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Videoconference Public Meeting
on Patient-Focused Drug Development
for Systemic Sclerosis

Moderated by Robyn Bent, RN MS, CAPT
U.S. Public Health Service
Tuesday, October 13, 2020
10:00 a.m.

Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

Reported by: Janel B. Folsom
JOB No.: 4080451

A P P E A R A N C E S

1
2 List of Attendees: (by videoconference)

3 Nikolay Nikolov, M.D., Director of the Division of

4 Rheumatology and Transplant Medicine in the

5 Office of Immunology and Information in the

6 Center for Drug Evaluation and Research, FDA

7 Theresa Mullin, Ph.D., Associate Director for

8 Strategic Initiatives, FDA

9 Dinesh Khanna, M.B.B.S., Professor University of

10 Michigan

11 Rachael Glaser, M.D., Clinical Team Leader, Division

12 of Rheumatology and Transplant Medicine, FDA

13 Keith Hull, M.D., Officer, Division of Rheumatology

14 and Transplant Medicine, FDA

15 Raj Nair, M.D., Acting Team Leader, Division of

16 Rheumatology and Transplant Medicine, FDA

17 Shera Schreiber, M.D., Medical Reviewer, Office of

18 Tissues and Advanced Therapies, Center for

19 Biologics, Evaluation and Research

20 Rebecca Rothwell, Ph.D., Statistician and Team Leader,

21 Division of Rheumatology and Transplant Medicine

1 A P P E A R A N C E S (Cont'd)

2 Maryjoy Mejia, M.D., Medical Officer, Division of

3 Dermatology and Dentistry

4 Snezan Trajovic, M.D., Team Leader, Division of

5 Dermatology and Dentistry

6 Onyeka Illoh, O.D., Division of Clinical Outcome

7 Assessment

8 Shannon Cole, Operations Research Analyst, FDA

9 Amy Gietzen, Panelist

10 Julie Jeffers, Panelist

11 Rosemary Lyons, Panelist

12 Amy Harding, Panelist

13 Kimberly Bennett-Eady, Panelist

14 Isa, Patient

15 Laura, Patient

16 Sheri, Patient

17 Monica Cicchetti, Panelist

18 Demi Trice, Panelist

19 Anita DeVine, Panelist

20 Jackie Latka, Panelist

21 Susan Nyanzi, Panelist

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A P P E A R A N C E S (Cont'd)

Noelle, Patient

Kristina, Patient

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

2 MS. BENT: Good morning, everybody. I'm
3 Robyn Bent in the Office of Center Director within the
4 Center for Drug Evaluation and Research at FDA. I will
5 serve as the discussion facilitator for today's
6 meeting which is part of an FDA initiative called
7 "Patient Focused Drug Development."

8 We have a full agenda and I'm going to
9 briefly walk you through it. We'll start with opening
10 remarks from Dr. Nikolay Nikolov, Director of the
11 Division of Rheumatology and Transplant Medicine in
12 the Office of Immunology and Information in the Center
13 for Drug Evaluation and Research here at FDA.

14 After Dr. Nikolov's opening remarks,
15 we'll hear from Dr. Theresa Mullin, Associate Director
16 for Strategic Initiatives who will talk about the
17 FDA's patient-focused drug development efforts.

18 We'll then spend some time hearing from
19 Dr. Dinesh Khanna from the University of Michigan who
20 will provide us with the background on systemic
21 sclerosis. Then we'll get into our discussion with

1 individuals who are living with systemic sclerosis or
2 scleroderma and their loved ones and Dr. Khanna.

3 We'll have two sessions. Our first
4 session will focus on the health effects and daily
5 impacts of systemic sclerosis that matter most to
6 individuals. Our second session will focus on your
7 thoughts about current approaches to managing systemic
8 sclerosis.

9 I'll better explain the meeting format
10 and process right before we get into our first panel
11 session. At first, I want to touch on a few logistics
12 and a few housekeeping points.

13 This meeting is taking place in a
14 fully-virtual setting and is focused on hearing on
15 people who have personal experiences with systemic
16 sclerosis. Throughout the day, we'll have polling
17 questions and you'll have the opportunity to share
18 your experiences by using either the chat feature in
19 the bottom right corner of the meeting screen or by
20 calling the phone number that we will be putting on
21 the screen throughout the meeting.

1 This meeting is being webcast and the
2 live webcast is being recorded. Both the webcast and
3 transcripts of today's meeting will be archived on our
4 website.

5 With that, it is my pleasure to
6 introduce Dr. Nikolay Nikolov who will be providing
7 our opening remarks.

8 DR. NIKOLOV: Good morning, everyone.
9 Just want to make sure that there is audio and video.

10 MS. BENT: Yes.

11 DR. NIKOLOV: Yes. Good morning,
12 everyone. Welcome to this virtual public meeting on
13 patient-focused drug development for systemic
14 sclerosis hosted by the FDA. We're excited to be here
15 today to hear from you; the patients, your loved ones,
16 and caregivers about how you think about systemic
17 sclerosis and what you look for in systemic sclerosis
18 treatments.

19 The agency, the scientific community,
20 and other stakeholders have recognized the significant
21 gaps in our understanding of this complex and

1 devastating disease from the perspective of patients
2 and their families.

3 I understand we have representations
4 from patients, caregivers, and advocates and I thank
5 you all for being here today and being part of this
6 meeting to share your powerful stories with us.

7 We are here today to -- you are here
8 today to educate us about what are the things that are
9 most important to you as patients, families and
10 caregivers who deal with this chronic illness and
11 we're here to listen and try to better understand the
12 very important perspective that patients with systemic
13 sclerosis and your families and the struggles you face
14 every day.

15 The FDA has recognized the needs to
16 have all stakeholders involved and particularly
17 patients in identifying the key elements of clinical
18 development such as endpoints and outcomes that would
19 represent more accurately the burden of disease. In
20 that respect, the FDA's committed to including
21 patients' perspective in drug development.

1 While FDA plays a critical role in drug
2 development, we're just one part of the process. We
3 protect and promote public health by evaluating the
4 safety and effectiveness of new therapies, but we do
5 not develop drugs or conduct clinical trials. This is
6 done by other partners and stakeholders, including
7 medical product developers, healthcare providers, and
8 federal partners who are also present today.

9 Today's meeting will give us all an
10 opportunity -- important opportunity to hear directly
11 from you about the symptoms that matter most to you,
12 the impact the disease has on your daily lives, and
13 your experiences with current available treatments.

14 Information provided for this format
15 can better influence the benefit risk assessment of
16 new therapies, identify areas of unmet need, and help
17 drug developers and regulatory authorities design
18 programs that are more relevant to address how
19 patients feel and function. This has resulted in
20 patient groups having a significant impact on drug
21 development in recent years.

1 Today's meeting is a very important
2 dialogue and I hope that this is just the beginning
3 that will lay the foundation for future conversations.
4 The systemic sclerosis community is very engaged and
5 eager to participate in this effort which is evident
6 from the impressive attendance at this virtual
7 meeting.

8 This meeting is as important to us as
9 it is to you. So thank you for joining us. We really
10 appreciate this opportunity and are looking forward to
11 a very productive discussion today.

12 With this, I will turn it over to
13 Dr. Theresa Mullin who will provide backgrounds on the
14 FDA's patient-focused drug development efforts. Thank
15 you.

16 MS. MULLIN: Hello. I'm Theresa Mullin
17 and I'm the Associate Director for Strategic
18 Initiatives at the FDA Center for Drug Evaluation and
19 Research and I'm very glad that you are able to join
20 us today for this meeting.

21 I'm going to give you an overview of

1 FDA's patient-focused drug development initiative
2 which this meeting is part of. Next slide, please.

3 And so I want to start with saying a
4 little bit about FDA's role in medical product
5 development and evaluation. Now FDA's mission is to
6 protect and promote public health and part of that is
7 to evaluate the safety and effectiveness of new drugs.
8 And while we play a critical role in overseeing drug
9 development, we're just part of that process. FDA does
10 not develop drugs nor do we conduct clinical trials
11 for the development of drugs.

12 However, our review divisions do
13 evaluate the result of those trials and we do oversee
14 and provide oversight during drug development,
15 including clinical trial oversight and so that's how
16 we're able to really ensure safety and effectiveness
17 of the drugs and the integrity of development process.
18 Next slide, please.

19 And so what is patient-focused drug
20 development and how does that fit into this? Well,
21 PFDD is a systematic approach to help ensure that

1 patients' experiences, perspectives, needs, and
2 priorities are captured and are meaningfully
3 incorporated into drug development and evaluation.
4 Next slide, please.

5 The evaluation that we do for new drugs
6 means that we really need to understand the patient's
7 perspective and patients are uniquely positioned to
8 inform FDA's understanding of clinical context and
9 regulatory decision making. Prior to PFDD meetings, we
10 didn't really have a lot of mechanisms for collecting
11 patient info. They were really limited to discussions
12 that would occur with regard to specific applications
13 that were under review, for example, through an
14 advisory committee meeting, and only a few patients
15 can participate in those meetings and they need to
16 undergo conflict of interest screening and meet other
17 criteria.

18 PFDD meetings provided us with a more
19 systematic way to obtain patient's perspectives on the
20 severity of the condition and the impact that that
21 condition on your daily life and their assessments of

1 available treatments, how well those treatments are
2 working for them. Next slide, please.

3 So this slide gives you a sort of
4 timeline for how long we've been doing our patient-
5 focused drug development meetings and bringing
6 stakeholders together to hear the patient's voice in a
7 given disease area. We established this program in
8 2012 and we've been conducting these meetings since
9 2013.

10 As so far, FDA has conducted over 25 of
11 these meetings, and we also have established
12 externally led patient-focused drug development
13 meeting option to really expand the capacity here to
14 have more meetings, because patient groups were
15 telling us that they really wanted to conduct a
16 meeting in their disease area.

17 And so we really value the information
18 we've been collecting in these meetings. It's been
19 extremely in informing and giving FDA insights about
20 what it's like to live with the disease. Next slide,
21 please.

1 And so this gives you a sense of the
2 range of the diseases that we've been exploring and
3 hearing about in patient-focused drug development
4 meetings and you can see it's a very wide range of
5 disease area, and yet in every one of these meetings,
6 we have asked similar kinds of questions about the
7 impact of the burden of the treatments and the
8 questions that worked very well in helping us get a
9 better understanding.

10 And in addition to these meetings,
11 we've had over 30 at this point and counting
12 externally-led meetings, for patient-focused drug
13 development. Next slide, please.

14 These meetings are sort of set up in a
15 townhall style of discussion format which is different
16 from the typical public meeting that FDA might have.
17 They begin with an overview of the clinical background
18 and currently-available treatment typically provided
19 by one of our senior medical staff. And that's
20 followed by a session that's focused on hearing
21 patients' views on the symptoms and impacts of the

1 condition on their life.

2 We begin this with a panel of patients
3 and caregivers who will give their first-hand
4 experience about that -- symptoms and daily impacts
5 and that provides a nice springboard for the
6 facilitated discussion to bring in more voices from
7 other people who are participating in the meeting. And
8 that's followed by a session on the current treatment
9 options.

10 And again, we begin with a small panel
11 of patients and caregivers talking about their
12 experiences and their story, and that provides a good
13 springboard for the discussion of others' experiences
14 with treatments and what the treatments are able to --
15 duplications and where they fall short. Next slide,
16 please.

17 Each patient-focused development
18 meeting is tailored, to a degree, to meet that
19 specific disease area. And FDA does encourage patient
20 advocates, researchers, drug developers, healthcare
21 providers and others to attend these meetings,

1 however, our focus is hearing directly from the
2 patients and their caregivers.

3 And so we ask others to remain silent
4 and stay in listening mode during these discussions so
5 that we can all hear directly from patients and
6 caregivers and patient representatives.

7 And then after PPFDD meeting, a voice of
8 the patient report is developed to summarize what we
9 have heard from patients and caregivers during that
10 meeting. Next slide, please.

11 So with that, I want to thank you again
12 for joining us today. We're really looking forward to
13 hearing what you have to tell us about what it's like
14 to live with systemic sclerosis and we know that it'll
15 be extremely valuable to us in our work going forward.
16 Thank you again.

17 MS. BENT: I'd like to thank
18 Dr. Mullin. Obviously, I'm a bit biased, but I think
19 these PFDD meetings really hold an important place in
20 incorporating the patient voice into the medical
21 product development process.

1 And now I'd like to ask Dr. Dinesh
2 Khanna to unmute and turn on his video to begin his
3 presentation that will provide us with an overview of
4 systemic sclerosis. Dr. Khanna?

5 DR. KHANNA: Good morning, everybody.
6 And it is a great pleasure to be here. Now let me pin
7 my slides.

8 So good morning, again. It's a great
9 privilege and pleasure to be presenting on scleroderma
10 and systemic sclerosis. I think in a very important
11 meeting on the patient-focused group development for
12 systemic sclerosis. Next slide.

13 Here are my appropriate disclosures,
14 although I'm not talking about any therapeutics today.
15 Next slide.

16 So what is scleroderma? It's an
17 altering [ph] disease and the word comes from two
18 Greek words, sclero, meaning hard, and derma, meaning
19 skin.

20 There are approximately 200,000 to
21 250,000 people in the U.S. who suffer from

1 scleroderma. As I show below, scleroderma can be
2 divided into localized format that usually affects
3 young people, and systemic sclerosis or systemic
4 scleroderma.

5 I think with our estimate, there are
6 approximately 75,000 to 80,000 people in U.S. who
7 suffer from systemic sclerosis. Next slide.

8 So this slide is from a review article
9 that I and Professor Christopher Denton from London
10 published. And I will walk through this slide.

11 The upper panel are patients who have
12 early diffuse scleroderma. What you see is marked skin
13 pigment. You see hand contracted in the middle and you
14 see a person who had this diffuse scleroderma. And I
15 will define these terminologies. For about 15 years,
16 you will see pinning of the nose and pinning of the
17 lips.

18 On the left lower panel is a patient or
19 two patients who have limited scleroderma, something
20 called "CREST syndrome," C-R-E-S-T. You see a little
21 bit of skin thickening in the Panel B, but you also

1 see evidence of what we call "tanglasia" in the
2 gentleman on the left lower side, some nail changes
3 and calcinosis

4 But what we worry quite a bit as
5 clinician is the multisystem involvement with the
6 digital involvement, Raynaud's phenomenon, digital
7 ulcers. Unfortunately, amputation, GI involvement in
8 the middle panel, lung fibrosis, pulmonary
9 hypertension, cardiac involvement, cardiac fibrosis
10 and lower panel renal crisis, disability and
11 calcinosis.

