might expect from a
2 public meeting by a government agency. We're
3 happy to say that. Our intent is really to foster
4 open dialog on -- about people's personal
5 experiences living with their conditions. We are
6 going to be navigating through the spectrum of GI
7 disorders today. Our goal is not to focus on any
8 one particular condition, but to identify the
9 commonalities and perhaps the differences amongst
10 your experiences and perspectives.
11 We have the two topics. The questions
12 that are really framing our discussion are found
13 in the back of your agenda on the second page and
14 you can see those. And the first topic, again,
15 focuses on the symptoms that matter most to you,
16 which ones have the most significant impact on
17 your life? How do they affect your ability to do
18 specific activities and how they change over time?
19 What's critical to hear today is the
20 specific examples of your symptoms. How do you
21 describe them? What terms do you use? What
22 activities can you not do? What might surprise

1 FDA if they knew that you can't do this activity
2 but you really want to or you're limited in that
3 activity? And what makes a flare? And what's the
4 difference between your worst days and your best
5 days? So, we're going to get into that in just a
6 few minutes. And then, after the break, we'll
7 come back and talk about the current approaches to
8 treating functional GI disorders. And we know
9 it's a complex treatment regimen. What we are
10 going to try to tease out is what is the role of
11 pharmaceutical treatments within that treatment
12 regimen? How well are they working for you? What
13 are their downsides? What do you wish they could
14 do better?
15 For each of those topics, we're going to
16 first hear from a panel of patients. We have no
17 caregivers. They're all patients today who will
18 be coming up. And I'm going to ask those who are
19 in Topic 1 to start to make your way to the front
20 and bring your name tags, if you can. You can sit
21 anywhere up here.
22 The purpose of these panel comments is

1 really to set a good foundation for our discussion
2 by hearing brief snapshots of four different sets
3 of experiences. Each of the panelists has
4 prepared about four minutes of remarks. After
5 that, we will move into a facilitated discussion
6 and we will engage all of the patients,
7 caregivers, patient advocates in the room to
8 really build on the discussion. What's similar to
9 what you heard reflected up here? What's
10 different? We have -- staff will be coming around
11 with microphones so you don't need to get up.
12 We'll come to you. And I ask that you please
13 state your first name. We don't need your last
14 name, just your first name, every time you speak
15 so that we can capture that. And because we have
16 so many conditions, please state your disorder or
17 your primary disorder or a few disorders that
18 you're speaking about. Please try to limit your
19 responses and keep them focused to the topic
20 that's being discussed or the question that's
21 being asked, the symptom that's being talked
22 about. We hope that we, you know, get to come to

1 you several times, and so this will just help our
2 discussion move forward. I'll ask, periodically,
3 with a show of hands if you agree with what
4 someone said or if you don't agree. So, that's
5 another way we can get input.
6 We have also some polling questions,
7 which just give us a little bit more insight and
8 aid our discussion, if we can hand out the little
9 polling clickers. We have these little clickers
10 that you can push a button. We're going to have
11 some practice with this in a bit. These are not
12 at all meant to be scientific questions or a
13 polling or a survey of any kind. It's just to aid
14 our discussion. You know, who's in the room, what
15 kind of experiences you have, and where we can
16 really move the discussion. We ask that patients
17 and patient representatives only please.
18 And then, the webcast, I mentioned that
19 there's a strong showing on the webcast. And you
20 are playing a very valuable contribution to this
21 meeting. Sometimes the folks who are on the
22 webcast are slightly different in terms of

1 representation than the people in person, and we
2 hope that you're typing furiously in response to
3 the questions that we ask, and we're collecting
4 all this information. We'll be summarizing -- if
5 we don't read yours out, we'll be summarizing it
6 periodically through the day and it's being
7 captured.
8 We're also going to go to the phones
9 occasionally to give those of you who are
10 participating remotely and opportunity to
11 contribute. I ask the same ground rules apply.
12 Please keep your comments, if you're commenting on
13 the phone, tailored to the topic that we're on so
14 that we can gather a few more phone comments.
15 We also want your comments -- comments
16 from you and others who you know who haven't been
17 able to attend the meeting. Reach out to your
18 networks and get your peers and your colleagues
19 and your -- those of you in your support groups to
20 also contribute to us by sending comments through
21 the public docket. If there's something we can't
22 get to today, we didn't flesh out in detail, you

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1 can also -- we want you to comment as well. And
2 that's basically a website that you visit. You
3 click on a comment now button and you can type in
4 a comment or you can upload a Word document. If
5 you have any trouble, go to the patient- focused
6 email address that we provided. Our docket will
7 be open until July 13th. Again, these comments
8 will be reviewed by us and summarized -- included
9 into our summary report.
10 There are some more resources at FDA. I
11 just want to point out to you we have the FDA
12 Office of Health and Constituent Affairs. And is
13 someone from that office here today? Yes, in the
14 back, we have Andrea Tan. So, that office runs
15 the patient representative program that Theresa
16 talked about. So, if you're interested in
17 furthering your engagement with FDA, go find
18 Andrea and she can give you more information.
19 Within our seat of the drug side of FDA, we have a
20 professional affairs and stakeholder engagement,
21 and is Chris here? He's floating around. He's
22 also one -- you can stand up, Chris. He's also

1 one that if you have questions, particularly if
2 you're a patient organization and have questions
3 or comments or want to contribute, continue to
4 contribute, please identify him and their
5 information. These -- our web slides will be
6 posted, so you can contact them directly.
7 There are a few ground rules just to
8 make sure that our discussion is as most effective
9 for all of us involved. We really encourage
10 patients to contribute to the dialog. That's who
11 we -- that's a perspective we really want to hear.
12 Caretakers, loved ones, and advocates, we want to
13 hear your perspectives, too. If you can, what
14 your role is, is what might others that you know
15 who have these conditions, what might their
16 perspectives be, and can you round this out a bit
17 to build on what we hear from the patients who are
18 in the room. We are going to try to accommodate
19 everyone who wants to share today. And again, if
20 we don't get to everything that you want to share,
21 that's what the docket's for. Please follow up
22 with that.

1 The industry, the others in the room, we
2 ask that you stay in listening mode. There is an
3 open public comment, as we mentioned that you can
4 contribute if you have something you'd like to
5 share.
6 The FDA is here to listen. We may not
7 be able to address every question that may be on
8 your mind about drug development, about FDA. Our
9 role really is to listen to you. But there will
10 be evaluation forms, and if you have a specific
11 question, write it out there with your contact,
12 your email, and we will try to find the answer to
13 that question for you.
14 As have been described, our discussion's
15 really narrowly focused, symptoms, impact, burden,
16 and then treatment. We know that there are so
17 many issues that you face regarding diagnosis,
18 regarding getting the adequate care and support
19 that you need. We're not going to be able to
20 delve in as deeply to those topics today. Again,
21 you can tell us that through the docket, if you
22 want to explain -- provide more of your thoughts

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1 on that.
2 We also will be talking about treatments
3 throughout the day. And our discussion -- when we
4 talk about treatments, it's not our intent to come
5 out at the end of the day and say, "This treatment
6 works great. This treatment's not great." What
7 we're looking is, what is it about treatments in
8 general that you find beneficial? How do you know
9 they they're beneficial? How do you know that
10 they're working for you and what are their
11 downsides in general? That helps generally expand
12 our context.
13 The opinions expressed here are personal
14 opinions and demonstrating respect is of paramount
15 importance. This discussion is going to touch
16 upon very sensitive topics. And we respect you
17 and appreciate so much your willingness and
18 courage to share those. And everyone in the room
19 is here to support -- we want to hear from you.
20 We want to earn from you. So, we hope that you
21 feel comfortable to share your thoughts.
22 Finally, we want your feedback on the

1 meeting. What we learn here today will help us as
2 we continue to design and implement further future
3 Patient-Focused Drug Development meetings. There
4 are evaluation forms on the desk.
5 With that, okay, I guess we're on to the
6 polling questions. Does everyone have their
7 clickers? So, when we ask the question, you can
8 choose A. I think it's also 1. Or whatever
9 number corresponds to your -- to the right choice
10 for you. So, where do you live? Within the
11 Washington, D.C., metro area, click
12 A. And B, outside of the metro area. And
13 if you're on the web, you should be seeing these
14 questions as well, and you just click in the right
15 choice.
16 Okay, so we can see the results. So,
17 two thirds of you deal with the Beltway every day
18 -- one third of you deals with the Beltway every
19 day and two thirds of you have the pleasure of
20 only once in a while dealing with the Beltway.
21 So, thank you very much. And on the web --
22 MR. THOMPSON: Ninety percent outside

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1 of D.C.

2 DR. EGGERS: And the web does like that.

3 You're from all over, we hope.

4 Are you male, A? B, female?

5 We knew this coming in. We have a big,

6 robust representation from women, but as Laurie

7 mentioned, this condition affects everyone. So,

8 on the web and in the docket, if you can go out

9 and reach out to people who are men and get them

10 to share their experiences, we do -- it's very

11 important that we hear from men as well.

12 Have you or your loved one ever been

13 diagnosed as having a functional GI disorder?

14 So, for the remainder of the set of

15 questions, some of you are here with clickers,

16 you're here as a loved one or as an advocate. For

17 the purposes of the clickers, we're going to ask

18 that the remainder of these questions, that it's -

19 - every clicker is from one person, so if you're

20 the person living with the condition, you've got

21 the clicker, or if you're a caretaker and you're

22 here on behalf of someone who's not here, use the

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1 clickers. But otherwise, please keep -- no more
2 use of the clickers.
3 Which of the following functional GI
4 disorders do you have? And you know, some of you
5 here have some things other than functional GI
6 disorders. We think most of you have some form of
7 a functional GI disorder. So, you might be an
8 other. You can choose all that apply. A,
9 irritable bowel syndrome; B, gastroparesis; C,
10 chronic persistent symptomatic gastroesophageal
11 reflux despite standard therapeutic interventions.
12 I'm going to guess, if they have GERD, is this the
13 one that they -- close enough? Close enough. If
14 you have GERD, do C. D, chronic idiopathic
15 constipation. And E, some other.
16 These numbers indicate, as Laurie said,
17 many of you have multiple things. And it's great
18 to see we have reflection of -- across the
19 spectrum, some more than others.
20 On the web?
21 MR. THOMPSON: Forty-three percent
22 irritable bowel syndrome, 60 percent

1 gastroparesis, 27 percent GERD or other, and 29
2 percent chronic idiopathic, and 24 percent other.
3 DR. EGGERS: Thank you. What is your
4 age or your loved one's age? A, younger than 18;
5 B, 18 to 30; C, 31 to 40; D, 41 to 50; E, 51 to
6 60; F, 61 to 70; or G, 71 or better.
7 So, this means that we have a nice -- we
8 have a robust range in the middle in person. And
9 what do we have on the web?
10 MR. THOMPSON: A very similar range.
11 Four percent under 18; nine percent 18 to 30; 31
12 percent for both for both 31 to 40 and 41 to 50;
13 14 percent 51 to 60; and 11 percent 61 to 70.
14 DR. EGGERS: It's going to be very
15 important if advocates and if others, if you can
16 help support finding perspectives that can be
17 shared through the docket on the pediatric and the
18 older populations, that would be very helpful.
19 We're going to be staying in this discussion today
20 toward the middle.
21 And with that, we will move on to the
22 Topic 1 discussion. We're going to go through and

1 ask each of you to share your remarks. You're
2 going to push the red button, and we'll go through
3 -- there may be some clarifying questions we have
4 at the -- beyond, but unless it's a real burning
5 clarifying question, we'll probably just move
6 right into the next person. So, we will start with
7 Tanya.
8 MS. TAYLOR: Hi, my name is Tanya
9 Taylor. I have gastroparesis along with a number
10 of other of the esophageal, dysmotility, small
11 intestinal dysmotility, and colonic inertia, which
12 actually led to removal of my colon. The three
13 things -- I'm going to read what I wrote. It's, I
14 think, easier that way. The three things that are
15 most bothersome for me in this life is the pain,
16 nausea, and the inability to eat. I very rarely
17 get a hunger pain, and that started quite some
18 time ago. There are a number of specific
19 activities I can't do. I cannot go out with
20 friends and be able to keep up. And that's been
21 seven years, I guess, been seven. I've lost most
22 of my friends because of that. I do not sleep more

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1 than three hours at a time because of pain and
2 tachycardia and shortness of breath. I've been
3 unable to take normal showers for a couple of
4 years because of the weakness and blackout spells
5 that the water instigates. The routine for me to
6 get washed up is it takes a one- to three-hour
7 period for me to get washed up, because I have to
8 take too many breaks to rest.
9 And once in a blue moon, my husband and
10 I get to go to a friend's house, but I think it's
11 been several years since we've done that. We used
12 to go out and eat. That was one of our favorite
13 things to do, and we haven't been able to do that
14 for five-plus years. My granddaughter, I haven't
15 been able to take her to the park by myself. I
16 have to have an adult come with me, because I'm
17 just too weak. I'm 114 pounds now, but I was 94
18 pounds when I first started back on the IV
19 nutrition again, and you have a little more
20 strength being this weight, but I know when I was
21 94 pounds, I could even do less than I do now. On
22 my bad days, I'm not able to get dressed. I'm too

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1 weak. I generally am in the bed.

2 I haven't been able to do laundry,

3 cleaning, cooking, anything like that in I know at

4 least four years. And I used to love to clean,

5 cook, and do all of those things. On my best

6 days, it takes an hour to get washed up and that

7 includes the rest time. Putting my hair -- using

8 my muscles, I'm always fatigued and it just kind

9 of sets me back, so I have to get the energy to

10 keep up. On the worst days, I could be

11 hospitalized or throwing up constantly. I had to

12 have two Botox injections because of that.

13 And during the early stages, when I was

14 younger, I've had pain and problems the entire

15 time, constipation, diarrhea, bloody stools, all

16 of that. And having to deal with that, even in

17 high school, I ended up having to eat baby food

18 for one of the years in high school. And when I

19 was real young, my grandmother would send me out

20 back to pick mint and she would chew on mint with

21 me to get that nausea down.

22 And then as I started getting into my

1 30s -- this didn't become life threatening until
2 2007, so I am living on IV nutrition, which I have
3 with me. I stay on that during the day. If I use
4 it at night, then I have to get up and go to the
5 bathroom even more so, which interrupts that,
6 maybe, three-hour sleep I get. So, I have to make
7 sure I get sleep. And the symptoms are like a
8 roller coaster ride. They do vary in degrees, and
9 today, I'm sitting here and talking. I am in a lot
10 of pain sitting here. The nausea is, like,
11 dealing with food poisoning. And you just learn
12 to live with this stuff. Doctors will look at me
13 and not believe I'm in the degree of pain that I'm
14 in and pass me over a lot of times because of it.
15 And different things that make this
16 worse, any type of stress, whether it's positive
17 or negative, it doesn't matter. Any of it makes
18 it worse. I can have a great time and try to
19 laugh. I end up having to hold my belly, because
20 the pain's too much. When everyone else is
21 sitting around eating -- most everything in the
22 country revolves around food. There's, like,

1 there's nothing that doesn't revolve around food,
2 so it's a health issue that keeps us out of normal
3 functioning life. And for me, I was very active.
4 I had owned my own businesses. I was a single
5 parent for a long time. I'm remarried, but I have
6 no life from this stuff. Doesn't seem that most
7 people understand what's happening. And most
8 people don't think it's as difficult as it is.
9 They'll say that you can modify it with diet.
10 Everybody's different. There's not one person
11 that's the same. We might have similar issues, but
12 somebody might be able to eat one thing that
13 somebody else can't. And it's such an outlandish
14 type of illness to get a hold of that you can't
15 base, I guess, how one person is feeling on
16 another. We're not the same in any respect.
17 DR. EGGERS: Any final remarks, Tanya?
18 Final points that you want to make sure you get
19 across?
20 MS. TAYLOR: Thank you. Different types
21 of foods that if I try to eat something that's a
22 smoothie that has vegetables in it, the

1 vegetables, even if they're juiced, will turn my
2 stomach and make it into such pain that I'm on the
3 floor in a ball or I'm in my bed in a ball. So,
4 those types of things do increase it and anything
5 with preservatives and anything like that. And
6 that's all I remember.
7 DR. EGGERS: Thank you so much, Tanya.
8 And now, we'll have Cynthia.
9 MS. BENS: I'd like to thank FDA for
10 having this meeting today, and actually, for
11 inviting me to come and speak about my experience
12 as a patient with irritable bowel syndrome. My
13 name is Cynthia Bens and I live locally. I was
14 diagnosed with IBS approximately a year and a half
15 ago. And I say I was diagnosed a year and a half
16 ago, but I feel like this is something I've really
17 been dealing with since I was a teenager, all
18 through my 20s and 30s. I have a family that's
19 made up largely of boys, and not that they were
20 unsympathetic, but I was just told most of my life
21 that I had a nervous stomach. And it was mostly
22 because every time I had any sort of abdominal

1 symptoms, it was around the time that I had
2 something really stressful going on at school or
3 some really emotional times in my life, during a
4 teenager, that really just forced me to accept it
5 as a part of life.
6 And then I hit my 30s. I think this is
7 something that's probably going to be a theme. I
8 see it already. I began experiencing a lot of
9 cramping, a lot of bloating, and irregularity, and
10 it was almost a daily occurrence. The cramping
11 and bloating were so bad and they still are, for
12 the most part. And they're the two symptoms that
13 I'd say affect my life the most. At times, they
14 can be really severe. I'm doubled over in pain.
15 And on occasion, I have to miss work because the
16 cramping and bloating are coupled with loose and
17 unpredictable bowel movements. I will call this
18 from now on my major flare-ups.
19 I first started talking about my
20 symptoms with my primary care doctor. Over the
21 course of a few years, he suggested that I just
22 try to work out more and relieve stress. I have a

1 pretty stressful job. He also suggested things
2 like, oh, just take a probiotic. You're probably
3 having a lot of caffeine, cut bac on the caffeine.
4 But nothing that I really did made a significant
5 impact in my life.
6 And I started becoming really
7 emotionally distressed. I was irritable, because
8 I had almost daily discomfort. I was really
9 moody, mostly because of my growing frustration.
10 That's something from my perspective, most people
11 didn't have to think about. I'm learning that
12 that's not the case. It's just a lot of people
13 don't talk about it. But it was really sort of
14 driving my life. And there was one day that I was
15 having a major flare-up that I just sort of hit a
16 wall and I said, I need to do something about
17 this. And so, I brought up my computer and I
18 started researching gastroenterologists that
19 accept my insurance, and I just closed my eyes and
20 picked on. Not the best way to do it, but I went
21 in and I made an appointment that week. I went in
22 to see my gastroenterologist. And, you know, I

1 think that most people here realize, this is not
2 something that's comfortable to talk about. And
3 so, my doctor, when he walked in, he saw that I
4 was really stressed out about the whole situation.
5 And he said, "So, it says in your chart you're
6 here for a colonoscopy." And of course, I have a
7 really sick sense of humor, and so I laughed. But
8 it totally set me at ease and more than I have
9 with any doctor, I just laid it out on the table
10 and I said, "Here's what I deal with." And he
11 said, you know, based on my symptoms, he thought
12 that I should go for a CT scan to rule out Crohn's
13 disease. Also I had to have a fecal test, which,
14 you know, both of those are incredibly unpleasant
15 experiences. But I was able to avoid the
16 colonoscopy, because when I went for my follow-up
17 to find out what my test results were, he just
18 basically showed me the Rome criteria and said,
19 "You have irritable bowel syndrome." So, I knew,
20 at least, what I had. And, you know, like any
21 good patient I just hoped he would write me a
22 script for a pill and I'd walk out the door and

1 I'd start feeling better. Little did I know, that
2 was not going to be the case at all. And I
3 started my long journey. To really sort of
4 encapsulate what I do, most people will look at me
5 and they don't think that there's anything wrong
6 with me. But I struggle on a daily basis. I
7 don't wake up any day feeling great. I wake up
8 most days I have cramping and bloating. I have
9 bloating so bad, I can't even fit into my work
10 clothes. I just have a range of clothes that I
11 sort of pick on a daily basis what I feel like
12 wearing and what I can wear. That's if I'm well
13 enough to go to work.
14 My doctor did prescribe medication
15 called hyoscyamine. It's not really the
16 foundation of my treatment regimen at all, because
17 I speak for a living. That's what I largely do,
18 and so having dry mouth to the point of sandpaper
19 makes my job very difficult, and also it comes
20 with constipation, for the most part, so then I
21 have bloating and cramping of a different kind, so
22 it's just weighing that. But I've learned to do a

1 lot of different things. I do acupuncture. I do
2 two different types of yoga. I meditate. But the
3 most dramatic changes have been to my diet. And
4 you are right, until you have a functional GI
5 disorder, you do not realize how much your life
6 revolves around food. And from that point on,
7 your life will do nothing but revolve around food
8 and what you can't have.
9 My doctor gave me a nice stack of papers
10 when I left his office, and it was mostly, you
11 know, what foods you should try to remove from
12 your diet and what you can start reintroducing
13 back, and a nice big old 30-page sheet of what
14 sort of limitations I should make to my dietary
15 intake. And of everything I was told to cut out
16 of my diet, I can only introduce back a handful of
17 vegetables. I can only introduce back things like
18 honey. I'm hypersensitive to artificial
19 sweeteners, which are in everything. It's in
20 cough medicine. I mean, I had a cold and I went
21 and when I found out I could not have artificial
22 sweeteners, there was one cough medicine that I

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1 could take and it was not an oral, it was a pill.
2 It's a real problem.
3 And, let's see, what else? I had to
4 eliminate high fiber foods, cruciferous
5 vegetables, no alcoholic beverages. Any one or a
6 combination of it is going to trigger one of my
7 major episodes. And so, I feel like I'm that
8 annoying woman when I go out to a restaurant,
9 because there's no one plate of food that's on a
10 menu that I can actually eat. I also do a lot of
11 luncheons for my job and, you know, I eat in
12 social situations and I really can't do that
13 effectively anymore. So, in most cases, I carry a
14 bagful of snacks that I know are not going to
15 really trigger anything to the extent that you can
16 predict that. You really can't predict that. So,
17 you know, that's really sort of what my daily
18 life's been like.
19 And at least once a year, I have a major
20 flare-up, and so, I had to talk to my employers
21 about the fact that I have this condition, which
22 is a really uncomfortable conversation to want to

1 have with any of your employers. And, you know,
2 on the days that I can't go to work because I feel
3 so bad, I don't want to eat anything. I don't
4 want to leave my house. I just basically lay
5 around and hang out and, you know, get behind on
6 work. It's not necessarily that it's something I
7 feel like I'm really managing my life effectively.
8 DR. EGGERS: Any final thoughts?
9 MS. BENS: Yeah. And so, you know, the
10 one thing that I would say, I know that there are
11 people here who are developing drugs. I would
12 say, you know, please don't focus just solely on
13 certain symptoms. I know that this is something
14 that I'm managing in various ways. I don't feel
15 like I'm eating the most nutritious diets. I'm
16 afraid that I'm leaving myself vulnerable to a lot
17 of diseases, so please also don't just focus on
18 the symptoms. Try to get to the bottom of what's
19 causing it and help us cure it, because it's
20 something that I'm not the only one suffering
21 with. There's 48 percent of the people who are
22 logging on through the web. I'm just the one

1 that's up here talking about it. So, there's a
2 real need. Thank you.
3 DR. EGGERS: Thank you, Cynthia.
4 Now we're going to Carrie.
5 MS. REILY: Hi, my name is Carrie Reily.
6 I actually came down from Syracuse, New York. So,
7 we drove about -- my family and I drove six hours,
8 it's how important we deemed this. I was
9 diagnosed, finally, after years, in July. I have
10 severe gastroparesis. I did the four-hour gastric
11 emptying study, which is not fun at all. I had to
12 glow in the dark. I joked about my kids, I glew
13 in the dark for days afterwards.
14 The three symptoms that have an impact
15 on my daily life are the pain and discomfort. And
16 when I say "pain," to me it's like, my stomach is
17 trying to work. It's trying to digest that glass
18 of water I drank or cookie or pretzel I ate,
19 because I'm so nauseous. I just want something in
20 my stomach to join the pain medication. Or I'm
21 hungry and my stomach's saying, oh, it's time to
22 eat, but you can't eat, but you're hungry and it

1 hurts because you're hungry. Anybody that's been -
2 - you're starving is basically what I'm doing.
3 Discomfort is when I do drink or if I
4 drink too much or if I ate too much, my stomach
5 hurts. I mean, it looks like I'm pregnant and I'm
6 not. It hurts to move. Sometimes, it gets so bad
7 it hurts to breathe, because it's pushed up on
8 your lungs and it hurts. It hurts on your rib
9 cages. It makes you stomach hard. Wearing
10 clothing is horrible, because you have different
11 size clothing. I have my yoga pants and I have
12 four different sizes of them, because I never know
13 how I'm going to be that day. The pain is
14 temporary, but the discomfort will last for hours
15 and hours. Our society revolves around food for
16 pain, for pleasure, for social activities.
17 There's not one thing you can do where you don't
18 have food. Nothing, You can't -- you go weddings,
19 funerals, it doesn't matter. It's all food
20 related. It's hard. It's hard to be a part of
21 anything. My friends, family, they don't
22 understand this disease. And a lot of them, they

1 don't invite me to things. My family, my kids
2 don't get invited to that birthday party or that
3 meeting at school, because they know I can't make
4 it or I'm not going to be able to eat the food, so
5 the parents feel weird and don't invite me or my
6 kids.
7 My biggest problem I have lately is
8 lethargy. I have two -- my kids are nine and 12.
9 I can't do the normal mom activities. I can't
10 take them to dance lessons, baseball games. It's
11 hard for me to sit through my son's two-, three-
12 hour baseball game without getting sick. And the
13 bathrooms are either very far away or it's a port-
14 a-potty, and nobody wants to be sick in there.
15 It's just horrible. Even just to come down here,
16 I gave six hours, I had to plan rest periods. We
17 had to drive halfway, spend the night, and then
18 take off some more the next day. It's a matter of
19 -- it's not even so much that day. It's the days
20 leading up to it and the days afterwards. I know
21 that the next two, three days, I'm going to really
22 have to plan to sleep almost a whole day and make

1 sure that I have to be -- I can take care of
2 myself. I can't, to make sure, like, even going
3 to the grocery store is horribly challenging.
4 Between the smells of those wonderful free
5 samples, but even the bakery department, it's a
6 very hard thing to do and then to know that you
7 can't eat anything in there that you're even
8 buying. I still have to take care of the kids and
9 cook and clean, and it's a very, very hard thing
10 to do.
11 In the mornings are horrible. I wake up
12 in the morning, it's really bad to the point that
13 my husband had to take a different job so he could
14 be home in the morning to take the kids to school
15 for me, because I can't do it anymore. I'm very
16 limited on what I can and can't do. Everyone in
17 my family feels this. Unfortunately, my kids are
18 more self-sufficient than they probably should be.
19 They had to make -- they learned how to make
20 peanut butter and jelly sandwiches when they were
21 four, because they had to be able to feed
22 themselves something if mommy's having a bad day.

1 And it's very hard to see. My daughter couldn't
2 make it today. She's actually sitting outside and
3 walking around, because she's nine, and just even
4 reading my comments, she couldn't get through it
5 all without crying, because she's scared I'm going
6 to die. That was very, very hard, because she
7 wanted to come down and she wanted to be with me
8 and support me, but they couldn't make it -- they
9 couldn't deal with the stress of even knowing what
10 I go through. I try to hide it from them so they
11 don't know. They don't know how sick I am. You
12 know, I'm fighting with doctors on a daily basis
13 not to get that feeding tube so I don't have -- so
14 they don't have to see that. It's very hard.
15 This morning, it was unfortunate. I had
16 a cup of tea at breakfast at the hotel, because I
17 was tired. And I threw that up, and
18 unfortunately, my kids were in the room with us,
19 and it was very hard for them. Like, our family
20 vacations revolve around medical things. From
21 Syracuse, we go to Pennsylvania and go to
22 Philadelphia to go see a doctor there, because

1 there's nobody in New York that can help me. My
2 date night, that was our date night. We drove to
3 Philadelphia. It was great, you know, that was
4 our date. We don't get that kind of thing. A
5 good day for me isn't a day. It's hours. There's
6 never a day where I can say, "Oh, this is a great
7 day." No, it's, "Look, I had a couple of good
8 hours today, and will I have to pay for them
9 tomorrow or the next day?"
10 It's, you know, even on the good day
11 where I'm having those good few hours, I can't --
12 I still have to stop and rest. It's still not --
13 I still know I can't push myself. It's very hard.
14 A good day would be not to throw up all day long,
15 to have a little bit more energy and not be able -
16 - just to be able to do something to get out of my
17 house and see my kid's dance recital or my son
18 play his baseball game.
19 The bad days do outweigh the good. A
20 bad day, I can't leave my bedroom. Luckily, my
21 bathroom's right next door to it. I can't leave
22 my bathroom, my bedroom. And I'm lucky that I

1 don't end up in the emergency room, which
2 everybody does, because, of course, you say you're
3 in pain, they think you're a drug-seeker, which
4 unfortunately, we get labeled very quickly.
5 Everybody says, "Oh, I'm in pain," "Oh, wait, you
6 must mean that you have to -- you have a drug
7 problem." So, you're pushed to the back of the
8 line. They don't seem to understand that just
9 because you say the word "pain," doesn't mean
10 you're there to get drugs. It's very hard to get
11 a doctor, especially emergency room or urgent care
12 center to realize that.
13 DR. EGGERS: Any final thoughts, Carrie?
14 Final things you want to share?
15 MS. REILY: Every day is a struggle,
16 whether it's being tired and nausea and just
17 everything in general is just hard. It's the
18 pain, it's the nausea, it's having to have the
19 puke bucket in the car to make sure you get there
20 on time and you're there for your kids. Thank you
21 for having us and for doing this. Thank you.
22 DR. EGGERS: Thank you very much,

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1 Carrie.
2 And now we have Bettemarie.
3 MS. BOND: Hi, my name is Bettemarie.
4 Thank you. I want to thank the FDA for doing
5 this. And I'm honored to be here. I've struggled
6 so much with my GI condition ever since I was
7 younger. And just knowing that some of what I
8 went through might be able to help somebody else
9 in the future just makes a big difference. I have
10 a mitrochondrial disorder, and I have autonomic
11 dysfunction, gastroparesis, overall gut
12 dysmotility through my entire GI tract, esophageal
13 spasms, intestinal spasms, biliary dyskinesia with
14 a smooth muscle disorder, pancreatitis, and
15 chronic constipation. That's just to name a few
16 things. Hypoglycemia myoclonus on top of all of
17 that.
18 Due to my GI disorder, I've been on IV
19 nutrition for 25 years. And I started out
20 originally on tube feedings, however my gut did
21 not tolerate that. And so, then it progressed
22 onto TPN. And at first, I hated it. I wanted no

1 parts of it. But through family, friends, and a
2 wonderful organization for patient support called
3 the Oley Foundation, with that it helped me see
4 the TPN as an abling device and how it enabled me
5 to live my life. You know, you go from being a
6 dog on a leash all the time to actually -- to me,
7 my TPN and my PCA pump are like wings are to an
8 eagle. It allows me to be me. It gives me energy
9 to do the things that I want to do in life.
10 The pain was so severe when I was
11 younger. Oh, my goodness. And kind of just like
12 what you mentioned, from having severe pain
13 continuously, I became very good at hiding it. I
14 could look totally fine, but yet be in severe
15 pain. I was very good at joking with -- talking
16 and telling jokes as a way of distracting myself,
17 that it was hard for the doctors to really
18 understand that I was in pain. Also, the first
19 thing they go to, oh, it's stress. Take time off.
20 Next thing they go to, oh, you must be anorexic. I
21 love to eat. Oh, my goodness, if I could, I'd be
22 eating.

1 So, that's just a little bit of the
2 struggles just with getting a diagnosis. And then
3 with a lot of the testing, because it is a
4 functional GI disorder, a lot of the tests come
5 back normal until they finally get around to,
6 okay, well, what are the pressures and what's the
7 motility like. So, that took years. Like, it's
8 not something that just happens right away.
9 Thankfully, my parents took me to specialists all
10 over the country in order to figure out and to
11 determine what was going on.
12 As I mentioned, the pain was very
13 severe. I would go into Children's Hospital and
14 live in there three to four months at a time,
15 several times a year. And finally, we did a lot of
16 trials with different medications and I've had
17 numerous surgeries, but the pain continued.
18 Finally, we found one medication. I'm on a PCA
19 pump, which is -- oh, my goodness, that thing is
20 wonderful. With that I have IV pain medication.
21 And I actually use less pain medication with that.
22 I can just hit a bolus. I get a continuous rate.

1 With that and with managing techniques, I ended up
2 fighting to improve my life. And I ended up
3 working for 14 years all while connected to the
4 PCA pump and getting my TPN at night. My last few
5 years, I actually worked with my TPN running
6 during the day right in my backpack. As a side
7 effect of -- I've done very well with not many
8 episodes of sepsis, but this last few years, I've
9 had multiple episodes of sepsis and that was very
10 challenging, because with that, I've lost a lot of
11 functional ability. So energy is a big factor,
12 just being able to take a shower, take care of
13 myself. I now have a CAN that comes out and helps
14 me for 42 hours a week just doing ordinary,
15 everyday things. And as everybody has mentioned,
16 it's kind of like a give and take with what you
17 want to do. Okay, well, I want to do this, so now
18 I need to rest. But then, how is it going to
19 affect me afterwards?
20 Another big way that this has affected
21 me and my life is, as everybody's mentioned is
22 eating. Everything does revolve around food. I'm

1 just going to take it a little bit in a different
2 way. Due to my biliary pancreatic issues, I can't
3 have any fats or oils. A drop will send me into
4 pancreatitis and the severe pain and stuff. And
5 I've tried going out buying foods, however, the
6 labeling is just -- I wish it was a little bit
7 better. For example, I would buy fat free frozen
8 yogurt, but yet it would have cookie pieces in it.
9 I would eat it, I'd get bad. I'd call the
10 company. Oh, well, the yogurt's fat free, but not
11 the cookie pieces. And it's tricky. Just like
12 there's some candy, some gummy candy and Gummy
13 Bears. There no oil listed in the ingredients,
14 however, I ate it, I'd get bad. I'd call the
15 company and they'd say, "Well, oil is used on the
16 -- to coat the mold. So, it's not really an
17 ingredient, so we don't have to list it." So,
18 stuff like that is very challenging, because it's
19 still used in making the product, but yet for me,
20 I'm very sensitive and it causes a whole chain of
21 reactions. Going out to eat can be very
22 challenging. I love going out to eat. I'm not

1 eating. I'm just sitting their enjoying the meal.
2 Years ago, it was nice because I could maybe take,
3 like, a can of soup that I could have and I could
4 ask them to heat that up. Nowadays, it's harder
5 to find a place that would actually heat up a can
6 of soup for me, because you're not allowed to take
7 prepared items into the restaurants. But I do
8 enjoy the social interactions. I wish --
9 sometimes, I can get a waiter or waitress to fix
10 the soup for me.
11 Some other things, the constipation has
12 been a huge issue, the bloating, all of the
13 intestinal symptoms, the spasms. But with the
14 constipation, oh, my goodness, it's not only with
15 the motility of things moving slowly, not at all
16 moving, or even moving backwards, but physically
17 at times, I'm unable just to kind of push it out
18 whether it's soft or hard. And then, at times, it
19 feels like I'm passing razor blades. So,
20 something as simple as a bowel movement is not
21 simple at all.
22 And then, your whole GI system is

1 interconnected, so you start getting backed up at
2 the lower end, well, now that's affecting the
3 upper end and how much food you can put in and how
4 much stuff you can drink. So, it's all
5 interrelated. You kind of have to keep the lower
6 end moving if you want to try to get the upper end
7 to move. Medications can help a little.
8 DR. EGGERS: Any final thoughts,
9 Bettemarie? Any final thoughts?
10 MS. BOND: Yeah, one thing with just --
11 with the eating, sometimes it's easier -- I feel
12 so much better if I don't eat at all. Oh, my
13 goodness. But I would enjoy to eat. Sometimes,
14 if I do try to take a taste, a bite of food, you
15 know, the food tastes good. You want to take
16 another bite. You want to take another bite. But
17 usually just three bites could fill me up. And
18 then that fourth bite can just send me right over
19 the hill. So, sometimes it's just as simple as
20 that, just a little bite could cause a lot of
21 pain, but the pain is one of my biggest issues,
22 and the fatigue.

1 But thank you for trying to come up with
2 this. Oh, my, when I was younger that's all I
3 kept -- was like, okay, maybe down the road
4 there'll be a new medication. Maybe there'll be a
5 new treatment or something, but it seems like
6 there's not one thing that really makes a huge
7 difference, but it's a lot of little pieces that
8 kind of come together that help the symptoms, and
9 that just makes the quality of life during that
10 day a little bit better.
11 DR. EGGERS: Thank you so much. Thank
12 you, Bettemarie. I'm going to invite -- if you
13 want to stay up here, you can, or you can return
14 to your seats wherever you feel most comfortable
15 with, any of you.
16 I need to go get that microphone over
17 there, so give me one second.
18 I just want to thank you guys so much
19 for your courage. It's hard for me to stand up
20 here and maintain my composure while you're
21 telling about your difficult struggles you've
22 lived with for your whole life, maybe not always

1 as badly as it is now. But can I ask for a round
2 of applause to --
3 (Applause.)
4 We give them such an unfair assignment, which is
5 boil everything down to a few minutes. And I know
6 it's so difficult. We are going to be touching on
7 many of the things you talk about. Some of it
8 will be in Topic 2. But to begin the discussion
9 to just kind of set the stage, can we have a show
10 of hands to see how many of you heard, at least,
11 heard your story, your experiences reflected in at
12 least one of the women up here.
13 Anyone who -- I'm not going to ask you
14 to say it now. Anyone whose is completely
15 different?
16 Then you have represented your peers
17 well. So, thank you very much.
18 We are going to dig into this a little
19 bit more now. To start us off, we're going to
20 start with a few polling questions. And this is
21 only going to get at the tip of the iceberg, I
22 think, about what the symptoms are and how --

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1 throughout your body system. But we have here
2 focused on symptoms that are related to the upper
3 GI, the abdomen and up. And what we first want to
4 note is to see what symptoms we have collectively
5 reflected here and on the web.
6 Which of the following upper GI symptoms
7 have you or your loved one experienced in the past
8 year? You can check all of them that apply. Give
9 you a few minutes to do that.
10 Unsurprising, many, many of them,
11 looking like that the most common here are
12 vomiting and nausea and feeling of fullness,
13 followed by heartburn and abdominal pain and
14 discomfort. With those in mind, I'm going to move
15 to the next question. And on the web, first, is
16 it roughly the same?
17 MS. GIAMBONE: Yes. We had vomiting or
18 nausea as the top most experienced symptom, and
19 then we followed by abdominal pain or discomfort,
20 and bloating.
21 DR. EGGERS: So, now we want to -- we
22 knew that not everyone might experience every

1 symptom, but of those symptoms that you experience
2 now, which -- looking only at these upper GI
3 symptoms, which one of these -- or which one to
4 three of these have the most significant impact on
5 your life? And again, you can choose up to three
6 of them.
7 All right, so the abdominal pain -- I
8 don't -- the abdominal pain, most of you who said
9 that you have it have rated it as one of the top
10 three. Similarly with vomiting or nausea followed
11 by bloating.
12 And on the web, can we just get a sense
13 of what we're getting?
14 MS. GIAMBONE: Yep, similar to in the
15 meeting room, it's vomiting or nausea followed by
16 abdominal pain or discomfort, and then followed by
17 feeling of fullness or inability to eat a full
18 meal.
19 DR. EGGERS: Thank you very much. Let's
20 focus on abdominal pain or discomfort. We heard
21 very eloquently the experiences here. What I'd
22 like to hear, I'd like to hear someone build upon

1 that, the feelings of the abdominal pain or
2 discomfort. And as you describe your --
3 especially if they're slightly different. What
4 terms do you use, and how do you distinguish
5 between pain, discomfort, bloating, and all of
6 those terms? That's very important to us as we
7 try to tease apart what terms mean to people. So,
8 would anyone like to volunteer to describe that
9 symptom first? We have the mikes and they'll come
10 to you. If you can just say your name first and
11 what condition or conditions you have. We'll go
12 here and then we'll go over there. With
13 Katharine.
14 KATHARINE: Hi, my name's Katharine. I
15 have gastroparesis. First, can I just say thank
16 you for coming and talking, and thanks to the FDA
17 for even having this meeting. But the way I
18 differentiate pain and discomfort, the best I can
19 explain is the pain is -- both of them are
20 crippling, but the pain is so crippling that I can
21 end up in a ball on the floor and I can't move.
22 But discomfort, it's like a duller pain. I can do

1 things to kind of ignore it. But it's still
2 there, it's just not as severe.
3 DR. EGGERS: Is it sharp? Sharp versus -
4 - the first one's sharper than the second one,
5 discomfort?
6 KATHARINE: Yes. It's a much sharper
7 pain and it's continuous. Discomfort, it's
8 continuous, but it doesn't -- like -- I forgot
9 your name. Like you said, the discomfort lasts a
10 very long time, but the pain can come and go.
11 DR. EGGERS: I'm seeing some head nods.
12 Those of you that said abdominal pain, you want to
13 raise your hands, if that -- if you, if this is
14 your experience and perspective, well, it
15 resonates with you. Anyone have a different --
16 oh, we'll come here.
17 MS. WOLFSON: Hi, my name is Lynn
18 Wolfson, and I have gastroparesis and
19 Hirschsprung's disease and dysmotility of my
20 entire digestive tract. I find that after I try
21 to eat -- I'm on a feeding tube. But after I try
22 to eat even a very small amount, I get stomach

1 pains, but if I lay down for an hour or two after
2 I get the stomach pains, I'm able to handle them
3 and they could dissipate. But if they continue on
4 further than that, within the two hours that I
5 laid down, and generally when I lay down -- I have
6 an ostomy, my bag will fill up with gas and also
7 with fecal matter. I generally feel better.
8 However, many times I can -- many times I have
9 episodes where I just continue and the pain just
10 doesn't get any better. And there's nothing that I
11 can do. I just feel totally crippled by the pain,
12 can't do anything. There's so many times I find
13 that when I go to an ER when the pain just
14 continues for two, three days a week. And they'll
15 ask me about my discomfort. And I feel so
16 insulted when they ask me about my discomfort.
17 There's something wrong with that word.
18 Discomfort to me is a pebble in your shoe or a
19 wedgie with your underwear. It is not what's
20 happening with my abdomen. And it makes me very
21 angry for them to think that I want to spend the
22 afternoon or the evening or the night in the ER

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1 because I have discomfort.
2 DR. EGGERS: Thank you very much, Lynn.
3 You got a lot of head nods to that.
4 We'll take another one right here.
5 MS. SARRIS: I just wanted to elaborate
6 a little bit on what you were saying and what all
7 the ladies were saying. My name is Elizabeth
8 Sarris. I, too, have gastroparesis. I also have
9 GERD. I also have irritable bowel syndrome and
10 several other health issues we're not going to
11 talk about today. But anyway, I think discomfort
12 is chronic for those of us who have the diagnosis.
13 And I think for the FDA, that's good information.
14 I'm also in the health profession. So, my
15 language may be a little stronger. I think
16 abdominal -- when I hear abdominal pain, I think,
17 like this young lady -- I'm sorry, I forgot your
18 name -- said, can be incapacitating. The
19 discomfort is something we live with on a daily
20 basis. Now, whether the discomfort is horrible
21 that day or I can pull through the day with it,
22 that's variable. But abdominal pain defines true

1 pain that is, on some level, incapacitating,
2 whether it involves vomiting, ceasing activity,
3 not being able to take a shower, those are all, I
4 think, just to embellish.
5 And then, the abdominal thing pain with
6 the hospital, I recently had a hospitalization,
7 and many times what they'll do, the nurses have a
8 pain scale, right. And so, I was just going to
9 speak to the pain scale. And, I guess, there
10 hasn't been another way of identifying that.
11 DR. EGGERS: I'm going to ask if there
12 are any follow-up questions from you on pain.
13 Yes, go ahead, Donna.
14 DR. GRIEBEL: So, I'd like to follow up
15 on what you just said about the pain scale. It
16 sounds like you're frustrated with the pain scale,
17 or did I misinterpret that?
18 MS. SARRIS: I think, as health
19 professionals and as the FDA, I think we all have
20 to be good listeners. And I think we really need
21 to be tuned in to the patient, not just on a pain
22 scale basis. I think in many situations, the pain

1 scale is adequate and even more so identifying how
2 severe it is, if they can administer pain meds or
3 whatever it is they have to do. It's
4 significantly great with children. But I also
5 think that identification of what that
6 interpretation is, and perhaps part of the problem
7 is, I'm not sure how educated our medical people
8 are regarding this kind of disorder, regarding any
9 of these disorders. And so, you know, perhaps
10 there's a misunderstanding in that regard.
11 DR. EGGERS: We have -- taking, maybe
12 Tanya.
13 MS. TAYLOR: I wanted to add on to that
14 pain scale. One of the reasons I wasn't quite
15 ready today is because of this pain thing. And
16 so, I left out a lot of things because of that.
17 This pain scale, when you go in to these ERs and
18 these people have this pain scale, our pain is not
19 on that scale. Our pain is somewhere way out
20 here. So, when we can't get that across to people
21 who don't experience this, and to be in a buckled
22 over -- you are, you're in a ball. You cannot

1 move. And then have people call you drug- seekers
2 or instigate your pain to where then it's even
3 rising further because they want you in this pain
4 scale, and I truly believe it's because of the
5 lack of education. I truly believe that this --
6 oh, well, you have constipation pain. You don't
7 understand constipation pain if you've got this
8 kind of a health issue. So, I just -- for us, I
9 think that needs to be adjusted or people need to
10 understand.
11 DR. EGGERS: Carrie and Bettemarie, are
12 your perspectives similar, generally similar,
13 something different?
14 MS. BOND: One of the problems is, is
15 when you have the pain, you can hide it, is you
16 don't look like the faces on there -- on the pain
17 scale. So, I could be, like I would be bent over,
18 but yet be smiling. And so, that's where some
19 trouble can fall in with others understanding.
20 But one thing that I wanted to mention
21 that was a little different is the doctors were so
22 focused on my most severe pain with the biliary

1 and the pancreatic and that the other stuff was
2 kind of overlooked, and it wasn't until 10-12
3 years later when I saw a different GI and he said,
4 "Well, you know, it's okay. You can have
5 different types of GI pain." You know, this may
6 hurt the most, but you can have the bloating pain.
7 You can have the pain from the stuff backing up
8 and intestinal spasms and so it was just so
9 refreshing to hear a doctor admit that there are
10 different types of abdominal pain as well, but
11 usually they focus in on just the one.
12 DR. EGGERS: Thank you so much. I want
13 to make sure that we get to some of the other
14 symptoms, but it sounds like -- I'm going to ask
15 for folks on the web to write in on this, too.
16 Graham, are we getting anything from the
17 web on pain?
18 MR. THOMPSON: We're getting a lot of
19 similar-type comments, people talking about sharp
20 pain, sharp abdominal pain, or general aches in
21 the lower abdomen. A few people talking about how
22 pain is generally the sharper, and discomfort is

1 kind of more of the ache or the more manageable
2 version of pain. One person said her seven-year-
3 old describes her pain as a cramp in her belly and
4 her back. And a lot of comments like that.
5 DR. EGGERS: Okay, thank you.
6 So, please elaborate on this. If
7 there's something in the docket, this is a topic
8 of much interest. Yes, go ahead.
9 DR. GRIEBEL: Just one follow-up
10 question. So, when we're talking to companies
11 about the clinical trial and what it's going to
12 look like and how will we measure how the drug is
13 affecting symptoms, pain is a common symptom. And
14 I'm hearing pain and discomfort. If you were
15 having a day where you were not doubled over in
16 pain and you had a pain scale and you had to say,
17 what's my worst pain that I had today, but you had
18 discomfort, would you fill out that pain scale
19 based on your discomfort, or would you consider
20 the discomfort something else that you should have
21 been measuring on a different scale?
22 DR. EGGERS: Carrie, yes.

1 MS. REILY: It's two separate issues,
2 because on a daily basis there's discomfort. But
3 you could flare up and you're -- be in pain. And
4 pain, unfortunately -- if you're in chronic
5 discomfort, that pain is worse, because in a pain
6 scale, you're at that five. You're at 105.
7 You're not at five. Your discomfort is five on a
8 regular basis, and that's what they don't
9 understand is we live at that constant state of
10 five. So, when you say pain, our discomfort is
11 always at a five. You need to take into
12 consideration -- you need almost like two separate
13 scales, almost like -- people in constant chronic
14 pain versus the people who just stubbed their toe
15 and are in pain. It's two totally different
16 things. I can tell you -- my kids joke with me,
17 like, "Mommy, oh, look, I hurt my toe." I'm like,
18 "I don't want to hear about it." Like, I
19 understand, but you don't know what real pain is.
20 I live in a constant state of five, because that's
21 my discomfort level. If was going to the ER,
22 though, I wouldn't be much higher. If I'm actually

1 at a state where I have to go somewhere, I'm much
2 higher, and they don't take it seriously, because
3 you're not.
4 DR. EGGERS: Well, we have one more
5 comment here from Ceciel.
6 CECIEL: I think that question, Donna,
7 is very relative to what's going on or what has
8 happened. So, I had a severe episode of functional
9 abdominal pain last Thursday. Just happened to
10 have a full day of meetings and conference calls
11 that day. And if you had asked me on Wednesday
12 what my general severe pain was, I would have put
13 it higher than I would have on Friday when the
14 episode wasn't as bad because in my memory was the
15 day before. So, I think that if you ask the
16 patient to look at the scale and say generally
17 speaking where are you at, if I had just had a
18 severe episode yesterday, then I'm going to tell
19 you, oh, I'm great today, because this isn't
20 yesterday. So, I think that that's relative and
21 it's really hard in dysfunctional GI, because you
22 get away from a severe episode and so some of us -

1 - I'm so sorry for your pain all the time. I
2 don't have it all the time. But when I have an
3 episode, it's bad. And in my -- in the work that
4 I do, there are certain times when I have lots of
5 meetings and a lot of things going on that I can't
6 afford to have an episode. Generally, that's when
7 it happens, right? But because this is a roller
8 coaster ride, you can ask me the same set of
9 questions today, ask me again next Monday, and ask
10 me again the next Monday, and I'm going to answer
11 it differently every time.
12 DR. EGGERS: There one question from
13 Laura.
14 DR. MULDOWNEY: So, frequently, when we
15 do clinical trials, we ask people to fill out
16 these scales every day. So, because we understand
17 that it can be very variable from day to day. And
18 a lot of times, our question is, what was your
19 more severe pain in the last 24 hours? But my
20 question is to you is, do we need to be evaluating
21 pain differently? Do we need to be asking
22 different kinds of pain? Are there different

1 kinds of pains you have that need different
2 questions? Should it just be one question, how
3 severe was your pain? Or do we need more focused
4 questions?
5 DR. EGGERS: Then we'll go here and then
6 we'll come to the striped sweater.
7 DEBBIE: Hi, my name's Debbie. I have a
8 diagnosis of gastroparesis and several other GI
9 issues, but I do think, for me, what I experience
10 most often is, like a diffuse low burning and a
11 sort of sour acidic feeling in my stomach. And I
12 think what I'm hearing is that, you know, some
13 people have really severe pain that's very
14 disabling to where you're doubled over, but a lot
15 of us with functional GI problems have chronic,
16 ongoing severe discomfort that lasts for a lot of
17 -- you know, like our waking hours, and is very
18 debilitating in terms of doing things like
19 socializing and being able to concentrate at work.
20 But, like, I would never rate my pain, like, as
21 eight or nine or ten. So, it does seem like it
22 would be really helpful when drugs are being

1 evaluated to not just get at the most severe pain
2 that you've had that day, but how much it's
3 relieving the sort of background, ongoing chronic
4 discomfort that a lot of these disorders cause.
5 MARY: My name is Mary and to address
6 that question, I would think rather than just
7 using, like, the Baker-Wong Pain Scale, that there
8 needs to be more descriptive terms as well. I
9 mean, yes, it is sharp and writhing at times.
10 Like, for me, on an average day, I live with a
11 discomfort level between a one and a two. But on
12 my really bad flare-ups, I have gastroparesis,
13 IBS, and GERD. I'm at an -- so I would think that
14 for evaluation of drugs that there needs to be
15 more descriptive terminology for people to be
16 able, okay, is it sharp, is it burning, is it
17 achy, is it -- you know, those kind of things need
18 to be in there as well, rather than just the
19 regular one to ten scale.
20 DR. DIMICK: So, maybe we need to ask
21 descriptive terms and we need to ask things like
22 not just how severe it was, but how disabling it

1 was, how many hours during the day it lasted?
2 MARY: Exactly.
3 DR. DIMICK: All these more pointed
4 questions.
5 MARY: Exactly.
6 DR. DIMICK: Because it's different day
7 and night. How much did it interfere with your
8 sleep?
9 MARY: We heard from the audience
10 daytime and nighttime.
11 DR. DIMICK: Yeah, so, like, how much
12 does it -- did it interfere with your sleep last
13 night?
14 DR. EGGERS: We'll take one more and
15 then I'll -- if there's no more questions, it
16 looks like, so we'll take one more here.
17 JILLIAN: I'm Jillian. I have
18 gastroparesis. I have lived with these symptoms
19 for all of my life. And I think, to some extent,
20 I have to be coached as to what pain is. I have
21 severe GERD and if you asked me if it was painful,
22 I would never say yes, because I've always lived

1 with it. I mean, to me, that's not pain. So,
2 when you have something you're dealing with for
3 such a long period, it may be painful to most
4 people, but to someone who's living with it, it's
5 just there. Not to erode the discomfort or pain
6 levels that anybody's feeling, but I just know I
7 don't consider it pain anymore after such a long
8 period of time.
9 DR. EGGERS: Andrew, did you have a
10 question?
11 DR. MULBERG: For the last string of
12 comments regarding pain and how to measure it, can
13 people comment on functioning? And are there any
14 common themes of not being able to function that
15 we can understand? It seems the numbers don't
16 correlate with people's perceptions of their pain.
17 UNIDENTIFIED VOICE: We're saying that
18 it should go with the numbers because somebody
19 could not be able to function at, say, ten, where
20 some people have pain all the time. They --
21 somebody that has pain all the time can function
22 at a ten, where somebody with the same pain

1 occasionally can't function when at a number two.
2 DR. EGGERS: Are there specific types of
3 functioning that -- when you say functioning --
4 UNIDENTIFIED VOICE: When you get the
5 pain constantly, you can function and tolerate
6 more amounts of pain, and that could be a ten for
7 somebody. And they may rate it as a two, because
8 they're able to function. Where somebody else
9 could have that exact pain would rate it as a ten
10 and not (indiscernible).
11 DR. EGGERS: So, it sounds like you're
12 saying at least it has to go hand in hand.
13 UNIDENTIFIED VOICE: Yes.
14 DR. EGGERS: We have one there and then
15 --
16 DEBBIE: Yeah, I was just going to say
17 that I think there are so many areas that the
18 discomfort can cross that it would be pretty easy
19 to ask people to rate to what extent it affected
20 their ability to fall asleep, their ability to
21 concentrate at work, their socializing with
22 friends, their ability to eat meals. I think you

1 could easily come up with five or ten activities
2 of daily life that participants in clinical trials
3 could be asked to rate the extent to which they
4 suffered, you know, inability to do those things
5 or their symptoms were relieved.
6 DR. EGGERS: I'm going to -- unless
7 there's any burning questions from here about
8 pain, I think we should move on just for the sake
9 of time. I'm never really quite the most popular,
10 because I'm always saying we have to move on, but
11 there is the docket and on the web, and so,
12 continue to write this in. It sounds like we
13 could have spent all day on just this issue.
14 I do want to touch upon the vomiting and
15 nausea. We did hear some of it up here. Does
16 anyone have an experience with vomiting and
17 nausea? Again, think about how we talked about
18 pain. What terms do you use to describe that
19 feeling that you'd want to share? We're going to
20 go right here. We haven't heard from you yet.
21 MS. PASINKOFF: Hi, my name is Carol
22 Pasinkoff. I have severe gastroparesis, and I

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1 suffer from unrelenting nausea all day. I take
2 any medicine, anti-nausea medicine that's out
3 there, and it doesn't even come close to helping
4 me with my nausea. I mean, I always explain it to
5 people, like, think about when you have a stomach
6 flu, and it's like, you're throwing up and you're
7 so nauseous and you can't move and you don't want
8 to get out of bed. Well, this is what I live
9 with. It's like being seasick all time. It's
10 like being -- having a stomach virus all the time.
11 It just doesn't want to go away. It's brutal.
12 You know, in the beginning, I was vomiting a lot.
13 We managed to get a handle on my vomiting, but the
14 nausea, nobody has been able to come up for
15 anything for me for nausea. It's terrible.
16 DR. EGGERS: We have -- we'll go to
17 Katharine.
18 KATHARINE: I, too, have nausea on a
19 daily basis. It goes up and down from the moment
20 I wake up in the morning to the time I go to bed.
21 I'm woken up in the middle of the night because
22 I'm nauseous, and sometimes I have to puke. My

1 vomiting has been under control since I first got
2 gastroparesis. But, yeah, you can't go out
3 anywhere. You can't do anything for the fear that
4 you're going to just end up vomiting right in
5 front of everyone, or you can't concentrate. You
6 can't focus because that nausea, too, is just so
7 debilitating. I can't focus on classwork. I
8 can't enjoy conversations, because that nausea is
9 just, like she said, it's there all the time.
10 It's like being sick all the time.
11 DR. EGGERS: We'll go back here.
12 DEBBIE: This is again about
13 gastroparesis. I suffered from nausea from my
14 other GI issues, but about five years ago, I
15 started having incredible, unrelenting severe
16 nausea. The only time I felt good during the day
17 was the first hour that I was awake when my
18 stomach had been empty for about 12 hours. I
19 would take my Zegerid, which I take for gastritis
20 and GERD, and in about an hour when I had
21 breakfast, within a half an hour to an hour, I
22 started feeling nauseous. With each subsequent

1 meal that I ate, it got more severe to the point
2 that by the early afternoon, I just really felt
3 horrible. It is so debilitating, and I didn't
4 really, at first, realize that it was associated
5 with eating. Once I did, I had a gastric emptying
6 study done, and I was immediately put on
7 domperidone, and I have to say I'm so thankful,
8 because I got immediate and 100 percent relief
9 from the nausea. As long as I take a capsule
10 before I have my lunch and dinner, I have not
11 experienced any nausea in the last four and a half
12 years since I've been taking it. So, I just want
13 people to know about that for those who are
14 suffering with nausea, it really is so miserable.
15 And you don't look like you're in misery, and
16 especially, I didn't have any vomiting, so I
17 didn't really look like somebody who was
18 suffering, but it really is miserable and it did
19 impact so much of my life. And to be put on that
20 drug and to have such relief with no side effects
21 has really been so helpful to me.
22 DR. EGGERS: We'll be talking about the

1 treatments in the second half of the course. I'm
2 going to take one more on nausea with Meredith.
3 MEREDITH: I have gastroparesis and
4 chronic unexplained nausea and vomiting. To the
5 nausea, my first gastroenterologist told me early
6 on that he thought chronic nausea was one of the
7 most demoralizing physical sensations a human
8 being could experience. And I really felt that as
9 to be very true. I equate chronic nausea as very
10 similar to chronic pain. It interferes with your
11 functional activities. My nausea, until I had
12 relatively successful treatment, was so bad and
13 vomiting upwards of 20 to 30 times a day. I kept
14 little Zip-loc baggies on my person all the time
15 so I could lean over and puke into a Zip-loc bag
16 and zip it up and throw it into the nearest trash
17 can.
18 A couple of other points about vomiting
19 and nausea, the closest I've ever come to dying
20 from my gastroparesis was actually -- I inhaled at
21 the same time I was vomiting. I almost choked on
22 my own vomit. That's a very scary thing.

1 And the last point about vomiting and
2 nausea, one of the long-term consequences of
3 vomiting 20 to 30 times a day for several years in
4 a row is, we were talking about this at the table,
5 is I've experienced significant dental decay. I
6 am 38 and I'm moving towards full prosthetic teeth
7 in the next couple of years. So, there are long-
8 term consequences as well.
9 DR. EGGERS: We want to move on. I just
10 want to see, does this resonate -- the experiences
11 about nausea have resonated. If you have more,
12 please, again, write about it in the docket.
13 On the web, are we having any comments
14 on nausea, vomiting?
15 MR. THOMPSON: A lot of similar comments
16 that people have -- either their in constant
17 states of nausea. They don't think of nausea as
18 pain. They associate often with vomiting. One
19 person talking about her child said that she
20 describes her nausea just as feeling sick. And if
21 it progresses to a low moan, it means that she's
22 about to vomit. And a lot of similar comments.

1 DR. EGGERS: Thank you. I'm going to
2 ask the panel if there's any questions on any of
3 these symptoms that you'd like to know more about
4 or why people raised them. Yes?
5 DR. KOVACS: Meredith, you mentioned
6 that you vomit 20 to 30 times a day, and I just
7 had a question. Are you counting the number of
8 times that you physically, let's say, go to a
9 toilet to vomit, or the number of times something
10 comes out in that one episode at the toilet?
11 MEREDITH: It would include maybe what
12 would be described as regurgitation, so any time
13 something came from my stomach into my mouth. And
14 I stopped going to the toilet, because it was
15 exhausting to go 20 or 30 -- that's why I carried
16 around the Zip-loc bags.
17 DR. EGGERS: Another question? Lara?
18 DR. DIMICK: It sounds to me like we
19 obviously need to evaluate nausea with several
20 questions by itself, you know, duration, is it
21 constant, is it intermittent, you know, how
22 (indiscernible) is it, how much does it interfere

1 with you functioning in social -- socially and
2 (indiscernible) vomiting, also not only number of
3 episodes, but amount. Although, that might be
4 very difficult to quantify, but I mean, it seems
5 like -- because some people have mostly nausea and
6 some people have mostly vomiting that maybe you
7 could help us on the web to think about the
8 questions that would be helpful for you to be able
9 to explain it.
10 DR. EGGERS: I really encourage you to
11 do this homework assignment. Write down the
12 questions. You can send multiple comments to the
13 web. We don't care how often you hit that comment
14 now button. Just jot them down to answer this
15 question. I think it's really important. Lara --
16 Laurie.
17 DR. MULDOWNEY: And this is actually not
18 on this slide, but it's not on the next one
19 either, I don't believe. But I heard a theme
20 about just overwhelming fatigue. And I was just
21 curious. I think I heard that from a lot of the
22 patients suffering from gastroparesis, if that is

1 something that everybody is experiencing,
2 particularly those of you who may not have
3 gastroparesis as well. I'm interested if that
4 sort of covers everybody.
5 DR. EGGERS: Is the fatigue -- can I ask
6 a follow-up question to that? Is the fatigue
7 because of -- primarily because of some of your
8 other symptoms that just expend your energy and
9 cause your fatigue, or is it something even when
10 you don't have the symptom, even you are -- have a
11 more average day, not maybe in an intense flare-
12 up, is the fatigue still present?
13 UNIDENTIFIED VOICE: (Indiscernible).
14 UNIDENTIFIED VOICE: But even on the bad
15 -- the good days, you still are fighting some form
16 of fatigue. All of us with chronic illnesses know
17 about the spoon theory. You have to save your
18 spoons and count which spoons you're going to use
19 for what -- you know, if I do this, then tomorrow,
20 am I going to be able to do that? No, maybe not,
21 you know. So you have to make judgment calls.
22 And sometimes that means missing things you really

1 want to do, but it is what it is.
2 DR. EGGERS: Down here.
3 MEREDITH: I have lots to say about
4 this. I just wonder if a lot of -- some of the
5 fatigue that we experience with functional GI-
6 related disorders is related to nutritional
7 deficiencies that we develop, like anemia. It's
8 exhausting if undiagnosed and untreated.
9 DR. EGGERS: We'll go to Katharine and
10 then we're going to go to Carrie, and then I think
11 we'll move on.
12 KATHARINE: I was just going to expand
13 on the malnutrition. I've lost about 20-some
14 pounds since this started, and I was only 117 at
15 first. So, the fatigue, even on good days, it's -
16 - like you said, even on good days, there is
17 fatigue, a lot of it. It's hard being able to
18 exercise, which everyone suggests to do to help
19 with the symptoms. You know, with class again,
20 I'm tired in class all the time. It's hard to
21 focus because of the fatigue, but I think it's a
22 lot of the malnutrition, not being able to eat.

1 DR. EGGERS: Thank you, Katharine.
2 We'll go to Carrie.
3 CARRIE: With the fatigue, whether we
4 have the vomiting or the nausea, you can't eat.
5 So, even if you feel like you're going to throw
6 up, you're not going to want to eat anything. So,
7 you're not getting those necessary vitamins. And
8 it isn't just like a one-time thing. The vitamins
9 built up in your system, so you may not eat for a
10 couple days. Well, those vitamins, you depleted
11 your supply, so it's a -- it will take you two
12 weeks just to build back up to where you're
13 supposed to be. So, whether you're having a good
14 day or a bad day, you're still depleting that
15 little supply you already have and it's really
16 hard to keep that balance. I suffer from all the
17 time, my doctors are constantly, like, oh, you can
18 use this vitamin, you need this vitamin. And the
19 thing is, those vitamins, they're not easy to
20 digest either themselves. I mean, they're
21 horrible to take and taste horrible, which makes
22 you want to throw them up. I mean, I, myself, have

1 switched to liquid vitamins, chewable vitamins.
2 And it's just trying to find ones that I can
3 actually keep down and keep my levels up without
4 having to get the IV fluids or the liquid
5 nutrition. It's even -- it's just really hard to
6 keep the levels up and sustain them, because they
7 get -- that's why we're constantly tired, because
8 you don't keep your vitamin levels high enough.
9 And they say the best source of Vitamin D is the
10 sun. Well, I can't go outside in the sun. Just
11 to walk outside and you get outside to be in the
12 sun is exhausting. It is a constant battle to see
13 and keep where you're supposed to be because of
14 this pain. You can't eat because you're in pain.
15 You can't eat because you're nauseous. It's just
16 a combination of everything that we face on a
17 daily basis, you can't keep that nutrition where
18 it's supposed to be.
19 DR. EGGERS: I want to be fair -- one
20 more. Is it a different perspective? Okay, we'll
21 take one more and then we're going to move on to
22 the lower GI symptoms.

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1 LYNN: My name is Lynn, again. I find
2 that I have to take a minimum of a two-hour nap
3 every afternoon. Generally, by two o'clock, I'm
4 done. I have to rest from 2:00 to 4:00. I do
5 find there are certain things that, if I need to
6 get through the day, like today, that I do. For
7 instance, I went swimming this morning. So, I do
8 swim 16 laps in an Olympic pool or I go to
9 aquasize class. I also go to acupuncture and
10 massage once a week. And I find on those days
11 when I have acupuncture and massage and/or that I
12 swim, I find I can go a little further, and eat
13 very little on those days as well.
14 DR. EGGERS: We'll be following up on
15 these non-pharmaceutical treatments after a bit.
16 It is at the time when the agenda says
17 we would be taking a break, but if you all give us
18 permission, we're going to go until three o'clock
19 and then we'll take a break, but please feel free
20 to get up if you need to, whenever. I do want to
21 make sure we get to the other symptoms and then
22 talk about a wrap-up on this topic.

1 So, can we go to the next slide. And if
2 you're on the phone, we're going to be teeing up
3 the phone. And since we're so limited on time
4 with the phone, if you were looking for comments,
5 we would welcome your comments on symptoms and
6 ways that you experience the symptom that has not
7 been mentioned yet. We're teeing that up. We'll
8 come at the end of this brief discussion here on
9 the lower GI-related symptoms.
10 First, we just want to know what is
11 experienced in the room. So, we're going to ask
12 to choose all that apply. Which of the following
13 lower GI-related symptoms have you or your loved
14 one experienced in the past year?
15 So, many of you experienced many things,
16 the most frequent being the gas or flatulence.
17 And on the web, what are we getting?
18 MR. THOMPSON: Similar results.
19 DR. EGGERS: You've really tested my
20 abilities there. So, let's now go on to the next
21 one. So, given what you experienced, which have
22 the most -- of these, of these symptoms, which has

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1 the most significant impact on your life? Choose
2 up to three symptoms.
3 So, the gas or flatulence comes out as
4 the number one -- the most frequently mentioned
5 here, followed by hard or dry stools and sense of
6 urgency. Okay, so you -- we won't be able to cover
7 all of this in the next few minutes, but we'll do
8 as best we can. And on the phone, what are -- on
9 the web, what are we getting?
10 MR. THOMPSON: A little bit different,
11 about 40 percent for the frequent, loose watery
12 stools, hard or dry stools, or rectal pain.
13 Sixty-six percent gas or flatulence and about 20
14 percent for the other three.
15 DR. EGGERS: So, I think -- I'm going to
16 turn to my colleagues. Is there a symptom that
17 you would really like to know more about why they
18 -- how they conceptualize it and why they picked
19 it? Should I go with the gas or the flatulence?
20 I don't think we heard about it as much up here,
21 so let's hear -- can someone explain how they did
22 it? Let's come here first.

1 JILLIAN: So, as insignificant as it
2 sounds, gas is extraordinarily painful if it's
3 stuck and if you have gastroparesis, it does not
4 move. And it doesn't -- it's just like having
5 food in your gut. That's the reason for the
6 bloating and the abdominal pain.
7 DR. EGGERS: So, it's contributing to
8 the symptoms that we talked about in the first
9 part of the session?
10 JILLIAN: Correct.
11 DR. EGGERS: I'm getting a lot of head
12 nods.
13 JILLIAN: Because then you get backed
14 up. You get nauseous. It's a vicious cycle, and
15 so, I don't perceive in my situation personally, I
16 don't perceive gas any less threatening than food.
17 I still feel the discomfort we talked about that's
18 chronic. I still can have abdominal pain from it.
19 It's not moving. We have a paralysis of sorts.
20 So, you know, that's --
21 DR. EGGERS: Thank you very much. Any
22 different experiences or different

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1 conceptualizations of the gas or flatulence?
2 We'll go with Meredith.
3 MEREDITH: I just am wondering how much
4 research needs to be done on gas and flatulence.
5 Is it really just a small bowel bacterial
6 overgrowth that seems to be a fairly constant
7 thing amongst those with lower GI dysmotility or
8 even upper GI dysmotility.
9 DR. EGGERS: Okay. Did we get any
10 comments on the web regarding this?
11 MR. THOMPSON: We had a few people say
12 that gas and flatulence can be very painful. It
13 can cause severe bloating, that it's embarrassing
14 and makes it difficult to go out in social
15 situations and things like that.
16 DR. EGGERS: Okay. Then I'm going to
17 suggest we -- oh, go ahead, Bettemarie, you go
18 ahead while I'm formulating the question to ask.
19 MS. BOND: Just on a different note, not
20 about the gas or flatulence, but this may sound a
21 little strange, but when things don't move at all
22 and it gets so backed up, I did a prep for the

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1 colonoscopy, and I had to do a two-day because I'm
2 so backed up and I didn't even go with that stuff.
3 Over- the-counter medications just cause a lot of
4 spasms and just increase the pain drastically.
5 Not many medications really help, but I would
6 actually have to -- I wouldn't go unless I had
7 enemas. And then eventually, they were working
8 less and less, but I actually had to plan when I
9 was going to get an enema. Like, it sounds kind of
10 strange, but you just get so uncomfortable. And
11 then, as I mentioned before, the one just kind of
12 then triggers other problems and other issues.
13 It's just a different take on it.
14 DR. EGGERS: Can anyone explain -- we
15 haven't heard sense of urgency described in as
16 much -- we heard a little bit up there, but I want
17 to make sure, are there any different
18 conceptualizations other than what was described
19 on the panel for how you think about that and why
20 it got rated?
21 KATHARINE: You were talking about sense
22 of urgency?

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1 DR. EGGERS: Yes.
2 KATHARINE: Okay. With a sense of
3 urgency, just for me, is that if it hits, I got to
4 go, because if I wait, it causes so much more pain
5 and then I can't go later. I can't go at all.
6 So, you need to go when you need to go. And then,
7 working retail or working anywhere, you can't just
8 get up and go to the bathroom when you need to.
9 DR. EGGERS: Tanya.
10 MS. TAYLOR: I had that written, but I
11 didn't touch on that. That sense of urgency, and
12 as for most of the -- I know I have fecal
13 incontinence. If I cannot get to the bathroom,
14 I'll just -- there are times that I don't even
15 know I'm going and I'm going. And this -- when
16 you get to severe stages of this, the colon acts
17 like a plug. And not one -- so, when they took
18 that colon out, this is not -- this information
19 needs to be discussed and it's not being
20 discussed. There was not one cell in the colon
21 that was functioning. They weren't dead. They
22 were just in a state of paralysis. So, the organ

1 itself looked perfectly healthy. So, to the naked
2 eye, to a colonoscopy and a laparoscopy, you could
3 never tell that the colon was not functioning.
4 So, when they had to -- I had that removed after
5 the perforation, for at least 10, maybe 15 years,
6 I had to move the food through my colon when I was
7 able to eat. And unfortunately, my small
8 intestine is slowing like the colon did, but if
9 these cells aren't functioning and we're losing
10 organs and it's acting like a plug, and so, you
11 said, I mean, you can't get cleaned out. You
12 can't go to the bathroom. I guess that what gets
13 these cells started again, is there something that
14 maybe can be a drug or something that can be
15 looked at to get the cells to begin to function
16 again to get the organ to function again?
17 DR. EGGERS: Thank you very much, Tanya.
18 So, I want to make sure we get to the
19 phone. Are there any phone -- okay, we have no
20 phone. Okay.
21 I'm going to give -- if anyone on the
22 FDA has a final question before we move into the

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1 break.

2 MS. BREZOCZKY: Hi, my name is Kelly

3 Brezoczky, and I do clinical research in this

4 particular area. And I would just encourage the

5 FDA, as you look at lower GI-related symptoms that

6 you also explore language here. You know, these

7 are very difficult topics for people to describe.

8 And I think we had a very rich, robust discussion

9 about pain and discomfort and different ways that

10 people feel that. When it comes to the particular

11 symptoms of the lower GI tract, incontinence is

12 not a word that's patient- friendly. And even if

13 you look at the NIH studies that have been done to

14 understand what's happening with leakage in the

15 lower GI tract, the question in the Haynes

16 research is, have you experienced any accidental

17 leakage of liquid or solid stool? And so,

18 incontinence is a big word that people tend to

19 correlate with heavy bowel movements or loss of

20 full bowel control. And often the symptom isn't

21 necessarily that. It can be accidental-type

22 leakage of smaller volumes, not necessarily larger

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1 volumes. And so, I would encourage you to really
2 look at some of the research that's been done in
3 this area as you're looking at that particular
4 symptom, because I think incontinence is a really
5 big word that, unfortunately, many people do not
6 relate to. But yet, if you turn around and ask,
7 well, do you experience any accidental leakage of
8 liquid or solid stool, everybody will raise their
9 hand.
10 And I really commend -- I think it's
11 Tanya, for actually raising this, because I think
12 this is one of the symptoms that nobody likes to
13 talk about. Nobody likes to say or hear the word
14 fecal incontinence. And I've done a lot of
15 research in this area that I'll speak later about.
16 But I just think this is a really important
17 symptom that we get the language right as we work
18 to improve outcomes for this population.
19 DR. EGGERS: Thank you very much. And
20 what was your name, again?
21 MS. BREZOCZKY: Kelly Brezoczky.
22 DR. EGGERS: Kelly, thank you very much.