12 SO as we talk about this disease, we
13 must admit the multisystem heterogeneous involvement
14 of this systemic autoimmune disease. Next slide.

15 So I only have one slide on
16 pathogenesis of scleroderma. I must state that over
17 the last 10 to 20 years, we have made leaps on
18 understanding the pathogenesis of the disease.

19 Any autoimmune disease we think about
20 an environmental trigger. We think about the role of
21 your DNAs and your epigenetics without the environment

1 of factors that are veritable but do not affect
2 through DNA sequence, and that leads to in scleroderma
3 what we roughly call, "tripartite pathogenesis" or a
4 "three-pronged pathogenesis."

5 On the left side I'm showing you
6 vascular involvement, vasculopathy. Almost everybody
7 with systemic sclerosis have Raynaud's phenomenon.
8 Unfortunately, some of them develop this digital ulcer
9 as shown on the left side and marked and remarkable
10 fibrosis of the internal vessels.

11 There is dysregulated immune system,
12 autoimmunity with scleroderma auto antibodies and that
13 results in fibrosis not just of the skin, of the
14 musculoskeletal system, but also internal organs. Next
15 slide.

16 So let's talk a little bit about
17 epidemiology of systemic sclerosis. I'm focusing
18 largely on or in United States.

19 The peak age of onset is 30 to 50 years
20 with a female predominance of three to five to one. It
21 is similar to other autoimmune diseases such as

1 rheumatoid arthritis and lupus erythematosus. It's a
2 rare autoimmune disease and this is the work done by
3 Professor Maureen Mayes in Detroit, Michigan published
4 in 2001 where she estimated a prevalence of 276 cases
5 per million.

6 In Europe, it's a little bit less; 88
7 to 160. And if you look at that incidents which are
8 all the new cases every year, there are only about 19
9 cases per million per year.

10 So here is my calculation. If we
11 estimate 328 million people in the United States --
12 that's based on the Google search I did -- there are
13 about approximately 6,000 new scleroderma people that
14 are diagnosed every year. So truly an orphan disease.

15 It's quite heterogeneous as I showed
16 you in the slide. And I think as a clinician who runs
17 a very large scleroderma program, I'm reminded on a
18 daily basis the high morbidity and the high mortality
19 among all rheumatic diseases. Next slide.

20 So this slide is to classify.
21 Classification is used by epidemiologists and

1 physicians for clinical trial and for epidemiological
2 purposes to define the prevalence, incidence and other
3 aspects. But the slide is only highlighting that
4 systemic sclerosis is not just skin involvement.

5 The first row shows you the skin
6 tightening, but then there are other aspect: the
7 fingertip -- the nailfold capillaries, the
8 telangiectasias around the face and the palm, the lung
9 involvement, the Raynaud's phenomenon, scleroderma
10 autoantibodies. It's truly a multi-system disease that
11 can affect different organs. Next slide.

12 So when as a clinician I see a person
13 with scleroderma, the first question I ask myself is
14 do they have systemic sclerosis? I use a
15 classification criteria to help me, and then I further
16 divide people into limited cutaneous, and diffuse
17 cutaneous scleroderma.

18 One thing it's very important to
19 clarify for the audience, limited does not mean only
20 limited to skin. Limited as shown on the left side of
21 the slide are people who may have finger, veins,

1 forearm, face, and neck involvement.

2 On that -- and that's 60 percent of all
3 the systemic sclerosis people that have systemic
4 sclerosis in the U.S.

5 On the right side are diffused
6 cutaneous which have a lot more skin thickening of the
7 upper arms also and thighs. And there are five to ten
8 percent of patients who have sine scleroderma. In
9 other words, they do not have any skin thickening, but
10 they have scleroderma antibodies and they do have
11 internal organ involvement. Next slide.

12 So my patients come to me, you know, I
13 spend about 60 to 90 minutes giving the initial visit,
14 and it's important for us to do that because most of
15 the things that happen in systemic sclerosis happen
16 early in the disease.

17 Here is a distribution the natural
18 history from University of Pittsburgh cohort provided
19 to me by Professor Tom Metzger there and what I'm
20 showing you, the diffuse patient where the skin
21 thickening is progressing over the first two to five

1 years, but more importantly, that's when people get
2 lung fibrosis also known as interstitial lung disease,
3 muscle involvement, tendon involvement, contractures,
4 Raynaud's phenomenon, digital ischemia -- involvement,
5 myocardial involvement.

6 And therefore, my role as a clinician
7 without having very effective therapies is to really
8 educate the patients and make them be aware that these
9 complications may occur and I will go over my
10 clinician viewpoint, how I manage these patients. Next
11 slide.

12 Why we differentiate between diffuse
13 and limited is because people with diffuse disease
14 have a higher mortality due to higher and more
15 progressive internal organ involvement. Here's a slide
16 that shows diffuse scleroderma patients are more
17 likely to have -- and heart involvement, renal
18 involvement, large joint contractures and reduced
19 survival. On the right side of the slide, are limited
20 to cutaneous patients and the only combination that
21 seem to be higher is pulmonary arterial hypertension,

1 which is a later complication of systemic sclerosis.

2 Next slide, please.

3 In our practice, we also look at the
4 autoantibodies, scleroderma autoantibodies and that's
5 shown on the left side and it help us to prognosticate
6 that tells me as a clinician that you are more likely
7 to develop pulmonary arterial hypertension. You are
8 more likely to develop interstitial lung disease such
9 as topoisomerase 1. You are more likely to develop
10 scleroderma renal crisis such as RNA polymerase III.

11 I also want you to be aware of the
12 right side of the slide where we have been looking at
13 the gene expression. These are the branches that I'm
14 very, very, you know, excited about that I can -- and
15 other clinicians can define this from skin biopsy and
16 blood whether you have fibrotic pathways that are
17 activated or predominately inflammatory pathways that
18 are activated. Next, please.

19 So here is one slide on a clinician
20 viewpoint. You come to my office and apart from
21 education, this is what I'm thinking. I need to screen

1 you for early organ involvement. I cannot prevent
2 internal organ involvement if possible. Can I reduce
3 your disability, and can I decrease the progressive
4 disease in the heart, lungs, and other organs? That is
5 what I am thinking as a clinician.

6 And on the left side are patients with
7 Raynaud's phenomenon, active digital ulcers, marked
8 vascular arthrofibrosis of the -- pulmonary
9 hypertension and we tend to use medications that are
10 vasodilators, such as calcium channel blockers -- and
11 all the pulmonary atrial hypertension approved
12 medications.

13 On the right side are patients who have
14 predominantly lung fibrosis, skin fibrosis, heart
15 fibrosis, and we go to non-FDA approved medications
16 such as immunosuppressant therapies; mycophenolate
17 mofetil methotrexate, anti-fibrotic therapies, a new
18 FDA therapy called nintedanib, or stem cell
19 transplantation.

20 So this is my point of view as I am
21 talking to you, giving the first year of your disease.

1 Can I prevent something? Can I screen effectively? Can
2 I reduce a disability, and most importantly, can I
3 decrease if you have lung fibrosis, can I stop the
4 progression of the disease? Next slide, please. Next.

5 So here are two slides that had a big
6 impact on how I tell -- how I think about and how I
7 change my point of view of outcome measures.

8 This is a study that we did and we
9 published in a journal called "Journal of Scleroderma
10 and Related Disorders," where we asked people with
11 early scleroderma how they feel. And here's a patient
12 of mine that really touched me and he said, "It feels
13 like all the time that I have a mask on and stretched
14 out of shape, especially over my chest, lung, and
15 expanding and not expanding. Of my body, this bit are
16 the tightest." Next slide, please.

17 And I want to talk about the journey of
18 a person who is diagnosed with scleroderma. The
19 initial symptoms are non-specific fatigue, pain,
20 constitutional symptoms, losing weight. You start to
21 have puffy fingers, thickening of the skin, Raynaud's

1 phenomenon. And this leads you to go to your primary
2 care doctor. Primary care doctor sends you to a
3 rheumatologist. Rheumatologist maybe a orthopedist
4 send you to us. So there is a lot of misinformation.
5 There is a lot of misdiagnosis, such as rheumatoid
6 arthritis and lupus. There's a lot of frustration that
7 is involved.

8 On average, patients take about one
9 year from the onset of symptoms to come into our
10 clinic. There are treatment that are not FDA approved
11 and I think I really applaud FDA to have this be a
12 meeting, and you can see what people feel;
13 fearfulness, exhaustion, pain, unpredictable cause
14 depression, limiting function, complications that are
15 associated with the disease. Next slide, which is my
16 final slide.

17 So as a clinician, as a trialist who
18 has been doing clinical trials for the last 20 years,
19 these are the lessons that are thought about last week
20 when I was developing these slides. I think there is
21 so much enthusiasm among the sponsors to do clinical

1 trials of scleroderma. It's a wonderful time.

2 We have learned so much about
3 pathogenesis, but it's getting difficult to find
4 people who qualify because of an orphan disease. It is
5 difficult to find scleroderma community because lack
6 of expertise outside the scleroderma community. There
7 has been marked heterogeneity in the traditional
8 outcome measures we use.

9 You have seen me pinch the skin, you
10 have seen us do lung function tests and I think
11 finally the focus of this meeting is that there's lack
12 of patients' voice as primary and provable endpoints.

13 So I thank you for your time. I have
14 one more last slide thanking, you know, University of
15 Michigan where I work and I look forward to this
16 wonderful meeting. Thank you for the opportunity
17 again.

18 MS. BENT: Thank you so much,
19 Dr. Khanna. I think it's really helpful for us to have
20 this presentation to set the stage for what we're
21 about to hear from our panelists and meeting attendees

1 who have lived experiences with scleroderma.

2 DR. KHANNA: Thank you.

3 MS. BENT: Thank you. Moving on, I'd
4 like to share with you a bit more of how this meeting
5 will proceed.

6 It's been truly an honor to work with
7 the patient -- or the panelists that you'll meet in
8 just a moment, as we've prepared for today's meeting,
9 and thank you to Dr.'s Nikolov, Mullin, and Khanna for
10 the really helpful presentation that give us some
11 context to think about this next part of the meeting.
12 It's really yours.

13 If you're new to this area of what FDA
14 does and what medical product development is, then I
15 hope we gave you a little bit of background on that
16 and especially some of the key terms and words we'll
17 be using today.

18 Before we kick off this next part of
19 the meeting for those of you with lived experiences
20 with scleroderma or systemic sclerosis or the stars of
21 the show, I just want to share a bit of information in

1 the terms of kind of an orientation to help you
2 understand the meeting structure and why we set it up
3 this way because it's very purposeful and intentional.

4 So for those of you that are here
5 representing yourselves or your loved ones with lived
6 experiences with systemic sclerosis or scleroderma,
7 you are the experts and have the -- and the expertise
8 that you have is what we're all here to hear.

9 We kind of flipped the script on the
10 type of meeting that most of us go to where you have a
11 lot of medical professionals giving presentations and
12 having discussions while you listen. Today we reverse
13 that.

14 We've heard some opening remarks from
15 some experts in their field. But you are the experts
16 in your field. You are the ones who know what the
17 systemic sclerosis is like to live with.

18 So our goal today, as we start this
19 discussion portion of our meeting, is to really foster
20 an open dialogue of personal experiences and
21 perspective on systemic sclerosis. Our two main topics

1 for discussion are health affects and daily impacts of
2 systemic sclerosis or scleroderma followed by current
3 approaches to treatment.

4 We'll kick off each session with a
5 panel of individuals with systemic sclerosis. There
6 are five panelists for the first topic. After the
7 panelists, we'll broaden the dialogue to include other
8 individuals and family members who are joining us on
9 this webcast.

10 Anyone who is watching the meeting who
11 identifies as a person with scleroderma, systemic
12 sclerosis or a family member, loved one is welcome to
13 participate. Aside from the panelists, we don't really
14 have anyone else identified to speak, so we need all
15 of you out there to kind of share your experiences in
16 order for this meeting to be successful.

17 And the purpose of the panel
18 presentations, it's really build -- or the purpose of
19 the -- of the open dialogue portion, is really to
20 build on the experiences shared by the panel. And I'll
21 ask a number of follow-up questions.

1 Throughout the day, polling will be
2 done by a computer or cell phone, and as I mentioned
3 previously, we're taking comments from online through
4 the meeting chat feature and via telephone if you've
5 got something to add.

6 So this is your opportunity to really
7 build on the kind of invitation that the panel will
8 create to open up what is really a tough subject
9 matter and we know that. Just feel -- feel the
10 empowerment that you have in this meeting today to be
11 heard not only by the FDA, but by representatives from
12 medical product developers, researchers, and
13 clinicians about systemic sclerosis and what you'd
14 like to see happen to help those with systemic
15 sclerosis.

16 So if you'll please take this
17 opportunity and we hope that this will be your
18 invitation to participate with us in the discussion.

19 So we really encourage you to call in
20 by a phone to share your comments, and when speaking,
21 you can remain anonymous. I mean, you don't have to

1 give us your name. You may state your name if you
2 want, but we really -- what we really care about is
3 your experience. And so when you call in, there's a
4 couple of things that will help us.

5 One is if you stay on the topic we're
6 discussing, whatever topic we're talking about. If
7 we're talking about symptoms or if we're talking about
8 daily impact. Try to think about what that topic is
9 and stay as close to that topic as possible.

10 Obviously, there -- you know, in a
11 fully virtual setting, there's a little bit of a lag
12 time, so there's some flexibility in that, but if we
13 can stay as close as possible, that would be -- that
14 would be great.

15 It's also helpful if you can keep your
16 points to maybe just on one or two things so that we
17 can go to as many people who want to speak as
18 possible. And for transparency, we request that at the
19 time of your first comment that you disclose if you're
20 affiliated with an organization that has an interest
21 related to systemic sclerosis or if you have

1 significant financial interest in systemic sclerosis
2 drug development.

3 If you're submitting comments via the
4 webcast, you can provide whatever name you'd like.
5 Don't worry about us being overwhelmed by comments. We
6 can handle it. We'll try to summarize them as much as
7 possible. We'll do our best to share the comments we
8 receive via the web platform.

9 If for some reason we're not able to
10 read all of the comments out loud today, your comments
11 will be incorporated in our final summary report. So
12 they definitely will be impactful.

13 And so now as Dr. Mullin mentioned
14 earlier, we also have a public docket for this meeting
15 that will be open until December 15th. We encourage
16 you to share your experiences and expand on what we
17 discussed today through the public docket.