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1 We're going to move into the break, but
2 what I want to -- if I can say, from our
3 perspective, the planning team, we get so much out
4 of the summaries that get sent to us to help
5 identify who's going to be on the panel, because
6 you use the terms that you want to use that
7 connect with you. So, as you -- there are so many
8 symptoms we didn't get to talk about. As you
9 describe them, if you write to the docket or as
10 you're putting on the web, use the terms that make
11 sense to you and we'll figure out what you mean,
12 rather than feeling like you have to use technical
13 terms, because it's more important, to your point,
14 that we know how you are conceptualizing and how
15 you are feeling and how you are speaking about
16 this with others and with your doctors.
17 So, with that, we'll take a 15-minute
18 break and start again at 3:15. Thank you.
19 (Break from 2:57 p.m. until 3:07 p.m.)
20 DR. EGGERS: -- the Topic 2 panelists to
21 work their way to the front.
22 All right. We have a lot more ground to

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1 cover, so I'm going to ask that we get started.
2 The format of the afternoon is just like the
3 format of the -- I mean, the format now is just
4 like the format earlier. I do want to mention one
5 thing that we got from the web. I just want to
6 point out that we had an overwhelming response to
7 the question about fatigue. And so, it sounds like
8 we could have had a lot -- well, we could have had
9 a lot more discussion on any topic. But on that
10 one, too, so, if those on the web, and you hear
11 fatigue is one thing really to discuss further in
12 the docket.
13 We have five panelists to kick off our
14 discussion of Topic 2 on the treatment approaches.
15 And so, what we're looking here, and again, the
16 questions that were guiding our discussion on the
17 second half of your agenda is what you're
18 currently doing to treat your condition and
19 symptoms and what specific aspects of your
20 condition that that addresses, and how well does
21 it do so? And the downsides to those treatments.
22 And then, an ideal treatment.

1 We are going to be covering a wide range
2 of treatments, pharmaceutical, surgical, devices,
3 et cetera. As we go through, we'll try to pull
4 out as much as we can, the role of pharmaceutical
5 treatments in that. But we have five great panel
6 comments to get us started, and we have someone
7 who is participating on the phone, and so, I'm
8 going to start with her. Her name is Anne. Anne,
9 are you on the phone?
10 MS. SIROTA: Yes, I am.
11 DR. EGGERS: Again, we've asked them
12 each to prepare a few minutes of comments, so,
13 Anne, we would love for you to kick us off. Thank
14 you.
15 MS. SIROTA: Thank you. Thank you for
16 having me speak. I was diagnosed with diarrhea
17 predominant IBS 26 years ago after a month-long
18 bout of diarrhea. Today, I continue to have
19 frequent, at times, daily diarrhea, urgency,
20 abdominal pain, heartburn, bloating, and
21 incontinence. Over the 26 years that I've had
22 this, I have alternated conventional medicine

1 treatments and complementary medicine approaches.
2 I have tried different dietary protocols, taken
3 prescription and over-the-counter meds, tried
4 acupuncture, homeopathy, chiropractic, Chinese
5 herbal remedies, supplemental vitamins and
6 minerals. I get temporary relief, but none of the
7 treatments have been permanent or even last very
8 long.
9 In the first few years, I first tried a
10 restricted diet, and I took Xanax, Lomotil,
11 Imodium, anti-spasmodic, and some fiber products.
12 When those didn't work, I tried complementary
13 medicine approaches. The Chinese herbs were the
14 most effective, but they were very difficult to
15 take, and I wasn't sure they were safe. And then
16 I couldn't take them because of insurance issues
17 and I had to stop.
18 Over the 26 years, I also took part in
19 several studies that included support groups,
20 hypnosis, and therapy sessions specifically for
21 IBS, which included reading information, breathing
22 techniques, and meditation practice. Some were

1 more effective than others, at least temporarily.
2 I also tried anti-depressants.
3 Desipramine, which has scary side effects, so I
4 didn't take it. Lexapro, Cymbalta, Wellbutrin.
5 They didn't really help.
6 In between each alternative treatment, I
7 would go back on the Imodium. So, it some ways
8 it's the most reliable for short-term relief. It
9 also has the rebound effect and I developed a
10 tolerance to it, so I have to keep taking more and
11 more.
12 A few years ago, I was taking Verapamil
13 for palpitations and found it to be very effective
14 in controlling the diarrhea and the pain. This
15 was probably the longest lasting relief I ever
16 had, but the Verapamil has some dangerous side
17 effects and I had to stop. And then the diarrhea
18 came back worse than ever. Again, I tried
19 acupuncture, hypnosis, Chinese herbs. And then I
20 went back on Imodium. Again, it didn't work
21 completely and I was getting a rebound effect.
22 Over the past three or four years, the IBS has

1 become progressively worse. I've had multiple
2 episodes of diarrhea, urgency, some incontinence,
3 abdominal pain, gas, bloating, heartburn, a little
4 bit of nausea.
5 Two years ago, I was taking up to eight
6 Imodium caplets a day, though they did not always
7 work. I still had diarrhea almost every day,
8 sometimes more than once. Two years ago, in the
9 fall of 2013, I consulted with a naturopath. She
10 prescribed several supplements such as probiotics
11 and vitamin support and some minerals. Two of the
12 supplements, glutamine and activated charcoal
13 seemed to have the most immediate relief. The
14 naturopath believes that taking Imodium, as much
15 as I do or as much as anyone does, may make it
16 harder for the GI system to heal properly.
17 The naturopath also put me on a low
18 FODMAP diet. FODMAPs are basically carbohydrates.
19 They're sugars that are osmotic, means that
20 pulling the water from the digestive track and
21 they don't digest or absorb well and could become
22 fermented aggravating the IBS. The combination of

1 the FODMAP diet and the supplements seemed to work
2 better than most other treatments. I was
3 definitely better for a while. However, a low
4 FODMAP diet is very restrictive and hard to
5 maintain even over the initial six weeks. It's an
6 elimination diet where you reintroduce foods a
7 little -- one at a time.
8 After about 15 months of relative well-
9 being, the diarrhea urges and stomach pains now
10 continue on and off. The symptoms can occur at
11 any time, any place. Bad days cause a great deal
12 of anxiety and depression and I have a hard time
13 concentrating, focusing on other tasks. I use
14 motivation. I become obsessed about my symptoms.
15 Certain foods can make it worse, but
16 sometimes it's just dairy -- just eating that
17 triggers an episode. Currently, then, to address
18 the IBS, I'm taking Bentyl, which is an anti-
19 spasmodic, a probiotic, Vitamin D, digestive
20 enzymes, fish oil, glutamine, and other herbal
21 combinations, plus, if I need it, Imodium and
22 deactivated charcoal. I feel that the IBS is

1 barely managed. Over the years, I've seen six or
2 seven different gastroenterologists. None of the
3 treatments have been totally successful. I feel
4 like conventional medicine has not really taken
5 into consideration the debilitating effect of the
6 symptoms or the effect on my daily life. I
7 sometimes wonder whether other diagnostic tools
8 may lead to better treatment. I think I have had
9 more positive and encouraging results from
10 complementary medicine, though even there, nothing
11 has been permanent. Complementary medicine has
12 provided other diagnostic tools and other
13 treatments that are not available in conventional
14 medicine. Obviously, I would like to find a cure
15 for the IBS, but if anything, something to treat
16 the symptoms, diarrhea, urgency, incontinence and
17 the pain. We needs meds or other treatments that
18 will prevent the symptoms of poor digestion and
19 poor absorption and would reduce the inflammation
20 that actually caused the diarrhea.
21 IBS seems to be more of a confluence of
22 symptoms. So, a gentle med or supplement without

1 a possibility of serious side effects, without the
2 rebound effect, one that would not lead to
3 tolerance would be a tremendous relief. On an
4 immediate basis, I would like to have a medicine
5 or supplement that would have a very immediate
6 result, so if I feel an episode coming on, I'd be
7 able to avoid it and gain some security wherever I
8 am.
9 Thank you for allowing me to speak.
10 DR. EGGERS: Thank you very much, Anne.
11 And you can't see us in the room as well, but you
12 have been speaking to a group that understands and
13 has been nodding their heads to what you're
14 saying, so we thank you very much for that.
15 MS. SIROTA: Thank you.
16 DR. EGGERS: Now, we will go on to have
17 Lynn.
18 MS. WOLFSON: Good afternoon. My name
19 is Lynn Wolfson, and I'm here from Fort
20 Lauderdale, Florida. I am honored to be here. I
21 came to speak about my rare genetic disorder,
22 Hirschsprung's disease. I was born with this

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1 disease and have had it all 56 years of my life.
2 Consequently, the intestines, which do not have
3 ganglion cells or have ganglion cells which are
4 formed but not functioning, do not have rhythmic
5 peristalsis. This results in severe constipation,
6 vomiting, obstructions, distention, intestinal
7 ruptures, and lots of pain. There is no cure for
8 Hirschsprung's disease. I spent the first four
9 years of my life taking milk of magnesia, getting
10 enemas and suppositories regularly, and eating
11 very little. I was very much underweight,
12 constipated, projectile vomiting, and frequently
13 in pain. I began my surgeries in 1963 at the age
14 of four. I had a full rectal thickness biopsy, an
15 intestinal resection, an intestinal rupture, a
16 colostomy, and a colostomy closure by the time I
17 was eight years old. By the time I became an
18 adult, I had very bad reflux. I was still very
19 much underweight. I was five foot four and a half
20 inches, and 103 pounds when I got married at age
21 27.
22 I tried many medications for GERD, such

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1 as Reglan, Zantac, Prevacid, Prilosec, Tagamet,
2 and Protonix. Nothing seemed to work. During the
3 delivery of my first child, I was vomiting bile
4 and then blood. In addition, I would get severe
5 intestinal infections while pregnant. After my
6 second child was born, I had a laparoscopic Nissen
7 fundoplication. The vomiting finally stopped,
8 however, my abdomen grew very large. I had severe
9 abdominal pains and multiple intestinal
10 infections. My lungs started to become affected
11 from the pressure from my abdomen. I developed
12 asthma as an adult. My pain started to worsen. I
13 was in a lot of pain after eating. My distention
14 grew until I looked six months pregnant. I was
15 severely constipated. I was physically unable to
16 defecate. I had another full rectal thickness
17 biopsy to check for ganglion cells like when I was
18 four years old.
19 In 2002, the colorectal surgeon was
20 shocked to find that I was still positive for
21 Hirschsprung's disease. There were no ganglion
22 cells present on any of the biopsies. The surgeon

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1 repeated the surgery I had when I was a child.
2 Five days later, another intestinal rupture and my
3 second colostomy. In 2003, I had more surgery.
4 During this surgery, my colostomy was closed down,
5 my rectum was removed. I had a colo- anal
6 connection and and ileostomy was formed.
7 Unfortunately, I also lost 15 units of blood and
8 ended up on life support in trauma/intensive care
9 for five days. During this surgery, several
10 nerves were inadvertently slashed causing me to
11 have a neurogenic bladder and neuropathy in my
12 legs. The ileostomy was closed a few months
13 later. The constipation, nausea, and pain
14 continued. My gall bladder was removed. My
15 constipation issues got worse. I was taking
16 prescription laxatives multiple times a day, lost
17 total fecal control, was in pain, and still had
18 fecal impactions. I was still very thin.
19 In April 2006, it was found that 90
20 percent of my colon was non-functioning. In
21 addition, my fifth cervical disc had herniated and
22 ruptured as a result of malnutrition. In August

1 2006, I had the surgery to remove my entire colon,
2 rectum, and anus, and to get a permanent
3 ileostomy. I started to do better. I finally
4 started to gain some weight. My ileostomy is the
5 best thing to happen to me. No more laxatives,
6 enemas, suppositories, sitting on the toilet,
7 constipation, or rectal exams. In 2008, more
8 surgery with a new ileostomy. In 2011, I had
9 another intestinal obstruction, more surgery,
10 another ileostomy. In September 2012, I got
11 sepsis and then ten days later, sepsis again. I
12 tried going off of TPN in December 2012. It
13 lasted until April 2013, when I could not tolerate
14 the pains from eating. I start J-tube feedings in
15 May. I had another obstruction in June 2013.
16 More surgery in August 2013 with a seventh ostomy
17 and a G-J-tube. I'm happy to say that my last
18 hospitalization was in July 2014. I am now going
19 to Mayo Clinic in Minnesota who has been able to
20 manage my condition so I can have quality of life.
21 I eat very minimally, wear my J-tube feeding, and
22 hook up my gastric bag when I feel nauseated or

1 bloated. Bottom line is, I am the happiest bag
2 lady.
3 I do find the area around the J-tube to
4 develop skin tabs and to be very sore. I have
5 tried silver nitrate and stomahesive powder.
6 Nothing seems to work. I just keep the area clean
7 and the plate of my tube within an quarter inch of
8 my abdomen. My J- tube is 750 cc's of Peptamen
9 1.5 daily. I have found this formula works much
10 better for me than when I was on Vivonex Plus with
11 Pro-Stat, baby rice cereal, and glutamine. I also
12 take Align to minimize my bloating symptoms. I
13 have Hyoscyamine to take prior to eating, but find
14 that it makes me too tired. I prefer to lay down
15 after I eat for one to two hours for the pain to
16 dissipate. It is very important to me to have a
17 clear head and to be in control. In addition, I
18 also take Vitamin C and Methenamine Hippurate to
19 make my urine more acidic, to reduce the quantity
20 of urine infections from catheterizing. For my
21 intestinal absorption issues, I take sodium
22 bicarbonate and magnesium gluconate. I find that

1 the most difficult part of the day is the pain I
2 get about an hour after eating which lasts up to
3 two hours. I have not found a medication which I
4 could take which does not make me tired or make my
5 head foggy. I also find that the formula does not
6 give me enough strength to make it through the day
7 without taking a two-hour nap. I have periods of
8 time where the pain does not dissipate after two
9 hours and continues for days to weeks. I believe
10 this is when I get pseudo-obstructions or
11 intestinal infections. Unfortunately, there is
12 nothing to be done during those times. This
13 occurs every four to six months. I have a
14 wonderful nurse with me eight hours a day and my
15 service animal, Zev. He helps me up and down steps
16 and curves, carries my handbag, let's me know when
17 my ostomy bag is leaking, and can carry things in
18 his mouth for me.
19 I am very grateful to have been given
20 the gift of life. I am married for 29 years and
21 have two beautiful daughters who are both
22 biomedical engineers and in medical school. I am

1 very active within my community. I swim, I tutor
2 students in math, knit hats for cancer patients,
3 run a book club, lobby for more money to be
4 appropriated by Congress for research in digestive
5 diseases, and I travel the world with my family.
6 My goal is to inspire others to live life to their
7 fullest despite their intestinal illnesses. I do
8 this by sharing my story with professionals such
9 as you who can make changes to improve the life of
10 others with digestive diseases. I dream of the
11 day when no one will be born with Hirschsprung's
12 disease.
13 (Applause.)
14 DR. EGGERS: Thank you very much, Lynn.
15 MS. CHILSON: Hi, my name is Julian
16 Chilson and I'm from Richmond, Virginia. I have
17 had gastroparesis symptoms for as long as I can
18 remember. Constant nausea, stomach pain, inability
19 to exercise, weight gain, ongoing breathing
20 issues, and lung pain. I have pushed myself to
21 live a normal life, because doctors told me
22 nothing was wrong. In October of 2009, my body

1 collapsed. From then on, my lungs stayed full, I
2 threw up every meal, my heart rate stayed
3 elevated, my blood pressure high, and I was unable
4 to breath or move without difficulty. My weight
5 went up to 240 pounds, although I could not keep a
6 single meal down. I often was unable to stand up
7 or walk on my own.
8 For the next four years, I went from
9 specialist to specialist to get answers. I kept
10 hearing there was no reason for me to be so sick.
11 I asked several doctors to be referred to a GI.
12 None would, because I was too sick. At the end of
13 four years, I was told there was nothing else that
14 could be done for me. In desperation, I
15 researched local acupuncturists, made an
16 appointment. Within minutes, she told me my
17 digestive tract was not able to digest food
18 properly. She instructed me to eat only chicken
19 broth and crock pot chicken until I felt stronger.
20 She gave me an acupuncture treatment from which I
21 immediately felt improvement for the first time in
22 four years.

1 For the next eight months, my doctors
2 were amazed by my sudden improvement, but doubted
3 I had gastroparesis. I asked to be referred to a
4 GI again. They refused. After eight months, I had
5 a really bad flare. The one doctor finally agreed
6 to send me to a GI for the purpose of proving to
7 me I did not have gastroparesis. That GI ended up
8 diagnosing me with severe gastroparesis and
9 inertia of the small intestine. Immediately, I
10 was prescribed Zofran and banned from eating all
11 vegetables. Soon after, he put me on Reglan,
12 because I was having severe fatigue issues. I was
13 able to start eating regularly, suffered less
14 nausea and dizziness, but still suffered from
15 severe fatigue. With Reglan, I was able to reduce
16 Zofran used by quite a bit, but not completely.
17 This past February, I had a Botox
18 injected into my pylorus. I feel like a different
19 person. I can now drink water and expand what I
20 eat. Because my insurance does not like covering
21 Botox, I am scheduled for a pyloroplasty later
22 this summer. But even after the Botox, I was

1 having severe fatigue issues and excessively high
2 heart rate. A cardiologist determined that my
3 metabolism was off kilter from being sick for so
4 long and was acting like I was still in the middle
5 of that -- where I was a few years ago. Three
6 weeks ago, I started Diltiazem, a medicine that
7 was not a beta blocker, because of the aspiration
8 issues. It is steadily increasing my energy
9 without excessive heart rate.
10 As a result of severe aspiration, I have
11 an extreme sensitivity to smoke, chemicals, and
12 their residues, leading to multiple ER visits.
13 Recently a dietician contacted me to try Vitamin E
14 due to studies that it helps build allergic
15 responses in the respiratory system. The full
16 effect kicks in after 16 weeks. After six weeks,
17 I am seeing improvement. I can now handle some
18 exposures with little effect if I take my rescue
19 inhaler as soon as possible. Gummy vitamins,
20 Vitamin D, and probiotics help my system function.
21 I am continuing with acupuncture with great
22 success, and yoga has helped me in getting my

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1 bowels to move regularly. Nutrition drinks are
2 not an option for me, since I am soy and dairy
3 intolerant, unable to handle dairy or dairy
4 substitutes and corn sweeteners.
5 A change I would like to see made for
6 gastroparesis symptoms is to include weight gain
7 in addition to weight loss as a critical symptom
8 of gastroparesis. GES testing should be included
9 for those who are suffering ongoing, unidentified
10 GI issues as part of the standard testing regime.
11 Thank you and thank you so much for having this
12 meeting for us. We really appreciate it.
13 DR. EGGERS: Thank you, Julian.
14 Meredith.
15 MS. HOLT: Hi, I'm Meredith Holt. I
16 live in Washington, D.C. I have a diagnosis right
17 now of chronic unexplained nausea and vomiting,
18 but I say that with some trepidation, because I've
19 also had a diagnosis of gastroparesis, so
20 basically, I sometimes pass and sometimes fail the
21 gastric emptying studies.
22 Treatment for me, since 2010, has

1 included for my terrible debilitating nausea and
2 vomiting, domperidone. I've also had multiple
3 Botox injections to the pyloric valve, various
4 PPIs, Phenergan, Zofran, Marinol, dietary
5 modifications, Reglan. I eventually ended up on
6 TPN and then on feeding tubes. And then, in
7 August of 2013, following a two-and-a-half month
8 inpatient hospitalization, the result -- because I
9 could no longer even take in tepid water, my GI
10 doctor started me on a trial of Zyprexa, which is
11 currently on the market as an atypical anti-
12 psychotic medication to treat my nausea, because
13 there was one small study that showed that Zyprexa
14 might be efficient in treating nausea. And within
15 literally 30 days, I had a complete turnaround in
16 my symptoms. Zyprexa I take now daily. I still
17 have Marinol and Zofran as PRNs to take when my
18 nausea flares. Right now, I'm very fortunate to
19 be able to eat relatively normally. I still have
20 to avoid high fiber foods. So, like I still dream
21 of eating a green salad. I can't drink thick
22 liquids. Fatty foods tend to trigger abdominal

1 pain, nausea and vomiting. But the Zofran is very
2 effective at treating the nausea and the vomiting.
3 So, I also had a really drastic surgery
4 in 2012 called a median arcuate ligament release
5 that was meant to alleviate some of the pain and
6 bloating that I had with my gastroparesis. It was
7 also unsuccessful. So, I'm very grateful that
8 Zyprexa has worked for me. It has been a complete
9 game changer. It keeps me out of the hospital. I
10 haven't been in the hospital for gastroparesis
11 since August of 2013. I don't -- and I was able to
12 have my feeding tube removed after two or three
13 months of starting with Zyprexa. I don't think
14 the Zyprexa does anything to cure my GI
15 dysmotility, but it does keep the major symptoms
16 at bay. So, for that, I am grateful. And I'm
17 able to work full-time. I still struggle, like
18 many of you, at a lot of social events, because
19 many social events are centered around food, and
20 often fatty foods, which is very tricky. And I
21 feel, again, super grateful that Zyprexa has
22 really changed the quality of my life over the

1 last couple of years.

2 DR. EGGERS: Thank you very much,

3 Meredith.

4 MS. PASINKOFF: Good afternoon. I'd

5 like to thank the FDA for giving me this

6 opportunity to share the devastating effects of

7 digestive disorders. My name is Carol Pasinkoff.

8 I have GERD, chronic constipation, and idiopathic

9 gastroparesis. I cannot eat more than a few bites

10 of food, and I am tube fed. Every single day I

11 suffer from unrelenting nausea, abdominal

12 swelling, pain, regurgitation, burping that

13 sometimes is constant, and constipation. Some

14 days are worse than others, and on my really bad

15 days, I am bedridden. I never know what to expect

16 day to day, and sometimes hour to hour. Due to

17 the unpredictability of my symptoms, I cannot

18 work, I have difficulty performing everyday tasks

19 and chores, and have become isolated from my

20 friends and social activities. Through the years,

21 I have tried everything that is available,

22 including Botox injections into the pylorus

1 muscle, erythromycin, Reglan, which has a black
2 box warning from the FDA, Marinol, Cytotec,
3 Mestinon, Carafate, herbal and holistic remedies,
4 and many different proton pump inhibitors. None
5 of these helped. Every day, I take over ten
6 different medications to treat my symptoms,
7 including four medications specifically for
8 nausea, and which some days they don't help at
9 all. The nausea is brutal. I cannot function at
10 all when they don't help. Some anti-nausea drugs,
11 like promethazine and Compazine causes too many
12 side effects for me. Some drugs that can possibly
13 help against nausea, such as Mend, my insurance
14 will not cover, because they are specifically for
15 people who are undergoing chemotherapy. These
16 drugs are extremely expensive. I was prescribed
17 domperidone, which is not FDA approved, and it
18 gives me minimal relief, even taking the maximum
19 dosage. I was on Zelnorm, which helped my severe
20 constipation, but it was pulled from the market.
21 I was put on Amitiza, which helped with the
22 constipation, but caused me to faint. My chronic

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1 constipation became so severe that I had to have
2 90 percent of my colon removed. I still have
3 constipation and need to take Linzess every day,
4 as well as over-the-counter products to help me
5 have a bowel movement. Prior to being approved
6 for the gastric electric stimulator, I was
7 vomiting everything I ate and drank and was
8 severely malnourished and dehydrated. I was
9 placed on TPN for two years, but after becoming
10 septic twice, TPN was stopped. A G-tube was
11 placed in my stomach for decompression, which
12 helps empty my stomach of bile through the day.
13 And a J-tube was placed in the small intestine for
14 feeding. I have been tube fed through the J-tube
15 for the last nine years. As per my doctor's
16 advice, every day, I try to eat a few bites of
17 food. No matter what I eat, and sometimes when I
18 haven't even eaten, I burp, regurgitate, and my
19 abdomen becomes very distended to the point where
20 I look like I'm seven months pregnant. A heating
21 pad or an ice pack and a Tramadol do little to
22 alleviate my pain. My doctors will not prescribe

1 any stronger pain med, as any opiate causes
2 constipation. At the moment, being tube fed and
3 taking the numerous supplements and drugs keeps me
4 alive and nourished, but there is no cure for
5 gastroparesis. Doctors try to treat all the
6 symptoms. Some days my symptoms are tolerable, but
7 most days I have no relief. My doctors say they
8 have tried everything that is available to treat
9 my symptoms, and although they now believe that
10 the motility of my small intestine and esophagus
11 are slowing down, there is still no further
12 treatment options that can be recommended. This
13 is very depressing and I hold on to the hope that
14 something will be developed to specifically treat
15 the symptoms of gastroparesis.
16 There are clinical trials going on in
17 the United States to treat people who have
18 gastroparesis caused by diabetes, but many of us
19 who have gastroparesis do not have diabetes. An
20 ideal treatment for my condition would be a drug
21 that is developed that can help alleviate the
22 extreme nausea from gastroparesis. Also, a drug

1 to increase motility in the stomach that can
2 diminish the bloating and pain after a few bites
3 of food and enable me to eat like a normal person.
4 Although I have the gastric electric stimulator,
5 also known as the pacer, it does not actually pace
6 the stomach. It sends signals to the stomach to
7 help reduce nausea and vomiting. Perhaps a device
8 can be developed that actually assists the stomach
9 in contracting. Thank you for this opportunity
10 for speaking to the FDA today.
11 DR. EGGERS: Thank you very much, Carol.
12 Again, you can stay up here or you can head back
13 to your chairs, whatever you feel more comfortable
14 doing.
15 I'm just going to head over -- it takes
16 a couple seconds, and I never know that, so
17 usually everyone misses the first word I say, but
18 I've learned to wait. Again -- the puppy needed
19 some air.
20 (Laughter.)
21 Again, please another round of applause to these
22 women and to Anne.

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1 (Applause.)
2 And to Zev, thank you, Zev. I think you're the
3 first of our four-legged friends to have joined us
4 in one of these meetings.
5 There was a lot that we heard in these
6 panel comments today. We heard about -- I'll call
7 it multi- motile, for lack of anything better. It
8 doesn't even get close to what you're dealing
9 with. But the combination, the complexity of the
10 surgeries, the devices, the treatments, the
11 treatments that you've had to try over and over.
12 For some of you, it's managed things better, and
13 for others, you still are struggling as much as
14 you have been. Does this resonate with you? Do
15 you hear your experiences in here even if the
16 details aren't the same? And we think, again,
17 that you have represented the patients in the room
18 well.
19 We have as much of a challenge to get
20 through Topic 2 as we had through Topic 1, and we
21 will take it as we go. I want to first ask a
22 question about pharmaceutical treatments that

1 you're on, and we have a polling question for you
2 in the room and on the web, if you can get your
3 clickers. Does anyone need one? Raise your hand,
4 if you need one. Everyone's got one, okay. This
5 is where it gets to be a real test for me, because
6 I can't always pronounce the drug names, so if I
7 stumble, please help me out here, FDA.
8 Have you ever used any of the following
9 prescription or investigational drug therapies to
10 help reduce the symptoms of your GI disorder?
11 Amitiza, Linzess/Linaclotide, B. Maybe -- if
12 anyone needs me to read them out, I will,
13 otherwise, I'll just let you read them here.
14 The largest is other. We will try to
15 tease that out a little bit more. And proton pump
16 inhibitors. But it looks like there's several of
17 you taking a number of other things except
18 Lotronex we don't have on here.
19 On the web, do we have experiences?
20 MR. THOMPSON: So, 53 percent say other,
21 66 percent say Prilosec or proton pump inhibitor,
22 and then the other ones are very similar.

1 DR. EGGERS: Now, remember, this is not
2 all survey. This is not research here. It's just
3 to get a sense of what you're collectively trying
4 in the room. We heard descriptions about the
5 products that have worked really well or have not
6 worked really well. Let's find -- if anyone wants
7 to build on what we heard, especially from
8 Meredith, again, it's not so much exactly what
9 treatment it is, but how you knew what you valued
10 out of a treatment when you think it really worked
11 for you, what you noticed in the improvement, what
12 you -- how long it took, et cetera. Those are the
13 type of things we'd like to hear about. So, can we
14 start -- we'll start here with Bettemarie and then
15 we'll go on. A pharmaceutical treatment that has
16 worked for you well.
17 MS. BOND: Recently, well, a little over
18 a year and a half ago, I started on Mestinon, the
19 autonomic neurologist started me on that. But
20 what's great is I'm actually able to start eating
21 again. I'm eating tiny bits of food, and so,
22 that's huge. But it's also helped my skeletal

1 muscles. And one thing that showed improvement
2 was she bumped the dose up and my niece came over,
3 spent the night. I actually sat up with her,
4 watched a movie. And then, the next morning, I
5 put this headband on her and I helped wrap her
6 hair around it. We dried her hair. And I can't
7 even do my own hair. Like, I have my CNA help me
8 with mine. And so that, being able to spend time
9 with her and helping her do her hair that day was
10 a huge sign of improvement. So, sometimes, like,
11 little things that just improve the quality of
12 life, like spending time with family, with
13 friends, little things like that can really make
14 the biggest difference in life.
15 DR. EGGERS: Can you just repeat what
16 the name of the product was.
17 MS. BOND: Mestinon.
18 DR. EGGERS: Anyone else have an
19 experience they would like to share? If you're on
20 the web, please do so. We have back here.
21 ELLEN: I'm sorry for the panelists who
22 have not had luck with domperidone. I have had

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1 tremendous luck with domperidone. Domperidone
2 makes it possible for me to eat.
3 DR. EGGERS: One more here.
4 DEBBIE: I just want to second that. As
5 I said before, when I was diagnosed with
6 gastroparesis and I had tried other things like
7 dietary change and small meals, nothing had any
8 effect. And when I started on domperidone, I had
9 immediate, complete, reliable relief, which I've
10 had for the past four and a half years. I mean,
11 that drug has been a godsend. And I have had
12 absolutely no adverse effects. If I miss a dose,
13 I'm immediately nauseous, so needless to say, that
14 does not happen often, but it has worked
15 wonderfully for me with absolutely no problems.
16 DR. EGGERS: Right here, we'll go with
17 Elizabeth.
18 ELIZABETH: Thanks. I was looking that
19 way. Not to be boring, but I advocate the
20 domperidone treatment. I was in a bad, very dark
21 place. It saved my life, literally. I've been on
22 it for about seven years with great success. I

1 have a quality of life. I feel very blessed.
2 There is, however, a great deal of frustration,
3 because it is not an FDA-approved drug. And there
4 are many challenges that go along with that. So,
5 you know, that's a whole other discussion.
6 DR. EGGERS: Is this about this drug or
7 a different drug? You can go ahead. We will
8 transition to a negative.
9 KATHARINE: With the domperidone, I hear
10 that it's really helping a lot of people, and I
11 know it's different for each case of
12 gastroparesis, but what's really frustrating is, I
13 can't get a doctor to prescribe that to me no
14 matter what I tell them, no matter how many times
15 I've gone crying to them that I need something.
16 I've taken Zofran, Phenergan, promethazine, PPIs,
17 everything. Everything that you guys have taken.
18 And it's really unconventional, but the only thing
19 that helps me be able to get through the day is
20 marijuana. And I can't even get Marinol, even
21 though it actually does help. I can go to school,
22 I can eat. I have an appetite. I don't get

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1 nauseous if I smoke before I eat as well, but it's
2 illegal. And I don't want to be smoking it,
3 because it has adverse effects. My biggest
4 problem is, there's these treatments out there,
5 and yet they make it seem so difficult and
6 there's, like, all this red tape and all of this
7 things that you have to go through just to get
8 help. I'm not even seeing a GI doctor until July
9 7th to even discuss domperidone. That's two months
10 away and that's just, you know, really
11 disheartening.
12 DR. EGGERS: We have heard in many of
13 the comments that were sent in to help us prepare
14 the difficulty in getting the care and the
15 treatment and getting the treatments you want.
16 So, that point is very well taken. So, thank you.
17 It was a perfect point to make, so thank you very
18 much.
19 Can we -- on the web, are we getting
20 anything about treatments that have worked well
21 and what's made them work?
22 MS. GIAMBONE: Let's see, we have

1 received a few treatments that did not work too
2 well.
3 DR. EGGERS: Go ahead and say those.
4 MS. GIAMBONE: Okay, similar to what was
5 said in the room. Reglan did not work. Side
6 effects were too bad. Xifaxan caused
7 lightheadedness and stomach pain. Some people
8 said that they've tried Zofran, Amitiza, and
9 neither worked. Linzess didn't work and it caused
10 intense pain. We did have a few that said that
11 they also tried to domperidone -- I apologize for
12 saying that wrong. A few people said that it did
13 not work for them. Some said they were too scared
14 to use it, while another did say it worked well
15 and it gave some feeling of hunger.
16 DR. EGGERS: To the FDA panel, we do
17 have some time if you want to explore any on this
18 list, any that surprised you that you wanted to
19 hear more about or anything before we move on.
20 Donna.
21 DR. GRIEBEL: Just a quick follow-up
22 question. So, the Marinol, the reason why you

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1 can't get that is just because it's not covered by
2 your insurance, because of the indication or --
3 CATHERINE: My doctor just told me to go
4 to Colorado and try getting it there. That was
5 his actual words, because it's illegal.
6 MS. KORVICK: I was curious about the
7 people that said that domperidone worked for them.
8 I was just wondering, in light of our previous
9 conversation, what particular symptoms did it
10 relieve for the people that it worked for?
11 ELLEN: So, I have gastroparesis and the
12 way I describe my sensation is that it is
13 nauseating, but it's nauseating because I have a
14 chronic condition of sewer mouth. It's like,
15 gases coming back up from my GI system exiting in
16 the wrong direction. Domperidone is a magic
17 bullet for me in a very small dose, ten milligrams
18 twice a day taken before breakfast and dinner.
19 And I can't eat without having that experience,
20 and -- unless I take the domperidone.
21 DEBBIE: And just as a quick follow-up
22 for me, it immediately relieved the nausea, which

1 I had, which just nothing else did anything to
2 relieve at all, but it was instantaneous.
3 DR. EGGERS: I think we had one -- oh,
4 we have lots of experience.
5 MS. TAYLOR: I actually am going back
6 one to the Marinol, I guess I didn't get my hand
7 raised. The Marinol, we've all through the
8 country talked about this with the marijuana.
9 There are so many people that are finding so much
10 relief from the marijuana through the country who
11 are -- some doctors have even put some of the
12 medications down and have them just using the
13 marijuana, which is actually stimulating appetite,
14 decreasing pain, so I'm not sure -- and decreasing
15 the nausea as well. The Marinol, there were some
16 that that helped. Most people that took that said
17 it didn't help them where the marijuana did. But I
18 do want to acknowledge on that, because we have so
19 much discussion on a daily basis that goes on
20 about that product helping.
21 DR. EGGERS: Thank you very much, Tanya.
22 Okay, we'll take one more and then we'll

1 go to -- take two more.
2 MARY: I was just going to comment on
3 the domperidone. I had a hard time obtaining it
4 even though I had an IND licensed prescriber at
5 Johns Hopkins. I was told I had to get it from
6 Canada while I was hospitalized at Hopkins. But I
7 knew my own research and I knew there were certain
8 compounding pharmacies that were FDA-, as far as
9 the powder itself, approved. So, I -- while I was
10 admitted, I found a local pharmacy who, you know,
11 my mom was nice enough to drive there and pick it
12 up, and then they started giving it to me while I
13 was in the hospital. At the time, I was on TPN,
14 and it took a while. I was doing 10 milligrams
15 four times a day. After a week, I still wasn't
16 seeing any improvement, so they bumped me up to 20
17 milligrams four times a day.
18 I was discharged with an NJ tube,
19 because I still wasn't getting anything, and I
20 didn't want to do a bunch of other factors in the
21 mix, because I wanted to know, as far as variables
22 what was working and what wasn't. So, I was

1 discharged. I was still on the 20 milligrams four
2 times a day. After two weeks of being home, my NJ
3 tube got clogged, so we pulled it out, but we
4 didn't put another one in. Rather, I went to baby
5 food and liquids. And after another week, I was
6 starting to be able to eat again. So, for me,
7 yes, domperidone has worked, but it hasn't been
8 complete success, because after the 20 milligrams,
9 I started with the prolactin elevations, so I had
10 to go back down to 10 milligrams and, I mean, and
11 I know that at times, I have to stop completely
12 off of it, because I became a (indiscernible) to
13 Reglan, because it just stopped working. And I'm
14 afraid that if I continue to use domperidone
15 continuously, I'm going to get the same reaction.
16 So, I -- during -- I peak for a while and use it,
17 and then I come off of it, then I use it, and then
18 I come off of it. But just to give you an
19 experience.
20 DR. EGGERS: Thank you very much, Mary.
21 We'll have Lynn.
22 MS. WOLFSON: Hi. There was one thing

1 that we hadn't discussed. I find, even though I'm
2 on it, and I haven't heard anyone else mention it.
3 When I was on TPN and also on J-tube feeding, I
4 find the hardest part is dealing with the hunger
5 that I still get. And if I eat, then I'm in pain.
6 So, it's dealing with that hunger. And I was
7 wondering if there's a medication -- I don't know
8 if anyone else is having that problem with still
9 feeling hunger, if there's a medication that could
10 take that hunger away so we wouldn't have to
11 determine whether or not we want the pain of
12 hunger or the pain from eating.
13 DR. EGGERS: Anyone have an experience
14 that can address Lynn? Something that has
15 addressed that? And on the web, invite you to send
16 in a comment, if you do.
17 MS. TAYLOR: I understand what you mean
18 about that pain whether your stomach's empty or
19 not, because either way, it is a lot of pain. I
20 started eating ice a couple of years ago when I
21 wasn't able to tolerate anything at all. I very
22 rarely get hungry. It just doesn't happen, but

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1 when there's rare occasions that I do get hungry,
2 I start eating the crushed ice, and that is the
3 only thing that I've been able to do to help
4 subside that pain that you're talking about.
5 DR. EGGERS: Let's go into other types
6 of downsides of treatments that you're on. Again,
7 we don't necessarily care exactly what treatment
8 it is, but what downsides bother you most of the
9 pharmaceutical treatments that you've tried? So,
10 we'll start here with Katharine.
11 KATHARINE: I just think it's a huge
12 problem that you'll be prescribed something to
13 help a symptom, but the side effects are that
14 symptom. The anti- depressants that are supposed
15 to help slow down gastric symptoms -- gastric
16 emptying. And that really worries me. I'm taking
17 a drug that actually could be counter productive.
18 DR. EGGERS: Any other -- okay, we'll go
19 over there with Meredith.
20 MEREDITH: Less anybody think that I'm
21 saying that Zyprexa is like a magic bullet drug, I
22 want to add that the side effects that I have from

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1 that are hyperglycemia, so I'm now pre-diabetic
2 and I actually have to take a diabetes drug to
3 lower my blood sugars, since the Zyprexa is
4 increasing. I also gained a ton of weight really
5 fast, and also now have some cholesterol issues,
6 not related to food, but related to the Zyprexa.
7 And then secondly, the surgical intervention that
8 I had, the median arcuate ligament release, which
9 is, albeit a rare treatment, for whatever reason,
10 during the surgery, my -- I developed -- I'm
11 drawing a blank as to the words -- I developed
12 Addison's disease. My adrenal glands infarcted
13 during the surgery, so now I have Addison's as
14 another sort of diagnosis. So, I feel like
15 there's certainly no magic bullet on the market.
16 We all have side effects from the drugs that are
17 meant to treat our symptoms.
18 DR. EGGERS: Thank you. Any other
19 downsides? Bettemarie?
20 MS. BOND: Just a few points. Years
21 ago, I tried so many different medications, and
22 you just feel like a lab rat trying them. And

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1 then also, you start, like, "Did that help? Did
2 it not help?" And it almost gets to be a mind
3 game at times. So, you just kind of have to go
4 with it and just not even think about it and
5 there's something -- if you notice a difference,
6 that's great. Also, I'm on many different
7 medications and the cost just adds up.
8 Thankfully, I have good health insurance. As I
9 mentioned earlier, I worked for 14 years and I
10 officially retired due to medical reasons. It
11 sounds so much nicer than disabled or on
12 disability. But any event, insurance is a huge
13 issue for covering the therapies. The TPN itself
14 is really expensive, and looking into some of the
15 different types of healthcare plans through the
16 Health Market, they didn't cover everything. The
17 Medicaid didn't cover the different doctors that I
18 could see. Right now, I'm paying my COBRA, and
19 that's $750 a month just to have the good
20 insurance, but now I will transition into
21 Medicare. And I've heard some horror stories with
22 going into Medicare. So, that's just -- I can go

1 on forever about that, but there are just some
2 major issues that people face. Now, as a young
3 adult when I was trying to gain my independence, I
4 was on my parents' plan, then I was on Medicaid
5 and Medicare, actually, back then. But trying to
6 become independent and trying to get a job was
7 another issue, all while on IV nutrition and
8 covering all of my therapies. But where there's a
9 will, there can be a way at times.
10 DR. EGGERS: Thank you very much.
11 Are we getting anything on the web?
12 MS. GIAMBONE: So, we've also heard a
13 few people say that they're using gastric
14 pacemakers, an Enterra device to control nausea.
15 We've also gotten more feedback on domperidone
16 saying that it's worked and it's relieved nausea
17 and pain. One person tried Desipramine and said
18 they had tachycardia issues. Several also
19 mentioned erythromycin and a few said it didn't
20 work, it caused more pain. And also Reglan, a few
21 others mentioned that it's had some neurological
22 side effects.

1 DR. EGGERS: Before going off of the --
2 MS. BOND: With the insurance, what's
3 really frustrating is when you find something that
4 helps and then the insurance is denying it. For
5 the first time in years, I tried the -- I was
6 switched to Nexium and I wasn't having all that
7 regurgitation in my mouth, but now, the insurance
8 is saying, oh, I have to go back and try these
9 other medications. Well, I've done that, like,
10 it's been 25 years. So, it's really frustrating.
11 And that's just one little example of the
12 insurance denying stuff.
13 DR. EGGERS: So, with thinking of these
14 downsides, I want to have one question before we
15 move on that's going to focus in on side effects.
16 Has anyone in the room or on the web stopped a
17 medication that was working for you to a degree
18 that you can say, "Yes, I can tell this works for
19 me," but you stopped it because of some side
20 effect or some adverse reaction that you were
21 having? We have Carol and then we have Meredith.
22 MS. PASINKOFF: Promethazine actually is

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1 the one medicine that does help me with my nausea,
2 but it causes me to have restless leg syndrome.
3 And if I take more than one Promethazine, I will
4 be up for days, like pacing the house, rubbing my
5 legs, putting heating pads on them. I mean, I
6 can't take it. It's just --
7 DR. EGGERS: But you still take it when
8 -- you've just cut back on it. You still take it
9 sometime.
10 MS. PASINKOFF: If I'm very desperate
11 and I'm miserable and rolled up in bed, yes, I
12 will take it, but I do suffer the side effects for
13 it.
14 DR. EGGERS: Okay, thank you.
15 Meredith and then someone back here.
16 MEREDITH: Reglan was showing promise
17 for me years ago when I started taking it, but I
18 quickly started developing some early Tardive
19 dyskinesia-type symptoms.
20 DR. EGGERS: Okay, and so you stopped.
21 And one more back here?
22 UNIDENTIFIED VOICE: Kind of along the

1 same lines of -- I can't take any of the drugs,
2 Reglan, Compazine, Phenergan, anything that
3 crosses the brain/gut barrier. I have some
4 neurological issues. They all cause me to be
5 really restless and jittery and anxious. And they
6 had to stop them, because they were afraid of
7 permanent, like, neurological damage, which I do
8 end up having neurological damage, they were
9 afraid -- they had to stop it early because of
10 that fear.
11 DR. EGGERS: So, we could tee up the
12 phone if anyone on the -- who's remotely
13 participating wants to address one of those two
14 questions, either one that you -- a product that
15 you're taking that we haven't talked about that
16 has worked wonders for you, or a product that was
17 working pretty well or had some benefit, but you
18 had to stop taking it because of a side effect.
19 And again, we don't really care about what those
20 treatments are, but what those side effects were
21 and what that benefit was.
22 And while we do that, then I'm going to

1 move on to our next polling question. As we know,
2 that it's not just pharmaceutical treatments. You
3 have reiterated that. But besides those drug
4 therapies that we've been talking about, what else
5 are you doing to help reduce your symptoms or
6 manage your functional GI disorder? You can
7 choose all that apply. And I'll just let you read
8 through those.
9 UNIDENTIFIED VOICE: (Indiscernible).
10 DR. EGGERS: I think -- yes, it doesn't
11 -- we'll just explain what you mean, because over-
12 the- counter is a hard one. Lots of stuff is
13 over-the- counter. We don't define that very
14 well, but if that's what you included, that's good
15 to know.
16 So, dietary management is the most
17 frequent in the room. And on the web, what do we
18 have as the top most frequent ones?
19 MR. THOMPSON: Dietary management at 82
20 percent and over-the-counter at 59, and nothing
21 else above 45.
22 DR. EGGERS: So, I don't think we need

1 to get too much more into dietary management. I
2 think we heard it very nicely so far. So, we can
3 delve into a few of these. We did hear about --
4 well, let's talk about the over-the-counter ones
5 and just briefly, what did you include in that
6 when you were talking about those? What type of
7 medicines? Was it the medicines to treat mainly
8 gastrointestinal symptoms or were there some other
9 symptoms that you're trying to address with an
10 over-the-counter?
11 So, I think we probably have a sense of
12 what the over-the-counters are. And I think we
13 have a sense of what the medical devices or the
14 surgical treatments -- I'm going to guess that the
15 gastroparesis patients in here are a large part of
16 that. Are there any other devices or surgical
17 treatments that have not yet been described that
18 have worked really -- that have been very
19 important to you. Then we'll come here.
20 UNIDENTIFIED VOICE: This is, perhaps,
21 the first patient advocate. I'm the mother of a
22 deceased gastroparesis patient. And he did have a

1 gastric -- someone else did mention an implant or
2 a pacer as they called it. So, that was -- in its
3 initial stage, that was about eight years ago, it
4 was quite effective and they considered, at that
5 time -- this was done at Temple University, which
6 was one of the locations that was a special place
7 that you could get medications that hadn't been
8 approved, whether they came from Canada or not.
9 And we did, in fact, use a compounding pharmacy
10 for some of the medications, which had the effect
11 -- some were very effective for a time. I think
12 it's important to mention this pacer, because it
13 can be very effective for people. And when it was
14 initially introduced, it was considered that it
15 would be effective if it did anything. Not that
16 it made you totally better, if it did anything.
17 So, to that extent, it was effective for my son,
18 and initially, the first five -- four and a half
19 years, I think, it did fairly well, but you have
20 to -- I don't know if there are newer versions,
21 but the version he had had to have the battery
22 replaced, which is kind of funny when you think

1 about it. And so, things got worse and worse, and
2 I found that we were going to the emergency room,
3 like, every other week. And it finally dawned on
4 us that maybe the darn thing wasn't working. So,
5 when the battery was replaced, it did perk up a
6 little bit, but never -- it never really did -- it
7 never solved the problem, but I say it's very
8 worth investigating for those people who are
9 having a terrible time, because any relief can be
10 better than nothing.
11 DR. EGGERS: Thank you very much. And
12 we'll come here.
13 AMY: Hi, my name is Amy. I've had
14 gastroparesis for three years. I've went through
15 Botox. It did help. But then, my insurance said
16 no more, because they said it's cosmetic surgery,
17 even though it was helping. In January, I had a
18 tube put into my colon and I was very sick from
19 it. I had three infections within a six-week
20 period. And then, in March, they took the tube
21 out and I actually have a trap door now and a
22 hook. I put a hook into that every night and hook

1 to a bag, and I run Johnson & Johnson baby shampoo
2 through my body. Now, that makes me very sick
3 every day of my life now. And it's taken between
4 an hour to two and a half hours to run this bag
5 through my body. But I am still getting sick
6 every day from it. But my stomach is still
7 compacted yet, but not as much, and the vomiting
8 has gotten less now, but it is working somewhat.
9 DR. EGGERS: Thank you very much. I'm
10 going to go back there.
11 MARY: I just want to talk about
12 Enterra. I do have the gastric neuro stimulator.
13 And it was kind of a big lifesaver for me, but I
14 will tell you some downsides as well. As we were
15 increasing my rate, I started getting shocks. And
16 so, then speaking with the Medtronic
17 representatives and my GI docs and whatnot, we
18 decided that I needed a covering over the leads.
19 So, we went back in laparoscopically. She put a
20 layer of omentum over the leads and that helped
21 the shocking temporarily, because I had, as my --
22 it's a progressive disorder, so at some point, it

1 wasn't doing what it should, so we increased the
2 rate even more, and then I started the shocking
3 again. So, we had to decrease the rate. So, now,
4 I'm at a catch-22. Yes, it helps, but not like it
5 was.
6 DR. EGGERS: Thank you very much, Mary.
7 Do we have anyone on the phone? None on
8 the phone?
9 Do we have any web comments on devices
10 or surgeries?
11 MS. GIAMBONE: Yes. We also got some
12 comments -- one person had a gastro neuro
13 stimulator. Another one had a tube in the cecum to
14 give retrograde enemas.
15 DR. EGGERS: Thank you.
16 MR. THOMPSON: Actually, I think Anne
17 would like to say something. Anne, are you there?
18 MS. SIROTA: Yes, it's more than about
19 the devices, so it's okay. (Indiscernible).
20 DR. EGGERS: Okay, we'll come back to
21 you.
22 So, for -- about a device?

1 KATHARINE: I've never -- I haven't had
2 this done and I haven't heard any stories about
3 it. And it was only done at Johns Hopkins, but it
4 was called a stent that gets put into your
5 pylorus. Has anyone -- that's my question.
6 DR. EGGERS: Is that what you're getting
7 -- are you getting this summer? No, you had --
8 UNIDENTIFIED VOICE: Me? No, I had a
9 stent put in. It comes out after a while. It's
10 not a permanent solution. It's the same as the
11 Botox, right? It just opens the pylorus out
12 temporarily.
13 MARY: Dr. John Clark is my physician
14 and he is he one that had been running that trial.
15 And he had had good success with it, and he even
16 asked me to do it. But because it was a clinical
17 trial and I live in Richmond, Virginia, it just,
18 you know, logistics, because I was, like, "Well,
19 what if it malfunctions? Can I get it done, taken
20 out down there?" Because my GI felt comfortable
21 doing that, but he's, like, "No, you can't. You'd
22 have to come back up here." So, but as far as it

1 helping, he has seen improvement in the population
2 that he has done it in. And he said it's kind of
3 like a segue between trying to figure out if --
4 not really a permanent solution, but a segue to
5 see if pyloroplasty would be of benefit. So --
6 DR. EGGERS: Thank you. So, if you
7 notice the agenda, we are at a time when we would
8 stop, I think. But I think we can cut a little
9 bit into the open public comment, so we can go for
10 another ten minutes or so with this discussion.
11 I'm getting -- these are the people who give me
12 permission.
13 MR. THOMPSON: I think we have about 12
14 people signed up for open public comment.
15 DR. EGGERS: Then good. I just want a
16 show of hands on the acupuncture, needling, herbal
17 remedies, those more complementary things. Just a
18 show of hands, how many of you agree with -- and I
19 don't remember who said it, one of you -- Julian,
20 that it is a very, very important part of your
21 overall management? So, we have several hands.
22 We won't be able to get into this, but in the

1 docket, please feel free to explain how those are
2 and build on what we heard.
3 I do want to make sure that we talk
4 about what an ideal treatment would be, so if
5 there's any more questions from -- any questions
6 on any of these treatments from FDA? We've got a
7 lot of rich stuff.
8 Well, I was going to move on from these
9 and ask a specific question. Is there one that
10 we've talked about --
11 MS. TAYLOR: Dry needling is something
12 that I'd like to share about. Dry needling is not
13 in every state. And I was in the process of being
14 worked up for a small intestine transplant, hadn't
15 eaten for a year and a half, only ice chips. And
16 I was walking hunched over. I didn't even know I
17 couldn't stand up straight. So, the first time I
18 had this dry needling, five trigger points were
19 released in my stomach. I didn't realize it, but
20 I started to stand up straight that day. My
21 stomach growled. I got a real live hunger pain
22 and I ate that day. Then I had dry needling again

1 three days later. All told, there was four
2 sessions and 48 trigger points released in my
3 stomach and a lot more to go. Now, when these
4 trigger points release, it feels like a snake
5 moving and then a balloon deflating when it
6 actually is released, and it takes these muscles
7 that are just strangling the intestines, and had I
8 not done this, I would have no idea this would
9 ever work. I started actually eating. I started
10 eating solid food, and I have not eaten solid food
11 in a year and a half or more at that time. But I
12 can eat again, because you can feel the muscles
13 contract back. And they snap back into a knot,
14 which is just as painful as releasing the knot,
15 but I'm really wondering if, like, a managed
16 therapy of that type of looking even in that type
17 of direction might help, because had I not known
18 that it would release trigger points, I really
19 thought I was going to have to get that small
20 intestine transplant. So, I'm not looking in that
21 direction anymore. Thank you.
22 DR. EGGERS: Thank you.

1 I'm going to ask a show of hands
2 question. And it can be a show of hands on the
3 web, too, so if you want to chime in. How many of
4 you, given today, where you're at today, where
5 you've been in the past, share the experience and
6 the fortune of Meredith who find that you're in a
7 better place than you were and you feel that
8 you're pretty well managed?
9 We're not going to delve into your
10 experiences right now. I want to know a show of
11 hands of the people who are not that fortunate and
12 do not experience that. You're still struggling
13 as much as you ever have been.
14 Okay. For those of you who are raising
15 your hands, what's the one -- absent a complete
16 cure that's probably outside the scope of our
17 abilities to discuss today, but what would you
18 say, yes, I would feel -- this would be something
19 that is beneficial to me. What aspect would you
20 like to see improved -- what symptom or some sort
21 of aspect of your condition?
22 UNIDENTIFIED VOICE: So, I'm one of the

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1 very minorities in the room in that I have IBS and
2 functional dyspepsia and we have a lot of
3 gastroparesis people in the room. I think it's
4 different on the web. But for me, I just wish I
5 had more options of things that I can do. And I
6 know in the last couple years, we've gotten two
7 new drugs for constipation, which is fabulous, but
8 it's, like -- it seems like the process must be
9 really difficult to get these drugs through
10 because it's, like, I kind of do some research and
11 there's things out there that might be coming, but
12 then there's nothing coming. And there's just not
13 a lot of options that I think are safe, because I
14 have a belief in research, so I'm not going to go
15 and buy the herbals and things that haven't been
16 strictly tested. And so, I think if I just had
17 more options, I would be happier.
18 DR. EGGERS: Anything else? Any other
19 aspect that you're really looking for? Katharine,
20 then we'll go with Tanya.
21 KATHARINE: Mine's not really a symptom.
22 It's really the doctors and the medical field

1 themselves. I do have a caring doctor, but -- and
2 I know they can only do so much, but when it takes
3 months, weeks, you know, even a year to get the
4 treatments that we need, it's ridiculous. And
5 then you go in and your doctor doesn't take you
6 seriously at all. You have to be practically
7 dying in front of them to see how severe it is.
8 So, just listening better and actually seeming
9 like they care. I've had a lot of doctors just
10 write me off. And it's sad.
11 DR. EGGERS: We had Tanya and then --
12 and on the phone, if you want to contribute, as
13 well.
14 MS. TAYLOR: When it comes to the
15 symptoms, pain and nausea are my two top. If pain
16 and nausea could be controlled, I could feel human
17 again. I was in the hospital one time where -- I
18 can only take them raw. I am a poor metabolizer
19 when it comes to most types of drugs. So, when I
20 was in the hospital and the pain was managed on IV
21 medication, my mouth is how I take it, which
22 barely works, but when it was managed on an IV

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1 medication and the nausea was managed, I was
2 laughing. I was having a good time. I mean, I
3 forgot what it was like to be human. I really
4 forgot what it was like to be a human being again.
5 So, those two tops, sometimes I think, if we could
6 have more options with that.
7 DR. EGGERS: We'll go here and then --
8 did you still have something Elizabeth? No? Then
9 we'll go to Julian.
10 JULIAN: For me, doctor education is
11 just huge, because diagnosis is usually the
12 hardest stuff. I mean, I was 45 years old before I
13 got diagnosed. And actually, I was talking to a
14 doctor who is just fresh out of her residency, and
15 basically, she said everything that she saw about
16 my gastroparesis case contradicted everything she
17 learned in medical school. And that actually kind
18 of scares me, especially when it's a doctor that
19 people go to as the first step.
20 DR. EGGERS: Thank you very much,
21 Julian. We had Anne on the phone. Anne, I didn't
22 quite catch what Anne wanted to be talking about.

1 MS. SIROTA: I was talking about -- when
2 you were talking about the drugs that had side
3 effects, that worked, but then had side effects.
4 I was going to mention Verapamil, the calcium
5 channel blocker, which is good for -- I mean, I
6 have palpitations, PAC. And I was taking that for
7 that. But what it did, it created another
8 problem. It was a heart block. I had a very slow
9 heartbeat. And so, I had to take -- get off of
10 it. So, that was a side effect of a drug that's
11 not even given for IBS, for diarrhea, IBS.
12 But the other thing I was going to say
13 was that I think that one of the issues is that
14 there isn't enough research being done on
15 alternative medicines. And I realize that for a
16 lot of people, the scientific proof is what's
17 needed, and that may be true for all of us, but I
18 have found more success with some of these over-
19 the-counter supplements, but I don't really know
20 if they're safe, because there is no research
21 being done.
22 DR. EGGERS: Thank you very much, Anne.

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1 Is there anyone else on the phone? We
2 could take one more comment.
3 We have two more minutes, if I can see
4 that far, my alarm clock. I'm going to ask, are
5 there any final questions from the panel to ask?
6 (No response.)
7 Then is there someone who maybe focused on
8 pharmaceutical treatments or your symptoms or your
9 experience with you condition that you've had this
10 perspective or this thought and it has not yet
11 been shared.
12 ELIZABETH: I was just going to say, as
13 a patient and a healthcare professional that the
14 realistic life we are in right now is to ask
15 questions, own your illness, own your symptom, be
16 forthright about it, and never hesitate to get a
17 second or even a third opinion. And pray that you
18 find a physician or a healthcare provider that
19 will listen. And that is key.
20 DR. EGGERS: Thank you very much,
21 Elizabeth.
22 We'll take one more and then we will

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1 wrap up. Bettemarie.
2 MS. BOND: Sometimes a big part of the
3 treatment is advocating for yourself and being
4 aware of what's out there and what's going on, not
5 only treatment-wise, but two things that really
6 have impacted my treatment and care, I was reading
7 articles and I actually took the article in to my
8 doctor and said, you know, "This helped that
9 person. I wonder if that could help me." And
10 they sent me out to Pittsburgh and Pittsburgh did
11 this radical surgery and helped take away some of
12 the worst part of the pain. And then, there was
13 another one that I read of a medication that was
14 in trial and they ended up connecting me with the
15 doctor. I couldn't use it, because it was still
16 in animal trials, but out of that came a meeting -
17 - a wonderful doctor who then really provided a
18 lot of help and support, so sometimes the
19 physicians may not be aware of things, but it's
20 actually doing your own research and care in
21 trying to find out about new trials and
22 medications and treatments and surgeries and

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1 stuff. And it's not -- you know, sometimes it can
2 take years to get a diagnosis. And it's not that
3 you want something to be wrong with you, but you
4 start wondering, oh, my goodness, I'm having this
5 and all these tests are coming out normal, am I
6 imagining it? And you know you're not, because
7 stuff's not right going on in your body. But when
8 they actually say, we finally figured out this is
9 what's going on, it's just you want the validation
10 that, yes, something is going on in your body, and
11 it's not that you're looking for something to be
12 wrong, it's just that you're looking for answers
13 to try to improve your life.
14 DR. EGGERS: Thank you so much. And I
15 think that is a great comment upon which to end
16 our discussion. This has been a truly remarkable
17 day and a thank you from all of us to you, to our
18 four-legged friends who have provided input, so,
19 please, a round of applause to all of you.
20 (Applause.)
21 We're going to move into open public comment,
22 because our discussion here is ended and Pujita's

1 going to come and do that, and I'll just put a
2 plug in to be as concise as possible, because we
3 did dip into the open public comment time. But I
4 think it was worth it. I think you'll all agree
5 with me. So, thank you very much.
6 MS. VAIDYA: Hello, everyone. I'd like
7 to thank you all for coming today. We're now
8 moving into the open public comment session, and
9 for those of you who are not aware, the purpose of
10 this session is to allow an opportunity for those
11 who have not had a chance to speak on issues that
12 are not related to our two main discussion topics
13 today. This is an opportunity for folks who are
14 not a patient or a patient representative to come
15 up and comment. Please keep in mind that we will
16 not be responding to your comments, but they will
17 be transcribed and be part of the public record.
18 Since we would like this to be a transparent
19 process, we encourage you to note any financial
20 interest that you may have that are related to
21 your comment. If you do not have any such
22 interest, you may state that for the record as

1 well.

2 So, we have collected sign-up before the

3 meeting and then during the break. We have 12

4 people signed up and about 20 minutes or so for

5 the session, so please be respectful of your other

6 colleagues here and other patients, and try to

7 stick to the two-minute limit. I have a timer

8 here, so if you start approaching the two-minute

9 mark, I will kind of try to nudge you along.

10 So, I'll run through the order of

11 speakers, and I apologize if I mispronounce your

12 name. So, we have Tegan Gaekano, Marilyn Geller,

13 Ellen Komichers, Carissa Haston, Amy Foore, Nancy

14 Ginter, Kelly Brezoczky, Ritu Verma, Mary Berger,

15 Bruce Zagnit, Debbie Fisher, and then Raymond

16 Panus. So, first, could I get Tegan to the mike,

17 please.

18 MS. GAEKANO: I'd like to start by

19 thanking all of the patients and family members

20 for bringing your stories, your courageous stories

21 here today. So, my name is Tegan Gaekano. I work

22 for a patient advocacy organization, the

1 International Foundation for Functional
2 Gastrointestinal Disorders, or IFFGD. And I do
3 appreciate this opportunity to present our
4 comments with you here today. I do have a few
5 prepared comments.
6 So, for almost 25 years, IFFGD has been
7 working on behalf of patients affected by the
8 functional GI disorders. We have conducted
9 research to learn about this population, sharing
10 our findings with the public, the healthcare
11 community, and with regulators such as FDA in
12 order to advance understanding of the burden of
13 illness and unmet needs of all of those affected.
14 As we have heard here today, the
15 functional GI disorders cause a tremendous
16 individual and societal burden both in term of
17 economic and personal costs. Disorders such as
18 IBS, chronic constipation, refractory GERD, and
19 gastroparesis can be debilitating, taking away a
20 person's ability to participate in daily life, in
21 family, social, educational, and employment
22 activities. In the case of gastroparesis, the

1 condition may sometimes be life threatening.
2 Although dozens of conditions have been
3 characterized as functional GI disorders affecting
4 the different segments of the GI tract, these
5 conditions share many common features. Among them
6 they are chronic. Effective treatments are few.
7 And most are characterized by combinations of
8 multiple symptoms that can greatly diminish
9 quality of life. Although research into the
10 functional GI disorders has long lagged behind the
11 study of structural disorders, we have seen
12 increasing interest over the past two decades in
13 these disorders. What we have found is that there
14 are too few effective treatments for these
15 disorders and that among patients, there is a high
16 level of dissatisfaction with the treatments that
17 are available. Treatments that work for simple
18 acute constipation, diarrhea, heartburn, stomach
19 pain, or nausea just to name a few are not
20 adequate for the chronic symptoms that accompany
21 the functional GI disorders.
22 MS. VAIDYA: Thank you, Tegan. Sorry,

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1 two minutes is up.
2 Next, could I get Marilyn Geller?
3 MS. GELLER: Thank you. I'm Marilyn
4 Geller from Celiac Disease Foundation. And I was
5 invited to speak because the symptoms of the
6 celiac disease population really are the same
7 symptoms as those with functional GI. The issue
8 is, for me, both personal and public. Celiac
9 Disease Foundation represents the three million
10 Americans with celiac disease, about two and a
11 half million undiagnosed who don't realize that
12 they have it. It's personal that I have a son
13 who's 22, and his father, who's now in his mid-
14 50s, both were not diagnosed for a large number of
15 years. Our son was diagnosed first at 15 with
16 lifelong symptoms. He suffered horrifically. His
17 father did the same and was not diagnosed until he
18 was 45. We spent years and thousands and
19 thousands of dollars dealing with functional GI
20 diagnoses. And the data that we've collected with
21 Celiac Disease Foundation is it's quite similar.
22 The vast majority of patients with celiac disease

1 are diagnosed first or misdiagnosed first with
2 functional GI disorders. And with the billions of
3 dollars spent in the testing and the treatments
4 for misdiagnoses, it becomes imperative that as we
5 look at the functional GI population in the
6 screening that we include celiac disease testing
7 as a standard of care. Thank you.
8 MS. VAIDYA: Thank you, Marilyn.
9 Next we have Ellen.
10 MS. KOMICHERS: Thank you so much for
11 holding this panel this afternoon. As I've said
12 earlier, I'm a patient with severe, but managed,
13 gastroparesis. Domperidone is my magic bullet.
14 With it, I can eat, without it, I cannot. My
15 gastroenterologist has informed me that there is
16 no safe alternative to domperidone for treating my
17 gastroparesis and that the special permission
18 process allowed by the FDA is opaque and
19 overwhelming. I need domperidone to stay healthy.
20 I am urging the FDA to put domperidone on its
21 positive list for compounding pharmacies so that I
22 may locally obtain safely- compounded, domestic

1 domperidone or failing that, that the FDA not
2 enforce the fact that domperidone is not on the
3 positive list. Thank you.
4 MS. VAIDYA: Thank you, Ellen.
5 Next we have Carissa Haston.
6 MS. HASTON: I am Carissa Haston and I
7 am the president and founder of G-PACT or the
8 Gastroparesis Patient Association for Cares and
9 Treatments. And I just want to thank the FDA for
10 working with us on this. We've been working for
11 15 years trying to get something like this going.
12 And I could say that, you know, we deal with tens
13 of thousand patients every single day and they
14 have been so hopeless. And finally, a lot of
15 those hopeless people are starting to feel a
16 little bit more hope like there might be some
17 progress towards this that we're finally getting
18 the attention that we need for these conditions
19 and there's a real focus on it. So, I just want
20 to thank you for working with us, and I also want
21 to thank the patients who went and filled out the
22 survey on our website to help get prepared for

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1 this. And I encourage people to keep doing that,
2 because that's a big part of understanding -- you
3 know, helping them understand.
4 A little bit about my story. I was
5 diagnosed with gastroparesis in 1994 at the age of
6 16. And basically, there was, like, I tried
7 Propulsid and erythromycin and I went into cardiac
8 arrest. I almost died. And so, they had to stop
9 those drugs. And by the year 2000, I developed
10 chronic intestinal pseudo- obstruction. They were
11 not able to feed me by a feeding tube, so I was
12 started on TPN. And because my gut was so slow, I
13 kept developing so many infections that were
14 backing up into my bloodstream from my gut, and
15 also because of the TPN. And I lost all my venous
16 access. I lost down to 68 pounds. They were not
17 able to feed me anymore. Basically, sent me home
18 from the hospital to die. And finally, they said,
19 okay, you can go to the University of Pittsburgh
20 for a five- organ transplant. And so, in 2006, I
21 had a five-organ transplant, and they did my small
22 bowel, stomach, pancreas, duodenum, and they had

1 to do my liver, because my liver had failed on
2 TPN. It was twice its normal size and full of
3 fatty deposits. They did not think -- when I got
4 there, I was the sickest patient that they had
5 ever seen. And they did not think I would even
6 make it to the transplant, and they were fortunate
7 to be able to find enough veins in me in
8 Pittsburgh. Hershey had blacklisted me for
9 central lines. Pittsburgh was able to find enough
10 veins to get me through transplant for TPN for 13
11 months. I had a 13-month wait, which is longer
12 than most people. They did not think that I was
13 going to make it to the transplant. And when I
14 had it done, by the time I had it done, I was so
15 sick, I had literally days, if not just hours to
16 live when my organs arrived.
17 MS. VAIDYA: Thank you, Carissa. Sorry.
18 Please submit your comments to the docket. We
19 really encourage you to do that.
20 MS. HASTON: All right.
21 MS. VAIDYA: Next, could I please have
22 Amy Foore.

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1 MS. FOORE: (Indiscernible).
2 MS. VAIDYA: Okay, that's fine. Go
3 ahead.
4 MS. HASTON: I'll try to finish up here.
5 So, anyway, then I -- my gastroparesis ended up
6 coming back. I did really well for four years.
7 It ended up coming back. But I had to go back on
8 TPN and my liver started to fail again, so they
9 had to eventually stop that. I finally -- my
10 colon shut down and I had my colon completely
11 detached a couple years ago, and now I'm on an
12 ileostomy for life, and I'm on feeding tube now as
13 well. And so, there's not any, like, treatment
14 options. But I face a future of kidney failure
15 from the transplant medications, the anti-
16 rejection meds. I have severe osteoporosis from
17 the steroids that they're using to treat the
18 transplant as well. And I was legally blind for
19 two years and they don't know why, but they think
20 possibly some of the IV antibiotics that I was on,
21 and some of the infections made me go legally
22 blind. And it's starting to come back, but I'm

1 still quite low vision. So, anyway, there are
2 just a lot of issues that come with this that --
3 and I'm loosing (indiscernible) in my brain. I
4 have dysautonomia and I also have mitochondrial
5 disease along with some other things. So, there's
6 a lot of issues that need to be addressed when
7 dealing with treatment options, because it's not
8 just the gut. There's other things going on as
9 well, so --
10 MS. VAIDYA: Thank you, Carissa.
11 Next, could I get Nancy Ginter, please.
12 MS. GINTER: Well, thank you all very
13 much again. By now, you know that I'm the mother
14 of a son who had gastroparesis. And as you all
15 also know now, it is a disastrous situation. So,
16 I want to just speak for a moment about that.
17 Some of the points that were brought up, one
18 that's most important, I think, and that is that
19 you are so delightfully and importantly embracing
20 the voice of the patient. And I think that many
21 of the folks here have talked about that in their
22 own experience that if the people they were

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1 dealing with in the medical profession had
2 listened more carefully to the voice of the
3 patient, they would have taken that voice more
4 seriously. And so, I'm all for taking it
5 seriously and I -- someone made a wonderful
6 suggestion about improving the language that we
7 use so that people will be truly understood and
8 can bring the language that's being asked for to
9 the patient's language and not the medical
10 language. And it's not, perhaps the standard that
11 we use today. So, that's my thought about the
12 functional GI disorders.
13 I happen also to work for the National
14 Foundation for Celiac Awareness. And like Marilyn
15 with the Celiac Disease Foundation, we're very
16 concerned about the diagnosis of those two and a
17 half million Americans who do have celiac disease
18 and don't know it. Many, many of them have been
19 told that they have irritable bowel. So, like
20 Marilyn, I hope that when that topic comes up and
21 a doctor says, "You have irritable bowel," they
22 might just think, maybe, just maybe this patient

1 has celiac disease. We would like -- our mission
2 is to get these folks diagnosed and to live life
3 to the fullest. And it can't happen until they
4 have -- until they, too, are taken seriously and
5 celiac disease is considered a serious, serious
6 illness that can have dramatic effects, just as
7 these functional GI disorders do. So, we're all
8 for taking it seriously.
9 And one of the other points that I'd
10 like to make, and I've spoken to a couple of folks
11 today. When the nominations -- I call it
12 nominations for serious diseases to be part of
13 this program or considered, we did submit celiac
14 disease as one of those. We did not win the
15 Academy Award. And so, I'm asking again if
16 there's another round of consideration or if
17 there's some time that we can submit that, and we
18 will put it on the docket that it be considered as
19 part of this program as well, so it will get the
20 attention. And again, as we have a new campaign,
21 we say, seriously, celiac disease.
22 MS. VAIDYA: Thank you, Nancy.

1 Next we have Kelly Brezoczky.
2 MS. BREZOCZKY: You did a nice job on my
3 name, by the way. Most people don't get that one.
4 So, I am Kelly Lewis Brezoczky. I am the founder
5 of the non-profit Healthy Mature Living
6 Foundation. Our first educational initiative is
7 ablinfo.org, and we developed that in
8 collaboration with Dr. Heidi Brown at the
9 University of Wisconsin-Madison. Dr. Brown and I
10 have also published in the International Journal
11 of Clinical Practice on the quality of impacts of
12 accidental bowel leakage as a symptom associated
13 with many common conditions, including the
14 functional gastrointestinal disorders discussed
15 today.
16 I will also separately state for the
17 record that I am the founder of Butterfly Health,
18 which has developed a new absorbent protection
19 product called butterfly, which some of you may
20 have heard of. I am not your ordinary industry.
21 I am the mother of three girls who, like all of
22 you today, felt compelled to make a difference. I

1 have spent too many years working with people who
2 experience accidental bowel leakage not to be here
3 today.
4 A comment I would like to make and leave
5 you with is that today I think you are listening
6 and talking about symptoms. But failing to focus
7 enough attention on the root cause and mechanism
8 that cause these conditions, especially in the
9 enteric nervous system. All of you here today
10 reflect the experience of many years of living
11 with a functional gastrointestinal disorder. Yet
12 many more millions suffer in silence wondering
13 slowly what is happening to them, wondering who to
14 turn to, especially when their physician tells
15 them that test after test comes back normal. The
16 thought I would like you to think about is how do
17 we get at the mechanism so that we can help people
18 sooner. Everybody that's in this room today is
19 reflecting and representing nearly a lifetime of
20 experience of something that has progressed. We
21 need to better understand the mechanism of action
22 if we are to get better treatments and better

1 physician care, because all of you are right.
2 Today, doctor education is one of the biggest
3 opportunities that we face. The pharmaceutical
4 companies will investigate mechanism when it is
5 only financially attractive to do so. This is not
6 happening sufficiently with the population here
7 today.
8 The FDA this morning spoke of the
9 enteric nervous system at the start of this panel.
10 If you look at any of the other neurological
11 diseases, you will see that they share a common
12 characteristic. They progress. Research on panic
13 and anxiety would show that it gets worse, not
14 better, if it's left untreated. If you look at
15 diseases like MS and Parkinson's, they will show
16 that the sooner you help the pathways, the
17 understanding of the pathways, the better.
18 Interestingly, with panic disorder specifically,
19 the literature is very clear that behavior
20 treatment is more likely to reduce relapse.
21 MS. VAIDYA: Thank you, Kelly.
22 MS. BREZOCZKY: Today we have listened

1 to stories of progression. I'd just like to ask
2 the FDA, I hope that you can follow up this
3 wonderful session with a nationally representative
4 survey so that you can get national sampling on
5 this topic, because I think it's far more
6 prevalent than people realize. Thank you.
7 MS. VAIDYA: Thank you, Kelly.
8 Next we have Ritu Verma.
9 DR. VERMA: Thank you. I'm a pediatric
10 gastroenterologist at Children's Hospital in
11 Philadelphia and I'm here to represent the kids.
12 I do have children, but I'm here to represent the
13 children with functional GI disorders. We have a
14 wonderful center, by the name of the Lustgarten
15 Motility Center, that has contributed money so
16 that we can actually study children who have these
17 conditions.
18 I think the FDA has taken on a huge,
19 huge task. I wonder how you go from here. So,
20 first of all, I think, from a children's
21 standpoint, there's not just the child, but
22 there's the child and the parent, and then there's

1 the child and the school, and child and the
2 friends. So, all of those things affect the
3 children. We've learned that this is not just a
4 medicine, but here we have more to do with the
5 function part of it. The child goes to school,
6 has abdominal pain, the teacher does not believe
7 the child. The child comes home, is upset, and
8 does not want to go back to school. So,
9 immediately, it's thought of that this child has
10 school phobia. It really is not school phobia.
11 The child is in pain and in discomfort. So, we
12 need to educate the children. We need to educate
13 the parents, and we need to educate the schools.
14 So, education has to be on many levels for the FDA
15 to see that this is going to be a success.
16 Partnership has to happen with parents.
17 We have to agree that our children should be part
18 of studies so that we can actually get more drugs.
19 Partnership has to be with industries.
20 Partnership has to be with insurance companies
21 that do not allow the children to have these
22 conditions -- to have these medications.