18 The comments will be incorporated in
19 our summary report as well. Anyone is welcome to
20 comment through the docket, whether you're joining us
21 via the web or you know someone who wasn't able to

1 participate today, but you think they have
2 something -- something to contribute. Please encourage
3 them to submit their comment.

4 You'll find the link on the slide here
5 and we'll also email this link to folks after the
6 meeting, to everyone who's registered for the event on
7 the website.

8 You can submit your comments as
9 anonymous, and I want you to keep in mind that if you
10 submit to the public docket, that is -- the word
11 "public" is there for a reason, and this will go to
12 the website. So please think about how much personal
13 information you want to share.

14 And we don't need -- again, we don't
15 really need your personal information again. We don't
16 care what your name is or where you live. We care
17 about what your experience is. So please keep that in
18 mind that what's important to us is really your
19 experience. So you can just say anonymous anonymous,
20 or just leave the part when you have to put your name
21 as empty.

1 So moving on to just a few ground rules
2 for our discussion today. We're here first and
3 foremost to listen to those with scleroderma, systemic
4 sclerosis, and their family members. We'll try to
5 accommodate everybody who would like to speak.

6 We're happy to see over 200 people on
7 the webcast today, and some of those who represent
8 research and drug development are also registered for
9 this meeting. We believe that the input that you hear
10 today will be important to you as well, and we just
11 ask again that you stay in listening mode.

12 FDA staff is really here to listen. We
13 know that you may have questions about drug
14 development or drug review, and if you have specific
15 questions, we encourage you to share them via email
16 with our FDA staff. Our contact information is on the
17 meeting website and we'll get back to you with more
18 information following the meeting.

19 As has been described, our discussion
20 today is focused first on the health effects of
21 systemic sclerosis and daily impact and then

1 approaches to managing those health effects. Our
2 discussion may touch on some scientific treatments,
3 however the discussion of any specific treatment
4 should be done in a way that helps us to understand
5 the broader issues, such as what health effects are
6 being addressed and how meaningful that it is to
7 patients and individuals and family members.

8 The opinions expressed here are
9 personal opinions. Therefore, demonstrating respect is
10 of paramount important. We very much appreciate what
11 complex and personal topics we're addressing in this
12 public meeting and we expect everyone to share this
13 appreciation with us.

14 Our discussion is going to focus on
15 health effects and treatments and we know that this is
16 a very complicated issue and there are many concerns
17 and many questions you have and things that you had to
18 think about living with systemic sclerosis and getting
19 the support that you need. These are all important.

20 Today we want to focus on the topics
21 the FDA needs most input on so that we can best

1 fulfill our goal in medical product development and
2 decision making.

3 And so while you take in the
4 information on the slide that outlines how to submit
5 comments, I'd like to take the opportunity to ask my
6 FDA colleagues on the FDA panel to turn on their video
7 and introduce themselves starting with Dr. Nikolay
8 Nikolov.

9 DR. NIKOLOV: Good morning, everyone. I
10 think you have seen me already. My name is Nikolay
11 Nikolov. I'm the director for the Division for
12 Rheumatology and Transplant Medicine. I am really
13 thrilled to be here and participate in this meeting.

14 MS. BENT: Rachael, I think you're
15 muted.

16 MS. GLASER: Thanks. Sorry about that.
17 Good morning. I'm Rachael Glaser. I'm a clinical team
18 leader in the Division of Rheumatology and Transplant
19 Medicine at the FDA.

20 DR. HULL: Hi. I'm Dr. Keith Hull. I am
21 a medical officer also in the Division of Rheumatology

1 and Transplant Medicine and looking forward to hearing
2 the patients' input today.

3 MR. NAIR: Hi. My name is Raj Nair. I'm
4 an acting team leader with the Division of
5 Rheumatology and Transplant Medicine and happy to be
6 here.

7 MS. SCHREIBER: Hello. My name is Shera
8 Schreiber. I'm a medical reviewer in the Office of
9 Tissues and Advanced Therapies within the Center for
10 Biologics, Evaluation and Research.

11 MS. ROTHWELL: Hi. I'm Rebecca
12 Rothwell. I'm the statistician and team leader for the
13 team that supports the Division of Rheumatology and
14 Transplant Medicine. Thanks.

15 DR. MEJIA: Hi. I'm Maryjoy Mejia. I'm
16 am medical officer with the Division of Dermatology
17 and Dentistry.

18 MR. TRAJOVIC: Good morning. My name is
19 Snezan Trajovic. I'm a team leader in the Division of
20 Dermatology and Dentistry.

21 DR. ILLOH: Hi, everyone. My name is

1 Onyeka and I'm an acting team leader in the Division
2 of Clinical Outcome Assessment and the mission of our
3 division is to integrate the vision voice into drug
4 development, so I'm very happy to be here. Thank you,
5 everyone.

6 MS. BENT: Thank you. From time to time
7 during the meeting, we'll turn back to our FDA
8 panelists to see if they have any follow-up questions
9 or clarifying questions about what we just heard. I
10 also want to introduce my colleague, Shannon Cole, who
11 will be keeping an eye out for comments that come
12 through the internet. She will be sharing those
13 comments through the meeting.

14 She will also be coordinating with our
15 other colleague, Lyna Merzoug, who you will speak to
16 if you call in to provide comments via phone.

17 So let me turn to Shannon, allow her to
18 introduce herself, and then we'll give everybody --
19 all of our FDA panelists a wave. Go ahead, Shannon.

20 MS. COLE: Good morning, everyone. My
21 name is Shannon Cole, and as Robyn mentioned, I will

1 be monitoring the webcast comments during today's
2 meeting.

3 MS. BENT: Great. Thanks so much.

4 So we'll have some polling questions
5 today and we're using a third-party application,
6 Mentimeter, to run our polling. Polling on
7 Mentimeter's site, menti.com, is anonymous and can be
8 done via cell phone or on your laptop or tablet.

9 Please note that we're not tracking
10 individual people's answers and we can only see
11 responses grouped by option.

12 You can access the Mentimeter poll in
13 two ways. You can use your cell phone camera to view
14 the QR code on the slide which will take you to the
15 survey, or you can go to www.menti.com and use the
16 digital code on the slide to enter the survey.

17 For some questions, you'll have one
18 answer. For others, you may have multiple answers.
19 These polling questions are meant to be a discussion
20 aid for today and are not a scientific survey.

21 So let me pause here and just make sure

1 that everybody has had an opportunity to see the QR
2 code and make sure that they are able to log into the
3 survey.

4 Okay. So with that, let's begin with a
5 polling question. So please get your cell phones or
6 computers ready and we'll move on to our first polling
7 question.

8 I apologize. I have multiple --
9 multiple screens, so I'm going to look to the side to
10 see the results of the polling questions occasionally,
11 just so that we can -- we can discuss them.

12 So with Question 1, we're starting with
13 some basic demographic questions, so that you can kind
14 of get familiar with the polling platform.

15 The Question 1 is one, "Do you live in
16 the Washington D.C. metropolitan area, including the
17 Virginia and Maryland suburbs?"

18 And you have two options; we have "yes"
19 and "no." All right. And there is a little bit of a
20 delay between when we launch the survey and when we
21 are able to see the results, just because it's about a

1 15 to 20 second delay. So we're going to give it just
2 another -- another second or two to -- to see the
3 results coming in and to see -- see how -- how it's
4 working.

5 All right. So this looks great and it
6 looks like everything is working. I'm hoping nobody is
7 having any challenges with the application. It's
8 usually pretty user friendly -- friendly application.

9 And I think that what we're seeing is
10 really kind of one of the -- one of the biggest
11 benefits of moving to this virtual setting, which is
12 that most of the people who are on the call with us
13 today are -- or on the webinar with us today, are not
14 from the D.C metropolitan area.

15 A lot of times, we have a little bit of
16 an overrepresentation in our in-person meetings. But
17 it's clearly not -- not -- not playing out in our --
18 in our virtual meeting setting. So that's -- that's
19 great. And I -- I hope that throughout the day we'll
20 have additional people kind of maybe more the west
21 coast people who thought that seven a.m. was a little

1 too early to start a meeting will be joining us.

2 But I understand we have over 200
3 people on the webinar now and it looks like it's just
4 continuing to grow. So -- so really -- really excited
5 about the potential for impact for this meeting. So
6 thank you all, and now we're going to move on to our
7 next question.

8 So Question 2, "Have you or your loved
9 one ever been diagnosed as having systemic sclerosis
10 or scleroderma?" And again, "yes," or "no" are the two
11 options here.

12 And we're just going to take a brief
13 pause while the results come in. All right. All right.
14 Great.

15 Okay. So from this point on, we're
16 going to ask that each polling question be answered
17 only by individuals with systemic sclerosis or someone
18 who is answering on behalf of a loved one with system
19 sclerosis or scleroderma.

20 And so we'll just give this a brief
21 moment while we're -- while the answers are still

1 coming in before we move on to Question 3.

2 All right. So now let's move on to
3 Question 3, and it looks like, as you can see from
4 this question, Question 2, we do have a really good
5 variety of people on the meeting today, both patients
6 and family members who are -- who are -- who are
7 living with scleroderma and systemic sclerosis and
8 also a lot of the regulators and medical product
9 developers and others who are really interested in
10 hearing what you've got to say.

11 And so that -- that -- that's really
12 great and I think that it really kind of captures what
13 we're hoping for in -- in the meeting.

14 So Question 3, "What is your age?" Now
15 remember if you're answering for a loved one, please
16 answer with their age, and just the -- just the age
17 range is perfect.

18 And the options are "younger than 18,
19 18 to 30, 31 to 40, 41 to 50, 51 to 60, 61 to 70," and
20 "71 or greater." And so this is -- this is -- we have
21 -- we have great diversity in range -- age range. As

1 you can see, we have a majority of people kind of in
2 that 51 to 60 area, but 50 -- 41 to 50 is really also
3 -- also close. And we have -- we have a lot -- good
4 number of people on the 30 to 40 range and the 60 to
5 70 range as well.

6 So again, a great -- a great variety. A
7 great -- a great spread of participation today and I
8 thank you guys so much for that.

9 Okay. So now we're going to move onto
10 our next question, which is, "Do you identify as
11 male" -- or, sorry, as -- "as female, male, or other"?

12 And again, these questions are
13 certainly not scientific. It doesn't really -- we're
14 not using this in a study. It's really just for us to
15 get an idea of who's participating with us today on
16 the webinar. It's kind of -- it's kind of hard and a
17 little anonymous to -- to kind of be in this virtual
18 setting where you can't look out at a roomful of
19 people and kind of see -- see who's there with you.
20 So -- so this is kind of -- we're just trying to -- to
21 decrease that anonymity and kind of -- kind of build a

1 community of people all here together with a common
2 purpose and a common goal behind it. Kind of move
3 forward.

4 And so, but, yeah. Some of these
5 questions are kind of a little weird, but they're
6 really -- they're really just helping us join kind of
7 come together as a community for -- for the duration
8 of this meeting, because we are going to be talking
9 about a lot of -- of personal things and personal
10 experiences.

11 It's nice to be able to feel a little
12 bit connected to the people who are talking and maybe
13 hopefully feel a little bit more comfortable sharing
14 your experiences because of that connection. So -- so
15 great. We see -- we see a majority of females. We do
16 see some males, and we do have somebody who identifies
17 as other.

18 So again, what a -- what a great kind
19 of diverse group that we've -- we've got going on here
20 and I think that's great. And it looks like the -- the
21 20 to 30 second delay, we're kind of catching up with

1 that and we're seeing -- seeing more and more
2 responses.

3 So, so wonderful. And so now we're just
4 going to move on to Question Number 5, which is, "What
5 is the length of time since your diagnosis?" And the
6 options here are "less than one year, one year to five
7 years, five years ago to ten years ago, more than ten
8 years ago," or "I'm not sure."

9 All right. And right now, it looks like
10 the majority of the people have been diagnosed for
11 more than 10 years, which, I mean, that -- that's a
12 long time, but we do have some people who are recently
13 diagnosed within the last -- within the last five
14 years and then some -- about four people who are
15 saying that they were diagnosed five to ten years ago.

16 So great. Thanks. Thanks for that. And
17 thanks to everybody. We really just have one more
18 question before we move to our first panel discussion.

19 And this question is a little more
20 complicated and I'm going to ask that you let me read
21 you the options for the answers because we ran into

1 some technical limitations and couldn't put in much
2 information into the answers as we had hoped.

3 So I'm just going to go ahead and read
4 them to you. The question is, "Which subtype of
5 systemic sclerosis or scleroderma have you been
6 diagnosed with? Select all or any that apply."

7 And so "A," we have is "Diffused,"
8 which is defined as "Skin tightening or thickening
9 affecting large areas of the body, organ damage,
10 potentially to a GI tract, kidneys, lung, and heart,
11 pain or arthritis, high blood pressure."

12 "B, Limited. Skin tightening or
13 thickening is limited to fingers, hands, or face,
14 heartburn, Raynaud's phenomenon, pain or arthritis,
15 CREST syndrome, red spots on the body as a result of
16 enlarged blood vessels."

17 Okay. "C" is "Sine, Symptoms of Organ
18 Disease including Raynaud's phenomenon but no skin
19 thickening."

20 "D" is "systemic sclerosis with overlap
21 syndrome, which is an overlap of features of other

1 systemic rheumatic diseases such as systemic lupus,
2 erythematosus rheumatoid arthritis, polymyositis or
3 Sjogren's syndrome."

4 "E" is "Other." And "F" is "I'm not
5 sure.

6 All right. And it looks like right now
7 what we're seeing is that we have a majority of people
8 with Diffused. A good number of people with Limited.
9 One person with Sine and about six people with
10 systemic sclerosis with overlap syndrome. So that's
11 great.

12 Again, we have a range of people
13 participating today and I think that's what we really
14 need to hear from. We don't need to hear from -- I
15 mean we -- we understand that everybody has kind of --
16 kind of their own experiences with everything, and
17 this will -- this will give us really a -- really a
18 good kind of big picture idea of what people -- what
19 people are -- are -- are experiencing and we hope that
20 those of you who are participating in the polling will
21 also participate with us actively in the discussing --

1 discussion.

2 So with that, let's start with our
3 first panel now. And I'm excited -- excited to hear --
4 to hear from this panel because -- so as we mentioned,
5 Topic 1 will focus on the health affect and daily
6 impact of systemic sclerosis and we have the five
7 panelists who will start off the session by sharing
8 their experiences.