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1 I also think what we have not talked
2 about here is non-invasive tests. No one talked
3 about breath tests that are available for
4 gastroparesis. So, I think sharing knowledge is
5 going to become important. So, from my
6 standpoint, knowledge has to be part of wherever
7 we go with these functional GI disorders and
8 knowledge at many levels. There's so much work
9 here to be done and I really commend the FDA that
10 you actually set up this forum. And I really am
11 quite interested to see what happens next. Not
12 going to be an easy task. Thank you.
13 MS. VAIDYA: Thank you, Ritu.
14 Next we have Mary Berger.
15 MS. BERGER: I'm going to talk about
16 some novel ways for drug companies to pursue other
17 options to help with functional GI illnesses. In
18 2013, there was a trial done to look at IV hemin
19 for GP at Mayo Clinic. They told wherein humans
20 and animal models of idiopathic GP, there was a
21 loss of the ICC cells. And that was needed for
22 sufficient stomach emptying. And it was shown by

1 another researcher, (indiscernible) that heme
2 oxygenase 1 is a target for gastrointestinal
3 disease. So, Dr. Farrugia at Mayo said a critical
4 role is oxidative stress, so why not look into
5 other areas and avenues of fighting free radical
6 formation, antioxidants at higher levels.
7 Because, for example, I started taking NAC, and
8 Alpha Lipoic Acid, to increase the glutathione
9 peroxidase in the mitochondria. And that started
10 helping me. So, more research into oxidative
11 stress.
12 Another thing is celiac disease. Half
13 of the patients with celiac disease do have
14 gastrointestinal motor abnormalities. Most of
15 them have some form of functional dyspepsia that
16 goes undiagnosed. So, it would be good if we
17 could find a better way to develop testing methods
18 for those with celiac disease, and use the ones we
19 have in a more efficient manner. It doesn't even
20 touch on the segment of the population that has
21 non-celiac gluten sensitivity, which probably have
22 some form of motor impairment as well.

1 But the key, I believe, to a cure, lies
2 in an article by Holter et al. in Neuropeptides
3 from 2012. What do NPY, PYY, and pancreatic
4 polypeptide do in the gut/brain access? Just look
5 at figures 1 and 2. It's not a one-drug cure, but
6 rather it's going to take multiple drugs. NPY in
7 the brain has an effect on food intake, anxiety,
8 mood, energy balance, and cognition. If this is
9 out of whack, what happens? With NPY an Y1 --
10 MS. VAIDYA: Excuse me, Mary. Sorry,
11 your two minutes is up. Please submit your
12 comments to the docket.
13 Next we have Bruce Zagnit.
14 MR. ZAGNIT: Thank you very much. I'm a
15 compounding pharmacist. And first of all, I'd
16 like to thank the FDA for allowing us to come in
17 and speak about these topics. I'd like to thank
18 the people who relayed their stories to us. It
19 must be on one hand, very difficult to relay those
20 stories, and the other hand, it must be very
21 comforting to know that you're speaking to a group
22 of people who really care.

1 As your survey shows, 60 percent of the
2 people who are taking domperidone currently or
3 taking domperidone in conjunction with other
4 drugs. Domperidone is a highly effective safe
5 treatment or adjunct for gastroparesis and emesis
6 with very limited side effects. The people who
7 are getting those prescriptions are either getting
8 them -- most of them are probably not getting them
9 through the FDA IND program, but rather are
10 getting them from outside the country from Canada
11 or Australia or from compounding pharmacies
12 throughout the country who are doing it without
13 the better wishes of the FDA. What I'm asking the
14 FDA is to change the regulations, put domperidone
15 on the positive list, and allow me and other
16 compounding pharmacies throughout the country to
17 provide this very vital, lifesaving drug to our
18 patients in hopes that it will make it more
19 accessible to them and there will be a lot more
20 benefit. That's it, thank you.
21 MS. VAIDYA: Thank you, Bruce.
22 And next we have Debbie Fisher. Debbie,

1 where are you?
2 MS. FISHER: I just want to say that I
3 know that there is no treatment that is going to
4 work for everybody, but for those of us who have
5 had good results with domperidone, it's really
6 frustrating and disheartening to know that there
7 are such efforts going on to restrict it from
8 patients. There are drugs that are FDA approved,
9 like Reglan and Compro that have severe
10 neurological effects that are irreversible and
11 they can only be used for a short period of time.
12 People become -- develop a tolerance to
13 erythromycin. There are few alternatives, and the
14 studies that have been done on domperidone for the
15 most part that have shown any negative effects
16 have been done on lactating women and people with
17 pre- existing cardiac risk factors.
18 So, I just -- and finally, I just want
19 to note that for the clinical guidance from the
20 Journal of the American Association of
21 Gastroenterologists notes that domperidone is
22 generally as effective as Metoclopramide with a

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1 lower adverse risk profile. And I just really
2 hope that people will understand how important it
3 is for patients who are suffering with this
4 problem to be able to get hold of this medication
5 that can be used safely, and to please put your
6 efforts into maybe developing clinical guidance
7 for doctors and compounding pharmacies and
8 patients rather than making this drug not
9 available.
10 MS. VAIDYA: Thank you, Debbie.
11 And last, finally, we have Raymond
12 Panus.
13 DR. PANUS: Hello. I'm Dr. Raymond
14 Panus, and I'm an employee of Enterra Health,
15 which is a medical foods company. And first, I'd
16 like to thank the FDA for putting this meeting
17 together. And I'd also like to thank all the
18 patients who provided their story for this
19 afternoon.
20 I would like to note that these meetings
21 often discuss a variety of drugs, both
22 prescription and over-the-counter products. They

1 discuss devices, dietary modification, and various
2 other therapies, such as supplements, herbals,
3 acupuncture, and other types of therapies. But
4 often these meetings do not discuss FDA-regulated
5 medical foods which are usually not part of these
6 discussions. And so, I was curious what the FDA
7 is doing to help support the study of medical
8 foods and FDA-regulated medical foods for the
9 management of GI disorders. And additionally, I
10 would also like to see that the FDA include FDA-
11 regulated medical foods in future discussions such
12 as these as well. Thank you.
13 MS. VAIDYA: Thank you, so much.
14 So, now, before we get started with our
15 last agenda item, I'd like to ask everyone to
16 leave your clickers at the table and we'll have
17 staff pick it up. And also, we have evaluation
18 forms. If you haven't gotten a chance to fill
19 those out, yet, please do. We definitely do read
20 them.
21 And so now, finally, I'd like to call
22 Dr. Andrew Mulberg to the stand for the closing.

1 DR. MULBERG: Thank you, Pujita. So,
2 within the spirit of staying within two minutes,
3 I'll do my best so I won't be thrown off the
4 stage. First of all, I want to thank Sara Eggers
5 and the Office of Strategic Programs and all of
6 the staff that was involved in producing what by
7 far for me here has been an amazingly empowering
8 powerful experience.
9 I also wish to thank all of the
10 panelists and the public speakers who shared a
11 tremendously honest and transparent communication
12 regarding their signs and symptoms in a public
13 forum. I find that, as a physician, not only
14 heartwarming, but truly educational, and I truly
15 appreciate it.
16 I think I'll just summarize this
17 wonderful afternoon by saying I've identified at
18 least three issues that I know will be added to by
19 all of us as we download from such a wonderful
20 meeting. There's a need for additional
21 pharmacotherapies and additional therapies to be
22 developed for the unmet need that has clearly been

1 discussed today.

2 I was struck by the profound repeated

3 communication that there's really a significant

4 ignorance in the medical community. Both -- since

5 I'm a pediatric gastroenterologist, I know Dr.

6 Verma, there is no ignorance there. But for the

7 adult community, there seems to be a need for

8 education.

9 Lastly, there is a tremendously

10 justified unmet medical need that you've

11 communicated to us today. And as has been

12 communicated by everyone here, the partnerships

13 amongst all of us with the device and pharma

14 companies, with you as a patient community, and

15 with us, with the academic physicians and us in

16 regulatory agencies, we really do value this kind

17 of input, and we look forward to sharing,

18 hopefully, new therapy and therapeutic advances

19 over the next few years, if not sooner. So, thank

20 you very much. Have a great evening.

21 (Whereupon, the above entitled matter

22 concluded)

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$750 151:19

1

1 27:19 35:8 38:22 136:20 193:2 194:5
1.5 122:9
10 106:5 146:14 147:10
100 90:8
10-12 77:2
103 118:20
105 79:6
10903 1:11
11 1:7 2:4 38:13
111 2:11
114 40:17
117 2:12 96:14
12 54:8 89:18 163:13 175:3
124 2:13
128 2:14
13 14:15 182:10
131 2:15
13-month 182:11
13th 31:7
14 38:13 62:3 151:9
15 106:5 115:8 120:7 178:15 180:11
15-minute 7:15 109:17
16 14:17 99:8 127:16 181:6
17 2:5
175 2:16
178 2:17
179 2:18
18 38:4,5,11
180 2:19
184 2:20
187 2:21
190 3:2
192 3:3,4
196 3:5
1963 118:13
197 3:6
199 3:7
1994 181:5

2

2 67:8 109:20 110:14 136:20 194:5
2:00 99:4
2:45 7:15,16
2:57 109:19
20 14:10 22:17 91:13 92:3 93:6,15 101:13 146:16 147:1,8 175:4
2000 181:9
2002 119:19
2003 120:3
2006 120:19 121:1 181:20
2007 42:2
2008 121:7
2009 124:22
2010 128:22
2011 121:8
2012 14:14 121:10,12 130:4 194:3
2013 14:13 114:9 121:13,15,16 129:7 130:11 192:18
2014 121:18
2015 1:7
2017 14:13
20993 1:12
20s 44:18
20-some 96:13
22 178:13
24 38:2 81:19
240 125:5
25 2:6 59:19 153:10 176:6
26 111:17,21 112:18
27 38:1 118:21
29 38:1 123:20

3

3:07 109:19
3:15 109:18
30 38:5,11 91:13 92:3 93:6,15 129:15
30-page 49:13
30s 42:1 44:18 45:6
31 38:5,11,12
38 92:6
39 2:7

4

4:00 99:4
40 38:5,12 101:11
41 38:5,12
42 62:14
44 2:8
45 19:1 156:21 169:12 178:18
48 51:21 165:2

5

5 2:3
50 38:5,12
50s 178:14
51 38:5,13
52 2:9
53 137:20
56 118:1
59 2:10 156:20

6

60 37:22 38:6,13 195:1
61 38:6,13
66 137:21
68 181:16

7

70 38:6,13
71 38:6
750 122:8
7th 142:9

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8

82 156:19

9

90 120:19 133:2

94 40:17,21

A

abdomen 68:3 72:20 77:21 119:8,11 122:8 133:19

abdominal 19:13 21:13 44:22 68:13,19 69:7,8,16,20 70:1 71:12 73:16,22 74:5 77:10,20 80:9 102:6,18 111:20 114:3 119:9 129:22 131:11 191:6

abilities 100:20 166:17

ability 26:17 62:11 86:20,22 176:20 201:8

able 30:17 33:7,19 39:20 40:13,15,22 41:2 43:12 47:15 54:4 55:21 57:15,16 59:8 62:12 72:2 74:3 82:19 83:16 85:14,19 86:8 88:14 94:8 95:20 96:17,22 101:6 106:7 117:7 121:19 125:17 126:13,15 129:19 130:11,17 138:20 139:8 141:19 147:6 148:21 149:3 163:22 181:11,17 182:7,9 197:4

ablinfo.org 187:7

abling 60:4

abnormal 9:5 18:17,18 20:11,12,15 21:1

abnormalities 18:21 193:14

abnormality 18:8 24:16

absent 166:15

absolutely 140:12,15

absorb 114:21

absorbent 187:18

absorption 116:19 122:21

academia 11:4

academic 200:15

Academy 186:15

accept 45:4 46:19

access 181:16 194:4

accessed 24:8

accessible 195:19

accidental 107:16 108:7 187:12 188:2

accidental-type 107:21

accommodate 32:18

accompany 177:20

accurate 201:7

ache 78:1

aches 77:20

achy 83:17

Acid 193:8

acidic 82:11 122:19

acknowledge 145:18

across 19:22 20:1 37:18 43:19 75:20

acting 106:10 127:4

action 188:21 201:10,14

activated 114:12

active 43:3 124:1

actively 16:2

activities 20:17 26:18,22 39:19 53:16 54:9 87:1 91:11 131:20 176:22

activity 27:1,3 74:2

acts 105:16

actual 144:5

actually 10:10 17:2,5 22:20 23:22 39:12 44:10 50:10 52:6 56:2 60:6 61:21 62:5 64:5 79:22 91:20 94:17 98:3 104:6,8 108:11 116:20 135:5,8 138:20 139:3 141:21 145:5,13 149:17 150:2 152:5 153:22 159:21 161:16 165:6,9 168:8 169:13,17 172:7,20 173:8 190:16 191:18 192:10

acupuncture 49:1 99:9,11 112:4 113:19 125:20 127:21 163:16 198:3

acupuncturists 125:15

acute 177:18

add 75:13 149:22

added 199:18

Addison's 150:12,13

addition 22:19 119:4 120:21 122:17 128:7

additional 199:20,21

additionally 198:9

address 31:6 33:7 83:5 115:17 148:14 155:13 157:9

addressed 148:15 184:6

addresses 110:20

adds 151:7

adequate 25:6 33:18 75:1

177:20
adjunct 195:5
adjusted 76:9
administer 75:2
Administration 1:9
admit 77:9
admitted 146:10
adrenal 150:12
adult 40:16 118:18 119:12 152:3 200:7
advance 176:12
advances 200:18
adverse 140:12 142:3 153:20 197:1
advice 133:16
advocacy 16:1 175:22
advocate 36:16 140:19 157:21
advocates 8:16 28:7 32:12 38:15
advocating 172:3
affairs 31:12,20
affect 10:3 18:8 26:17 45:13 62:19 191:2
affected 19:21 62:20 86:19 119:10 176:7,13
affecting 65:2 78:13 177:3
affects 36:7
afford 81:6
afraid 51:16
147:14 155:6,9
afternoon 5:7 6:8,21 8:7 11:14 72:22 90:2 99:3 110:2 117:18 131:4 179:11 197:19 199:17
afterwards 52:13 54:20 62:19
against 25:7 132:13
age 20:1 38:4 118:13,20 181:5
agencies 200:16
agency 5:2 26:2
agency's 4:16
agenda 6:8 7:16 26:13 99:16 110:17 163:7 198:15
agents 23:8
aggravating 114:22
ago 39:18 44:15,16 64:2 89:14 111:17 113:12 114:5,8 127:5,6 138:18 148:20 150:21 154:17 158:3 183:11
agreed 126:5
ahead 16:3 74:13 78:8 103:17,18 141:7 143:3 183:3
aid 29:8,13
air 135:19
al 194:2
alarm 171:4
albeit 150:9
alcoholic 50:5
Align 122:12
alive 134:4
allergic 127:14
alleviate 130:5 133:22 134:21
allotment 7:9
allow 174:10 191:21 195:15
allowed 64:6 179:18
allowing 117:9 194:16
allows 60:8
alosetron 23:20
Alpha 193:8
already 7:6 8:10 12:8 16:19 17:4 45:8 97:15
alternated 111:22
alternative 113:6 170:15 179:16
alternatives 196:13
am 4:6 41:1 42:2,9 56:11 92:6 95:20 103:3 111:10 117:8,20 121:18 122:1 123:19,20,22 126:21 127:17,21 128:2 130:16 131:10,15 145:5 160:5 168:18 173:5 179:20
180:6,7 187:4,17,20,21 192:10 201:8,11 202:4
amazed 126:2
amazingly 199:7
American 196:20
Americans 178:10 185:17
Amitiza 132:21 137:11 143:8
among 177:5,15
amongst 26:9 103:7 200:13
amount 71:22 94:3
amounts 86:6
Amy 159:13 175:13 182:22
anal 120:5
anatomic 18:7
and/or 99:11
Andrea 31:14,18
Andrew 3:7 5:7 85:9 198:22
anemia 96:7
angry 72:21
animal 11:1 123:15 172:16 192:20
Anne 2:11 111:8,13 117:10 135:22 161:16,17 169:21,22 170:22
annoying 50:8

anorexic 60:20
answer 33:12 81:10 94:14
answers 15:18 125:9 173:12
anti 115:18 129:11 149:14 183:15
antibiotics 183:20
antidepressants 24:4
anti-depressants 113:2
Antidiarrheals 23:7
anti-nausea 88:2 132:10
antioxidants 193:6
anti-spasmodic 112:11
anus 121:2
anxiety 115:12 189:13 194:7
anxious 155:5
anybody 53:1 149:20
anybody's 85:6
anymore 50:13 55:15 85:7 165:21 181:17
anyone 7:2,4 67:13,14 70:8 71:15 87:16 104:14 106:21 114:15 137:3,12 138:6 139:18 148:2,8,13 153:16 155:12 161:7 162:5 171:1
anything 8:2 41:3 44:4,5 48:5 50:15 51:3 53:21 55:7 72:12 77:16 88:15 89:3 97:6 116:15 130:14 136:7 142:20 143:19 145:1 146:19 148:21 152:11 155:2 158:15,16 167:18
anyway 73:11 183:5 184:1
anywhere 18:9 27:21 89:3 105:7
apart 70:7
apologize 143:11 175:11
a-potty 54:14
APPEARANCES 3:1
appetite 21:16 141:22 145:13
applause 67:2,3 124:13 135:21 136:1 173:19,20
application 10:21 11:20 12:2 14:9
applications 10:13 13:8 14:3 16:22
apply 30:11 37:8 68:8 100:12 156:7
appointment 46:21 125:16
appreciate 25:17 34:17 128:12 176:3 199:15
approaches 6:19 27:7 110:14 112:1,13
approaching 175:8
appropriated 124:4
approval 10:21
approved 24:7 132:17 133:5 146:9 158:8 196:8
approximately 19:1 44:14
April 120:19 121:13
aquasize 99:9
archived 8:4
arcuate 130:4 150:8
area 14:11 35:11,12 107:4 108:3,15 122:3,6
areas 86:17 193:5
aren't 106:9 136:16
array 23:2
arrest 181:8
arrived 182:16
article 172:7 194:2
articles 172:7
artificial 49:18,21
aside 6:21
asleep 86:20
aspect 166:19,21 167:19
aspects 12:21 15:15,21 110:19
aspiration 127:7,10
assess 11:19 25:2
assignment 67:4 94:11
assists 135:8
associate 92:18
associated 15:22 17:1 23:9 90:4 187:12
Association 180:8 196:20
asthma 119:12
astounding 22:16
ate 52:18 53:4 63:14 90:1 133:7 164:22
attend 30:17
attention 180:18 186:20 188:7
attorney 201:12
attractive 189:5
atypical 129:11
audience 8:18 84:9
August 120:22 121:16 129:7 130:11
Australia 195:11
autonomic 59:10 138:19
available 12:8 13:1 23:13 116:13 131:21 134:8 177:17

192:3 197:9
Avenue 1:11
avenues 193:5
average 83:10 95:11
avoid 47:15 117:7 129:20
awake 89:17
Award 186:15
aware 172:4,19 174:9
Awareness 185:14
away 54:13 61:8 80:22 88:11 142:10 148:10 172:11 176:19

B

baby 41:17 122:11 147:4 160:1
bac 46:3
backed 65:1 102:13 103:22 104:2
background 4:19 6:11 9:12 17:14 18:2 83:3
backing 77:7 181:14
backpack 62:6
backwards 64:16
bacterial 103:5
bad 40:22 45:11 48:9 51:3 53:6 55:12,22 57:19,20 63:9,14 80:14 81:3 83:12 91:12 95:14 97:14 115:11 118:18 126:5 131:14 140:20 143:6
badly 67:1
bag 72:6 91:15 121:22 122:1 123:17 160:1,4
bagful 50:14
baggies 91:14
bags 93:16
Baker-Wong 83:7
bakery 55:5
balance 97:16 194:8
ball 44:3 70:21 75:22
balloon 165:5
banned 126:10
barely 116:1 168:22
barrier 155:3
base 17:10 43:15
baseball 54:10,12 57:18
based 18:22 19:2 47:11 78:19
basically 20:16 22:12 31:2 47:18 51:4 53:2 114:18 128:20 169:15 181:6,17
basis 22:9 48:6,11 56:12 73:20 74:22 79:2,8 88:19 98:17 117:4 145:19
bathroom 42:5 57:22 105:8,13 106:12
bathrooms 54:13
bathroom's 57:21
battery 158:21 159:5
battle 98:12
bay 130:16
Bears 63:13
beautiful 123:21
became 60:13 118:17 133:1 147:12
become 42:1 114:1,21 115:14 119:10 131:19 152:6 192:5 196:12
becomes 133:19 179:4
becoming 46:6 133:9
bed 41:1 44:3 88:8,20 154:11
bedridden 131:15
bedroom 57:20,22
begin 67:8 106:15
beginning 88:12
behalf 36:22 176:7
behavior 189:19
behind 7:12 51:5 177:10
belief 167:14
believe 11:7 20:4 42:13 76:4,5 94:19 123:9 134:9 191:6 194:1
believes 114:14
belly 42:19 78:3
Beltway 35:17,18,20
beneficial 34:8,9 166:19
benefit 25:4 155:17,21 163:5 195:20
benefits 9:18,22 11:19 12:17 17:11 24:20
Bens 2:8 44:9,13 51:9
bent 76:17
Bentyl 115:18
Berger 3:3 175:14 192:14,15
besides 156:3
best 27:4 41:5 46:20 70:18 98:9 101:8 121:5 199:3 201:7
beta 127:7
Bettemarie 2:10 59:2,3 65:9 66:12 76:11 103:17 138:14 150:19 172:1
better 27:14 38:6 48:1 63:7 65:12 66:10 72:7,10 115:2,3 116:8 121:3 122:10 136:7,12 158:16 159:10 166:7 168:8 188:21,22 189:14,17

193:17 195:13
better-informed 13:22
beverages 7:12 50:5
beyond 39:4
bicarbonate 122:22
biggest 54:7 65:21 139:14 142:3 189:2
bile 119:3 133:12
biliary 59:13 63:2 76:22
billion 22:10,17
billions 179:2
biochemical 24:16
biomedical 123:22
biopsies 119:22
biopsy 118:14 119:17
birthday 54:2
bit 4:20 6:1,9 7:18 9:1,12 11:15 15:21 29:7,11 32:16 57:15 61:1 63:1,6 66:10 67:19 73:6 99:15 101:10 104:16 114:4 126:16 137:15 159:6 163:9 180:16 181:4
bite 65:14,16,18,20
bites 65:17 131:9 133:16 135:2
bits 138:21
black 132:1
blacklisted 182:8
blackout 40:4
bladder 120:11,14
blades 64:19
blank 150:11
blessed 141:1
blind 183:18,22
bloated 122:1
bloating 21:14 45:9,11,16 48:8,9,21 64:12 68:20 69:11 70:5 77:6 102:6 103:13 111:20 114:3 122:12 130:6 135:2
block 170:8
blocker 127:7 170:5
blockers 23:10
blood 119:4 120:7 125:3 150:3
bloodstream 181:14
bloody 41:15
blue 40:9
body 68:1 124:22 160:2,5 173:7,10
boil 67:5
bolus 61:22
Bond 2:10 59:3 65:10 76:14 103:19 138:17 139:17 150:20 153:2 172:2
book 124:3
boots 10:9
boring 140:19
born 117:22 119:6 124:11
bother 149:8
bothersome 39:15
Botox 41:12 126:17,21,22 129:3 131:22 159:15 162:11
bottom 51:18 122:1
bout 111:18
bowel 9:7 19:9 20:6 23:17,21 37:9,22 44:12 45:17 47:19 64:20 73:9 103:5 107:19,20 133:5 181:22 185:19,21 187:12 188:2
bowels 128:1
box 132:2
boys 44:19
brain 21:3 184:3 194:7
brain/gut 18:18 20:12,14 21:1 155:3
break 7:8,15,19 27:6 99:17,19 107:1 109:1,18,19 175:3
breakfast 56:16 89:21 144:18
breaks 40:8
breath 40:2 125:4 192:3
breathe 53:7
breathing 112:21 124:19
Brezoczky 2:21 107:2,3 108:21 175:14 187:1,2,4 189:22
brief 18:1 28:2 100:8
briefly 157:5
bring 4:13 27:20 185:8
bringing 175:20
broader 11:11
broth 125:19
brought 46:17 184:17
Brown 187:8,9
Bruce 3:4 175:15 194:13 195:21
brutal 88:11 132:9
bucket 58:19
buckled 75:21
build 28:8 32:17 69:22 97:12 127:14 138:7 164:2
built 97:9
bullet 144:17 149:21 150:15 179:13
bumped 139:2 146:16
bunch 146:20
burden 33:15 176:12,16

burning 39:4 82:10 83:16 87:7
burp 133:18
burping 131:12
businesses 43:4
butter 55:20
butterfly 187:17,19
button 5:3 29:10 31:3 39:2 94:14
buy 63:7 167:15
buying 55:8 63:5

C

caffeine 46:3
cages 53:9
calcium 170:4
campaign 186:20
Campus 1:10 8:17
Canada 146:6 158:8 195:10
cancer 124:2
candy 63:12
caplets 114:6
capsule 90:9
capture 28:15
captured 30:7
car 58:19
Carafate 132:3
carbohydrates 114:18
cardiac 181:7 196:17
cardiologist 127:2
care 33:18 45:20 55:1,8 58:11 62:12 94:13 120:8 142:14 149:7 155:19 168:9 172:6,20 179:7 189:1 194:22
carefully 185:2
caregivers 25:12 27:17 28:7
Cares 180:8
caretaker 36:21
Caretakers 32:12
caring 168:1
Carissa 2:19 175:13 180:5,6 182:17 184:10
Carol 2:15 87:21 131:7 135:11 153:21
Carrie 2:9 52:4,5 58:13 59:1 76:11 78:22 96:10 97:2,3
carried 93:15
carries 123:16
carry 50:13 123:17
case 46:12 48:2 141:11 169:16 176:22
cases 50:13
catch 169:22
catch-22 161:4
category 20:1
CATHERINE 144:3
catheterizing 122:20
cause 18:13 20:19 65:20 83:4 95:9 103:13 104:3 115:11 155:4 176:15 188:7,8
caused 116:20 132:22 134:18 143:6,9 152:20
causes 63:20 105:4 132:11 134:1 154:2
causing 51:19 120:10
cc's 122:8
ceasing 74:2
Ceciel 80:5,6
cecum 161:13
celiac 178:4,6,8,10,21,22 179:6 185:14,15,17 186:1,5,13,21 193:12,13,18
cell 105:20
cells 106:9,13,15 118:3 119:17,22 192:21
center 4:4 5:15 58:12 190:14,15
centered 130:19
central 21:5 182:9
cereal 122:11
certain 51:13 81:4 99:5 115:15 146:7
certainly 150:15
CERTIFICATE 201:1 202:1
certify 201:3 202:4
cervical 120:21
cetera 111:3 138:12
chain 63:20
chairs 135:13
challenge 136:19
challenges 141:4
challenging 55:3 62:10 63:18,22
chance 7:3 174:11 198:18
change 26:18 128:5 140:7 195:14
changed 130:22
changer 130:9
changes 49:3 124:9
channel 170:5
characteristic 189:12
characterized 9:3 18:10 177:3,7
charcoal 114:12 115:22
chart 47:5
check 68:8 119:17
chemicals 127:11
chemotherapy 132:15
chew 41:20
chewable 98:1
chicken 125:18,19
child 92:19

119:3,6 120:1 190:21,22 191:1,5,7,9,11
children 75:4 190:12,13,16 191:3,12,17,21
children's 61:13 190:10,20
Chilson 2:13 124:15,16
chime 166:3
Chinese 112:4,13 113:19
chips 164:15
chiropractic 112:4
choice 35:9,15
choked 91:21
cholesterol 150:5
choose 35:8 37:8 69:5 100:12 101:1 156:7
chores 131:19
Chris 31:21,22
chronic 9:7,10 18:5,10 19:11 20:8 23:18 37:10,14 38:2 59:15 73:12 79:4,13 82:15 83:3 91:4,6,9,10 95:16 102:18 128:17 131:8 132:22 144:14 176:18 177:6,20 181:10
cisapride 24:6
clarifying 39:3,5
Clark 162:13
class 96:19,20 99:9
classes 23:11
classification 19:6
classwork 89:7
clean 41:4 55:9 122:6
cleaned 106:11
cleaning 41:3
clear 122:17 189:19
clearly 199:22
click 31:3 35:11,14
clicker 36:19,21
clickers 29:9 35:7 36:15,17 37:1,2 137:3 198:16
Clinic 121:19 192:19
clinical 5:11,19 10:11,17,19 12:3 15:15 17:9,16 78:11 81:15 87:2 107:3 134:16 162:16 187:11 196:19 197:6
clock 171:4
clogged 147:3
close 7:7 37:13 88:3 136:8
closed 46:19 120:4,12
closely 10:14
closer 4:13
closest 91:19
closing 198:22
closure 118:16
clothes 48:10
clothing 53:10,11
club 124:3
CNA 139:7
coached 84:20
coaster 42:8 81:8
coat 63:16
COBRA 151:18
cognition 194:8
cold 49:20
collaboration 187:8
collapsed 125:1
colleagues 4:22 6:10 30:18 101:16 175:6
collect 12:2
collected 175:2 178:20
collecting 30:3
collection 17:8
collectively 68:4 138:3
colo 120:5
colon 39:12 105:16,18,20 106:3,6,8 120:20 121:1 133:2 159:18 183:10
colonic 39:11
colonoscopy 18:21 47:6,16 104:1 106:2
Colorado 144:4
colorectal 119:19
colostomy 118:16 120:3,4
combination 50:6 98:16 114:22 136:9
combinations 115:21 177:7
comes 48:19 62:13 93:10 101:3 107:10 162:9 168:14,19 185:20 188:15 191:7
comfortable 8:1 34:21 47:2 66:14 135:13 162:20
comforting 194:21
coming 13:18 14:1 17:19 27:18 28:10 36:5 70:16 117:6 144:15 167:11,12 173:5 174:7 183:6,7
commend 108:10 192:9
comment 6:21 7:2,4,5 14:16,17 31:1,3,4 33:3 80:5 85:13 94:13 146:2 148:16 163:9,14 171:2 173:15,21 174:3,8,15,21 188:4
commenting 30:12
comments 27:22 30:12,14,15,20 31:7 32:3 56:4 77:19 78:4 85:12 92:13,15,22 94:12 100:4,5

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103:10 111:6,12 136:6 142:13 161:9,12 174:16 176:4,5 182:18 194:12
committed 14:10
common 9:2 19:18 20:9 21:11,18 68:11 78:13 85:14 177:5 187:13 189:11
commonalities 26:9
commonly 23:5,7
Commonwealth 201:19
communicated 200:11,12
communication 18:19 20:13,14 21:1 199:11 200:3
communities 10:12
community 13:6 22:3 124:1 176:11 200:4,7,14
compacted 160:7
companies 10:11,15,17 14:1 78:10 189:4 191:20 192:16 200:14
company 12:1 63:10,15 197:15
compare 25:9
comparing 25:7
Compazine 132:11 155:2
compelled 187:22
complementary 112:1,12 116:10,11 163:17
complete 129:15 130:8 140:9 147:8 166:15 202:9
completely 67:14 113:21 126:16 147:11 183:10
complex 27:9
complexity 136:9
composure 66:20
compounded 179:22
compounding 146:8 158:9 179:21 194:15 195:11,16 197:7
Compro 196:9
computer 46:17
concentrate 82:19 86:21 89:5
concentrating 115:13
conceptualizations 103:1 104:18
conceptualize 101:18
conceptualizing 109:14
concerned 185:16
concerns 24:2
concise 174:2
concluded 200:22
condition 26:8 36:7,20 50:21 59:6 70:11 110:18,20 121:20 134:20 144:14 166:21 171:9 177:1
conditions 9:16 19:15 21:20 23:5 24:15 26:5 28:16 32:15 70:11 177:2,5 180:18 187:13 188:8 190:17 191:22
conduct 10:13
conducted 176:8
conducting 10:10
conference 80:10
conflict 13:10
confluence 116:21
Congress 124:4
conjunction 195:3
connect 109:7
connected 62:3
connecting 172:14
connection 120:6
consequences 92:2,8
Consequently 118:2
consider 78:19 85:7
consideration 79:12 116:5 186:16
considered 158:4,14 186:5,13,18
constant 79:9,13,20 92:16 93:21 98:12 103:6 124:18 131:13
constantly 41:11 86:5 97:17 98:7
constipated 118:12 119:15
constipation 9:11 19:10,12 20:7,8 21:14 23:9,17,18 37:15 41:15 48:20 59:15 64:11,14 76:6,7 118:5 120:13,15 121:7 131:8,13 132:20,22 133:1,3 134:2 167:7 176:18 177:18
Constituent 31:12
consulted 114:9
contact 32:6 33:11
contacted 127:13
context 6:10 12:4 13:21 14:8 34:12
continue 32:3 35:2 72:3,9 87:12 111:18 115:10 147:14
continued 3:1 61:17 120:14
continues 72:14 123:9
continuing 127:21
continuous 61:22 71:7,8

continuously 60:13 147:15
contract 165:13
contracting 135:9
contractions 20:18
contradicted 169:16
contribute 30:11,20 32:3,4,10 33:4 168:12
contributed 190:15
contributing 102:7
contribution 29:20
control 89:1 107:20 120:17 122:17 152:14
controlled 168:16
controlling 113:14
conventional 111:22 116:4,13
conversation 50:22 144:9
conversations 89:8
cook 41:5 55:9
cookie 52:18 63:8,11
cooking 41:3
coordinate 15:11
corn 128:4
correct 102:10 202:9
correlate 85:16 107:19
corresponds 35:9
cosmetic 159:16
cost 22:18 151:7
costs 22:6,8,11,12,16, 20 176:17
cough 49:20,22
counsel 201:8,12
count 95:18
counter 149:17 156:12,13
counting 93:7
country 42:22 61:10 145:8,10 195:10,12,16
couple 40:3 57:7 91:18 92:7 97:10 131:1 135:16 148:20 167:6 183:11 186:10
coupled 45:16
courage 34:18 66:19
courageous 175:20
course 18:11 19:7 23:19 24:3 25:1 45:21 47:6 58:2 91:1
Court 202:5,7
cover 22:22 101:6 110:1 132:14 151:16,17
covered 144:1
covering 14:18 15:2 111:1 126:20 151:13 152:8 160:18
covers 95:4
cramp 78:3
cramping 45:9,10,16 48:8,21
created 170:7
crippled 72:11
crippling 70:20
criteria 19:3 47:18
critical 12:4 26:19 128:7 193:3
crock 125:19
Crohn's 47:12
cross 86:18
crosses 155:3
cruciferous 50:4
crushed 149:2
crying 56:5 141:15
CT 47:12
cup 56:16
cure 51:19 116:14 118:7 130:14 134:4 166:16 194:1,5
curious 94:21 144:6 198:6
current 6:19 15:7 27:7
currently 12:8 110:18 115:17 129:11 195:2
curves 123:16
cut 46:3 49:15 154:8 163:8
CUTTING 202:4,13
cycle 102:14
Cymbalta 113:4
Cynthia 2:8 44:8,13 52:3
Cytotec 132:2

D

D.C 35:11 36:1 128:16
daily 10:3 24:22 45:10 46:8 48:6,11 50:17 52:15 56:12 73:19 79:2 87:2 88:19 98:17 111:19 116:6 122:9 129:16 145:19 176:20
dairy 115:16 128:2,3
damage 155:7,8
dance 54:10 57:17
dangerous 113:16
dark 52:12,13 140:20
darn 159:4
data 11:2 178:20
date 15:2 16:18 57:2,4
daughter 56:1
daughters 123:21
dawned 159:3
day 17:21 30:6 34:3,5 35:17,19 42:3 46:14 48:7 53:13

54:18,19,22 55:22 57:5,6,7,9,10,14, 20 58:15 62:6 66:10 73:21 78:15 80:10,11,15 81:16,17 83:2,10 84:1,6 87:13 88:1 89:16 91:13 92:3 93:6 95:11 97:14 99:6 114:6,7 120:16 123:1,6,14 124:11 131:10,16 132:5 133:3,12,16 139:9 141:19 144:18 146:15,17 147:2 160:3,6 164:20,22 173:17 180:13

days 22:18,19 27:4,5 40:22 41:6,10 48:8 51:2 52:13 54:19,20,21 57:19 72:14 95:15 96:15,16 97:10 99:10,13 115:11 120:2,9 121:11 123:9 129:15 131:14,15 132:8 134:6,7 154:4 165:1 182:15

daytime 84:10

deactivated 115:22

dead 105:21

deal 35:17 41:16 47:10 56:9 115:11 141:2 180:12

dealing 35:20 42:11 44:17 85:2 136:8 148:4,6 178:19 184:7 185:1

deals 35:18

Debbie 3:5 82:7 86:16 89:12 140:4 144:21 175:15 195:22 197:10

debilitating 82:18 89:7 90:3 116:5 129:1 176:19

decades 177:12

decay 92:5

deceased 157:22

December 121:12

decided 160:18

deciding 17:10

decisions 13:22

decompression 133:11

decrease 161:3

decreased 21:15

decreasing 145:14

deemed 52:8

deeply 33:20

defecate 119:16

deficiencies 96:7

define 156:13

defines 73:22

definitely 115:3 198:19

deflating 165:5

degree 12:6 42:13 153:17

degrees 42:8

dehydrated 133:8

delighted 4:7,8

delightfully 184:19

delivery 119:3

delve 33:20 157:3 166:9

demographic 19:22

demonstrate 24:21

demonstrating 34:14

demoralizing 91:7

dental 92:5

denying 153:4,12

department 55:5

depleted 97:10

depleting 97:14

deposits 182:3

depressants 149:14

depressing 134:13

depression 115:12

Deputy 5:8

describe 18:5 26:21 70:2,8 87:18 107:7 109:9 144:12

described 33:14 93:12 104:15,18 157:17

describes 78:3 92:20

descriptions 138:4

descriptive 83:8,15,21

design 35:2

designs 10:18,19

Desipramine 113:3 152:17

desk 7:6 35:4

desperate 154:10

desperation 125:14

despite 9:9 37:11 124:7

detached 183:11

detail 30:22

details 136:16

determine 25:15 61:11 148:11

determined 127:2

devastating 131:6

develop 96:7 122:4 193:17 196:12

developed 113:9 119:11 134:14,21 135:8 150:10,11 181:9 187:7,18 199:22

developing 51:11 154:18 181:13 197:6

development 1:5 4:16 8:9,22 10:8,10,15 11:12 13:22 14:2,5 33:8 35:3

device 60:4 135:7 152:14 161:22 200:13
devices 111:2 136:10 157:13,16 161:9,19 198:1
diabetes 134:18,19 150:2
diagnosed 36:13 44:14,15 52:9 111:16 140:5 169:13 178:14,15,17 179:1 181:5 186:2
diagnoses 178:20
diagnosing 126:8
diagnosis 18:21 19:5 22:15 33:17 61:2 73:12 82:8 128:16,19 150:14 169:11 173:2 185:16
diagnostic 116:7,12
dialog 7:1 9:20 26:4 32:10
diarrhea 19:11 21:15 23:8,21 41:15 111:16,18,19 113:14,17 114:2,7 115:9 116:16,20 170:11 177:18
die 56:6 181:18
died 181:8
diet 43:9 49:3,12,16 112:10 114:18 115:1,4,6
dietary 23:4 49:14 112:2 129:4 140:7 156:16,19 157:1 198:1
dietician 127:13
diets 51:15
difference 27:4 59:9 66:7 139:14 151:5 187:22
differences 26:9
different 10:2 14:11 25:22 28:2,10 29:22 42:15 43:10,20 48:21 49:1,2 53:10,12 55:13 61:16 63:1 67:15 70:3 71:15 76:13,21 77:3,5,10 78:21 79:15 81:22 82:1 84:6 98:20 101:10 102:22 103:19 104:13,17 107:9 112:2 116:2 126:18 132:4,6 141:7,11 150:21 151:6,15,17 167:4 177:4
differentiate 70:18
differently 81:11,21
difficult 22:7,22 43:8 48:19 66:21 67:6 94:4 103:14 107:7 112:14 123:1 142:5 167:9 194:19
difficulties 21:16
difficulty 125:4 131:18 142:14
diffuse 82:10
dig 67:18
digest 52:17 97:20 114:21 125:17
digestion 116:18
digestive 71:20 114:20 115:19 124:4,10 125:17 131:7
Diltiazem 127:6
Dimick 5:16 83:20 84:3,6,11 93:18
diminish 135:2 177:8
dinner 90:10 144:18
dip 174:3
direct 5:14 22:11 24:20
direction 144:16 165:17,21 201:6
directly 22:15 25:1 32:6
Director 5:5 8:11
disability 151:12
disabled 151:11
disabling 18:12 82:14 83:22
disastrous 184:15
disc 120:21
discharged 146:18 147:1
discomfort 20:19 46:8 52:15 53:3,14 68:14,19 69:16,20 70:2,5,18,22 71:5,7,9 72:15,16,18 73:1,11,19,20 77:22 78:14,18,19,20 79:2,5,7,10,21 82:16 83:4,11 85:5 86:18 102:17 107:9 191:11
discuss 10:17,18 110:11 142:9 166:17 197:21 198:1,4
discussed 28:20 105:19,20 148:1 187:14 200:1
discussion 4:6 6:2,13,16,22 7:17 16:9 26:12 28:1,5,8 29:2,8,14,16 32:8 34:3,15 38:19,22 67:8 100:8 107:8 110:9,14,16 141:5 145:19 163:10 173:16,22 174:12
discussions 198:6,11
discussion's 33:14
disease 6:17 9:9 11:17,21 12:5,6,10,16,20, 21 13:13,15,20 14:8,11 15:5,15,21,22

17:1,14 25:12 47:13 53:22 71:19 117:22 118:1,8 119:21 124:12 150:12 178:4,6,9,10,21, 22 179:6 184:5 185:15,17 186:1,5,14,21 193:3,12,13,18
diseases 14:16,18 17:3 18:8 51:17 124:5,10 186:12 189:11,15
disheartening 142:11 196:6
disorder 17:22 19:21 20:21 28:16,17 36:13 37:7 49:5 59:10,14,18 61:4 75:8 117:21 137:10 156:6 160:22 188:11 189:18
disorders 1:3 4:18 6:12,20 7:2 8:9,15 9:2,3,6,13,15,17 10:1,5 15:3 18:2,4,6,14,15 19:2,6,17 20:4 21:7 22:7 23:2,10,15 24:15 25:13 26:7 27:8 28:17 37:4,6 75:9 83:4 96:6 131:7 176:2,8,15,17 177:3,10,11,13,1 5,21 179:2 185:12 186:7 187:14 190:13
192:7 198:9
dissatisfaction 177:16
dissipate 72:3 122:16 123:8
distended 133:19
distention 21:13 118:6 119:13
distinguish 70:4
distracting 60:16
distressed 46:7
division 5:5,8,12,17,19 8:11,13 9:12 15:10,17 17:17
divisions 16:20
dizziness 126:14
docket 16:11 30:21 31:6 33:21 36:8 38:17 78:7 87:11 92:12 109:9 110:12 164:1 182:18 186:18 194:12
docket's 32:21
docs 160:17
doctor 22:20 45:20 47:3,9 48:14 49:9 56:22 58:11 77:9 126:5 129:10 141:13 142:8 144:3 168:1,5 169:10,14,18 172:8,15,17 185:21 189:2
doctors 22:13 56:12 60:17 76:21 97:17
109:16 124:21 125:11 126:1 133:22 134:7 145:11 151:17 167:22 168:9 197:7
doctor's 133:15
Doctors 42:12 134:5
document 31:4
documents 16:12
dog 60:6
dollars 178:19 179:3
domestic 179:22
domperidone 24:6 90:7 129:2 132:17 139:22 140:1,8,20 141:9 142:9 143:11 144:7,16,20 146:3 147:7,14 152:15 179:13,16,19,20 180:1,2 195:2,3,4,14 196:5,14,21
done 17:9 22:9 40:11 62:7 90:6 99:4 103:4 107:13 108:2,14 123:12 125:14 153:9 158:5 162:2,3,19 163:2 165:8 170:14,21 182:14 192:9,18 196:14,16
Donna 2:3 4:20 5:4 8:5,10 11:13,14,18 19:8 74:13 80:6
143:20
door 47:22 57:21 159:21
dosage 132:19
dose 139:2 140:12 144:17
doubled 45:14 78:15 82:14
doubted 126:2
download 199:19
downsides 27:13 34:11 110:21 149:6,8 150:19 153:14 160:14
dozens 177:2
Dr 1:14 2:3,4,5,6 3:7 4:2 5:4,7,10,13,16,1 8,20,22 8:7 9:11 11:13 17:15 25:19 36:2 38:3,14 43:17 44:7 51:8 52:3 58:13,22 65:8 66:11 68:21 69:19 71:3,11 73:2 74:11,14 75:11 76:11 77:12 78:5,9,22 80:4 81:12,14 82:5 83:20 84:3,6,11,14 85:9,11 86:2,11,14 87:6 88:16 89:11 90:22 92:9 93:1,5,17,18 94:10,17 95:5 96:2,9 97:1 98:19 99:14 100:19 101:15 102:7,11,21

103:9,16 104:14 105:1,9 106:17 108:19,22 109:20 111:11 117:10,16 124:14 128:13 131:2 135:11 138:1 139:15,18 140:3,16 141:6 142:12 143:3,16,21 145:3,21 147:20 148:13 149:5,18 150:18 152:10 153:1,13 154:7,14,20 155:11 156:10,22 159:11 160:9 161:6,15,20 162:6,13 163:6,15 165:22 167:18 168:11 169:7,20 170:22 171:20 173:14 187:8,9 190:9 193:3 197:13 198:22 199:1 200:5

dramatic 49:3 186:6

drank 52:18 133:7

drastic 130:3

drastically 104:4

drawing 150:11

dream 124:10 129:20

dressed 40:22

dried 139:6

drink 53:3,4 65:4 126:19 129:21

drinks 128:1

drive 54:17 146:11

driving 46:14

drop 63:3

drove 52:7 57:2

drug 1:5,9 4:4,16 8:8,21 9:19 10:8,10,11,15 11:11,21 13:7,15 14:5,9 31:19 33:8 35:3 58:6 76:1 78:12 90:20 106:14 134:20,22 137:6,9 140:11 141:3,6,7 149:17,21 150:2 156:3 170:10 192:16 195:17 197:8

drugs 5:15,21 8:14 10:14 14:2 23:6 25:15 51:11 58:10 82:22 83:14 132:10,12,16 134:3 150:16 155:1 167:7,9 168:19 170:2 181:9 191:18 194:6 195:4 196:8 197:21

drug-seeker 58:3

dry 48:18 101:5,12 164:11,12,18,22

due 59:18 63:2 127:14 131:16 151:10

duller 70:22

duodenum 181:22

duration 93:20

during 16:13 17:9 41:13 42:3 45:3 62:6 66:9 84:1 89:16 119:2 120:4,9 123:12 147:16 150:10,13 175:3

dying 91:19 168:7

dysautonomia 184:4

dysfunction 59:11

dysfunctional 80:21

dyskinesia 59:13

dyskinesia-type 154:19

dysmotility 39:10,11 59:12 71:19 103:7,8 130:15

dyspepsia 19:12 20:6 167:2 193:15

E

eagle 60:8

earlier 110:4 151:9 179:12

early 10:17,18 11:1 41:13 90:2 91:5 154:18 155:9

earn 34:20

ease 47:8

easier 39:14 65:11

easily 87:1

easy 86:18 97:19 192:12

eat 39:16 40:12 41:17 43:12,21 50:10,11 51:3 52:22 54:4 55:7 60:21 63:9,21,22 65:12,13 69:17 71:21,22 86:22 96:22 97:4,6,9 98:14,15 99:12 106:7 121:21 122:15 125:18 126:20 129:19 131:9 133:16,17 135:3 140:2 141:22 142:1 144:19 147:6 148:5 165:12 179:14

eaten 133:18 164:15 165:10

eating 42:21 51:15 60:22 62:22 64:1 65:11 90:5 115:16 118:10 119:13 121:14 122:13 123:2 126:10,13 129:21 138:20,21 148:12,20 149:2 165:9,10

economic 176:17

educate 191:12,13

educated 75:7

education 76:5 169:10 189:2 191:14 200:8

educational 176:21 187:6 199:14

effect 62:7 113:9,21 116:5,6 117:2 127:16,18 140:8 153:20 155:18 158:10 170:10 194:7

effective 13:1 32:8 112:14 113:1,13 130:2 158:4,11,13,15,1 7 177:6,14 195:4 196:22

effectively 50:13 51:7

effects 90:20 113:3,17 117:1 131:6 132:12 140:12 142:3 143:6 149:13,22 150:16 152:22 153:15 154:12 155:20 170:3 186:6 195:6 196:10,15

efficient 129:14 193:19

efforts 11:11 196:7 197:6

Eggers 2:6 4:2,3 5:22 25:19 36:2 38:3,14 43:17 44:7 51:8 52:3 58:13,22 65:8 66:11 68:21 69:19 71:3,11 73:2 74:11 75:11 76:11 77:12 78:5,22 80:4 81:12 82:5 84:14 85:9 86:2,11,14 87:6 88:16 89:11 90:22 92:9 93:1,17 94:10 95:5 96:2,9 97:1 98:19 99:14 100:19 101:15 102:7,11,21 103:9,16 104:14 105:1,9 106:17 108:19,22 109:20 111:11 117:10,16 124:14 128:13 131:2 135:11 138:1 139:15,18 140:3,16 141:6 142:12 143:3,16 145:3,21 147:20 148:13 149:5,18 150:18 152:10 153:1,13 154:7,14,20 155:11 156:10,22 159:11 160:9 161:6,15,20 162:6 163:6,15 165:22 167:18 168:11 169:7,20 170:22 171:20 173:14 199:4

EGGERSReported 1:14

eight 82:21 114:5 118:17 123:14 126:1,4 158:3

either 54:13 92:16 94:19 97:20 148:19 155:14 195:7

elaborate 73:5 78:6

electric 133:6 135:4

electrical 24:11

electronic 16:11

elevated 125:3

elevations 147:9

eliminate 50:4

elimination 115:6

Elizabeth 73:7 140:17,18 169:8 171:12,21

Ellen 2:18 139:21 144:11 175:13 179:9 180:4

eloquently 69:21

else 42:20 43:13 50:3 59:8 78:20 86:8 125:13 139:18 145:1 148:2,8 156:4,21 158:1 167:18 171:1

email 31:6 33:12

embarrassing 103:13

embellish 74:4

embracing 184:19

emergency 58:1,11 159:2

emesis 195:5

emotional 45:3

emotionally 22:1 46:7

employed 201:9,12

employee 197:14 201:11

employers 50:20 51:1

employment 176:21

empowering 199:7

empty 89:18 133:12 148:18

emptying 52:11 90:5 128:21 149:16 192:22

enable 135:3

enabled 60:4

enables 13:15

encapsulate 48:4

encourage 32:9 94:10 107:4 108:1 174:19 181:1 182:19

encouraging 116:9

Endpoints 5:21

enema 104:9

enemas 104:7 118:10 121:6 161:14

energy 41:9 57:15 60:8 62:11 95:8 127:8 194:8

enforce 180:2

engage 28:6

engagement 31:17,20

engineers 123:22

enjoy 64:8 65:13 89:8

enjoying 64:1

ensure 9:18

enteric 21:2 188:9 189:9

Enterra 152:14 160:12 197:14
entire 41:14 59:12 71:20 121:1
entitled 200:21
enzymes 115:20
episode 80:8,14,18,22 81:3,6 93:10 115:17 117:6
episodes 50:7 62:8,9 72:9 94:3 114:2
equate 91:9
ER 72:13,22 79:21 127:12
erode 85:5
Error 17:18
Errors 5:6,9 8:12
ERs 75:17
erythromycin 132:1 152:19 181:7 196:13
esophageal 39:10 59:12
esophagus 18:9 134:10
especially 4:8 16:22 58:11 70:3 90:16 138:7 169:18 188:8,14
established 19:4
estimate 22:8
estimates 19:19 22:17
et 111:3 138:12 194:2
ethnicity 20:2
evaluate 93:19
evaluated 25:5 83:1
evaluating 81:20
evaluation 4:5 33:10 35:4 83:14 198:17
evening 72:22 200:20
event 151:12
events 130:18,19
eventually 104:7 129:5 183:9
everybody 17:18 58:2,5 62:15 95:1,4 108:8 188:18 196:4
everybody's 43:10 62:21
everyday 62:15 131:18
everyone 4:2 11:9 32:19 34:18 35:6 36:7 42:20 55:16 68:22 89:5 96:18 135:17 174:6 198:15 200:12
Everyone's 137:4
everything 32:20 42:21 49:15,19 58:17 62:22 67:5 98:16 131:21 133:7 134:8 141:17 151:16 169:15,16
evidence 11:22 17:10
exact 86:9
exactly 84:2,5 138:8 149:7
example 18:20 63:7 153:11 193:7
examples 19:14 26:20
exams 121:7
exceed 17:11
except 137:17
excessive 127:9
excessively 127:1
Excuse 194:10
exercise 96:18 124:19
exhausting 93:15 96:8 98:12
existing 196:17
exiting 144:15
expand 34:11 96:12 126:19
expect 20:18 26:1 131:15
expend 95:8
expensive 132:16 151:14
experience 7:3 12:15,19 18:6 21:8 44:11 68:22 69:1 71:14 75:21 82:9 87:16 91:8 96:5 100:6 108:7 139:19 144:19 145:4 147:19 148:13 166:5,12 171:9 184:22 188:2,10,20 199:8
experienced 68:7,18 90:11 92:5 100:11,14,15,21 107:16
experiences 15:7 26:5,10 28:3 29:15 36:10 47:15 67:11 69:21 92:10 102:22 136:15 137:19 166:10
experiencing 12:18 13:12 45:8 95:1
experts 19:4
explain 33:22 70:19 88:4 94:9 101:21 104:14 156:11 164:1
explore 107:6 143:17
exposures 127:18
expressed 34:13
extent 50:15 84:19 86:19 87:3 158:17
extraordinarily 102:2
extreme 127:11 134:22
extremely 9:20 132:16
eye 106:2
eyes 46:19

F

fabulous 167:7
face 33:17 98:16

152:2 183:14 189:3
faces 76:16
facilitated 28:5
facilitator 1:14 4:6
fact 50:21 158:9 180:2
factor 62:11
factors 146:20 196:17
fail 128:20 183:8
failed 24:10 182:1
failing 180:1 188:6
failure 183:14
faint 132:22
fair 98:19
fairly 103:6 158:19
fall 76:19 86:20 114:9
familiar 21:12
family 44:18 52:7 53:21 54:1 55:17 56:19 60:1 124:5 139:12 175:19 176:21
Farkas 1:18 201:2,18
Farrugia 193:3
fast 150:5
fat 63:7,10
father 178:13,17
fatigue 65:22 94:20 95:5,6,9,12,16 96:5,15,17,21
97:3 110:7,11 126:12,15 127:1
fatigued 41:8
fats 63:3
fatty 129:22 130:20 182:3
favorite 40:12
FDA 4:5,22 6:10 10:7,14 25:19 27:1 31:10,11,17,19 33:6,8 44:9 59:4 70:16 73:13 74:19 106:22 107:5 131:5 132:2,17 135:10 137:7 143:16 146:8 164:6 176:11 179:18,20 180:1,9 189:8 190:2,18 191:14 192:9 194:16 195:9,13,14 196:8 197:16 198:6,10
FDA-approved 141:3
FDA-regulated 198:4,8
FDA's 8:21 9:18 11:19
fear 89:3 155:10
features 177:5
February 126:17
fecal 47:13 72:7 105:12 108:14 120:17,18
fed 131:10 133:14 134:2
feed 55:21 181:11,17
feedback 34:22 152:15
feeding 24:12 56:13 71:21 121:21 129:6 130:12 133:14 148:3 181:11 183:12
feedings 59:20 121:14
feel 7:20 24:22 34:21 44:16 48:11 50:7 51:2,7,14 54:5 65:11 66:14 72:7,11,15 97:5 99:19 102:17 107:10 115:22 116:3 117:6 121:22 126:18 130:21 135:13 141:1 150:14,22 164:1 165:12 166:7,18 168:16 180:15
feeling 43:15 48:1,7 68:12 69:17 82:11 85:6 87:19 89:22 92:20 109:12,15 143:15 148:9
feelings 70:1
feels 55:17 64:19 165:4
felt 89:16 90:2 91:8 125:19,21 162:20 187:22
female 36:4
fermented 114:22
fiber 50:4 112:11 129:20
field 167:22
fifth 120:21
fighting 56:12 62:2 95:15 193:5
figure 61:10 109:11 163:3
figured 173:8
figures 194:5
fill 65:17 72:6 78:18 81:15 198:18
filled 180:21
final 43:17,18 51:8 58:13,14 65:8,9 106:22 171:5
finally 4:7 16:6 24:10 34:22 52:9 61:5,15,18 119:7 121:3 126:5 159:3 173:8 180:14,17 181:18 183:9 196:18 197:11 198:21
financial 174:19
financially 189:5 201:13
finding 38:16 145:9
findings 176:10
fine 60:14 183:2
finish 183:4
first 4:22 6:9 7:8,17 14:17,18,22 26:14 27:16 28:13,14 40:18

45:19 59:22 60:18 68:3,15 70:9,10,15 71:4 89:1,17 90:4 91:5 96:15 100:10 101:22 102:8 112:9 118:8 119:3 125:21 135:17 136:3,21 153:5 157:21 158:18 164:17 169:19 175:16 178:15 179:1 187:6 190:20 194:15 197:15 199:4
fiscal 14:13,15
fish 115:20
Fisher 3:5 175:15 195:22 196:2
fit 48:9
five 14:11 19:20 79:6,7,10,11,20 87:1 89:14 110:13 111:5 118:19 120:2,9 158:18 164:18 181:20
five-organ 181:21
five-plus 40:14
fix 64:9
flare 27:3 79:3 95:11 126:5
flares 129:18
flare-up 46:15 50:20
flare-ups 45:18 83:12
flatulence 100:16 101:3,13,19
103:1,4,12,20
flesh 30:22
floating 31:21
floor 17:22 44:3 70:21
Florida 117:20
flu 88:6
fluids 98:4
focus 6:22 15:4 26:7 51:12,17 69:20 77:11 89:6,7 96:21 153:15 180:19 188:6
focused 4:17 28:19 31:5 33:15 68:2 76:22 82:3 171:7
focuses 26:15
focusing 115:13
FODMAP 114:18 115:1,4
FODMAPs 114:18
foggy 123:5
folks 6:4 29:21 77:15 174:13 184:21 186:2,10
follow-up 47:16 74:12 78:9 95:6 143:21 144:21
food 1:9 7:11 41:17 42:11,22 43:1 49:6,7 50:9 53:15,18,19 54:4 62:22 65:3,14,15 102:5,16 106:6 125:17 130:19 131:10 133:17 135:3 138:21 147:5 150:6
165:10 194:7
foods 43:21 49:11 50:4 63:5 115:6,15 129:20,22 130:20 197:15 198:5,8,11
Foore 175:13 182:22 183:1
foot 118:19
forced 45:4
foregoing 201:3
foregoing/ attached 202:8
forever 152:1
forgot 71:8 73:17 169:3,4
form 37:6 95:15 193:15,22
format 6:15 25:21 26:1 110:2,3,4
formation 193:6
formed 118:4 120:6
forms 33:10 35:4 198:18
formula 122:9 123:5
formulating 103:18
Fort 117:19
forthright 171:16
fortunate 129:18 166:11 182:6
fortune 166:6
Forty-three 37:21
forum 192:10
199:13
forward 29:2 200:17
foster 26:3
foundation 28:1 48:16 60:3 176:1 178:4,9,21 185:14,15 187:6
founder 180:7 187:4,17
four-hour 52:10
four-legged 136:3 173:18
fourth 65:18
framing 26:12
free 7:20 55:4 63:7,10 99:19 164:1 193:5
frequent 10:16 100:16 101:11 111:19 156:17,18
frequently 81:14 101:4 118:12
fresh 169:14
Friday 80:13
friendly 107:12
friends 39:20,22 53:21 60:1 86:22 131:20 136:3 139:13 173:18 191:2
friend's 40:10
front 27:19 89:5 109:21 168:7
frozen 63:7
frustrated 74:16
frustrating 141:12

153:3,10 196:6
frustration 46:9 141:2
full 6:8 22:22 69:17 80:10 92:6 107:20 118:14 119:16 125:1 127:15 182:2
fullest 124:7 186:3
fullness 68:12 69:17
full-time 130:17
fully 9:15
fun 52:11
function 24:22 85:14,19,21 86:1,5,8 106:15,16 127:20 132:9 191:5
functional 1:3 4:18 6:11,20 7:1 8:9,15 9:2,15 10:5 11:17 15:3 17:21 18:4,14 19:1,6,12,13,17, 21 20:6,7,20 21:7 22:6 24:15 25:13 27:8 36:13 37:3,5,7 49:4 61:4 62:11 80:8 82:15 91:11 96:5 156:6 167:2 176:1,8,15 177:3,10,21 178:7,19 179:2,5 185:12 186:7 187:14 188:11 190:13 192:7,17 193:15
functioning 9:5
43:3 85:13 86:3 94:1 105:21 106:3,9 118:4
fundoplication 119:7
funerals 53:19
funny 158:22
furiously 30:2
furthering 31:17
future 10:6 35:2 59:9 183:14 198:11

G

Gaekano 2:16 175:12,18,21
gain 117:7 121:4 124:19 128:6 152:3
gained 12:17 150:4
gall 120:14
game 54:12 57:18 130:9 151:3
games 54:10
ganglion 118:3 119:17,21
gas 72:6 100:16 101:3,13,19 102:2,16 103:1,4,12,20 114:3
gases 144:15
gastric 24:11 52:10 90:5 121:22 128:21 133:6 135:4 149:15 152:13 158:1 160:12
gastritis 89:19
gastro 161:12
gastroenterologist 46:22 91:5 179:15 190:10 200:5
gastroenterologists 46:18 116:2 196:21
Gastroenterology 5:6,8 8:12 17:17
gastroesophageal 9:8 37:10
gastrointestinal 1:3 17:21 19:2 20:21 21:7 22:7 157:8 176:2 187:14 188:11 193:2,14
gastroparesis 9:7 19:13 23:20 24:11 37:9 38:1 39:9 52:10 59:11 70:15 71:18 73:8 82:8 83:12 84:18 87:22 89:2,13 91:3,20 94:22 95:3 102:3 124:17 126:3,7,8 128:6,8,19 130:6,10 131:9 134:5,15,18,19,22 140:6 141:12 144:11 157:15,22 159:14 167:3 169:16 176:19,22 179:13,17 180:8 181:5 183:5 184:14 192:4 195:5
gather 30:14
gathering 4:17
Geller 2:17 175:12 178:2,3,4
gender 20:1
general 23:4 34:8,11 58:17 77:20 80:12
generally 18:7,20 34:11 41:1 72:5,7 76:12 77:22 80:16 81:6 99:3 196:22
genetic 117:21
gentle 116:22
GERD 37:12,14 38:1 73:9 83:13 84:21 89:20 118:22 131:8 176:18
GES 128:8
gets 53:6 103:22 106:12 137:5 151:2 162:4 189:13
getting 13:14 14:19 33:18 41:22 54:12 61:2 62:4 65:1 69:13 77:16,18 97:7 100:17 101:9 102:11 113:21 118:9 127:22 142:14,15,19 144:4 146:19 152:11 160:5,15 162:6,7 163:11 180:17 195:7,8,10
GI 4:18 5:17

6:12,20 7:2 8:9,15 9:2,4,5,15 10:5 11:17 15:3 18:4,5,14 19:6,17,21 20:17 21:4 24:15 25:13 26:6 27:8 36:13 37:3,5,7 49:4 59:6,12,18 61:4 64:22 68:3,6 69:2 77:3,5 80:21 82:8,15 89:14 96:5 98:22 103:7,8 107:11,15 114:16 125:11 126:4,6,7 128:10 129:9 130:14 137:10 142:8 144:15 156:6 160:17 162:20 176:8,15 177:3,4,10,21 178:7,19 179:2,5 185:12 186:7 190:13 192:7,17 198:9

GIAMBONE 68:17 69:14 142:22 143:4 152:12 161:11

gift 123:20

Ginter 2:20 175:14 184:11,12

GI-related 100:9,13 107:5

girls 187:21

given 11:20,21 100:21 123:19 166:4 170:11

gives 7:2 60:8 132:18

giving 131:5 146:12

G-J-tube 121:17

glands 150:12

glass 52:17

glew 52:12

glow 52:12

gluconate 122:22

glutamine 114:12 115:20 122:11

glutathione 193:8

gluten 193:21

goal 26:7 124:6

godsend 140:11

golden 15:19

gone 141:15

goodness 60:11,21 61:19 64:14 65:13 173:4

gotten 152:15 160:8 167:6 198:18

government 13:9 26:2

GP 192:19,20

G-PACT 180:7

Graham 77:16

granddaughter 40:14

grandmother 41:19

grateful 8:15 123:19 130:7,16,21

great 9:16 34:6 37:17 42:18 48:7 57:3,6 75:4 80:19 111:5 115:11 127:21 138:20 140:22 141:2 151:6 173:15 200:20

greatly 177:8

green 129:21

grew 119:8,14

Griebel 2:3 4:20 5:4 8:7,10 74:14 78:9 143:21

grocery 55:3

ground 10:9 30:11 32:7 109:22

group 9:6 18:5 19:4 25:13 117:12 194:21

groups 16:1 30:19 112:19

growing 46:9

growled 164:21

G-tube 133:10

guess 35:5 37:12 39:21 43:15 74:9 106:12 145:6 157:14

guidance 196:19 197:6

guiding 110:16

gummy 63:12 127:19

gut 21:3 59:11,20 102:5 181:12,14 184:8

gut/brain 194:4

guys 66:18 141:17

H

H2 23:10

hair 41:7 139:6,7,9

half 22:10 44:14,15 89:21 90:11 91:1 110:17 118:19 138:18 140:10 158:18 160:4 164:15 165:11 178:11 185:17 193:12

halfway 54:17

Hampshire 1:11

hand 29:8 86:12 108:9 137:3 145:6 194:19,20

handbag 123:16

handful 49:16

handle 72:2 88:13 127:17 128:3

hands 29:3 67:10 71:13 163:16,18,21 166:1,2,11,15

hang 51:5

happen 20:19 121:5 140:14 148:22 185:13 186:3 191:16

happened 80:8,9

happens 61:8 81:7 192:11 194:9

happier 167:17

happiest 122:1

happy 26:3 121:17

hard 53:9,20

54:11 55:6,9 56:1,6,14,19 57:13 58:10,17 60:17 64:18 66:19 80:21 96:17,20 97:16 98:5 101:5,12 115:4,12 146:3 156:12

harder 64:4 114:16

hardest 148:4 169:12

Haston 2:19 175:13 180:5,6 182:20 183:4

hated 59:22

hats 124:2

haven't 7:6 30:16 40:13,14 41:2 87:20 104:15 130:10 133:18 148:2 155:15 162:1,2 167:15 198:18

having 9:19 13:16 36:13 41:16,17 42:19 44:10 46:3,15 48:18 55:22 57:11 58:18,21 60:12 70:17 78:15 88:10 89:15 92:13 97:13 98:4 102:4 111:16 126:12 127:1 128:11 144:19 148:8 153:6,21 155:8 159:9 169:2 173:4

Haynes 107:15

head 71:11 73:3 102:11 122:17 123:5 135:12,15

headband 139:5

heads 117:13

heal 114:16

health 31:12 43:2 73:10,14 74:18 76:8 151:8,16 187:17 197:14

healthcare 151:15 171:13,18 176:10

healthy 106:1 179:19 187:5

hear 4:19 9:21 10:2,4 15:14,18 16:9 26:19 27:16 32:11,13,17 34:19 36:11 69:22 73:16 77:9 79:18 87:15 101:21 108:13 110:10 136:15 138:13 141:9 143:19 157:3

heard 8:10 17:3 28:9 67:10,11 69:20 84:9 87:20 94:19,21 101:20 104:15,16 136:5,6 138:4,7 142:12 148:2 151:21 152:12 157:2 162:2 164:2 176:14 187:20

hearing 28:2 78:14 82:12 125:10

heart 125:2 127:2,9 170:8

heartbeat 170:9

heartburn 21:13 68:13 111:20 114:3 177:18

heartburn-related 23:12

heartwarming 199:14

heat 64:4,5

heating 133:20 154:5

heavy 107:19

Heidi 187:8

Hello 174:6 197:13

help 9:21 15:11 29:1 35:1 38:16 51:19 57:1 59:8 65:7 66:8 94:7 96:18 104:5 109:4 113:5 127:20 132:8,10,13 133:4 134:21 135:7 137:7,10 139:7 141:21 142:8,13 145:17 149:3,13,15 151:1,2 154:1 156:5 159:15 165:17 172:9,18 180:22 188:17 189:16 192:17 198:7

helped 16:3 60:3 127:22 132:5,19,21 138:22 139:5 145:16 160:20 172:8,11

helpful 16:20 17:5,19 25:11 38:18 82:22 90:21 94:8

helping 13:7 16:2 88:3 139:9 141:10 145:20 159:17 163:1 181:3 193:10

helps 13:21 34:11 62:13 123:15 127:14 133:12 141:19 153:4 161:4

heme 193:1

hemin 192:18

herbal 112:5 115:20 132:3 163:16

herbals 167:15 198:2

herbs 112:13 113:19

hereby 201:3 202:4

Here's 47:10

hereto 201:13

herniated 120:21

Hershey 182:8

he's 31:21,22 162:21

hesitate 171:16

Hi 5:13 39:8 52:5 59:3 70:14 71:17 82:7 87:21 107:2 124:15 128:15 147:22 159:13

hide 56:10 76:15

hiding 60:13

high 41:17,18 50:4 98:8 125:3 127:1 129:20 177:15
higher 79:22 80:2,13 193:6
highly 195:4
hill 65:19
Hippurate 122:18
Hirschsprung's 71:19 117:22 118:8 119:21 124:11
hit 45:6 46:15 61:22 94:13
hits 105:3
hold 42:19 43:14 134:13 197:4
holding 179:11
holistic 132:3
Holt 2:14 128:15
Holter 194:2
home 55:14 147:2 181:17 191:7
homeopathy 112:4
homework 94:11
honest 199:11
honey 49:18
honored 59:5 117:20
hook 121:22 159:22
hope 28:22 30:2 34:20 36:3 134:13 180:16 185:20 190:2 197:2
hoped 47:21
hopefully 200:18
hopeless 180:14,15
hopes 195:18
Hopkins 146:5,6 162:3
horrible 53:10 54:15 55:11 73:20 90:3 97:21
horribly 55:3
horrifically 178:16
horror 151:21
hospital 61:13 74:6 130:9,10 146:13 168:17,20 181:18 190:10
hospitalization 74:6 121:18 129:8
hospitalizations 22:13
hospitalized 41:11 146:6
hotel 56:16
hour 41:6 54:12 72:1 89:17,20,21 123:2 131:16 160:4
hours 40:1 52:7 53:14,15 54:16 57:5,8,11 62:14 72:4 81:19 82:17 84:1 89:18 122:15 123:3,9,14 160:4 182:15
house 40:10 51:4 57:17 154:4
huge 64:12 66:6 138:22 139:10 149:11 151:12 169:11 190:18,19
human 91:7 168:16 169:3,4
humans 192:19
humor 47:7
hunched 164:16
hunger 39:17 143:15 148:4,6,9,10,12 164:21
hungry 52:21,22 53:1 148:22 149:1
hurt 77:6 79:17
hurts 53:1,5,6,7,8
husband 40:9 55:13
hyoscyamine 48:15 122:13
hyperglycemia 150:1
hypersensitive 49:18
hypnosis 112:20 113:19
Hypoglycemia 59:16

I

IBS 44:14 83:13 111:17 112:21 113:22 114:22 115:18,22 116:15,21 167:1 170:11 176:18
ICC 192:21
ice 133:21 148:20 149:2 164:15
iceberg 67:21
I'd 17:12 44:9 45:13 47:22 48:1 60:21 63:9,14 69:21,22 74:14 117:6 131:4 164:12 174:6 175:18 186:9 190:1 194:15,17 197:15,17 198:15,21
idea 14:7 165:8
ideal 110:22 134:20 164:4
identification 75:5
identified 199:17
identify 26:8 32:4 109:5
identifying 74:10 75:1
idiopathic 9:10 19:12 20:8 23:18 37:14 38:2 131:8 192:20
IFFGD 176:2,6
ignorance 200:4,6
ignore 71:1
III 19:3
ileostomy 120:6,12 121:3,4,8,10 183:12
I'll 4:12 11:9 29:2 84:15 105:14

108:15 136:6 137:13 156:7 174:1 175:10 183:4 199:3,16
illegal 142:2 144:5
illness 43:14 171:15 176:13 186:6
illnesses 95:16 124:7 192:17
I'm 4:3,5,8,22 5:4,10,11,13,16 8:10 11:14 17:16 25:19 27:18 37:12 39:13 40:16,17,22 41:8 42:9,13 43:5 44:2,3 45:14 46:11 48:12 49:18 50:7 51:7,14,15,16,20 ,22 52:19,20 53:2,5,13 54:4,21 55:15 56:5,12 57:11,22 58:5 59:5 61:18 62:22 63:20,22 64:1,17,19 66:12 67:13 68:14 71:11,21 72:2 73:14,17 74:11 75:7 77:14 78:14 79:17,22 80:1,18,19 81:1,10 82:12 83:13 84:17 87:6,9,10 88:21,22 90:7 91:1 92:6 93:1 95:3 96:20 99:3 101:15 102:11 103:16,18 104:1 105:15 106:21 110:1 111:7 115:18 117:19 121:17 124:16 128:15 129:18 130:7,16 133:20 135:15 138:20,21 139:21 140:13 142:8 145:14 147:13,15 148:1,5 149:16,20 150:1,10 151:6,18 154:10,11 155:22 157:14,21 160:9 161:4 163:11 165:15,20 166:1,22 167:14 171:4 173:4 178:3 179:12 183:11,12,22 184:3,13 185:4 186:15 190:9,11,12 192:15 194:14 195:13 197:13,14 200:5
imagining 173:6
immediate 90:8 114:13 117:4,5 140:9
immediately 90:6 125:21 126:9 140:13 144:22 191:9
Imodium 112:11 113:7,20 114:6,14 115:21
impact 19:22 21:21 26:16 33:15 46:5 52:14 69:4 90:19 101:1
impacted 21:22 172:6
impactful 12:21
impactions 120:18
impacts 15:6 187:11
impaired 21:8
impairment 193:22
imperative 179:4
implant 158:1
implement 35:2
implying 20:16
importance 34:15
important 9:14 10:4,7 15:6 17:20 24:18 25:10,16 36:11 38:15 52:8 70:6 94:15 108:16 109:13 122:16 157:19 158:12 163:20 184:18 192:5 197:2
importantly 19:14,22 184:19
impossible 4:10
improve 62:2 108:18 124:9 139:11 173:13
improved 166:20
improvement 125:21 126:2 127:17 138:11 139:1,10 146:16 163:1
improves 24:21
improving 185:6
inability 39:16 69:17 87:4 124:18
inadvertently 120:10
Inborn 5:6,9 8:12 17:17
incapacitating 73:18 74:1
inch 122:7
inches 118:20
include 9:6 93:11 128:6 157:5 179:6 198:10
included 20:3 31:8 112:19,21 128:8 129:1 156:14
includes 41:7
including 18:17 22:18 131:22 132:7 187:13
inclusive 19:8 21:18
incontinence 21:17 105:13 107:11,18 108:4,14 111:21 114:2 116:16
incorrect 22:4
increase 44:4 104:4 135:1 193:8
increased 16:4 161:1
increasing 127:8 150:4 160:15 177:12

incredible 89:15
incredibly 19:18 47:14
IND 146:4 195:9
independence 152:3
independent 152:6
indicate 37:16
indicated 23:16,19,20,22
indication 144:2
indirect 22:15
indiscernible 86:10 93:22 94:2 95:13 147:12 156:9 161:19 183:1 184:3 193:1
individual 176:16
individuals 13:5
individual's 21:21
industries 191:19
industry 11:4 17:1 33:1 187:20
inertia 39:11 126:9
infarcted 150:12
infections 119:5,10 122:20 123:11 159:19 181:13 183:21
inflammation 116:19
inform 12:14
informal 7:20,21
information 9:13 11:1,8 12:2 13:3,14 14:7 16:12,15 17:8 30:4 31:18 32:5 73:13 105:18 112:21
informed 179:15
ingredient 63:17
ingredients 63:13
inhaled 91:20
inhaler 127:19
inhibitor 137:21
inhibitors 23:10 132:4 137:16
initial 115:5 158:3
initially 158:14,18
initiative 4:17 6:11 9:1 11:16,18 187:6
injected 126:18
injections 41:12 129:3 131:22
inpatient 129:8
input 10:19 13:12 14:20 24:17 25:14 29:5 173:18 200:17
insight 29:7
insights 17:20 25:11
insignificant 102:1
inspire 124:6
instance 99:7
instantaneous 145:2
instigate 76:2
instigates 40:5
instructed 125:18
insulted 72:16
insurance 46:19 112:16 126:20 132:13 144:2 151:8,12,20 153:2,4,7,12 159:15 191:20
intake 49:15 194:7
intended 8:14
intense 95:11 143:10
intent 26:3 34:4
interactions 21:8 64:8
interconnected 65:1
interest 13:10 78:8 174:20,22 177:12
interested 31:16 95:3 192:11 201:13
Interestingly 189:18
interfere 84:7,12 93:22
interferes 91:10
intermittent 93:21
international 19:4 176:1 187:10
interpretation 75:6
interrelated 65:5
interrupts 42:5
intervention 150:7
interventions 9:10 37:11
intestinal 18:17,18 20:12,15,17 39:11 59:13 64:13 77:8 118:6,15 119:5,9 120:2 121:9 122:21 123:11 124:7 181:10
intestine 106:8 126:9 133:13 134:10 164:14 165:20
intestines 118:2 165:7
intolerant 128:3
introduce 49:16,17
introduced 158:14
investigate 189:4
investigating 159:8
investigational 137:9
invite 54:1,5 66:12 148:15
invited 54:2 178:5
inviting 44:11
involve 13:5
involved 32:9 199:6
involves 74:2
irregularity 45:9
irreversible 196:10
irritable 9:7 19:9 20:5 23:17,21