9 In about 30 minutes, when the panel is
10 done sharing their experiences, we'll move into the
11 interactive portion of our meeting by asking you about
12 your experiences. And if there's something that you
13 hear from a panelist that really resonates with you or
14 you want to share a bit of your experience, please
15 consider sharing your comments via the web or closer
16 to the end of the 30-minute period. Maybe around
17 11:15, 11:20, maybe call into 1-800-527-1401 to share.

18 And you should know that if you call in
19 to share your experiences and are placed on hold, the
20 hold music will actually be this meeting. So not
21 music, but this meeting, so you won't miss out on

1 hearing from our panelists if you -- if you call in to
2 speak.

3 And so with that, I would like to start
4 by inviting Amy Gietzen to share her experiences. Amy?

5 MS. GIETZEN: Hi. Thank you, Robyn. So
6 really my experience with scleroderma has been a
7 difficult one. I was diagnosed when I was 19, so, you
8 know, I was really young and just getting through a
9 typical day with scleroderma and how that really
10 impacts my life is, you know, it can depend on day-to-
11 day.

12 So, you know, I have Raynaud's, which
13 causes a lot of pain, numbness, sensitivity in my
14 fingers and in my feet. But there's also weakness and
15 pain in my joints and stiffness, making it hard to
16 bend, to reach things, you know, to stretch, to kneel.

17 So things like that which really make
18 it extremely hard to accomplish daily tasks. I also
19 tend to get really terrible ulcerated sores on my
20 fingertips and sometimes on my toes. So they're really
21 painful and bothersome and they take forever to heal

1 due to the poor circulation from Raynaud's and not
2 being able to clot my blood because of the
3 scleroderma.

4 So, you know, it's been really hard for
5 me to kind of get through my day-to-day life. But I
6 think, you know, if you have a good support system and
7 you have people who are willing to help you and you
8 have that positive drive just to get through each day,
9 you can find ways that you never would have thought of
10 to kind of make things happen. You know, like using
11 gadgets or just doing things differently.

12 So, yeah. I think that that helps. You
13 know, before I was diagnosed, I was really an active
14 person and I was a dancer for many years. I swam for
15 many years, and, you know, but with systemic sclerosis
16 and being diagnosed at 19, you know, you start to
17 realize that you can't really do those things that you
18 wanted to do and that you enjoyed doing.

19 So dancing became quite difficult for
20 me. You know, I had -- I had developed pulmonary
21 fibrosis so it was hard to breath and keep my stamina

1 up and, you know, one of my biggest heartbreaks with
2 this disease is not being able to finish college. I
3 was going to be a nurse and I just couldn't do it
4 anymore. I was really tire, fatigued, I had a lot of
5 problems with my hands. So it was a big regret.

6 You know, a good day for me would be
7 just being able to get out of bed and do things myself
8 and just kind of being able to go do something that I
9 enjoy, you know, like shopping with a friend or, you
10 know, having lunch with somebody.

11 And a bad day would really kind of be,
12 like, me in my PJ's all day with my cats, watching TV
13 because it literally hurts to breath, let alone get
14 out of bed. So I think that that's, you know, it --
15 but it can change over time.

16 Like, you can have good days, you can
17 have bad days, you can have things that you once
18 couldn't do before, you know, or things that you never
19 did that now you like to do. So I guess it all depends
20 on what kind of person you are and how you want to get
21 through certain things.

1 You know, for me, my disease, the
2 changes were hard and fast in the beginning. I
3 developed pulmonary fibrosis. I developed GERD along
4 with reflux. Difficulty swallowing, tightness of my
5 skin, especially around my mouth, elbows, fingers, and
6 wrists.

7 And that kind of seemed to even out for
8 about seven years, however, you know, I've never been
9 symptom free. I've never not had -- you know, never
10 not had an issue. So I know, you know -- I'll be
11 reaching my 20-year -- you know, 20 years of diagnosis
12 next February, so I think, you know, my symptoms have
13 always still progressed.

14 Now I have pulmonary hypertension. I
15 have a lot of heart issues. I have the telangiectasia,
16 like, from the top of my head to the bottom of my
17 toes. So I know I have contractures in my hands, which
18 makes things difficult.

19 So I started to have symptoms, looking
20 back now, when I was probably like 15 or 16, but I
21 wasn't diagnosed until I was 19. So, you know, it was

1 a little bit of a overlapping gap. Today I would say
2 my disease is pretty well managed, but, you know, it's
3 not really slowed down. But I have a really great team
4 that kind of make sure everything is going according
5 to plan and I stay really positive and on top of my
6 medications and my treatments and I'm really an
7 advocate for myself and my own body.

8 So I think that's really important if
9 you're a person living with scleroderma. You need to
10 be your own advocate and really speak for yourself.
11 It's your body. You're living in it and you need to
12 trust yourself in that you know, you know, what you're
13 doing and you really need to be educated on
14 scleroderma, because a lot of people don't know what
15 it is. So thank you.

16 MS. BENT: All right. Thank you, Amy,
17 for -- for being the first one to speak, but also,
18 most importantly, for -- for sharing -- for sharing
19 your experiences. There's a lot there and I think
20 we're going to talk about it a little bit more -- more
21 later, but now we're going to move on to Julie, who is

1 going to share -- share her experience. Julie?

2 MS. JEFFERS: Hi. Good morning.

3 MS. BENT: Good morning.

4 MS. JEFFERS: Amy did a really good
5 job. And I just want to say I'm not yet diagnosed. I'm
6 trying to be diagnosed. That is incredibly difficult,
7 but I do participate in some Facebook groups and from
8 doing that, I have come to know that this disease
9 affects everyone differently every day. And it's just
10 really challenging and really difficult.

11 But there were some questions that were
12 asked of us in order to participate, so I'm kind of --
13 want to go through those.

14 "Which aspects of systemic sclerosis
15 have the most significant impact?" So for me, I use an
16 alternative drug because I'm having trouble getting
17 diagnosed and that's called "low-dose naltrexone and
18 that controls the skin symptoms and -- for me. So my
19 biggest problem is fatigue.

20 Robyn asked me to concentrate on that
21 and when I say "fatigue," I don't mean I'm just tired.

1 I mean it's hard to explain how tired you are. You're
2 tired when you wake up in the morning. You take a nap
3 and you're still tired. It's just -- never ends, so
4 fatigue, GI difficulties are significant, the
5 shortness of breath is very limiting. The brain fog is
6 another thing that's a problem.

7 I get dizzy when I drive. I have pain.

8 And the next question was about
9 specific activities that are limited for me or I'm
10 unable to -- for me the biggest problem is work. And
11 the fatigue and the brain fog and the pain really
12 limit my work. So for me, I have to limit my work, I
13 have to change my work, I have to really concentrate
14 hard on my work, which makes me more tired.

15 I have to reschedule work. Actually, I
16 own a business for 23 years and I'm trying to sell the
17 business because I really -- I can't run it anymore.

18 Other things that are -- other
19 activities that are affected are -- you know, pretty
20 much everything. Daily tasks, housework is really hard
21 because, you know, your back hurts. Your joints hurt.

1 Everything hurts. Cooking meals, grocery shopping, I'm
2 too tired to go grocery shopping.

3 You know, so on good days, I just want
4 to say I'm still tired on good days. I still have to
5 limit my work. I still have random brain fog. But on
6 the worst days, I -- I -- I have to cut off things. I
7 have to reschedule things. And I have to say that most
8 days are bad days. There's very few what I would call
9 "good days."

10 The next question is, "How has your
11 systemic sclerosis changed over time?" Unfortunately,
12 it's worse. It started a couple of years ago and then
13 about every twelve months, it seems to worsen.

14 Next question, "Would you describe your
15 systemic sclerosis as being well managed?" I use many
16 things to help manage symptoms. I'm always looking for
17 things to help. I use diet. I use, you know, try to
18 exercise or stretch, at least. I see a Chinese doctor.
19 He does acupuncture and cupping. That helps. Massage
20 helps. You know, anything.

21 You are just constantly trying to find

1 things that will help. Sleep. You have to get rest and
2 sleep.

3 So next question, "What worries you
4 most about systemic sclerosis?" The heart and lung
5 involvement is really, really worrisome. So ...

6 "If I could change one thing about
7 systemic sclerosis, what would it be"? And it would be
8 that. That heart and lung involvement. That's -- a
9 really a worry and, yeah, it's the worst thing of
10 that. It's just a big, big concern. So thank you.

11 MS. BENT: Okay. Thank -- thank you so
12 much, Julie. I think -- I think that it was -- it was
13 really -- it was really helpful for us to -- to hear
14 about kind of all of the challenges that you're
15 facing, particularly the kind of the overall fatigue
16 and also all of the -- all the complaints, the things
17 that -- that you're really kind of concerned about as
18 you kind of work through -- work through the process.

19 So that was -- that was really helpful.
20 Thank you.

21 Now we're going to go to Rosemary who

1 is going to share her experience. Rosemary?

2 MS. LYONS: Hello, everybody. Can you
3 hear me all right?

4 MS. BENT: Hi, Rosemary. Yes, ma'am.

5 MS. LYONS: Very good. I may be the
6 longest diagnosed person in this group; almost 35
7 years. And so the last speaker, Julie, talking about
8 how it gets worse and worse. For me, it did get worse
9 and worse in the beginning, but there were then
10 periods that were good.

11 But it's still constantly a challenge
12 and I call it the "daily maze."

13 Temperature -- just talking about how
14 it is every day to live. So all the things -- all the
15 decisions you have to make every day so you can get
16 through a day.

17 Cold is a problem. I had the terrible
18 ulcers on my fingers. I couldn't take the cold. It
19 just painful. And moved 1,400 miles away from my
20 family from the north to the south, because it was
21 that bad. I had started to lose part of one finger. I

1 was miserable. I couldn't leave the house, but I had
2 to leave the house.

3 I also have overlap syndrome, so I also
4 have lupus and fibromyalgia. So I also can't take the
5 sun and the heat. So now I live in a place where
6 there's sun and heat, so I need to manage that.

7 I have a problem with artificial light.
8 So sitting in an office environment, I would become
9 very, very exhausted just from the overhead lights. I
10 had them take out the -- the bulbs over my desk. Of
11 course, they'd make fun of me for that. And I also
12 have fevers. And that's probably the lupus.

13 So I never know when I'm going to have
14 a fever and with the pandemic, my -- my fear is now I
15 want to go someplace or get out on a plane or do
16 something, and they're going to say, "You have a
17 fever." So that's something I fear.

18 Skin issues, although initially, I had
19 the hardening of the skin on my arms and my hands,
20 that type of thing, and some pain just to my face,
21 over time, that stopped. But my skin is very, very

1 sensitive.

2 So I have to be cognitive of what type
3 of fabric is touching my skin. And I have massive
4 allergies: food allergies, skin allergies, all kinds
5 of things. So I have to only use -- I've spent
6 thousands of dollars trying this soap, that soap, this
7 makeup, that detergent. Certain bedding, I can't sleep
8 in a bed if -- if I can't tolerate the bedding. My
9 shoes, I can't always have on closed shoes. So just
10 getting ready in the morning for skin issues, is -- is
11 a problem.

12 I may find something that works, and
13 then it doesn't work anymore. So constantly I'm
14 changing. As far as things that I like to do, going
15 back to what Amy was saying, I -- I played the piano.
16 I was pretty good and I -- I was a dancer and I did
17 choreography.

18 And -- and that's something that had to
19 go away a long time ago. I painted. I can do that a
20 little bit. Just putting on jewelry is difficult.
21 Buttons are difficult, so buying clothing, you have to

1 worry about how you clasp it.

2 Housework, if I'm having a good day, I
3 will choose to do some housework knowing that I will
4 have one to three days of recovery. So I can do the
5 housework, but I can't do the housework.

6 Food is the biggest problem. My biggest
7 issue for about the last 10 years has been the
8 gastrointestinal. So initially, it was the terrible
9 reflux, feeling like I can't swallow the food. I had a
10 very limited diet to begin with because of extreme
11 food allergies. But now, it's the impaired motility,
12 the digestion, and also the volume. So I -- I can
13 really only eat one meal a day. To eat more than one
14 meal a day is like emergency room time. That -- that
15 bad. Yeah.

16 The other thing is -- and I was going
17 to talk about when I had spoken about it with you
18 previously, is my story about sleeping. So when I
19 lived in the north, to go to bed, I wore pajamas and a
20 big, fluffy robe with a hood with gloves, with socks,
21 with slippers over that, under a bunch of blankets,

1 plus an electric blanket. And then my face was still
2 cold, so I ended up with a blanket over my face.

3 I couldn't sleep. I've never been able
4 to sleep. I've had this problem all of my life. Now
5 that I'm in the south, I -- on a 90-degree evening, I
6 can get by with one blanket and two comforters. But I
7 don't have to have the robe and the slippers and all
8 of that. At -- at night, the cold is worse and I get
9 terrible itching and I guess it's my blood vessels
10 are -- go into a spasm. So sleeping and eating are
11 giant problems, which, of course, it makes a whole
12 cycle of exhaustion.

13 I can sit for so long or stand for so
14 long or walk for so long. Some days, I can walk almost
15 half a mile, and sometimes, I can't walk at all. That
16 has a lot to do with the swelling and with the pain.
17 Lifting is out of the question. Stooping is a risk of
18 fainting.

19 As far as social activities, if I'm
20 going to -- and, of course, I haven't now for seven
21 months, but if I'm going to participate in something,

1 I have to know is it inside or outside, will I have a
2 place to sit down? I have to eat before I go so that
3 I -- I don't eat something I shouldn't eat and then
4 have a situation.

5 It takes me -- the gastrointestinal
6 issues, three -- it used to be one hour, now it's
7 three to four hours per morning to be able to be
8 dressed and out of the house, because of the issues.

9 Travel, it's the same thing. How long
10 is it going to be? Am I going to be able to use a
11 bathroom on the plane, or is there a bathroom along
12 the way? How strong am I going to be? And then the
13 other thing is, is that there are medications for all
14 of these different things, but I am allergic to many,
15 many medications. It causes something much worse.

16 The other thing is when you've had an
17 illness for this long, how long can you stay on some
18 of these medications without having an adverse effect
19 from the medication?

20 So in addition to that, fainting,
21 seizures, brain fog, wild weight differences. At the

1 very beginning of -- after my diagnosis, my weight
2 went down to 94 pounds, but I've been up to 145
3 pounds. So it's -- it's all -- I -- I think I've
4 evened out now. So I'm doing pretty well. But overall,
5 the nose bleeds, I -- I don't know. There's -- there's
6 a lot of things.

7 But I would say for anyone who is more
8 newly diagnosed, you have the internet. My diagnosis
9 was before Google. Someone said to me, "I think
10 somebody who has what you have is in People Magazine."
11 That was in the late '80s and that was all I had.

12 I went to the library. I couldn't even
13 find anything on it. One of the first physicians I saw
14 said, "Tell me about it. I've never seen this." So
15 there -- there -- there's a lot more as far as
16 resources and, you know, and -- and I guess the
17 positive thing I'd want to say is after 35 years, I'm
18 still here.

19 MS. BENT: Great. Thank you so much,
20 Rosemary. And -- and we're -- we're all -- we're all
21 very glad you're here. Both here and here at this

1 meeting. So -- so thank you -- thank you so much
2 for -- for sharing your experiences, and really for
3 sharing, kind of, a little bit -- a little bit of
4 ending on kind of a hopeful note, because I hope
5 that -- I hope that, you know, that -- that things
6 will continue to -- to get -- continue to get better,
7 so -- so thank you.

8 And now we're going to hear from Amy
9 Harding.

10 MS. HARDING: Good morning, everyone.
11 I'm happy to be part of this discussion today. I'd
12 like to share with you some more significant health
13 effects and daily impacts of having systemic sclerosis
14 that I have experienced.

15 I was diagnosed with scleroderma in
16 1998. I started having symptoms about a year before I
17 was diagnosed. My primary symptoms were starting with
18 my hands swelling and constant aching of my finger
19 joints and my wrists.

20 I though maybe perhaps had carpal
21 tunnel, because I worked on a computer a lot, but the

1 blood work proved it was scleroderma instead.

2 Initially the pain in my hands and
3 other joints, such as my knees and shoulders,
4 tightening of my skin, digital ulcers, heartburn, and
5 sensitivity to the cold had the most impact on my
6 life. Twenty-two years later, I must say the
7 calcinosis that I get in my fingers, my elbows, my
8 toes, my ears tops any of the prior symptoms.

9 All other symptoms have been manageable
10 through medications for the most part. Any activity
11 involving the use of my hands has become more and more
12 difficult. Opening jars is almost impossible. Typing,
13 I don't know how many times I have to correct a word
14 or two because I added an extra "M" or a "N" or some
15 other crazy letter in there.

16 Bending at my knees is not easy and I
17 find myself, I'm very cautious at when I do it,
18 because I'm afraid that I'm going to fall over and
19 potentially break something.

20 Dental appointments are extremely
21 stressful. I recently had two dental appointments in

1 the past month. I thought that my mouth was going to
2 rip apart, because it's much smaller than it used to
3 be. I can't open my jaw very wide. Fortunately, I did
4 have a very good dentist that were, you know, aware of
5 my situation and they were very kind doing the work.

6 Constant exhaustion. That has had a
7 huge impact on my daily life. Heartburn -- daily
8 heartburn limits what I can eat. The pain in my hands
9 makes simple things like washing dishes difficult.

10 Occasionally, I have really good days,
11 but it's difficult to figure out why yesterday was so
12 good and today is so lousy. I just have never been
13 able to get to the bottom of that.

14 On the worst days, depression really
15 kicks in for me. I suffer from chronic depression and
16 do take medication for that, but on my worst days, I
17 don't want to interact with anyone. I mostly want to
18 sleep so my mind shuts down and I don't have to deal
19 with the realities of scleroderma.

20 There is good news, though. I'm happy
21 to say at 57 years old, I have very few wrinkles

1 because there is so much collagen in my skin. Skin
2 tightening, though, has tapered off quite a bit. I
3 don't experience digital ulcers like I did in the
4 first 10 years of my disease. My Raynaud's and
5 heartburn have gotten worse and the calcinosis just,
6 for me, just puts it over the top.

7 I feel my scleroderma is managed as
8 well as it can be. My multitude of symptoms are being
9 managed with medication. Other things like calcinosis,
10 I'm just hoping and praying for some sort of treatment
11 or cure for that real soon.

12 My biggest worries about having
13 scleroderma are not being able to take care of myself
14 and dying young. If I could change anything about my
15 systemic sclerosis, it would be the constant pain and
16 the uncertainty about whether or not a new symptom
17 will present itself today or tomorrow or the next day.

18 Thank you for your time and I'm happy
19 to be here again.

20 MS. BENT: Thank you -- thank you so
21 much, Amy. And that was -- I mean, you raised some

1 symptoms that had not been mentioned before, and I
2 think that it will be really -- really good for us to
3 kind of explore as -- as we move forward in -- in the
4 panel.

5 Now we're going to go to our final
6 panelist for -- for this session, Kimberly.

7 So Kimberly, if you wouldn't mind going
8 ahead and sharing your experiences, that would be
9 great. Thank you.

10 MS. BENNETT-EADY: Certainly. Good
11 morning, everybody. I just want to take a quick
12 moment. Thank you so much to the other panelists for
13 sharing. I've heard so much of my own story in yours
14 and we're all connected. And I just want to thank you.
15 Sorry.

16 I can't remember living a day without
17 pain. For the last 24 years of my life, every single
18 day I've experienced varying degree of pain. My self-
19 examination, I've been living with pain longer than
20 without it.

21 I can remember the onset of my symptoms

1 began when I was just 19 years old and a junior in
2 college. It all started with what I thought was
3 systemic virus. I was assured that I would feel better
4 soon as I was hydrated and rested. I never felt
5 better. If anything, I began to feel worse. And it is
6 with every passing day it just got worse and worse.

7 And the travesty, I know there was
8 something in my pain had also changed. The magnitude
9 of my pain only intensified over the years and as my
10 chronological age increased, ironically, my pain did
11 the same.

12 This alarmed me. I knew that whatever
13 was happening to me, it had to be terrible. I just
14 couldn't put my finger on it and neither could any of
15 the providers I visited. I was often dismissed,
16 ignored, or belittled when explaining my pains. I
17 heard things like, "You're too fat. You're just
18 depressed. It's in your mind." But if you know me,
19 then you can attest to the fact that I love finding
20 solutions to problems.

21 So I spent the better part of another

1 six years trying to find answers and the symptoms that
2 plagued me never diminished. If anything, they had
3 become more acute.

4 I kept the severity of my pain to
5 myself for as long as I could. I never communicated
6 with my loved ones about the full extent of the
7 torment I was experiencing. I felt alone in isolation,
8 and I almost believed the disparaging remarks I
9 received from the culmination of some of those
10 doctors' visits. I started to doubt myself and I even
11 shouldered it in silence for fear of receiving further
12 trivializing remarks from those closest to me and I
13 just couldn't do that, so I kept it to myself.

14 However, my pain was that bad. It was
15 palpable. It was tangible. It was tethered to me. I
16 knew that it was very, very real and after a traumatic
17 experience of locking up in my bathtub for a half hour
18 by myself -- I lived alone -- I finally revealed my
19 truth regarding my pain.

20 By opening up and speaking out, I
21 received a helpful key puzzle piece to help me close

1 the searching chapter of nearly nine-year quest of
2 trying to find out what's happening to me. I was told
3 I needed to see a rheumatologist and request an ANA
4 test based upon the symptoms that I had described.

5 And just 10 days before my 20th
6 birthday, my beloved rheumatologist granted me the
7 gift of knowing. I received my answer, I was diagnosed
8 with systemic sclerosis.

9 I was a shell of who I used to be. My
10 skin was taut, discolored, itchy, shiny. My movements
11 were so stiff. My fingers had curved, and my dexterity
12 was compromised.

13 In the nearly nine years I went without
14 being diagnosed, I missed out on vital treatments.
15 Irreparable damage had been done to my body. My lungs.
16 My lungs are attacked aggressively. And at that visit
17 where I received my initial diagnosis results, my
18 rheumatologist decided to show me an X-ray of my
19 lungs.

20 Well, my lungs were not visible.
21 Instead, there were two murky clouds and they had

1 these, like, random nickel-sized holes that resembled
2 bullet wounds. That's what was looking back at me. And
3 at this current juncture of my life, my lungs have
4 continued to betray me.

5 I'm now in need of supplemental oxygen.
6 Oxygen is being forced into my nose through this not-
7 so-subtle cannula and -- because my lungs can no
8 longer work independently.

9 This is a symbiotic relationship. Who
10 am I kidding? I'm reliant upon this thing. Without it,
11 I'd be like a fish out of water, gasping for air.
12 Portable oxygen is my sustenance.

13 My lungs often cause me to feel full,
14 so I no longer get hungry in the traditional sense. I
15 usually have to force myself to eat or be prompted.
16 And the constant coughing has made me quite fearful of
17 eating a lot of the time. I'm fearful of aspirating
18 into my lungs for fear of infection or regurgitation.

19 My chronic cough has interrupted way
20 too many engaging conversation and ability from
21 expressing myself at any given moment. It's so

1 violent. Because of how suddenly and the impact of the
2 assault of coughing, which in turn causes my body to
3 writhe in pain, I swear I've injured and bruised a few
4 ribs because of this cough.

5 Most days I don't feel well, but not
6 everyone can detect that. Sadly, I masked my pain so
7 long with an unassuming smile, people don't know that
8 behind the smile is agony. There's intense level of
9 pain that I can't control at all, and most days, I
10 don't take any pain medication.

11 So I go throughout my entire day with
12 horrible pain, and yet I'm glad to be alive, so the
13 joy in my spirit comes through and I think that's what
14 people tend to see.

15 But then there are some days, oh, my
16 god, where I'm unveiled. Like, there is no mask to
17 don. Those days are hardest for me. I stay to myself.
18 Pretty much bedridden and would be able is like
19 folding into what I can only describe as a hibernation
20 type of deep sleep. It's my body's natural defense
21 response to help me endure the extremely intense pain.

1 I never know what the day will bring,
2 not until I make it to the next day. And when I do, I
3 open my eyes and my first thought is, "Wow, I made
4 it," and I'm super excited about that. I'm grateful,
5 because I no longer have to live in survival mode. I'm
6 going to live every day for it is; a gift. Thank you.

7 MS. BENT: Wow. So thank you so much,
8 Kimberly. And there's a lot to unpack in these
9 experiences and I think we really need to thank Amy
10 and Julie and Rosemary and Amy and Kimberly for
11 sharing their experiences.

12 And they did it -- did it really to
13 help us move the field of systemic sclerosis forward.
14 And so -- so thank you guys so much for that. And
15 for -- for those of you that would like to comment or
16 submit comments to be shared, as a reminder, here --
17 here is -- here is how to -- how to do that.

18 And so I guess now I'd ask, like, how
19 many of you heard your loved ones own experiences
20 reflected in the comments shared -- shared by at least
21 one of these speakers? In a virtual setting, it's not

1 really possible for me to see you nodding or
2 applauding in the way that we usually see in some of
3 our PFDD speaking meetings. So we're going to use some
4 more polling questions to get feedback from all of you
5 who are online -- who are joining us online. And
6 again, polling is limited to participants who have
7 lived experiences with systemic sclerosis either as
8 users or as family members and loved ones.

9 And if you have thoughts to share
10 related to discussion questions on screen, please
11 submit them via the web or over the phone. And so I
12 think if I -- if I recall, Shannon, do we have -- do
13 we have anybody who wanted to come in and -- and
14 share -- share some of their experiences as well?

15 I think if I recall, we have a call
16 from a caller in New York. Is that correct?

17 MS. COLE: Yes, we do. We have an
18 anonymous caller from Mayfield, New York. And they
19 would like to discuss overall health effects and daily
20 impacts.

21 MS. BENT: All right. So please --

1 please go ahead, Caller.

2 UNIDENTIFIED SPEAKER: Hello?

3 MS. BENT: Hello? Okay. So I'm not --
4 I'm not showing that we can hear the caller, so why
5 don't we give our producers a little bit of time to
6 kind of straighten out -- straighten out the audio
7 issues. And what we can do is, Shannon, did you -- did
8 you mention that -- that we had some -- received some
9 comments online that you might need -- might be able
10 to share with us?

11 MS. COLE: Yes. We have received a few
12 comments online, so I'll go ahead and kind of
13 summarize what I'm seeing here.

14 We received a comment from Rick who has
15 had systemic sclerosis for 10 years and he -- he
16 believes he's past the worst symptoms, but he
17 continues to have flare-ups and contractures in his
18 hands.

19 We also received a comment from Susan
20 and she -- she had a rapid onset when she was 50 years
21 old. It began with Raynaud's, which she didn't

1 understand at first, and then she experienced horrific
2 pain and swelling in her hands and fingers. It took
3 almost a year for her to get diagnosed and during that
4 time, she had skin tightening over her entire body and
5 so much pain that it was difficult to work.

6 She was working full time in a
7 demanding career and became so disabled that she
8 eventually had to quit. Her arms, hands, stomach, legs
9 were -- were hard like a rock, and she had
10 contractures in her hands. She also had very bad
11 fatigue.

12 Her face became so tight that it was
13 hard to eat and swallow, and she eventually had such
14 dental issues that she had to have nine teeth
15 extracted.

16 So -- so that's -- that's pretty much
17 what we're seeing on -- on the web right now and
18 really hearing -- hearing people's experiences with
19 their symptoms and many comments kind of discussing
20 those -- those contractures in the hands as well as
21 fatigue.

1 MS. BENT: Great. Thank you, Shannon,
2 and thank you to those of you who are -- are sharing
3 comments via the web.

4 At this point in time, I would like to
5 turn to my FDA colleagues and just see if -- if they
6 have any follow-up questions on anything that they
7 heard from -- from our panelists.

8 Go ahead, FDA panel, or FDA colleagues,
9 please.

10 DR. MEJIA: Hi. This is Joy from the
11 FDA -- from Dermatology and Dentistry. The first
12 panelist, Amy Gietzen, you had mentioned that you use
13 gadgets to kind of help with the daily function.

14 MS. GIETZEN: Yeah.

15 DR. MEJIA: I'm just wondering what
16 those gadgets were, how they assisted you, and if the
17 other panelist had, you know, work arounds throughout
18 the day, you know, ways to function better.

19 MS. GIETZEN: Yeah. For sure. Amazon is
20 a wonderful place. But, you know, I -- my hands had a
21 lot of self-amputations from sores. I don't know if

1 you can see.

2 So I needed stuff to be able to do
3 things independently because for me, I still wanted
4 that independence. So my dad, he's really great. He
5 helped me find, like, little gadgets to open pop cans
6 or jars. We found, like, a little gadget to help me
7 loop buttons into the buttonholes. You know, stuff to
8 put your shoes on, to reach things up high if you
9 couldn't reach them. He -- we -- we changed all the
10 knobs, like, in our kitchen and doors to those ones
11 where you just push down so I was able to open them,
12 instead of the turning knobs that I couldn't do.