37:9,22 44:12 46:7 47:19 73:9 185:19,21
isn't 57:5 80:19 97:8 107:20 170:14
isolated 131:19
issue 43:2 64:12 76:8 87:13 151:13 152:7 178:7
issues 18:16 33:17 43:11 63:2 65:21 73:10 79:1 82:9 89:14 104:12 112:16 120:15 122:21 124:20 126:12 127:1,8 128:10 150:5 152:2,18 155:4 170:13 174:11 184:2,6 199:18
item 198:15
items 64:7
it's 7:8 9:17 10:3,7 15:13 17:2,20 22:7,22 23:22 25:10,16 27:9 29:13 30:6 34:4 35:8 36:10,18 37:17 38:14 39:4,13 40:10 42:16 43:2,8,13 46:12 48:15,22 49:19 50:2 51:6,19 52:8,16,17,21 53:7,19,20 54:10,13,15,18,1 9 55:5,9,12 56:1,14 57:5,7,10,12,13 58:10,16,17,18 60:19 61:7 62:16 63:11,16,18 64:4,14,18 65:4,11,19 66:7,19 67:6 69:15 70:22 71:1,2,6,7 75:3 76:2,4 77:4 78:11 79:1,15 80:21 81:3 83:2 84:6 85:4 88:6,9,11,15 89:9,10 94:15,18 96:7,15,17,20,21 97:11,15 98:2,5,15,18 102:2,4,7,14,19 103:13 104:13 105:19 106:10 108:10 109:13 113:8 115:5,16 136:12 138:2,8,22 141:10,11,18 142:1 144:1,5,13,14 148:6 149:11 152:16,21 153:10 154:6 156:2 158:12 159:7,16 160:3,22 161:18,19 162:9,10 163:2 167:3,8,10,22 168:4,10 169:18 172:19 173:1,2,9,11,12 178:12,21 183:22 184:7 185:10 189:14 190:5 191:9 194:5,6 196:5
IV 40:18 42:2 59:18 61:20 98:4 152:7 168:20,22 183:20 192:18
I've 19:6 20:2 22:9 39:21 40:2 41:14 44:16 48:22 59:5,18 61:16 62:7,8,10 63:5 84:22 90:12 91:19 92:5 96:13 108:14 111:21 114:1 116:1 128:18 129:2 135:18 140:9,21 141:15,16 149:3 151:21 153:9 159:13,14 162:1 168:9 179:11 186:10 199:17

J

jam 7:17
January 159:17
jelly 55:20
Jillian 84:17 102:1,10,13
jittery 155:5
job 11:19 46:1 48:19 50:11 55:13 152:6 187:2
John 162:13
Johns 146:5 162:3
Johnson 160:1
join 52:20
joined 8:19 136:3
joining 13:19
joke 79:16
joked 52:12
jokes 60:16
joking 60:15
jot 94:14
Journal 187:10 196:20
journey 48:3
J-tube 121:14,21 122:3 133:13,14 148:3
judgment 95:21
juiced 44:1
Julian 2:13 124:15 128:13 163:19 169:9,10,21
July 31:7 52:9 121:18 142:8
June 121:15
justified 200:10

K

Katharine 70:13,14 71:6 88:17,18 96:9,12 97:1 104:21 105:2 141:9 149:10,11 162:1 167:19,21
Kelly 2:21 107:2 108:21,22 175:14 187:1,4 189:21 190:7
key 171:19 194:1
kick 110:13 111:13
kickoff 17:7
kicks 127:16
kidney 183:14

kids 52:12 54:1,6,8 55:8,14,17 56:18 58:20 79:16 190:11
kid's 57:17
kilter 127:3
kinds 81:22 82:1
kiosk 7:11,13
knew 27:1 36:5 47:19 68:22 138:9 146:7
knit 124:2
knot 165:13,14
knowledge 192:4,6,8 201:7
known 135:5 165:17
Komichers 2:18 175:13 179:10
KORVICK 144:6
Kovacs 5:20 93:5

L

lab 150:22
labeled 58:4
labeling 63:6
lack 76:5 136:7
lactating 196:16
ladies 73:7
lady 73:17 122:2
lagged 177:10
laid 47:9 72:5
language 73:15 107:6 108:17 185:6,8,9,10
laparoscopic 119:6
laparoscopically 160:19
laparoscopy 106:2
laps 99:8
Lara 5:16 93:17 94:15
large 119:8 157:15 178:14
largely 44:19 48:17
larger 13:16 107:22
largest 137:14
last 25:19 28:13 53:14 62:4,8 80:9 81:19 84:12 85:11 90:11 92:1 112:7 121:17 131:1 133:15 167:6 197:11 198:15
lasted 84:1 121:13
lasting 113:15
Lastly 200:9
lasts 71:9 82:16 123:2
lately 54:7
later 16:22 77:3 105:5 108:15 120:2,13 121:11 126:21 165:1
Lauderdale 117:20
laugh 42:19
laughed 47:7
laughing 169:2
Laughter 135:20
laundry 41:2
Laura 81:13
Laurie 2:5 5:10 9:11 17:13,15 36:6 37:16 94:16
laxatives 120:16 121:5
lay 51:4 72:1,5 122:14
layer 160:20
lead 22:3 116:8 117:2
leading 54:20 127:12
leads 160:18,20
leakage 107:14,17,22 108:7 187:12 188:2
leaking 123:17
lean 91:15
learn 6:1 18:13 35:1 42:11 176:9
learned 48:22 55:19 135:18 169:17 191:3
learning 46:11
leash 60:6
least 14:10 16:14 41:4 47:20 50:19 67:10,12 86:12 106:5 113:1 199:18
leave 16:11,14 51:4 57:20,21 188:4 198:16
leaving 51:16
led 39:12
leg 154:2
legally 183:18,21
legs 120:12 154:5
less 40:21 61:21 102:16 104:8 126:13 149:20 160:8
lessons 54:10
lethargy 54:8
let's 50:3 69:19 93:8 100:20 101:21,22 123:16 138:6 142:22 149:5 157:4
level 74:1 79:21 83:11 177:16
levels 85:6 98:3,6,8 191:14 192:8 193:6
Lewis 187:4
Lexapro 113:4
licensed 146:4
lies 194:1
life 10:3 21:22 24:22 26:17 39:15 42:1 43:3,6 44:20 45:3,5,13 46:5,14 49:5,7 51:7 52:15 60:5,9 62:2,21 66:9,22 69:5 84:19 87:2 90:19 101:1 116:6 118:1,9 120:8 121:20 123:20 124:6,9,21 130:22

139:12,14 140:21 141:1 160:3 171:14 173:13 176:20 177:1,9 183:12 186:2

lifelong 178:16

life's 50:18

lifesaver 160:13

lifesaving 195:17

lifetime 188:19

ligament 130:4 150:8

light 144:8

lightbulb 12:12

lightheadedness 143:7

likely 189:20

limit 28:18 175:7

limitations 49:14

limited 23:14,22 27:2 55:16 100:3 195:6

linaclotide 23:16

line 58:8 122:1

lines 155:1 182:9

Linzess 133:3 143:9

Linzess/ Linaclotide 137:11

Lipoic 193:8

liquid 98:1,4 107:17 108:8

liquids 129:22 147:5

list 14:16,20,21 19:8 21:18 63:17 143:18 179:21 180:3 195:15

listed 19:7 63:13

listen 33:6,9 171:19

listened 185:2 189:22

listeners 74:20

listening 6:14 33:2 168:8 188:5

lists 15:1

literally 129:15 140:21 182:15

literature 189:19

little 4:19 6:1,9 11:15 15:20 21:3 29:7,8,9 40:19 48:1 57:15 61:1 63:1,6 65:7,20 66:7,10 67:18 73:6,15 76:21 91:14 97:15 99:12,13 101:10 103:21 104:16 114:3 115:7 118:11 127:18 133:21 137:15 138:17 139:11,13 153:11 159:6 163:8 180:16 181:4

live 8:3 15:5 17:20 35:10 42:12 44:13 60:5 61:14 73:19 79:9,20 83:10 88:8 124:6,21 128:16 162:17 164:21 182:16 186:2

lived 66:22 84:18,22

liver 182:1 183:8

living 7:1 26:5 36:20 42:2 48:17 85:4 187:5 188:10

lobby 7:13 124:3

local 125:15 146:10

locally 44:13 179:22

located 5:2 7:12

locations 158:6

logging 51:22

logistics 162:18

Lomotil 112:10

long 12:13 43:5 48:3 57:14 71:10 85:3,7 90:9 92:7 112:8 124:17 127:4 138:12 177:10

longer 129:9 182:11

longest 113:15

long-term 92:2

loose 45:16 101:11

loosing 184:3

lose 4:11

losing 106:9

loss 107:19 128:7 192:21

lost 4:10 22:18 39:21 62:10 96:13 120:7,16 181:15,16

lot 11:3 14:17 18:13 19:15 22:8 42:9,14 45:8,9 46:3,12 49:1 50:10 51:16 53:22 61:3,4,15 62:10 65:20 66:7 73:3 75:16 77:18 78:4 81:5,18 82:14,16 83:4 88:12 92:15,22 94:21 96:4,17,22 102:11 104:3 108:14 109:22 110:8,9 119:13 130:18 136:5 141:10 148:19 164:7 165:3 167:2,13 168:9 170:16 172:18 180:14 184:2,6 195:19

Lotronex 137:18

lots 81:4 96:3 118:7 145:4 156:12

love 41:4 60:21 63:22 111:13

loved 32:12 36:12,16 38:4 68:7 100:13

low 82:10 92:21 114:17 115:3 184:1

lower 9:5 65:2,5 77:21 98:22 100:9,13 103:7 107:5,11,15 150:3 197:1

lubiprostone 23:16

luck 139:22 140:1

Luckily 57:20
lucky 57:22
lunch 90:10
luncheons 50:11
lung 124:20
lungs 53:8 119:10 125:1
Lustgarten 190:14
Lynn 2:12 71:17 73:2 99:1 117:17,19 124:14 147:21 148:14

M

magic 144:16 149:21 150:15 179:13
magnesia 118:9
magnesium 122:22
main 6:17 174:12
mainly 157:7
maintain 66:20 115:5
major 45:18 46:15 50:7,19 130:15 152:2
majority 178:22
male 36:4
malfunctions 162:19
malnourished 133:8
malnutrition 96:13,22 120:22
manage 121:20 156:6
manageable 78:1
managed 88:13 116:1 136:12 165:15 166:8 168:20,22 169:1 179:12
management 23:4 156:16,19 157:1 163:21 198:9
managing 51:7,14 62:1
manner 193:19
March 159:20
marijuana 141:20 145:8,10,13,17
Marilyn 2:17 175:12 178:2,3 179:8 185:14,20
Marinol 129:4,17 132:2 141:20 143:22 145:6,7,15
mark 175:9
market 12:8 129:11 132:20 150:15 151:16
married 118:20 123:20
Mary 3:3 83:5 84:2,5,9 146:2 147:20 160:11 161:6 162:13 175:14 192:14 194:10
massage 99:10,11
math 124:2
matter 6:18 26:15 42:17 53:19 54:18 72:7 133:17 141:14 200:21
matters 13:8
Mature 187:5
maximum 132:18
may 1:7 33:6,7 39:3 73:15 77:5 85:3 86:7 95:2 97:9 103:20 114:15 116:8 121:15 170:17 172:19 174:20,22 177:1 179:22 187:19
maybe 15:15 17:6 42:6 64:2 66:3,4,22 75:11 83:20 93:11 94:6 95:11,20 106:5,14 137:11 159:4 171:7 185:22 197:6
Mayo 121:19 192:19 193:3
MD 1:12
meal 64:1 69:18 90:1 125:2,6
meals 86:22 140:7
mean 49:20 53:5 58:6,9 70:7 83:9 85:1 88:4 94:4 97:20,22 106:11 109:11 110:3 140:10 147:10 148:17 154:5 156:11 169:2,12 170:5
means 38:7 92:21 95:22 114:19
meant 29:12 130:5 150:17
measure 24:20 78:12 85:12
measurements 25:4
measures 18:20
measuring 78:21
mechanism 188:7,17,21 189:4
med 116:22 134:1
median 130:4 150:8
Medicaid 151:17 152:4
medical 5:17 12:7 22:2 56:20 75:7 123:22 151:10 157:13 167:22 169:17 185:1,9 197:15 198:5,7,8,11 200:4,10
Medicare 151:21,22 152:5
medication 24:3 48:14 52:20 61:18,20,21 66:4 123:3 129:12 148:7,9 153:17 168:21 169:1 172:13 197:4
medications 22:14,21 61:16 65:7 104:3,5 118:22 132:6,7 145:12 150:21 151:7 153:9 158:7,10 172:22

183:15 191:22
medicine 49:20,22 88:2 111:22 112:1,13 116:4,10,11,14 117:4 127:6 154:1 191:4
medicines 157:7 170:15
meditate 49:2
meditation 112:22
meds 75:2 112:3 116:17 183:16
Medtronic 160:16
meet 12:9
meeting 1:4 4:7,15 6:14 7:4,21 8:2,9,20 9:14 11:7,17 13:16,18 15:3 16:7,13 25:22 26:2 29:21 30:17 35:1 44:10 54:3 69:15 70:17 128:12 172:16 175:3 197:16 199:20
meetings 8:22 10:16 13:13 14:6,10 15:11,20 16:3,7,19 17:4 25:10 35:3 80:10 81:5 136:4 197:20 198:4
members 175:19
memory 80:14
men 36:9,11
Mend 132:13
mention 76:20 110:4 148:2
158:1,12 170:4
mentioned 19:8 20:10,15 29:18 33:3 36:7 60:12 61:12 62:15,21 93:5 100:7 101:4 104:11 151:9 152:19,21
menu 50:10
Meredith 2:14 91:2,3 93:5,11 96:3 103:2,3 128:14,15 131:3 138:8 149:19,20 153:21 154:15,16 166:6
Mestinon 132:3 138:18 139:17
metabolism 127:3
metabolizer 168:18
Methenamine 122:18
methods 193:17
Metoclopramide 196:22
Metocloprimde 23:19
metro 35:11,12
Michael 1:18 201:2
MICHALE 201:18
microphone 4:13 66:16
microphones 28:11
mid 178:13
middle 4:11
38:8,20 88:21 127:4
mike 5:3 17:12 175:16
mikes 70:9
milk 118:9
milligrams 144:17 146:14,17 147:1,8,10
million 178:9,11 185:17
millions 188:12
mind 33:8 68:14 151:2 174:15
mine 139:8
minerals 112:6 114:11
Mine's 167:21
minimal 132:18
minimally 121:21
minimize 122:12
minimum 99:2
Minnesota 121:19
minorities 167:1
mint 41:20
minutes 4:21 7:10 9:2,13 27:6 28:4 67:5 68:9 101:7 111:12 125:16 163:10 171:3 175:4 178:1 194:11 199:2
misdiagnosed 179:1
misdiagnoses 179:4
misdiagnosis 22:3
miserable 90:14,18 154:11
misery 90:15
misinterpret 74:17
mispronounce 175:11
miss 45:15 140:12
misses 135:17
missing 95:22
mission 186:1
misunderstanding 22:2 75:10
mitochondria 193:9
mitochondrial 184:4
mitrochondrial 59:10
mix 146:21
mixed 19:11
moan 92:21
mode 33:2
models 192:20
modification 198:1
modifications 129:5
modify 43:9
mold 63:16
mom 54:9 146:11
moment 88:19 134:2 184:16
Mommy 79:17
mommy's 55:22
Monday 1:7

81:9,10
money 124:3 190:15
month 16:14 129:7 151:19
month-long 111:17
months 61:14 115:8 119:14 120:12 123:13 126:1,4 130:13 133:20 142:9 168:3 182:11
mood 194:8
moody 46:9
moon 40:9
morning 55:12,14 56:15 88:20 99:7 139:4 189:8
mornings 55:11
mostly 44:21 46:9 49:10 94:5,6
mother 157:21 184:13 187:21
motile 136:7
motility 18:17 61:7 64:15 134:10 135:1 190:15
motivation 115:14
motor 193:14,22
mouth 48:18 93:13 123:18 144:14 153:7 168:21
move 25:20 28:5 29:2,16 38:21 39:5 53:6 65:7 68:14 70:21 76:1 87:8,10 88:7 92:9 96:11 98:21 102:4 103:21 106:6,22 109:1 125:4 128:1 143:19 153:15 156:1 164:8 173:21
movement 64:20 133:5
movements 45:17 107:19
movie 139:4
moving 64:15,16 65:6 92:6 102:19 165:5 174:8
Mulberg 3:7 5:7,8 85:11 198:22 199:1
Muldowney 2:5 5:10 9:11 17:15,16 81:14 94:17
Mullin 2:4 5:13 8:22 11:10,13
multi 136:7
multiple 37:17 62:9 94:12 114:1 119:9 120:16 127:12 129:2 177:8 194:6
muscle 59:14 132:1
muscles 41:8 139:1 165:6,12
myoclonus 59:16
myself 40:15 51:16 55:2 57:13 60:16 62:13 97:22 124:20

N

NAC 193:7
naked 106:1
name's 70:14 82:7
Nancy 2:20 175:13 184:11 186:22
nap 99:2 123:7
narrowly 33:15
national 185:13 190:4
nationally 190:3
naturopath 114:9,14,17
nausea 21:9,14 39:16 41:21 42:10 58:16,18 68:12,18 69:10,15 87:15,17 88:1,4,14,15,18 89:6,8,13,16 90:9,11,14 91:2,4,5,6,9,11,19 92:2,11,14,17,20 93:19 94:5 97:4 114:4 120:13 124:18 126:14 128:17 129:1,12,14,18 130:1,2 131:11 132:8,9,13 134:22 135:7 144:22 145:15 152:14,16 154:1 168:15,16 169:1 177:19
nauseated 121:22
nauseating 144:13
nauseous 52:19 88:7,22 89:22 98:15 102:14 140:13 142:1
navigating 26:6
nearest 91:16
nearly 188:19
necessarily 24:17 51:6 107:21,22 149:7
necessary 24:13 97:7
needless 140:13
needling 163:16 164:11,12,18,22
negative 42:17 141:8 196:15
neither 143:9 201:8
nerves 21:4 120:10
nervous 21:2,5 44:21 188:9 189:9
networks 30:18
neuro 160:12 161:12
neurogenic 120:11
neurological 152:21 155:4,7,8 189:10 196:10
neurologist 138:19
neuropathy 120:11
Neuropeptides 194:2
newer 158:20

Nexium 153:6
nice 38:7 49:9,13 64:2 146:11 187:2
nicely 157:2
nicer 151:11
niece 139:2
night 42:4 54:17 57:2 62:4 72:22 84:7,13 88:21 139:3 159:22
nighttime 84:10
NIH 107:13
nine 38:11 54:8 56:3 82:21 133:15
Ninety 35:22
Nissen 119:6
nitrate 122:5
NJ 146:18 147:2
nobody 54:14 57:1 88:14 108:12,13
nodding 117:13
nods 71:11 73:3 102:12
nominations 186:11,12
non-celiac 193:21
none 112:6 116:2 125:12 132:4 161:7
non-functioning 120:20
non-invasive 192:2
non-pharmaceutical 99:15
non-profit 187:5
nor 201:9,13
normal 20:17,18 40:3 43:2 54:9 61:5 124:21 135:3 173:5 182:2 188:15
normally 129:19
Notary 201:1,19
note 68:4 103:19 174:19 196:19 197:20
notes 196:21 202:7
nothing 43:1 46:4 49:7 53:18 72:10 116:10 119:2 122:6 123:12 124:22 125:13 140:7 145:1 156:20 159:10 167:12
notice 151:5 163:7
noticed 138:11
nourished 134:4
novel 192:16
Nowadays 64:4
NPY 194:3,6,9
nudge 175:9
numerous 61:17 134:3
nurse 123:14
nurses 74:7
nutrition 40:19 42:2 59:19 98:5,17 128:1 152:7
nutritional 96:6
nutritious 51:15

O

Oak 1:10 8:17
objective 18:19
obsessed 115:14
obstruction 121:9,15 181:10
obstructions 118:6
obtain 179:22
obtaining 146:3
obviously 93:19 116:14
occasion 45:15
occasionally 30:9 86:1
occasions 149:1
occur 9:4 115:10
occurrence 45:10
occurs 123:13
o'clock 7:16,19 99:3,18
October 124:22
offer 7:3
office 4:3 5:14,21 8:13 15:11 31:12,13,14 49:10 199:5
officer 201:2
officially 151:10
Off-label 24:3
oh 46:2 52:21 57:6 58:5 60:11,19,20,21 61:19 63:10 64:14 65:12 66:2 71:16 76:6 79:17 80:19 97:17 103:17 145:3 153:8 173:4
oil 63:13,15 115:20
oils 63:3
okay 35:5,16 61:6 62:17 66:3 77:4 78:5 83:16 98:20 101:6 103:9,16 105:2 106:19,20 137:4 143:4 145:22 149:18 154:14,20 161:19,20 166:14 181:19 183:2
old 49:13 78:3 118:17 119:18 169:12
older 38:18
Oley 60:3
Olympic 99:8
omentum 160:20
one-drug 194:5
ones 10:12 12:15,16 26:16 32:12 98:2 137:22 156:18 157:4 193:18
one's 38:4 71:4
one-time 97:8
ongoing 82:16 83:3 124:19 128:9
onto 59:22
opaque 179:18

open 6:21 7:2 16:11,14 26:4 31:7 33:3 163:9,14 173:21 174:3,8

opening 4:21

opens 162:11

opiate 134:1

opinion 171:17

opinions 34:13,14

opportunities 189:3

opportunity 6:6 15:14,19 30:10 131:6 135:9 174:10,13 176:3

option 128:2

options 23:4,15 24:10 134:12 167:5,13,17 169:6 183:14 184:7 192:17

oral 50:1

order 7:9 19:5 61:10 175:10 176:12

ordinary 62:14 187:20

organ 105:22 106:16 181:20

organization 32:2 60:2 175:22

organized 15:8

organs 106:10 182:16

originally 59:20

osmotic 114:19

osteoporosis 183:16

ostomy 72:6 121:16 123:17

others 11:5 16:1 30:16 32:14 33:1 37:19 38:15 76:19 109:16 113:1 124:6,10 131:14 136:13 152:21

otherwise 37:1 137:13 201:13

outcome 201:14

outcomes 22:5 24:14,19 108:18

outlandish 43:13

outpatient 22:9

outside 35:12,22 56:2 98:10,11 166:16 195:10

outweigh 11:20 57:19

outweighs 9:19

overall 59:11 163:21

overgrowth 103:6

overlap 19:15

overlooked 77:2

over-the 156:13

over-the-counter 23:6 112:3 133:4 156:20 157:4,10 197:22

over-the-counters 157:12

overview 23:3

overwhelming 94:20 110:6 179:19

owned 43:4

oxidative 193:4,10

oxygenase 193:2

P

p.m 109:19

PAC 170:6

pace 135:5

pacemakers 152:14

pacer 135:5 158:2,12

pacing 154:4

pack 133:21

packed 7:17

pad 133:21

pads 154:5

page 2:2 26:13

pain 19:13 20:19 21:9,13 39:15,17 40:1 41:14 42:10,13 44:2 45:14 52:15,16,20 53:13,16 58:3,5,9,18 60:10,12,15,18 61:12,17,20,21 63:4 65:21 68:13,19 69:7,8,16,20 70:1,5,18,19,20, 22 71:7,10,12 72:9,11,13 73:16,22 74:1,5,8,9,12,15, 16,21,22 75:2,14,15,17,18 ,19 76:2,3,6,7,15,16, 22 77:5,6,7,10,17,2 0,22 78:2,3,13,14,16, 17,18 79:3,4,5,10,14,1 5,19 80:9,12 81:1,19,21,22 82:3,13,20 83:1,7 84:20 85:1,5,7,12,16,2 0,21,22 86:5,6,9 87:8,18 91:10 92:18 98:14 101:12 102:6,18 104:4 105:4 107:9 111:20 113:14 114:3 116:17 118:7,13 119:12,13 120:13,17 122:15 123:1,8 124:18,20 130:1,5 131:12 133:22 134:1 135:2 143:7,10 145:14 148:5,11,12,18,1 9 149:4 152:17,20 164:21 168:15,20 172:12 177:19 191:6,11

painful 20:22 84:21 85:3 102:2 103:12 165:14

pains 72:1,2 82:1 115:9 119:9 121:14

pain's 42:20

palpitations 113:13 170:6

pancreas 181:22

pancreatic 63:2 77:1 194:3

pancreatitis 59:14 63:4

panel 27:16,22 93:2 104:19 109:5 111:5 136:6 143:16 171:5 179:11 189:9

panelists 16:10 28:3 109:20 110:13 139:21 199:10

panic 189:12,18

pants 53:11

Panus 3:6 175:16 197:12,13,14

papers 49:9

paralysis 102:19 105:22

paramount 34:14

parent 43:5 190:22

parents 54:5 61:9 152:4 191:13,16

park 40:15

Parkinson's 189:15

participants 87:2

participate 7:5 176:20

participating 6:5 30:10 111:7 155:13

participation 15:16 16:5

particular 13:7,8,15 14:9 15:21 26:8 107:4,10 108:3 144:9

particularity 13:11

particularly 20:5 24:18 32:1 95:2

parties 201:10,12

Partnership 191:16,19,20

partnerships 200:12

party 54:2

Pasinkoff 2:15 87:21,22 131:4,7 153:22 154:10

pass 42:14 128:20

passing 64:19

past 68:7 100:14 113:22 126:17 140:10 166:5 177:12

pathways 189:16,17

patient 4:17 6:19 8:16 10:12 13:4 16:1,16 18:22 20:20 25:2 28:7 29:17 31:5,15 32:2 44:12 47:21 60:2 74:21 80:16 107:12 157:21,22 171:13 174:14 175:22 179:12 180:8 182:4 184:20 185:3,22 200:14

Patient-Focused 1:5 4:16 8:8,21 11:11 14:4 35:3

patient-reported 24:14,19

patients 6:18 7:1 8:16 9:22 12:11,13,15 13:5,6,12 15:14,18 17:3 18:6,12 19:16 21:6,8 22:5 24:4,9,18,22 25:7,12,21 27:16,17 28:6 29:16 32:10,17 94:22 124:2 136:17 157:15 175:6,19 176:7 177:15 178:22 180:13,21 193:13 195:18 196:8 197:3,8,18

patient's 185:9

Patients 21:22

pay 57:8

paying 151:18

PCA 60:7 61:18 62:4

PDUFA 14:12

peak 147:16

peanut 55:20

pebble 72:18

pediatric 38:17 190:9 200:5

peers 30:18 67:16

Pennsylvania 56:21

people 16:12 19:20 30:1 36:9 43:7,8 46:10,12 47:1 48:4 51:11,21 70:7 75:7,18,20 76:1,9 77:19,21 79:13,14 81:15 82:13 83:15 85:4,13,20 86:19 88:5 90:13 92:16 93:4 94:5,6 103:11 107:7,10,18 108:5 132:15 134:17 141:10 143:7,12 144:7,10 145:9,16 152:2,13 158:13 159:8 163:11,14 166:11 167:3 169:19 170:16 175:4 180:15 181:1 182:12 184:22 185:7 187:3 188:1,17 190:6 194:18,22 195:2,6 196:12,16 197:2

people's 26:4 85:16

Peptamen 122:8

per 133:15

perceive 20:21 102:15,16

percent 35:22 37:21,22 38:1,2,11,12,13 51:21 90:8 101:11,13,14 120:20 133:2

137:20,21 156:20 195:1
perception 18:18 20:12,16
perceptions 85:16
perfect 142:17
perfectly 106:1
perforation 106:5
performing 131:18
perhaps 26:9 75:6,9 135:7 157:20 185:10
period 40:7 85:3,8 159:20 196:11
periodically 29:2 30:6
periods 54:16 123:7
peristalsis 118:5
perk 159:5
permanent 112:7 116:11 121:2 155:7 162:10 163:4
permission 99:18 163:12 179:17
peroxidase 193:9
persistent 9:3,8 37:10
persists 9:9
person 6:3 25:19 30:1 36:19,20 38:8 39:6 43:10,15 78:2 91:14 92:19 126:19 135:3 152:17 161:12 172:9
personal 26:4 34:13 176:17 178:8,12
personally 102:15
person's 176:20
perspective 4:18 6:19 7:3 13:20 32:11 46:10 71:14 98:20 109:3 171:10
perspectives 16:10 26:10 32:13,16 38:16 76:12
pharma 200:13
pharmaceutical 27:11 111:2,4 136:22 138:15 149:9 156:2 171:8 189:3
pharmacies 146:8 179:21 195:11,16 197:7
pharmacist 194:15
pharmacotherapies 199:21
pharmacy 146:10 158:9
Phenergan 129:4 141:16 155:2
Philadelphia 56:22 57:3 190:11
phobia 191:10
phone 30:13,14 100:2,3,4 101:8 106:19,20 111:7,9 155:12 161:7,8 168:12 169:21 171:1
phones 30:8
physical 91:7
physically 4:9 22:1 64:16 93:8 119:15
physician 162:13 171:18 188:14 189:1 199:13
physicians 172:19 200:15
pick 41:20 48:11 146:11 198:17
picked 46:20 101:18
pieces 63:8,11 66:7
pill 47:22 50:1
pilot 14:6
Pittsburgh 172:10 181:19 182:8,9
pivotal 10:20
placed 133:9,11,13
plan 54:16,22 104:8 152:4
planning 109:3
plans 151:15
plate 50:9 122:7
play 57:18
playing 29:20
please 7:19 28:12,16,18 29:17 30:12 32:4,21 37:1 51:12,17 78:6 92:12 99:19 135:21 137:7 139:20 164:1 173:19 174:15 175:5,17 182:18,21 184:11 194:11 197:5 198:19
pleasure 35:19 53:16
plug 105:17 106:10 174:2
plus 115:21 122:10
point 31:11 48:18 49:6 55:12 90:1 92:1 109:13 110:6 133:19 142:16,17 160:22
pointed 84:3
points 43:18 91:18 150:20 164:18 165:2,4,18 184:17 186:9
poisoning 42:11
polling 29:6,9,13 35:6 67:20 137:1 156:1
polypeptide 194:4
pool 99:8
poor 116:18,19 168:18
popular 87:9
population 108:18 163:1 176:9 178:6 179:5 189:6 193:20
populations 38:18
port 54:13

position 12:14
positioned 12:19
positive 42:16 116:9 119:20 179:21 180:3 195:15
possibility 117:1
possible 127:19 140:2 174:2
possibly 132:12 183:20
posted 16:18 32:6
pot 125:19
pounds 40:17,18,21 96:14 118:20 125:5 181:16
powder 122:5 146:9
powerful 199:8
PPIs 129:4 141:16
practically 168:6
practice 29:11 112:22 187:11
pray 171:17
pre 196:17
pre-diabetic 150:1
predict 50:16
predominant 19:11 111:17
Preeti 5:18
prefer 122:14
pregnant 53:5 119:5,14 133:20
prep 103:22
prepare 111:12 142:13
prepared 28:4 64:7 176:5 180:22
prescribe 48:14 133:22 141:13
prescribed 24:4 114:10 126:10 132:16 149:12
prescriber 146:4
prescription 23:13 112:3 120:16 137:9 197:22
prescriptions 195:7
present 95:12 119:22 176:3
preservatives 44:5
president 180:7
pressure 119:11 125:3
pressures 61:6
pretty 46:1 86:18 155:17 166:8
pretzel 52:18
Prevacid 119:1
prevalence 20:3
prevalent 190:6
prevent 116:18
previous 144:8
Prilosec 119:1 137:21
primarily 95:7
primary 6:22 28:17 45:20
prior 122:13 133:5
PRNs 129:17
probably 7:9 39:5 45:7 46:2 55:18 113:15 157:11 166:16 193:21 195:8
probiotic 46:2 115:19
probiotics 114:10 127:20
problem 50:2 54:7 58:7 75:6 142:4 148:8 149:12 159:7 170:8 197:4
problems 41:14 76:14 82:15 104:12 140:15
procedures 22:4
proceeding 201:3 202:6,7,10
proceedings 201:4,6
process 6:15 10:8,16 14:19 164:13 167:8 174:19 179:18
produce 16:6
producing 199:6
product 63:19 139:16 145:20 155:14,16 187:19
productive 149:17
products 5:6,9 8:12 17:18 112:11 133:4 138:5 197:22
profession 73:14 185:1
professional 31:20 171:13
professionals 74:19 124:8
profile 197:1
profound 200:2
program 13:4 14:12,13 31:15 186:13,19 195:9
programs 4:4 5:14 14:1 24:9 199:5
progress 180:17 189:12
progressed 59:21 188:20
progresses 92:21
progression 190:1
progressive 160:22
progressively 114:1
projectile 118:12
prolactin 147:9
promethazine 132:11 141:16 153:22 154:3
promise 154:16
promotility 23:7
pronounce 137:6
proof 170:16
properly 114:16 125:18
Propulsid 181:7
Pro-Stat 122:11
prosthetic 92:6

protection 187:18
protocols 112:2
proton 23:10 132:4 137:15,21
Protonix 119:2
provide 6:10 17:19 18:1 23:3 33:22 195:17
provided 31:6 116:12 172:17 173:18 197:18
provider 171:18
providing 9:12 25:4
proving 126:6
pseudo 181:10
pseudo-obstructions 123:10
psychological 18:15
psychotic 129:12
public 1:4 6:21 7:2 14:16,19 26:2 30:21 33:3 163:9,14 173:21 174:3,8,17 176:10 178:8 199:10,12 201:1,19
published 187:10
Pujita 199:1
Pujita's 173:22
puke 58:19 88:22 91:15
pull 73:21 111:3
pulled 132:20 147:3
pulling 114:20
pump 23:10 60:7 61:19 62:4 132:4 137:15,21
puppy 135:18
purpose 6:13 27:22 126:6 174:9
purposes 36:17
pursue 192:16
push 5:2 29:10 39:2 57:13 64:17
pushed 53:7 58:7 124:20
putting 14:20 41:7 109:10 154:5 197:16
pyloric 129:3
pyloroplasty 126:21 163:5
pylorus 126:18 131:22 162:5,11
PYY 194:3

Q

quality 21:22 66:9 121:20 130:22 139:11 141:1 177:9 187:11
quantify 94:4
quantity 122:19
quarter 122:7
question 28:20 33:7,11,13 35:7 39:5 68:15 78:10 80:6 81:12,18,20 82:2 83:6 85:10 93:7,17 94:15 95:6 103:18 106:22 107:15 110:7 136:22 137:1 143:22 153:14 156:1 162:5 164:9 166:2
questions 15:12,17,19 26:11 29:6,12 30:3 32:1,2 35:6,14 36:15,18 39:3 67:20 74:12 81:9 82:2,4 84:4,15 87:7 93:2,20 94:8,12 110:16 155:14 164:5 171:5,15
quick 143:21 144:21
quickly 58:4 154:18
quite 25:22 39:17 75:14 87:9 126:16 158:4 169:22 178:21 184:1 192:11

R

race 20:1
radical 172:11 193:5
raise 71:13 108:8 137:3
raised 93:4 145:7
raising 108:11 166:14
range 38:8,10 48:10 111:1
ranging 22:10
rare 117:21 149:1 150:9
rarely 39:16 148:22
rat 150:22
rate 61:22 82:20 86:7,9,19 87:3 125:2 127:2,9 160:15 161:2,3
rated 69:9 104:20
rather 83:6,18 109:12 147:4 194:6 195:9 197:8
raw 168:18
Raymond 3:6 175:15 197:11,13
razor 64:19
reach 30:17 36:9
reaction 147:15 153:20
reactions 63:21
reading 56:4 112:21 172:6
ready 75:15
real 39:4 41:19 50:2 52:2 79:19 137:5 164:21 180:19
realistic 171:14
realize 47:1 49:5 58:12 90:4 164:19 170:15 178:11 190:6
realized 12:11
really 7:1 12:5 13:20 15:4 16:3 17:19 18:4,22