13 So I think you just have to work with,
14 like I said, finding ways to still keep that
15 independence and just kind of think about things in a
16 different way.

17 MS. BENNETT-EADY: Yes, I agree with
18 Amy. Gadgets are your friend. There are reachers that
19 I have to use to grab stuff. There are automatic jar
20 openers. I call them my "fancy-capable tools." Like if
21 you want to open a soda can, it's -- the ones that

1 help you open pill bottles. There's so much. And you
2 also, like -- it's, like, ingenuity, right? So you get
3 a straw, you put some tape on the end, you try to pick
4 up that coin off of the ground because we can't grab
5 it with our fingers and it's just amazing how
6 innovative we are.

7 MS. BENT: Great. Great. Thank you,
8 guys, for -- for answering that question.

9 Dr. Mejia, did you have -- have more
10 questions or -- or -- or perhaps Dr. -- Dr. Nikolov
11 has a question as well?

12 DR. NIKOLOV: Yes. Hi. Thank you for
13 this -- for these moving stories. I think we're
14 learning from -- from all of you and this is kind of
15 the purpose of -- of this meeting.

16 I have one question. I think Amy
17 Harding mentioned that she has calcinosis. I just
18 wanted to find out how does that impact her -- in what
19 way?

20 MS. HARDING: Sorry. Had to do a little
21 work to get myself unmuted there.

1 Calcinosis, I primarily get it in my
2 hands. Twice, two years ago, I had to be hospitalized
3 because I was in such pain with it and, you know, they
4 put me on some intravenous antibiotics and that sort
5 of stuff to make sure that I wasn't getting an
6 infection or anything like that.

7 But when I get it, it's really hard to
8 explain. It -- it's like this -- this little rock is
9 coming out of your fingers. And if you accidentally
10 touch it or hit it on anything, the pain just sends
11 you through the roof.

12 I mean, literally, I actually have
13 become quite good at getting the calcinosis to get to
14 the surface. I either soak my hands or I wrap them in
15 bandages with either Vaseline or, like, Neosporin, and
16 then eventually I can pull the calcium out, which
17 sounds kind of gross, but it's better out than it is
18 in.

19 And I pulled out some pretty big pieces
20 where it has actually brought me to my knees and put
21 me in tears. It hurt so bad.

1 MS. GIETZEN: Amy, have you had them
2 surgically removed? Like I've had some on my forearm
3 that they had to kind of take out and then stitch back
4 together.

5 MS. HARDING: Yeah. I had this thumb, I
6 had some surgically removed. Would I do that again? I
7 don't think so. Not that I can bend my fingers a whole
8 heck of a lot, but this, you know, has -- I can't bend
9 it at all. It's still a little bit numb.

10 And I don't blame that on the surgeon
11 or anything. I knew what I was getting into. And I
12 still get calcinosis in that thumb anyway. So it only
13 took it away for, you know, maybe a couple, two or
14 three years at the most.

15 MS. GIETZEN: Yeah. They can still come
16 back, like this will grow back, so it's -- it's like
17 a, you know, a -- waging a losing battle 'cause --

18 MS. HARDING: Exactly.

19 MS. GIETZEN: Yeah.

20 MS. HARDING: The worst case I did
21 have, though, was in my -- most recently was in my big

1 toe. I thought for sure that I had gout, although I'd
2 never had gout in my life, but my big toe got really
3 swollen and red and hot and it ended up being
4 calcinosis in my toe. I couldn't put my shoes on. I
5 could hardly walk. It was, yeah, just unbelievable.

6 And I don't know --

7 MS. BENT: And I think -- Sorry. Go
8 ahead.

9 MS. GIETZEN: I was going to say, I
10 don't know if I answered the Doctor's question or not,
11 but that's what I go through.

12 DR. NIKOLOV: No. Absolutely. You know,
13 this is what we want to hear. You know, how -- how all
14 of these different symptoms that -- or how all of
15 these manifestations you have affect you or impact
16 you, your quality of life and functioning. So that was
17 very helpful.

18 MS. BENT: Yeah. And I think Rosemary
19 might have just a brief something to -- something to
20 add regarding the calcinosis as well, so let me -- let
21 me turn briefly to you.

1 MS. LYONS: Thank you. The first time I
2 was aware of it, I -- I didn't even know what it was.
3 I went to the doctor because I thought I had hurt my
4 back, picking up my son. But I actually had it under
5 my shoulder blade, and it was very painful.

6 So I've had it in my hand since then. I
7 have it right now near my thumb. I also have three
8 small spots in my kidney that I think that's what it
9 is, too. But, yeah. The first time was the shoulder
10 blade. It hurts.

11 MS. BENT: Thank you, Rosemary. So I
12 understand that we -- we have somebody -- somebody on
13 the line. I believe Isa is -- do we have you on the
14 line so that you can share your experiences?

15 ISA: Hello? Hello?

16 MS. BENT: Hi. We can -- we can hear
17 you, but if there's a way to -- that the audio can
18 become a little bit louder, I think it would be
19 helpful for -- for everybody. I'm -- I'm not asking --
20 I'm not asking you that. I'm wondering if it's -- the
21 studio people can -- can work on that a little bit.

1 ISA: You guys there?

2 MS. BENT: Yes. Can you hear us?

3 ISA: Hello?

4 MS. BENT: Yep. We have you on the
5 line --

6 ISA: Yeah. I'm here. Can you guys hear
7 me? I can't hear you guys.

8 MS. BENT: We're going to play the
9 telephone game, then, I guess. Lyna, if you could ask
10 Isa to just go ahead, we will -- we'll -- we'll just
11 go with that.

12 ISA: Can you guys hear me?

13 MS. BENT: Yes.

14 ISA: Okay. Sorry. Yeah. I have been a
15 patient for five years and one of the things that I
16 kind of live with on a daily basis is whenever I need
17 to see a physician for general things; an example,
18 this fall, I had a really bad cough, and I knew it was
19 from -- I was in a farmland and it was from allergies
20 and I needed some allergy medication.

21 So I called the local doctor's office

1 and asked to be seen. An my doctor was out, so I was
2 going to see his PA. And when the PA got me the
3 appointment, they immediately called me back within a
4 half hour and said, "Oh, my gosh. You have such a rare
5 condition. I don't feel comfortable treating you. You
6 need to go to the emergency room."

7 So for something very simple that I
8 knew I just needed general care for, I had to go to
9 the emergency room, which led to a COVID test and a
10 chest X-ray and blood work and actually thousands of
11 dollars of expense because the doctors are so
12 uncomfortable -- general practitioners -- treating us
13 that I spent all this money for them to say, "Yeah. I
14 think it's allergies. Here's the allergy medicine.
15 Here's the prescription." And several hours later, I
16 was able to go home.

17 My doctor in Chicago -- I see some
18 wonderful, great specialists at Northwestern, but I
19 can't wait three hours for allergy medicine. And so
20 this often can be a problem when we have to go into a
21 ER for a common thing or see a dentist or doctor, an

1 eye doctor. They don't want to treat us.

2 And so the lack of knowledge day to day
3 by the general medical population I find I'm educating
4 them on my disease, and often, kind of leading them
5 when asking them for the treatments that I'm needing,
6 which is a really awkward situation to be in.

7 MS. BENT: All right. Thank you. I
8 think that that really -- that that echoes, I think,
9 kind of something that Amy Harding was touching on
10 earlier about when she was talking about going to --
11 to the dentist and really having a specific dentist
12 who understood the condition and kind of understood
13 the -- the challenges that kind of went -- went with
14 that.

15 And it sounds like -- it sounds like
16 now, particularly with COVID, it's kind of added an
17 entirely new dynamic as far as the challenges of
18 receiving -- receiving routine care.

19 And I suspect, based on the number
20 on -- on the backside of the meeting, I can kind of
21 see our panelists who have -- who have their videos on

1 and there was a lot of -- a lot of head nodding
2 during -- during your -- during your -- your -- your
3 kind of telling us about your experiences. So I
4 suspect that this -- this is a -- an experience that
5 really resonates with probably a lot of people out
6 here.

7 And just based on kind of my survey of
8 five faces that I see now, and the amount of head
9 nodding that we've gotten. So -- so -- so thank you so
10 much for -- thank you so much for -- for sharing that.
11 It was really -- it was -- it was important for us to
12 hear and -- and I appreciate you -- you calling in.

13 Just to everybody else who's on --
14 who's on the line, we're -- we're looking at the
15 comments that are -- that are coming in and we're
16 looking at the phone calls. If there are any comments
17 that we are not able to get to as part of -- part of
18 the -- the meeting, we will absolutely include them
19 all in the Voice of the Patient Report so that
20 everything that you contribute will be captured and
21 kind of memorialized as an important component of this

1 meeting.

2 Now before we move on to our -- our
3 polling question, or our next set of polling
4 questions, so get your -- get your cell phones ready,
5 I wanted to turn briefly to Kimberly, who I think also
6 wanted to make a comment about calcinosis or share her
7 experiences very briefly -- briefly about that.

8 So Kimberly, can I turn back to you?

9 MS. BENNETT-EADY: Yes. Thank you so
10 much, Robyn. I was just going to share that at any
11 given time, five of my fingers are affected. And I use
12 my fingers every day, all day, because I'm a visual
13 designer -- X-designer, and I have to type.

14 And I find ways to, you know, use some
15 of the fingers that are working relatively well, but
16 Band-Aids, I have to rely on them, like, sometimes
17 doubling them up so the cushioning, like, I don't feel
18 the full impact of the pain. But, of course, there's
19 still pain, but it's -- it's just very hard to do what
20 I do and -- when I'm designing and -- I -- I push past
21 it. I don't really realize it in the moment, but at

1 the same time, it's like, oh, my gosh, like, I can't
2 believe that I am using literally five fingers just to
3 do my work.

4 And I think so many of us can
5 understand that.

6 MS. BENT: Yes. Thank you, Kimberly. I
7 think kind of putting it into context in a daily kind
8 of impact is -- is really kind of -- it kind of brings
9 home kind of the visual -- the visual of what the
10 actual impact is.

11 So I think these -- and I am, I swear,
12 I'm going to get to the polling questions, but I do
13 think that we have one more question from one of our
14 FDA panelists before -- before we -- we move on. So
15 let me -- let me turn to our FDA panelist and see
16 what -- what question you might have.

17 DR. TRAJKOVIC: Yeah. This is Snezan
18 Trajovic. I've noticed that most of you complain about
19 pain.

20 Can you describe this pain? Is it a
21 pain that is all over the body or if it is in certain

1 areas? I understand you have a lot of pain and
2 discomfort in your hands, but are there any areas
3 where you have pain? Can you describe that pain? Is
4 there something that makes it better or worse or --
5 and how you deal with it?

6 MS. BENT: Go ahead, Amy Gietzen.

7 MS. GIETZEN: So I think for myself --
8 I can't speak for the other ladies, but for myself,
9 it's almost like it -- I'm -- you know, I'm 38 but I'm
10 living in somebody's body who's, like, 85. So I have
11 the joint pain, muscle pain, stiffness, which causes
12 pain, and then if I overuse my hands too much, there's
13 pain. And it's like -- it feels like an achiness
14 like -- like your body's worn down type of pain.

15 And I've tried a lot of pain medicine,
16 you know, but that doesn't really make the pain go
17 away. It just kind of makes you not really care that
18 it hurts. Especially when you get digital ulcers, that
19 pain is like a pain that is indescribable. It is
20 almost like a nerve pain as well as if you got like a
21 little blow of air on it, it is excruciating.

1 So, I mean, I think it differs for
2 everybody, but I think it's just like a constant achy
3 stiffness of feeling like your body is just worn out.

4 MS. BENNETT-EADY: For me, it feels
5 like -- to add onto what Amy's saying, it is an ache,
6 but the pains vary. So sometimes, it's muscle and bone
7 pain. Sometimes it feels like bone and only, or just
8 muscle pain, 'cause you're so inflamed, like, you can
9 actually see your skin, like the raises, the
10 inflammation, like if you're having an extremely bad
11 day, you can touch it and you can feel the -- like the
12 lumps of your tissue. It's excruciating.

13 So think about when you have the flu
14 and how everything hurts and you just -- the fatigue,
15 the pain, everything associated all at the same time,
16 but magnify that by, like, a gazillion, and that's
17 what it feels like.

18 MS. BENT: I -- so thanks. Yeah. I was
19 going to ask if anyone else had anything to add, so
20 Amy, please go -- yeah. So I was muted when I started
21 to ask, so sorry about that.

1 MS. HARDING: That's okay. I -- I agree
2 with the two ladies. For instance, what hurts me the
3 most, you know, I used to have all the muscle pains
4 and all that, but now, I have a lot of pain in my
5 hands. It's as if all the skin that was on my hands to
6 cushion the bones is no longer there and it's like
7 you're hitting your raw bone on something
8 accidentally.

9 Like if I reach into a cupboard and I
10 hit the shelf accidentally, it -- the pain is -- it
11 makes you want to scream. It's just so -- it's hard to
12 explain. There are -- there are no words to explain
13 it. It just radiates throughout my hands and up my arm
14 and -- and, you know, it'll stay like that for, you
15 know, a good five minutes and I'm dancing around the
16 kitchen trying to shake my hands so they feel better.

17 So it's just -- it's just an enormous,
18 enormous amount of pain that we live with.

19 DR. TRAJKOVIC: Thank you very much.

20 MS. BENT: Thank you, ladies. And I
21 suspect that we'll be back to you in just a moment,

1 but I did want to at this time kind of move on to a
2 polling question, which is -- which is "Of all of the
3 symptoms you've experienced because of your systemic
4 sclerosis, which do you consider to have the most
5 significant impact on your daily life?"

6 And so for this question, as the
7 polling question, please feel free to choose up to
8 three answers. The first one -- option being, "A,
9 hardening or tightening of patches of skin. B, skin
10 thickening. B -- or C, digital ulcers, D, painful cold
11 sensitivity in hands or feet, Raynaud's phenomenon, E,
12 heartburn or difficulty swallowing, F, digestive
13 symptoms such as cramps, bloating, diarrhea,
14 constipation, G, arthritis, H, fatigue, or I, other
15 symptoms not mentioned."

16 And for our panelists, if you want to
17 look down at your cell phone and -- and participate,
18 that is -- that is perfectly fine as -- as fine as
19 well.