20:13 21:4 22:16 24:18 25:9,11,14,16 26:3,12 27:2 28:1,8 29:16 32:9,11 33:9,15 44:16 45:2,3,4,14 46:4,6,8,13 47:4,7 48:3,15 50:12,15,16,17,2 2 51:7 54:21 55:12 60:17 63:16 66:6 74:20 80:21 82:13,22 83:12 87:9 90:2,4,14,17,18, 21 91:8 94:10,15 95:22 97:15 98:5 100:19 101:17 103:5 104:5 108:1,4,10,16 110:11 113:5 116:4 126:5 128:12 130:3,22 131:14 138:5,6,10 139:13 141:10,12,18 142:10 149:16 150:4 151:14 153:3,10 155:5,19 157:18 159:6 163:4 165:15,18 167:9,19,21,22 169:3 170:19 172:5,17 178:6 182:19 183:6 191:10 192:9,10 194:22 196:5 197:1 200:3,16

reason 102:5 125:10 143:22 150:9

reasons 24:8 75:14 151:10

reauthorized 14:12

rebound 113:9,21 117:2

received 143:1

recently 74:6 127:13 138:17

recital 57:17

recommended 134:12

record 174:17,22 187:17 201:7

recorded 8:3 201:4

recordings 202:8

rectal 101:12 118:14 119:16 121:7

rectum 18:9 120:5 121:2

recurrent 9:4

red 5:2 39:2 142:6

reduce 116:19 122:19 126:15 135:7 137:10 156:5 189:20

reduced 201:5

refer 14:5

reference 16:21

referred 125:11 126:3

referring 21:2

reflect 188:10

reflected 28:9 67:11 68:5

reflecting 188:19

reflection 37:18

reflux 9:8 37:11 118:18

refractory 176:18

refreshing 77:9

refused 126:4

regard 75:10

regarding 33:17,18 75:8 85:12 103:10 199:12

regime 128:10

regimen 27:9,12 48:16

registration 7:6,7

Reglan 119:1 126:11,15 129:5 132:1 143:5 147:13 152:20 154:16 155:2 196:9

regular 79:8 83:19

regularly 118:10 126:13 128:1

regulated 198:11

regulations 195:14

regulators 176:11

regulatory 200:16

regurgitate 133:18

regurgitation 93:12 131:12 153:7

Reily 2:9 52:5 58:15 79:1

reintroduce 115:6

reintroducing 49:12

reiterated 156:3

rejection 183:16

relapse 189:20

relate 18:16 20:11 108:6

related 22:15 53:20 68:2 96:6 150:6 174:12,20 201:9

relative 80:7,20 115:8 201:11

relatively 91:12 129:19

relay 194:19

relayed 194:18

release 130:4 150:8 165:4,18

released 164:19 165:2,6

releasing 165:14

reliable 113:8 140:9

relief 90:8,20 112:6 113:8,15 114:13 117:3 132:18 134:7 140:9 145:10 159:9

relieve 45:22 144:10 145:2

relieved 87:5 144:22 152:16

relieving 83:3

relying 25:14

remainder

36:14,18
remarkable 173:16
remarks 4:21 8:6 28:4 39:1 43:17
remarried 43:5
remedies 112:5 132:3 163:17
remember 10:7 44:6 124:18 138:1 163:19
remotely 30:10 155:12
removal 39:12
remove 49:11 121:1
removed 106:4 120:5,14 130:12 133:2
repeat 139:15
repeated 120:1 200:2
replaced 158:22 159:5
report 16:17 31:9
reported 202:5
Reporter 202:5
Reporter's 202:7
reports 16:18,20 17:5
represent 10:9 24:19 190:11,12
representation 30:1 36:6
representative 13:4 31:15 174:14 190:3
representatives 11:4 29:17 160:17
represented 18:3 20:4 67:16 136:17
representing 13:6 188:19
represents 178:9
rescue 127:18
research 4:5 103:4 107:3,16 108:2,15 124:4 138:2 146:7 167:10,14 170:14,20 172:20 176:9 177:9 189:12 193:10
researched 125:15
researcher 193:1
researchers 10:12
researching 46:18
resection 118:15
residency 169:14
residues 127:12
resonate 92:10 136:14
resonated 92:11
resonates 71:15
resources 31:10
respect 34:14,16 43:16
respectful 175:5
respiratory 127:15
responding 174:16
response 14:19 30:2 110:6 171:6
responses 28:19 127:15
responsibility 9:18
rest 40:8 41:7 54:16 57:12 62:18 99:4
restaurant 50:8
restaurants 64:7
restless 154:2 155:5
restrict 196:7
restricted 112:10
restrictions 24:1
restrictive 115:4
restrooms 7:12
result 9:4 117:6 120:22 127:10 129:8
results 10:18,22 35:16 47:17 100:18 116:9 118:5 196:5
retail 105:7
retired 151:10
retrograde 161:14
return 66:13
review 15:10,17 16:20
reviewed 31:8
reviewer 5:11,17,19,21 17:16
reviews 8:14
revising 14:20
revolve 43:1 49:7 56:20 62:22
revolves 42:22 49:6 53:15
rhythmic 118:4
rib 53:8
rice 122:11
rich 16:9 107:8 164:7
Richmond 124:16 162:17
ride 42:8 81:8
ridiculous 168:4
rising 76:3
risk 10:1 196:17 197:1
risks 9:19 11:20 12:18 17:11
Ritu 3:2 175:14 190:8 192:13
road 66:3
robust 36:6 38:8 107:8
role 27:10 32:14 33:9 111:4 193:4
rolled 154:11
roller 42:8 81:7
Rome 19:3 47:18
room 11:5 13:19 28:7 29:14 32:18 33:1 34:18 56:18 58:1,11 69:15 100:11 117:11 136:17 137:2 138:4 143:5 153:16 156:17 159:2 167:1,3

188:18
root 188:7
roughly 68:16
round 32:16 67:1 135:21 173:19 186:16
routine 40:5
row 92:4
rubbing 154:4
rule 47:12
rules 30:11 32:7
run 12:3 124:3 160:1,4 175:10
running 62:5 162:14
runs 31:14
rupture 118:15 120:2
ruptured 120:22
ruptures 118:7

S

sad 168:10
safe 112:15 167:13 170:20 179:16 195:4
safely 179:22 197:5
safety 10:22 11:1 24:2
sake 87:8
salad 129:21
samples 55:5
sampling 190:4
sandpaper 48:18
sandwiches 55:20
Sara 1:14 2:6 4:3 15:7 199:4
Sarris 73:5,8 74:18
Sarrit 5:20
sat 139:3
Saturday 4:9
save 95:17
saved 140:21
saw 47:3 77:3 169:15
scale 74:8,9,15,16,22 75:1,14,17,18,19 76:4,17 78:16,18,21 79:6 80:16 83:7,19
scales 79:13 81:16
scan 47:12
scared 56:5 143:13
scares 169:18
scary 91:22 113:3
scheduled 126:21
school 22:18 41:17,18 45:2 54:3 55:14 123:22 141:21 169:17 191:1,5,8,10
schools 191:13
scientific 29:12 170:16
scope 166:16
screening 13:10 179:6
script 47:22
seasick 88:9
seat 31:19
seats 66:14
second 26:13 66:17 71:4 91:1 110:17 119:6 120:3 140:4 171:17
secondly 150:7
seconds 135:16
security 117:7
seeing 22:20 35:13 71:11 127:17 142:8 146:16
seekers 76:1
seem 43:6 58:8 82:21 142:5
seemed 114:13 115:1 119:2
seeming 168:8
seems 66:5 85:15 94:4 103:6 116:21 122:6 167:8 200:7
seen 21:19 22:8,9 116:1 163:1 177:11 182:5
segment 193:20
segments 177:4
segue 163:3,4
self-sufficient 55:18
send 21:5 41:19 63:3 65:18 94:12 126:6 148:15
sending 30:20
sends 135:6
sensation 144:12
sensations 91:7
sense 47:7 69:12 101:5 104:15,21 105:2,11 109:11 138:3 157:11,13
sensitive 34:16 63:20
sensitivity 127:11 193:21
sent 109:4 142:13 172:10 181:17
separate 79:1,12
separately 187:16
sepsis 62:8,9 121:11
September 14:14 121:10
septic 133:10
series 8:20
serious 9:16 117:1 186:5,12
seriously 80:2 168:6 185:4,5 186:4,8,21
served 7:8
service 123:15
session 102:9 174:8,10 175:5 190:3
sessions 15:8 112:20 165:2
sets 28:2 41:9
setting 6:9 7:21 15:12
seven 39:21 116:2 133:20 140:22

seventh 121:16
seven-year 78:2
several 19:8 29:1 40:11 61:15 73:10 82:8 92:3 93:19 112:19 114:10 120:9 125:11 137:16 152:18 163:21
severe 45:14 52:10 60:10,12,14 61:13 63:4 71:2 75:2 76:22 80:8,12,18,22 81:19 82:3,13,16 83:1,22 84:21 87:22 89:15 90:1 103:13 105:16 118:5 119:4,8 126:8,12,15 127:1,10 132:19 133:1 168:7 179:12 183:16 196:9
severely 119:15 133:8
severity 12:5,10,20 15:4
sewer 144:14
shampoo 160:1
share 32:19,20 33:5 34:18,21 36:10 39:1 58:14 87:19 131:6 139:19 164:12 166:5 177:5 189:11
shared 38:17 171:11 199:10
sharing 124:8 176:9 192:4 200:17
sharp 71:3 77:19,20 83:9,16
sharper 71:4,6 77:22
sheet 49:13
she's 56:2,3,5 92:21
shocked 119:20
shocking 160:21 161:2
shocks 160:15
shoe 72:18
short 196:11
shortness 40:2
short-term 113:8
showed 15:8 47:18 129:13 139:1
shower 62:12 74:3
showers 40:3
showing 29:19 154:16
shown 192:22 196:15
shows 20:13 195:1
shut 183:10
sick 47:7 54:12,14 56:11 89:10 92:20 125:10,12 127:3 159:18 160:2,5 182:15
sickest 182:4
sign 7:5 139:10
signals 21:5 135:6
signed 163:14 175:4
significant 21:21 26:16 46:4 69:4 92:5 101:1 200:3
significantly 75:4
signs 18:15,22 21:11,18 199:12
sign-up 7:7 175:2
silence 188:12
silver 1:12 122:5
similar 28:8 38:10 43:11 69:14 76:12 91:10 92:15,22 100:18 137:22 143:4 178:21
Similarly 69:10
similar-type 77:19
simple 64:20,21 65:19 177:17
single 43:4 125:6 131:10 180:13
Sirota 2:11 111:10,15 117:15 161:18 170:1
sit 27:20 54:11
sitting 42:9,10,21 56:2 64:1 121:6
situation 47:4 102:15 184:15
situations 50:12 74:22 103:15
six 52:7 54:16 115:5 116:1 119:14 123:13 127:16
Sixty-six 101:13
six-week 159:19
size 53:11 182:2
sizes 53:12
skeletal 138:22
skills 201:8
skin 122:4
slashed 120:10
sleep 39:22 42:6,7 54:22 84:8,12
slide 20:13 94:18 100:1
slides 32:5
slightly 29:22 70:3
slip 7:18
slow 149:15 170:8 181:12
slowing 106:8 134:11
slowly 64:15 188:13
small 39:10 71:22 103:5 106:7 126:9 129:13 133:13 134:10 140:7 144:17 164:14 165:19 181:21
smaller 107:22
smells 55:4
smiling 76:18
smoke 127:11 142:1
smoking 142:2
smooth 59:14
smoothie 43:22
snacks 50:14
snake 165:4

snap 165:13
snapshots 28:2
so-called 10:20
social 50:12 53:16 64:8 94:1 103:14 130:18,19 131:20 176:21
socializing 82:19 86:21
socially 22:1 94:1
societal 176:16
society 53:15
socio-economic 20:2
sodium 122:21
soft 64:18
solely 51:12
solid 107:17 108:8 165:10
solution 162:10 163:4
solved 159:7
somebody 43:12,13 59:8 85:18,21,22 86:7,8 90:17
someone 4:13 29:4 31:13 36:22 69:22 85:4 101:21 111:6 154:15 158:1 171:7 185:5
sometime 154:9
somewhat 160:8
somewhere 7:15 75:19 80:1
son 57:17 158:17 178:12,15 184:14
son's 54:11
sooner 188:18 189:16 200:19
sore 122:4
sorry 73:17 81:1 139:21 177:22 182:17 194:10
sort 16:21 20:14 23:3 44:22 46:13,15 48:3,11 49:14 50:17 82:11 83:3 95:4 150:14 166:20
sorts 102:19
sound 103:20
sounds 74:16 77:14 86:11 87:12 93:18 102:2 104:9 110:7 151:11
soup 64:3,6,10
sour 82:11
source 11:8 98:9
soy 128:2
spasmodic 115:19
spasms 59:13 64:13 77:8 104:4
speak 4:12 25:20 28:14 44:11 48:17 74:9 108:15 111:16 117:9,21 174:11 178:5 184:16 194:17
Speaker 2:2
speakers 175:11 199:10
speaking 28:18 80:17 109:15 117:12 135:10 160:16 194:21
special 15:13 24:9 158:6 179:17
specialist 125:9
specialists 61:9
specific 26:18,20 33:10 39:18 86:2 110:19 164:9
specifically 24:11 112:20 132:7,14 134:14 189:18
spectrum 23:1 26:6 37:19
spells 40:4
spend 6:9 54:17 72:21 139:8
spending 139:12
spent 87:13 118:8 139:3 178:18 179:3 188:1
spirit 199:2
spoke 189:8
spoken 186:10
sponsor 11:22 12:1
sponsoring 12:1
sponsors 17:1
spoon 95:17
spoons 95:18
Springs 1:12
stack 49:9
staff 28:10 198:17 199:6
stage 67:9 158:3 199:4
stages 41:13 105:16
stakeholder 31:20
stand 31:22 66:19 125:6 164:17,20 198:22
standard 9:9 37:11 128:10 179:7 185:10
standardize 19:5
standpoint 190:21 192:6
start 4:11 14:15 15:9 27:19 39:6 48:1 49:12 65:1 67:19,20 109:18 111:8 121:14 126:13 138:14,20 149:2,10 151:1 173:4 175:8,18 189:9
started 14:14 39:17 40:18 41:22 45:19 46:6,18 48:3 59:19 89:15,22 96:14 106:13 110:1 111:6 119:10,12 121:3,4 127:6 129:10 138:18,19 140:8 146:12 147:9 148:20 154:17,18 160:15 161:2 164:20 165:9 181:12 183:8 193:7,9 198:14
starting 130:13

147:6 180:15 183:22
starving 53:2
state 28:13,16 79:9,20 80:1 105:22 164:13 174:22 187:16
states 19:20 92:17 134:17
status 20:2
stay 33:2 42:3 66:13 135:12 179:19
stayed 125:1,2
staying 38:19 199:2
steadily 127:8
stent 162:4,9
step 169:19
steps 123:15
steroids 183:17
stick 175:7
stimulating 145:13
stimulation 24:12
stimulator 133:6 135:4 160:12 161:13
stomach 44:2,21 52:16,20 53:4,9 71:22 72:2 82:11 88:5,10 89:18 93:13 115:9 124:18 133:11,12 135:1,6,8 143:7 160:6 164:19,21 165:3 177:18 181:22 192:22
stomach's 52:21 148:18
stomahesive 122:5
stool 107:17 108:8
stools 41:15 101:5,12
stop 57:12 112:17 113:17 147:11 155:6,9,18 163:8 181:8 183:9
stopped 93:14 119:7 133:10 147:13 153:16,19 154:20
store 55:3
stories 151:21 162:2 175:20 190:1 194:18,20
story 67:11 124:8 181:4 197:18
straight 164:17,20
strange 103:21 104:10
strangling 165:7
Strategic 4:3 5:14 199:5
strength 40:20 123:6
stress 42:16 45:22 56:9 60:19 193:4,11
stressed 47:4
stressful 45:2 46:1
strictly 167:16
string 85:11
striped 82:6
strong 6:5 29:19
stronger 73:15 125:19 134:1
struck 200:2
structural 18:7 24:16 177:11
struggle 48:6 58:15 130:17
struggled 59:5
struggles 61:2 66:21
struggling 4:14 136:13 166:12
stubbed 79:14
stuck 102:3
students 124:2
studies 107:13 112:19 127:14 128:21 191:18 196:14
stuff 42:12 43:6 63:4,18 65:4 77:1,7 104:2 153:12 156:12 164:7 169:12 173:1
stuff's 173:7
stumble 137:7
style 26:1
subdivided 19:10
submit 10:13 16:13 182:18 186:13,17 194:11
submitted 10:21 11:22
subsequent 89:22
subside 149:4
substitutes 128:4
subtype 19:11
success 16:4 127:22 140:22 147:8 162:15 170:18 191:15
successful 91:12 116:3
sudden 126:2
suffer 19:16 88:1 97:16 131:11 154:12 188:12
suffered 87:4 89:13 126:13,14 178:16
suffering 20:20 51:20 90:14,18 94:22 128:9 197:3
sufficient 192:22
sufficiently 189:6
sugars 114:19 150:3
suggest 19:19 103:17
suggested 45:21 46:1
suggestion 185:6
suggests 96:18
summaries 109:4
summarize 199:16
summarized 31:8
summarizing 30:4,5
summary 31:9

summer 126:22 162:7
sun 98:10,12
super 130:21
supplement 116:22 117:5
supplemental 112:5
supplements 114:10,12 115:1 134:3 170:19 198:2
supply 97:11,15
support 10:21 30:19 33:18 34:19 38:16 56:8 60:2 112:19 114:11 120:8 172:18 198:7
supposed 97:13 98:13,18 149:14
suppositories 118:10 121:6
sure 32:8 42:7 43:18 55:1,2 58:19 75:7 77:13 99:21 104:17 106:18 112:15 145:14 164:3
surgeon 119:19,22
surgeries 22:14 61:17 118:13 136:10 161:10 172:22
surgery 120:1,3,4,9 121:1,8,9,16 130:3 150:10,13 159:16 172:11
surgical 111:2 150:7 157:14,16
surprise 26:22
surprised 143:18
survey 29:13 138:2 180:22 190:4 195:1
sustain 98:6
swallowing 21:16
sweater 82:6
sweeteners 49:19,22 128:4
swelling 131:12
swim 99:8,12 124:1
swimming 99:7
switched 98:1 153:6
symptom 28:21 68:18 69:1 70:9 78:13 95:10 100:6 101:16 107:20 108:4,17 128:7 149:13,14 166:20 167:21 171:15 187:12
symptomatic 9:8 37:10
symptoms 6:18 9:4 10:3 18:6,11,15,22 20:11 21:9,12,19 23:12 26:15,20 33:15 42:7 45:1,12,20 47:11 51:13,18 52:14 64:13 66:8 67:22 68:2,4,6 69:1,3 77:14 78:13 84:18 87:5 93:3 95:8 96:19 98:22 99:21 100:5,9,13,22 101:2 102:8 107:5,11 108:12 109:8 110:19 115:10,14 116:6,16,18,22 122:12 124:17 128:6 129:16 130:15 131:17 132:6 134:6,9,15 137:10 144:9 149:15 150:17 154:19 156:5 157:8,9 168:15 171:8 177:8,20 178:5,7,16 188:6 199:12
syndrome 9:7 19:9 20:6 23:17,21 37:9,22 44:12 47:19 73:9 154:2
Syracuse 52:6 56:21
system 21:3,6 64:22 68:1 97:9 114:16 127:15,20 144:15 188:9 189:9
systematic 13:2 17:7

T

table 5:1 47:9 92:4 198:16
tabs 122:4
tachycardia 40:2 152:18
Tagamet 119:1
tags 27:20
tailor 15:20
tailored 30:13
taking 7:19 22:20 75:11 90:12 99:17 113:10,12 114:5,14 115:18 118:9 120:15 123:7 132:18 134:3 137:17 149:16 154:17 155:15,18 170:6 176:19 185:4 186:8 193:7 195:2,3
talk 11:10 14:1 20:15 27:7 34:4 46:13 47:2 50:20 67:7 73:11 99:22 108:13 109:8 157:4 160:11 164:3 192:15
talked 28:21 31:16 87:17 102:8,17 145:8 155:15 164:10 184:21 192:1,2
talking 9:1 22:12 23:1 34:2 42:9 45:19 52:1 60:15 70:16 77:19,21 78:10 90:22 92:4,19 104:21 149:4 156:4 157:6 169:13,22 170:1,2 188:6
Tan 31:14
Tanya 2:7 39:7,8 43:17 44:7 75:12 105:9 106:17 108:11 145:21 167:20 168:11
tape 142:6

Tardive 154:18
target 193:2
task 4:10 190:19 192:12
tasks 115:13 131:18
taste 65:14 97:21
tastes 65:15
Taylor 2:7 39:8,9 43:20 75:13 105:10 145:5 148:17 164:11 168:14
tea 56:16
teacher 191:6
team 109:3
tease 27:10 70:7 137:15
technical 109:12
techniques 62:1 112:22
tee 155:11
teeing 100:2,7
teenager 44:17 45:4
teeth 92:6
Tegan 2:16 175:12,16,21 177:22
Temple 158:5
temporarily 113:1 160:21 162:12
temporary 53:14 112:6
ten 22:10 82:21 83:19 85:19,22 86:6,9 87:1 121:11 132:5 144:17 163:10
tend 107:18 129:22
tens 180:12
tepid 129:9
term 18:5 92:8 176:16
terminology 83:15
terms 26:21 29:22 70:4,6,7 82:18 83:8,21 87:18 109:6,10,13
terrible 88:15 129:1 159:9
test 47:13,17 137:5 188:15
tested 100:19 167:16
testing 22:4 61:3 128:8,10 179:3,6 193:17
tests 61:4 173:5 192:2,3
thank 5:22 6:2 11:5,13 13:18 17:14,18 25:18 35:21 38:3 43:20 44:7,9 52:2,3 58:20,21,22 59:4 66:1,11,18 67:17 69:19 70:15 73:2 77:12 78:5 93:1 97:1 102:21 106:17 108:19,22 109:18 111:13,15 117:9,10,14,15 124:14 128:11,13 131:2,5 135:9,11 136:2 142:16,17 145:21 147:20 150:18 152:10 154:14 159:11 160:9 161:6,15 163:6 165:21,22 169:20 170:22 171:20 173:14,17 174:5,7 177:22 178:3 179:7,8,10 180:3,4,9,20,21 182:17 184:10,12 186:22 189:21 190:6,7,9 192:12,13 194:14,16,17 195:20,21 197:10,16,17 198:12,13 199:1,4,9 200:19
thankful 90:7
Thankfully 61:9 151:8
thanking 175:19
thanks 70:16 140:18
that's 13:13 14:5 21:17 22:17 25:2,18 28:20,21 29:4 31:2 32:10,11,21 39:20 43:11,21 44:6,18 45:7 46:10,12 47:2 48:12,17 50:9,17 52:1 53:1 59:15 61:1 65:2 66:2 70:6 73:13,22 76:18 79:8,20 80:20 81:6 82:13 85:1 88:2 91:22 93:15 98:7 102:5,17,20 107:12 108:2 138:22 141:5 142:9,10 151:6,19,22 153:11,15 156:14 162:5 166:16 170:10 181:2 183:2 184:18 185:8,11 188:18 195:20
the-counter 104:3 170:19
theme 45:7 94:19
themes 15:9 85:14
themselves 55:22 97:20 168:1
theory 95:17
therapeutic 9:9 37:11 200:18
therapies 23:13 24:5,7 137:9 151:13 152:8 156:4 198:2,3 199:21
therapy 24:21 112:20 165:16 200:18
thereafter 201:5
Therefore 9:19
there'll 66:4
there's 8:1 12:6 18:7,12 23:14 24:16 29:19 30:21 42:22 43:1,10 48:5 50:9 51:21 52:1

53:17 57:1,5 63:12 66:6 72:10,12,17 75:10 78:7 79:2 84:15 87:7 93:2 137:16 142:4,6 148:7,9 149:1 150:15 151:5 152:8 164:5 167:11,12 180:19 183:13 184:5,8 186:16,17 190:21,22 192:8 199:20 200:3

Theresa 2:4 5:13 8:22 11:10 31:15

they'd 63:15

they'll 43:9 70:9 72:14 74:7

they're 9:3 12:19 18:10 19:18 27:17 34:9,10 44:1 45:12 70:3 86:8 97:19,20 114:19 152:13 170:20 183:17

they've 143:8

thick 129:21

thickness 118:14 119:16

thin 120:18

third 35:18 171:17

thirds 35:17,19

THOMPSON 35:22 37:21 38:10 77:18 92:15 100:18 101:10 103:11 137:20 156:19 161:16 163:13

thoughts 25:17 33:22 34:21 51:8 58:13 65:8,9

thousand 180:13

thousands 178:18,19

threatening 42:1 102:16 177:1

three-hour 40:6 42:6

threw 56:17 125:2

throughout 10:15 21:4 34:3 68:1 195:12,16

throw 57:14 91:16 97:5,22

throwing 41:11 88:6

thrown 199:3

Thursday 80:9

timer 175:7

tiny 138:21

tip 67:21

tired 56:17 58:16 96:20 98:7 122:14 123:4

today 4:6,12,15 6:6 8:17 9:21 10:2 13:17 15:2 17:19 18:3 20:5 25:17 26:7,19 27:17 30:22 31:13 32:19 33:20 35:1 38:19 42:9 44:10 56:2 57:8 73:11 75:15 78:17 80:19 81:9 99:6 111:18 135:10 136:6 166:4,17 174:7,13 175:21 176:4,14 185:11 186:11 187:15,22 188:3,5,9,18 189:2,7,22 200:1,11

Today's 8:20

toe 79:14,17

toilet 93:9,10,14 121:6

tolerable 134:6

tolerance 113:10 117:3 196:12

tolerate 59:21 86:5 121:13 148:21

tomorrow 57:9 95:19

ton 150:4

tools 116:7,12

top 59:16 68:18 69:9 156:18 168:15

topic 26:14 27:19 28:19 30:13 38:22 67:8 78:7 99:22 109:20 110:9,14 136:20 185:20 190:5

topics 6:17 26:11 27:15 33:20 34:16 107:7 174:12 194:17

tops 169:5

total 120:17

totally 47:8 60:14 72:11 79:15 116:3 158:16

touch 34:15 87:14 105:11 193:20

touching 67:6

toward 7:13 38:20

towards 92:6 180:17

TPN 59:22 60:4,7 62:4,5 121:12 129:6 133:9,10 146:13 148:3 151:13 181:12,15 182:2,10 183:8

track 114:20

tracking 24:17

tract 9:6 20:17 21:5 59:12 71:20 107:11,15 125:17 177:4

trade-offs 15:16

Tramadol 133:21

transcribed 8:3 174:17

transcript 202:6,8

transcription 202:1,9

Transcriptionist 202:14

transition 141:8 151:20

transparent 174:18 199:11

transplant 164:14 165:20 181:20,21 182:6,10,13

183:15,18
trap 159:21
trash 91:16
trauma/intensive 120:8
travel 124:5
treat 8:15 12:10 23:8,11,17 110:18 116:15 129:12 132:6 134:5,8,14,17 150:17 157:7 183:17
treating 6:20 27:8 129:14 130:2 179:16
treatment 10:5 12:17 23:3 24:10,20 25:8 27:9,11 33:16 34:5 48:16 66:5 91:12 110:14,22 113:6 116:8 125:20 128:22 134:12,20 138:9,10,15 140:20 142:15 149:7 150:9 164:4 172:3,6 183:13 184:7 189:20 195:5 196:3
treatments 9:17 10:1,6 12:7,22 15:7,22 22:4 23:1 25:3 27:11 34:2,4,7 91:1 99:15 110:21 111:2,5 112:1,7 115:2 116:3,13,17 136:10,11,22 142:4,15,20 143:1 149:6,9 155:20 156:2 157:14,17 164:6 168:4 171:8 172:22 177:6,14,16 179:3 188:22
treatment's 34:6
Treatments 177:17 180:9
treatment-wise 172:5
tremendous 117:3 140:1 176:15
tremendously 199:11 200:9
trepidation 128:18
trial 10:17 15:15 78:11 129:10 162:14,17 172:14 192:18
trials 10:11,13,19,20 11:1 12:3 17:9 25:6 61:16 81:15 87:2 134:16 172:16,21
tricky 63:11 130:20
tried 63:5 112:2,3,9,12 113:2,18 118:22 121:12 122:5 131:21 134:8 140:6 143:8,11 149:9 150:21 152:17 153:5 181:6
trigger 50:6,15 129:22 164:18 165:2,4,18
triggers 104:12 115:17
trouble 31:5 76:19
true 73:22 91:9 170:17 201:6 202:9
truly 76:4,5 173:16 185:7 199:14
try 4:12 27:10 28:18 32:18 33:12 42:18 43:21 45:22 49:11 51:18 56:10 65:6,14 70:7 71:20,21 111:3 127:13 133:16 134:5 136:11 137:14 144:4 153:8 173:13 175:6,9 183:4
trying 14:7 15:11 52:17 66:1 98:2 138:3 150:22 152:3,5,6 157:9 163:3 172:21 180:11
tube 56:13 59:20 71:21 122:7,8 130:12 131:10 133:14 134:2 146:18 147:3 159:18,20 161:13 181:11 183:12
tubes 24:13 129:6
tuned 74:21
turn 5:3 8:5 11:10 17:12,22 44:1 101:16 108:6 188:14
turnaround 129:15
turnout 6:5
tutor 124:1
twice 133:10 144:18 182:2
two-and-a-half 129:7
two-day 104:1
two-hour 99:2 123:7
two-minute 175:7,8
type 31:3 42:16 43:14 138:13 157:6 165:16
typed 202:6
types 22:19 43:20 44:4 49:2 77:5,10 86:2 149:5 151:15 168:19 198:3
typewriting 201:5
typically 18:10
typing 30:2

U

unable 40:3 64:17 119:15 125:3,6 128:3
uncomfortable 50:22 104:10
unconventional 141:18
undergoing

132:15
underlying 18:13
understand 8:18 9:15,21 12:4 13:21 21:20 23:14 43:7 53:22 58:8 60:18 76:7,10 79:9,19 81:16 85:15 107:14 148:17 181:3 188:21 197:2
understanding 76:19 176:12 181:2 189:17
understands 117:12
understood 25:5 185:7
undertaken 11:16
underwear 72:19
underweight 118:11,19
undiagnosed 96:8 178:11 193:16
unexplained 91:4 128:17
unfair 67:4
unfortunate 56:15
unfortunately 55:17 56:18 58:4 79:4 106:7 108:5 120:7 123:11
unidentified 85:17 86:4,13 95:13,14 128:9 154:22 156:9 157:20 162:8 166:22
unique 12:14
15:13
uniquely 12:19
United 19:20 134:17
units 120:7
University 158:5 181:19 187:9
unless 39:4 87:6 104:6 144:20
unmet 12:6 176:13 199:22 200:10
unnecessary 22:3
unpleasant 47:14
unpredictability 131:17
unpredictable 18:11 45:17
unrelenting 88:1 89:15 131:11
unsuccessful 130:7
Unsurprising 68:10
unsympathetic 44:20
untreated 96:8 189:14
upload 31:4
upon 34:16 69:22 87:14 173:15
upper 9:5 65:3,6 68:2,6 69:2 103:8
upset 191:7
upwards 91:13
urgency 21:15 101:6 104:15,22
105:3,11 111:19 114:2 116:16
urgent 58:11
urges 115:9
urging 179:20
urine 122:19,20
useful 17:2
usually 65:17 77:11 135:17 169:11 198:5

V

vacations 56:20
VAIDYA 174:6 177:22 179:8 180:4 182:17,21 183:2 184:10 186:22 189:21 190:7 192:13 194:10 195:21 197:10 198:13
validation 173:9
valuable 9:20 11:8 29:20
value 10:4 200:16
valued 138:9
valve 129:3
variable 73:22 81:17
variables 146:21
variety 24:8 197:21
various 51:14 129:3 198:1
vary 42:8
vast 178:22
vegetables 43:22 44:1 49:17 50:5
126:11
veins 182:7,10
Venkataraman 5:18
venous 181:15
Verapamil 113:12,16 170:4
Verma 3:2 175:14 190:8,9 200:6
versa 21:6
version 78:2 158:21
versions 158:20
versus 71:3 79:14
via 8:19
vice 21:6
vicious 102:14
view 9:22
Virginia 124:16 162:17 201:19
virus 88:10
vision 184:1
visit 31:2
visits 22:13 127:12
vital 195:17
vitamin 97:18 98:8,9 114:11 115:19 122:18 127:13,20
vitamins 97:7,8,10,19 98:1 112:5 127:19
Vivonex 122:10
voice 4:8,11 16:16 85:17 86:4,13 95:13,14 154:22

156:9 157:20 162:8 166:22 184:20 185:2,3
volumes 107:22 108:1
volunteer 70:8
vomit 91:22 92:22 93:6,9
vomiting 21:14 68:12,17 69:10,15 74:2 87:14,16 88:12,13 89:1,4 90:16 91:4,13,18,21 92:1,3,14,18 94:2,6 97:4 118:6,12 119:3,7 128:17 129:2 130:1,2 133:7 135:7 160:7
vulnerable 51:16

W

wait 58:5 105:4 135:18 182:11
waiter 64:9
waitress 64:9
wake 48:7 55:11 88:20
waking 82:17
walk 47:22 98:11 125:7
walked 47:3
walking 56:3 164:16
wall 7:13 46:16
warning 132:2
washed 40:6,7
41:6
Washington 35:11 128:16
wasn't 75:14 77:2 80:14 112:15 146:15,19,22 148:21 153:6 159:4 161:1
watched 139:4
water 4:14 40:5 52:18 114:20 126:19 129:9
watery 101:11
ways 10:2 51:14 100:6 107:9 113:7 192:16
weak 40:17 41:1
weakness 40:4
wear 48:12 121:21
wearing 48:12 53:9
web 6:4,5,7 8:19 11:5 32:5 35:13,21 36:2,8 37:20 38:9 51:22 68:5,15 69:12 77:15,17 87:11 92:13 94:7,13 100:17 101:9 103:10 109:10 110:5,10 137:2,19 139:20 142:19 148:15 152:11 153:16 156:17 161:9 166:3 167:4
webcast 8:3 13:20 16:8 29:18,19,22
website 8:4 16:17 31:2 180:22
we'd 138:13
weddings 53:18
wedgie 72:19
Wednesday 80:11
week 46:21 62:14 72:14 99:10 146:15 147:5 159:3
weeks 97:12 115:5 123:9 127:6,16 147:2 168:3
weighing 48:22
weight 40:20 121:4 124:19 125:4 128:6,7 150:4
weird 54:5
welcome 4:2 8:8 11:9 100:5
welcoming 8:6
we'll 4:18 6:9 7:7,18,19 25:20 27:6 28:12 30:4,5 39:2,5 44:8 70:11,12 71:16 73:4 82:5,6 84:14,16 88:16 89:11 90:22 96:9,11 97:2 98:20 99:14,19 100:7 101:7 103:2 109:11,17 111:3 138:14,15 140:16 145:22 147:21 149:10,18 156:11 157:19 159:12 161:20 167:20 169:7,9
171:22 198:16
Wellbutrin 113:4
well-controlled 25:6
WENDY 202:4,13
we're 6:12 7:14 8:15,21 13:16 14:2,9,18,22 20:16 22:12 23:1 24:17 25:14 26:2 27:5,15 29:10 30:3,8,13 33:19 34:7 35:5 36:17 38:19,22 43:16 52:4 67:19 69:13 73:10 77:18 78:10 85:17 87:19 96:10 98:7,21 99:18 100:2,3,7,11 106:9 109:1 110:15 166:9 173:21 174:7 180:17 185:15 186:7
we've 11:16 16:19 17:2,4 40:11 111:11 145:7 152:12,15 156:4 164:6,10 167:6 178:20 180:10 191:3
whack 194:9
whatever 7:22 35:8 75:3 135:13 150:9
whatnot 160:17
whenever 99:20
whereas 20:19
wherein 192:19

Whereupon 200:21
wherever 66:14 117:7 192:6
whether 11:19 12:22 17:10 25:3 42:16 58:16 64:18 73:20 74:2 97:3,13 116:7 148:11,18 158:8
White 1:10 8:17
whole 6:13 13:6 47:4 54:22 63:20 64:22 66:22 141:5
whom 201:2
who's 29:14 36:22 85:4 109:5 155:12 178:13
whose 67:14
wide 111:1
widespread 13:12
willingness 34:17
win 186:14
wings 60:7
Wisconsin-Madison 187:9
wish 27:13 63:6 64:8 167:4 199:9
wishes 195:13
woken 88:21
Wolfson 2:12 71:17,18 117:18,19 147:22
woman 50:8
women 24:1 36:6 67:12 135:22 196:16
wonder 96:4 116:7 172:9 190:19
wonderful 16:8 55:4 60:2 61:20 123:14 172:17 185:5 190:3,14 199:17,19
wonderfully 140:15
wondering 103:3 144:8 148:7 165:15 173:4 188:12,13
wonders 155:16
work 10:14 22:18 45:15,22 48:9,13 51:2,6 52:17 81:3 82:19 86:21 108:17 109:21 112:12 113:20 114:7 115:1 119:2 122:6 130:17 131:18 142:21 143:1,5,9,13 152:20 165:9 175:21 177:17 185:13 192:8 196:4
worked 62:5 130:8 138:5,6,10,16 140:14 142:20 143:9,14 144:7,10 147:7 151:9 152:16 155:16 157:18 164:14 170:3
working 10:11 15:1 25:15 27:12 34:10 62:3 104:7 105:7 146:22 147:13 153:17 155:17 159:4 160:8 176:7 180:10,20 188:1
works 25:22 34:6 122:9 153:18 168:22
world 124:5
worries 149:16
worse 22:5 42:16,18 79:5 113:18 114:1 115:15 120:15 131:14 159:1 189:13
worsen 119:12
worst 27:4 41:10 78:17 172:12
worth 159:8 174:4
wrap 139:5 172:1
wrap-up 99:22
write 33:11 47:21 77:15 87:12 92:12 94:11 109:9 168:10
writhing 83:9
written 105:10
wrong 48:5 72:17 124:22 143:12 144:16 173:3,12
wrote 39:13

X

Xanax 112:10
Xifaxan 143:6

Y

Y1 194:9
Yep 69:14
yesterday 80:18,20
yet 60:14 63:8,19 76:18 87:20 100:7 108:6 142:5 157:17 160:7 171:10 188:11 198:19
yoga 49:2 53:11 127:22
yogurt 63:8
yogurt's 63:10
York 52:6 57:1
you'll 7:5 16:17 149:12 174:4
young 41:19 73:17 152:2
younger 38:4 41:14 59:7 60:11 66:2
yours 30:5
yourself 172:3
yourselves 8:1
you've 8:10 36:20 66:21 76:7 83:2 100:19 136:11 149:9 154:8 166:5 171:9 200:10

Z

Zagnit 3:4 175:15 194:13,14
Zantac 119:1
Zegerid 89:19
Zelnorm 24:6 132:19

Zev 123:15 136:2

zip 91:16

Zip-loc 91:14,15 93:16

Zofran 126:10,16 129:4,17 130:1 141:16 143:8

Zyprexa 129:10,13,16 130:8,13,14,21 149:21 150:3,6

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