20 Let me -- let me kind of go over here.
21 Sorry, looking away so I can see the results.

1 And it looks like -- it looks like what
2 we're seeing is -- is that we have about 20 percent of
3 people with -- who are -- who have identified
4 Raynaud's phenomenon as one of the most significant
5 impacts. 16 percent of -- or, sorry, 18 percent of
6 people looking at digestive system. 16 percent
7 fatigue. And so I think that that is -- that sounds
8 consistent with what we heard from both Dr. Khanna at
9 the beginning and also our panelists who are -- who
10 are talking about it.

11 But it also looks like there is a -- a
12 broad range across of -- which are the most
13 significant -- which symptoms have the most
14 significant impact.

15 And so with that, while you guys are
16 finishing up the polling questions, I know that we
17 have a caller on the line, Laura, who would like to
18 share kind of some of her experiences and things, so
19 let me -- let me turn now to Laura.

20 Please go ahead.

21 LAURA: I was out of the bell curve

1 age-wise for receiving this diagnosis of the diffuse
2 systemic scleroderma. I was 60. And before I started
3 having symptoms, about four or five months before this
4 diagnosis, I didn't have any healthcare providers
5 caring for me. I was on no medication. And within a
6 very short period of time, from this diagnosis, I have
7 the interstitial lung disease. I had to go on oxygen
8 24/7 at 4 liters. My skin is tightening. My hands are
9 becoming deformed. I have all the internal organ
10 issues that we're hearing from the other panelists and
11 folks calling in.

12 Mine have gotten so severe with the GI
13 tract and my bladder that I have incontinence with the
14 bladder and the bowel, so that dramatically changes
15 your quality of life and confines me to my home a lot
16 of days when I'm dealing with those types of issues.

17 And with systemic scleroderma, what I
18 haven't heard from anyone is how -- besides the
19 typical other autoimmunes that we deal with Raynaud's
20 and Sjogren's and stuff, our medications that we have
21 to take just to stay alive and just the disease

1 process in itself of the scleroderma, we can have
2 other very serious diseases happen to us as well.

3 And this summer I was diagnosed with
4 multiple myeloma, which is cancer of the bone marrow
5 and my kidneys. So I am dealing with those challenges
6 as well now.

7 So this disease is so multi-diverse and
8 with some of the support groups that I am involved
9 with on social media, I find that those folks that are
10 not in a large community where they might have access
11 to university medical centers or multi-specialty
12 facilities, that you have physicians that have never
13 seen our type of problem. And we are very challenged
14 with getting diagnosed and getting on the medication
15 sooner rather than later so that we can help avoid
16 some of the progression of the disease.

17 I have not had to deal with that, but I
18 was in a very -- my career was a very rewarding one. I
19 worked in the medical field for 49 years. I had to
20 medically retire from that after getting this disease
21 and getting so ill. I also had a private practice for

1 19 years as a massage practitioner, seeing patients
2 with life-limiting diseases, and I had to close that
3 practice.

4 The governor appointed me to work with
5 the Department of Health for two terms for the State
6 of Washington. I was also an instructor in massage,
7 and I had to -- to resign from all of these positions.
8 I also worked at a national level and I had to resign
9 from that position. My body, I do not have the energy
10 or the strength or the stamina to do these types of
11 things that I so thoroughly enjoyed before.

12 It has just completely devastated my
13 career in every aspect, and I have had to move in with
14 one of my children who has helped when I am needing it
15 because of this disease.

16 MS. BENT: Wow. Thank -- thank you,
17 Laura. That was -- that was -- I'm sure -- I think
18 that that really kind of picks up on the thing that we
19 heard, that it's not just the health symptoms. Its'
20 kind of all of -- all of the implications that the
21 health symptoms kind of lead to and the limitations

1 that -- that -- that we're hearing from -- from our
2 panelists and others.

3 So it's more than just the health
4 impacts. So thank you for that.

5 And now I would like to turn to Sheri
6 who we -- is also on the line to kind of share some of
7 her experiences and thoughts.

8 SHERI: Hi. My name is Sheri and I'm
9 from -- can you hear me?

10 MS. BENT: Yes. Yes. Sorry. Thank you.

11 SHERI: I'm from Farmington, Michigan
12 and I actually am blessed to have my scleroderma. I
13 have limited scleroderma which mostly affects my -- I
14 love the term "limited," first of all. When you say
15 "limited" to someone with scleroderma, they just don't
16 feel like that does it. I hate the word "limited."
17 It's limited to my fingers, obviously, my GI tract,
18 but what everybody is saying today is just such an
19 inspiration to me.

20 I do get my care at the University of
21 Michigan, where Dr. Khanna spoke earlier, and if it

1 wasn't for that university, I don't know where I would
2 be with my healthcare.

3 Laura, I could really hear what you
4 were saying. You need to get quick health, and I
5 actually moved from Arizona to be under this umbrella
6 of comprehensive scleroderma clinics that -- I don't
7 know where I'd be without it.

8 But what I wanted to talk about was my
9 Raynaud's. Raynaud's to some people, if they don't
10 have scleroderma, is just this blue, pink, white
11 change of finger color. But if you have scleroderma
12 with Raynaud's, it's much more crippling than what it
13 sounds like.

14 Obviously, you're not getting the blood
15 flow to your fingertips. I get calcinosis under my
16 nails and it feels like you hit your finger with a
17 hammer, and you need to almost drain that blood.
18 That's what would happen to a normal person.

19 Well, I get that with every flare-up of
20 calcinosis that I get. And although the medical staff
21 hates this, I drain it just so I -- I believe Amy was

1 saying -- and I drain it myself because if I go into
2 the ER with this pain, nobody wants to touch a finger
3 that looks like it's infected. They don't know that
4 it's liquid calcinosis that looks like toothpaste. So
5 I just do it at home, and it saves everybody a lot of
6 time.

7 The other thing I do to improve my
8 Raynaud's is I get an IV infusion -- it was called
9 Flolan, the medication, but now I believe it's --

10 And I believe Europe has it already in
11 effect, and I don't know if the FDA has approved it
12 here, or how it all works. But anyways, I checked
13 myself into the hospital and get the infusion of --.
14 They have a 30-hour infusion now and it's given
15 through an IV. I don't have a port for it. And most
16 people can do 30 hours and it's fine.

17 For some odd reason with this very
18 individual disease, I had to go for the five-day
19 infusion where you just do, like, six hours a day. And
20 with COVID, nobody wants to be in the hospital for
21 that many days.

1 So I've been going without and I know
2 my neuropathy is terrible. You don't know how many
3 dishes I have broken, and my husband is just, like,
4 "Forget it. I'll do the dishes for you, honey." So
5 that's a pro, right? Right there.

6 But building your social -- somebody
7 was talking about your support system. And you know, I
8 think all of us with this immune -- autoimmune disease
9 that's life altering, we not only need to find what
10 our new normal is, but I think you would agree that we
11 have to get a support system that really will give us
12 what we need to make it through.

13 And we're part of a peer mentoring
14 program at U of M. I don't know if other places have
15 it or not, but I hear a lot of you saying you're on
16 Facebook group as well. And Laura, I'm with you, I
17 need someone to tell me that they have incontinence.

18 When I pooped myself at 40 looking for
19 my child's first bathing suit for his swim meet, which
20 I'm still going to do, I want to know that there's
21 someone else out there that did this. You know? And

1 that just helps us mentally move on.

2 I could talk for hours about this
3 disease. If you saw me, I don't look sick, but what I
4 do is find my new normal. I find the support I need
5 and the medications that we need, and I also agreed
6 with someone else. What if I take the small purple
7 pill for 40 years? What's that going to cause, right?

8 So anyways, I just wanted to thank all
9 the panelists. I wanted to share a little bit about my
10 experience and I put in another question about bone
11 grafts. So if somebody finds that, I'm just curious if
12 anyone has had bone grafting in their mouth and if
13 they could share that experience.

14 Anyways, have a great day. Be blessed.
15 Thanks.

16 MS. BENT: Okay. Thank you so much. And
17 I -- I would like to just touch on the fact that the
18 reason that these panelists did not speak a lot on
19 treatment is not because they don't have extensive
20 experience with multiple different treatments, but
21 because we asked them to kind of focus -- stay focused

1 on the Topic 1 Session that were really focusing on
2 the health effects and daily impact.

3 In our second session, will be -- will
4 be treatment, and so -- so I guess I just wanted to
5 put that out there so -- so that you know that
6 obviously, everybody who is here on this panel
7 certainly has kind of extensive thoughts and -- and
8 experiences with the -- with the -- with the
9 treatments, but -- but -- but we're just kind of --
10 that's our post-lunch, kind of, conversation.

11 So with that being said, I didn't know
12 if I can -- I can turn back to you guys on the panel
13 and see if you had any experiences with -- with
14 what -- with what Sheri was asking about or -- and
15 then I do think that one of our FDA panelists also
16 has -- has a -- has a follow-on question.

17 So anybody have any -- any thoughts
18 related to what we heard from Sheri?

19 Okay. Go ahead, Amy Gietzen.

20 MS. GIETZEN: Yeah. I think she was
21 correct in saying, like, it's amazing to have a

1 support system. I have my parents who are amazing and
2 my dad's retired, so he's kind of like my travel
3 buddy. But, yeah, I work really closely with the
4 Scleroderma Foundation and I do a lot of virtual
5 support groups with young adults and I work very
6 closely with a bunch of other organizations, with the
7 SPIN organization out of Montreal.

8 You know, I think it's really important
9 to find support where you can, whether it be on
10 Facebook, whether it be your local scleroderma support
11 groups, whether it be seeing a therapist. I think, you
12 know, you need somebody to talk to, even if it's
13 another patient that you kind of just connect with.

14 It's so important to be able to be --
15 feel like you're being heard and like somebody is
16 taking your -- your truth or your journey into
17 consideration. You know what I mean? Like I think
18 that's so important.

19 MS. BENT: Okay. Thank you. Thank you.
20 So let me -- let me turn now to our FDA panelist.
21 Onyeka, did you have -- did you have a follow-up

1 question that you wanted to -- to touch -- ask our
2 panelists while we -- while we still got them?

3 DR. ILLOH: Right. Yes. Thank you,
4 panelists, for sharing your inputs and this is so
5 informative. So I guess my follow-up question is in
6 terms of Raynaud's attack, are there other stressors
7 that will trigger a Raynaud attack for you guys other
8 than cold? So I'm just curious if you guys have any
9 other stressors that will trigger that.

10 And then the other question I have is
11 for some of your symptoms, for example, fatigue, I
12 would like to know if -- in terms of the frequency of
13 occurrence of the symptoms, are there days where the
14 severity of your symptoms spike up and other days
15 where it's better? So just wanted to know how, you
16 know, if there is fluctuation in the occurrence of
17 some of your symptoms, for example fatigue or pain.
18 Thank you.

19 MS. BENT: Go ahead, Rosemary.

20 MS. LYONS: Sorry. The unmute didn't
21 want to work.

1 As far as the spikes in the fatigue,
2 once that starts, there's nothing you can do. And you
3 never can predict it, or at least I cannot predict it.

4 So I can be having a good day and it
5 hits me and that's it.

6 And the first part of her question
7 was -- because I had a comment on that, too, but I
8 also have a brain fog.

9 MS. BENT: So that was the Raynaud
10 syndrome and whether it was just triggered by cold or
11 if it was triggered by other -- other items or --

12 MS. LYONS: Oh, no. No. It's
13 definitely -- because I left the cold world to come to
14 the tropical world and extreme stress, an emergency,
15 anger, lots of things. I can actually see it happening
16 and I don't always realize it's happening and somebody
17 else sees it. They can see my hands turning colors and
18 things happening to my hands.

19 I also have things happen to my face.
20 I -- on and off, I have the lupus rash for my face,
21 but no, it's not just the cold. All types of stressors

1 can set it off and just put my hands into total spasm.

2 MS. BENT: Okay. Thank you. Did
3 anybody -- did anybody else have anything they wanted
4 to -- to comment on in response to -- to the question
5 or else we can move on. We will move on. Kimberly?

6 MS. BENNETT-EDAY: Yeah. I just wanted
7 to add if I had too much caffeine or too much sugar,
8 that will also cause, like -- like more pain.

9 MS. BENT: Okay. Thanks, Kimberley. And
10 I see some -- I see some nodding with some of the
11 other panelists, so it might be that that is a -- that
12 is a shared experience as well, so -- so thank you.

13 Did you -- sorry. Sorry. Did you have
14 any -- any other follow-up questions or --

15 DR. ILLOH: No, that's it. Thank you
16 very much. Thank you.

17 MS. BENT: Great. Thanks so much. So
18 right now, we're going to move on to our next polling
19 question and following that polling question, we're
20 going to -- we're going to go to some of the comments
21 that we've received online, because we have received a

1 lot of comments and I want to be able to share them
2 with you.

3 So moving on to Question Number 8,
4 which is somewhat similar to -- to the -- to the
5 previous question, but there's -- there's a little
6 bit -- there's a little bit of a difference in that
7 this one is asking for you to focus on the single
8 symptom that you consider the most bothersome.

9 And I suspect that we may have missed a
10 few of -- few of the symptoms that are -- are
11 bothersome to people based on the conversations so
12 far, but -- but anyway, let's do the questions.

13 "So for all of the symptoms that you
14 have experienced because of your systemic sclerosis or
15 scleroderma, which single symptom do you consider the
16 most bothersome?"

17 And again, the options remain the same
18 as for the previous question, with "A" being
19 "hardening or thickening of patches of skin," "B"
20 being "skin" -- I'm sorry. First it's "hardening or
21 tightening of patches of skin." "B" would be "skin

1 thickening." "C" would be "digital ulcers. D, painful
2 cold sensitivity in hands or feet, Raynaud's
3 phenomenon." "E" would be "heartburn or difficulty
4 swallowing." "F, digestive symptoms like cramping,
5 bloating, diarrhea, constipation, G, arthritis, H,
6 fatigue," and "I, other symptoms not mentioned."

7 And so looking -- looking at -- looking
8 at that, it looks like -- there we go. So it's --
9 sorry. I'm still -- the digital ulcers seem to be a
10 very bothersome symptom. I -- I feel like bothersome
11 is really kind of an understatement of the impact
12 of -- of that, but so digital ulcers seem to be -- be
13 a large -- larger percentage of people find those the
14 most bothersome. Digestive symptoms about the same
15 with the arthritis and the Raynaud's phenomenon also
16 being significant.

17 Now we -- we understand that obviously
18 asking you to pick one of off a bunch of hugely
19 impactful symptoms is -- is difficult to do and it's
20 certainly not to discount kind of the -- the
21 challenges of all these symptoms together as well.

1 But looks like that's what we're
2 seeing. Raynaud's phenomenon is now up to 10 to 15
3 percent. And so while we're waiting to get some
4 additional feedback on this polling question, let me
5 turn to -- to my colleague Shannon and ask her to
6 provide us with a idea of kind of the comments that
7 we're seeing online from people who are participating
8 through the webchat. So Shannon?

9 MS. COLE: Thank you, Robyn. As I
10 mentioned earlier, we are planning to incorporate all
11 of the webcast comments into the -- the meeting
12 summary report. But I wanted to quickly summarize some
13 of the key themes that we're -- we're seeing in a lot
14 of these comments, such as difficulty sleeping and
15 Raynaud's phenomenon.

16 One participant mentioned that air
17 conditioning and stress can trigger their Raynaud's.
18 I'm also seeing comments about gastrointestinal
19 issues, such as heartburn and bloating and -- and also
20 some symptoms involving the mouth, such as a dry or
21 shrinking mouth and the roots of the teeth are

1 reabsorbing.

2 Participants are also speaking about
3 fatigue and the excruciating pain of calcinosis. We're
4 also hearing about the importance of early diagnosis
5 as well as extreme pain in the joints and the muscles.

6 One participant also mentioned that
7 walking has become difficult because it -- the cushion
8 in their feet has deteriorated and it feels like
9 they're walking on bones. And I wanted to just read
10 one -- one comment that kind of catches all of these
11 key things in one -- this -- this anonymous
12 participant is -- has had systemic sclerosis for 24
13 years. They have GI involvement, pulmonary fibrosis,
14 Raynaud's, calcinosis, dry mouth and eyes, fatigue,
15 skin tightening and occasional joint and muscle pain.

16 Raynaud's is the worst symptom and has
17 been on five different medications at a time, but they
18 still do not feel that their condition is well managed
19 at this time. They have frequent digital ulcers, which
20 take forever to heal and have caused permanent damage,
21 pitting, and scar tissue on their fingers. And they

1 say that the impact is cumulative. It's impacted
2 their -- their job and -- and their lifestyle and
3 that the calcinosis makes it extremely difficult to
4 use their hands as any pressure put on their fingers
5 causes nerve pain.

6 They also talk about GI symptoms,
7 difficulty swallowing. They need to drink after every
8 bite of food. And they eat small amounts throughout
9 the day, and can't eat a regular-sized meal because
10 they have delayed gastric emptying. Also difficulty
11 not feeling hungry and having reflux after they eat a
12 larger meal.

13 So those -- those are kind of the --
14 the things that we're seeing on the webcast at this
15 time.

16 MS. BENT: Great. Thanks so much,
17 Shannon, and I think that that was -- that was really
18 comprehensive, and I feel like maybe that kind of
19 helped us understand it's again, one of the -- one of
20 the frustrations of the virtual setting is that we
21 have about nine percent of people who have identified

1 "Other" as the symptoms that are -- are most
2 bothersome, and I don't really know that we have a way
3 of getting feedback from people. I mean, if you did
4 identify "Other" and you can type into the chat what
5 you -- what you would consider "Other," that would
6 be -- that would be really -- really helpful for us.

7 Let me turn briefly to -- to the
8 panelists and see if they have any thoughts, if there
9 was anything that -- if they have any thoughts or if
10 they would have chosen "Other" if they -- what "Other"
11 would have meant to -- to them.

12 So -- so let me -- let me -- let me
13 turn there again. Oop. Sorry. My office is falling
14 apart. Apologies for that. But so let me -- let me
15 turn to you guys. Do you have -- do you have any
16 thoughts on these results? Do you think that these
17 results really are reflective of kind of your
18 experiences for those of you who are involved in
19 support groups? Do they -- do they seem kind of
20 reflective of the experiences that you -- that you
21 know of from -- from others?

1 MS. GIETZEN: Yeah. I think so. I think
2 that if I had to pick -- if I picked the "Other," for
3 me it would probably be my pulmonary issues,
4 difficulty breathing, things like that. It's not
5 always just about the skin, but I know with
6 scleroderma, the main focus really kind of is the
7 skin, because it's a big issue.

8 But, yeah, it would be my -- my
9 breathing and then I have had some cardiac issues
10 where I've had extra beats or I've gone into
11 tachycardia from -- from fibrosis in the heart. So
12 that would be a -- one that I would probably consider
13 "Other."

14 MS. BENT: Okay. Thank you. That's
15 really -- that's really helpful and I think that with
16 that, actually, I -- it turns out that it is
17 actually -- it is 12:15 and we have actually kind of
18 made it through -- or I don't want to say made it
19 through, because this is really a valuable session. I
20 kind of wish we had -- we had -- we had given it a
21 little bit more time. But I feel like the -- I want to

1 make a quick plug for our docket comments reminder as
2 well as the comments that you guys are submitting on
3 the web, because I think we really -- I mean, it's
4 clear that we've really just barely scratched the
5 surface as far as the daily impact and get what you
6 guys are experiencing day to day.

7 So for those of you who are online, if
8 you want to submit comments either through the webcast
9 comment or if you want to submit them to the -- to the
10 federal docket, the public docket, to expand upon kind
11 of what you've heard, that would -- that would be --
12 that would be wonderful.

13 And I would just like to take this
14 opportunity to very, very much thank our -- our
15 amazing panelists who really took their time today and
16 took their time, really, over the last few weeks to
17 prepare all of their remarks and -- and really think
18 about this and really just open themselves up to kind
19 of -- kind of help us have a better understanding of
20 this.

21 And thank you to all of you who have

1 participated online thus far and with that, I just
2 want to say thank you and we have a 30-minute break
3 that's probably now going to be a 28-minute break in
4 order for everybody to go and kind of take a little
5 bit of the break. Hopefully get a little bit of lunch
6 or at least a sip of -- a sip of water and we'll be
7 back here at 12:45 eastern time. So thank you so much
8 and I will see you shortly. Thank you, everybody.

9 MS. GIETZEN: Thanks, Robyn.

10 MS. BENT: All right.

11 (Off the record.)

12 MS. BENT: -- had a -- a good break. We
13 have limited time, so we're going to move straight
14 into Topic 2.

15 As we mentioned, Topic 2 will focus on
16 current approaches to treatment of systemic sclerosis
17 or scleroderma, your experiences and your perspectives
18 on that, what you'd like to see in an ideal treatment,
19 if future treatments could be better, how could they
20 be better.

21 And we have five panelists who will

1 start off the discussion by -- by sharing their
2 experiences and their thoughts. Before we launch into
3 our panelists' experiences, I want to let you know
4 that our first question for the open discussion
5 session is actually three sets of questions, and it's
6 "What are you currently doing to treat your systemic
7 sclerosis, how has your treatment regimen changed over
8 time and why, and what symptoms would you like most --
9 would you like to be improved or resolved by
10 treatment."

11 So now we're about 30 minutes away from
12 people sharing their answers, but if you're interested
13 in responding to that question, please consider
14 sharing it via the internet or by calling into the 1-
15 800-527-1401 number.

16 So now I would like to start by
17 inviting Monica to share her experiences. So Monica,
18 go ahead.

19 MS. CICCHETTI: Hello, everyone. Can
20 you hear me?

21 MS. BENT: Yes. If we could just have

1 our other panelists mute their phones right now.

2 Perfect. Go ahead, Monica. Thank you.

3 MS. CICCHETTI: Thank you, Robyn.

4 First, I would like to thank the FDA organizers for
5 giving me the opportunity to be heard. I was diagnosed
6 with scleroderma three years ago. Twenty-two years
7 before that, my father had passed away of scleroderma.

8 Through this time, I learned that there
9 is a lot I can do that will determine the quality of
10 my life. So I decided to focus on lifestyle. First on
11 the physical level, I moved to change my diet, sleep,
12 and exercise.

13 We all know that diet is important and
14 I needed to find one that would be good for my GI
15 symptoms. After trying many, many different types of
16 diets, I ended up taking parts of many diets and
17 making one that my body would like.

18 Planning meals, shopping, cooking from
19 scratch, cleaning, these are time consuming, but none
20 of it would make a difference if I would not get
21 relaxed in my mind while eating. I became a

1 professional chewer. I really chew on food very well.
2 If I would not do that, I would not be able to swallow
3 my food very well, my digestion would be less
4 efficient, I would have serious problems absorbing
5 food nutrients.

6 So no more driving while eating in
7 downtown L.A. for me. Instead, I pray. I feel grateful
8 for having adequate food, healthy food on my table.

9 Another change in my lifestyle, sleep.
10 Even though I cannot fully control if I'm going to
11 wake up at night because of symptoms, I can control
12 the time I go to bed. When I don't sleep well, I
13 literally feel like I am dragging my feet uphill all
14 day long. My thinking, my speech are not clear and I
15 get so tired that I get irritable.

16 So I often compromise in not spending
17 the the time around the TV at night with my husband,
18 for getting more sleep, and it pays off.

19 And exercise. I have a wide variety of
20 exercise routines that I can practice. I can go out
21 for hikes or walk for Tai chi in good weather. If not,

1 I stay home, and I practice yoga. And if I am too weak
2 for yoga, then I can do chair yoga. And I also
3 practice yoga breathing exercises which can increase
4 moisture in my mouth, in my eyes.

5 By the time I am done, I feel good,
6 with more energy, which is precious when you have an
7 autoimmune condition. Now if I lose focus, I don't
8 exercise regularly, my joints will give me a reminder.
9 I can't -- I get to a point where doing anything feels
10 like a chore. So I have to keep moving all the time.

11 Mental and physical health go hand-in-
12 hand. So another partner in my life is my mental
13 wellbeing. My emotions. I attended workshops for
14 stress, anxiety management. I recently had counseling
15 during COVID quarantine. I also practice being patient
16 and mindful regularly.

17 It is not that easy at first, but if
18 you press on and you do not try too hard, it gets
19 easier with time. You can be mindful while walking,
20 observing nature, and while eating.

21 If I stop all practice, my mind starts

1 wondering, it works overtime. I start to worry about
2 the future, and I don't like that. The simple act of
3 breathing deeply promotes salivary secretion, supports
4 self -- factor helps our immune system, reduces stress
5 and inflammation as Dr. Sander -- found in his
6 research book.

7 Last, I would like to talk about my
8 spiritual life. I found that a deeper way of dealing
9 with stress, anxiety symptoms and the way of having a
10 more meaningful life is by living in peace with God,
11 with myself, with others. Practicing meditation,
12 mindfulness, getting closer to nature, and prayer gave
13 me that peace.

14 This is one of the best things that I
15 hope that I could have done in my life for myself and
16 my loved ones. I was sure that if you would like to do
17 something for yourself, you should let someone in. And
18 if you would like to do something for others, you
19 should better yourself as a person.

20 Finally, I would like to share that I
21 am grateful to have a mild type of scleroderma and I

1 do not take medications, although I take supplements
2 to support my nutrition. So I have the luxury of
3 managing my symptoms with lifestyle and I do not have
4 to take any risks related to medication or treatment
5 side effects.

6 Again, thank you so much for this
7 opportunity. Blessings to you all.

8 MS. BENT: Thank you so much, Monica
9 for sharing your thoughts and experiences. And we're
10 now going to move on to -- to Demi.

11 We are having a few audio issues, so
12 we're going to see if -- if Demi's audio is -- is
13 great, and then if not, then we might move on to Anita
14 and come back to -- come back to -- to Demi. But go
15 ahead, Demi. We'll give you a -- we'll give you a --
16 the audio a chance. Do you want to unmute? Yeah. There
17 we go. Go ahead.

18 MS. TRICE: The aspects of my sclerosis
19 that impacts my life the most is a --

20 MS. BENT: Stop.

21 MS. TRICE: Can you hear me?

1 MS. BENT: It's a little rough. Maybe
2 if we could have you log off, like, fully and log back
3 in and we can maybe move to -- move to Anita, because
4 I really want to make sure that everybody can -- can
5 hear your experiences and your story and I'm afraid
6 that with the audio issues, it might just -- we might
7 not be successful.

8 So Anita, is it okay if we can move to
9 you and then kind of, Demi, if you don't mind, kind of
10 completely logging off and logging back on to see if
11 that -- that will help the audio. That will be -- that
12 would be great.

13 MS. TRICE: Okay. Thank you.

14 MS. BENT: Sorry about that. Thank you.

15 MS. TRICE: Sure.

16 MS. BENT: Thanks so much, Anita.

17 MS. DEVINE: Thank you. As an
18 introduction, my name is Anita DeVine and I was
19 diagnosed with diffused systemic scleroderma 14 years
20 ago. Professionally, I had a doctorate in pharmacy,
21 which has greatly aided in my knowledge of my disease

1 and my treatments.

2 My disease course has run a gamut of
3 acute immune crisis in which I was very clearly ill to
4 now having scleroderma as a chronic debilitating
5 disease. So therefore, when I think about treatment,
6 the treatments have changed through the different
7 types of scleroderma that I have experienced.

8 Currently, my treatments have included
9 medications that will control symptoms only, but
10 unfortunately, they are not curative in intents. My
11 medication list includes high dose -- for severe
12 gastric and esophageal reflux, enalapril for renal
13 preservation, sildenafil [ph] to increase perfusion
14 and also hopefully aid in pulmonary hypertension,
15 levothyroxine and PRN opioids for pain.

16 I rarely take them, thank goodness,
17 but I will be discussing that a little bit later. I do
18 have to take a lot of Loperamide for my gut and my --
19 my symptoms are quite severe in my gastrointestinal
20 tract and there are days that I can hardly leave the
21 house without the Loperamide. I also take vitamins.

1 I previously had been on antineoplastic
2 and anti-inflammatory agents to try to stem the course
3 of my disease. However, unfortunately, the disease did
4 not abate.

5 My non-medication treatments have
6 included major hand surgery. There was one major and
7 fifteen minor hand surgeries. You can see the effects
8 of it. They were not wonderful, and it was extremely
9 difficult surgery.

10 I have been on dialysis because of
11 renal failure, which was due to my scleroderma. I
12 elevate my head at night to abate my reflux symptoms.
13 I use heat for localized pain. I have been on frequent
14 bouts of physical therapy. My diet, I am on a low-
15 sodium diet, because of my kidneys, and I exercise as
16 much as possible to maintain whatever limb function I
17 have left.

18 Unfortunately, my current treatment
19 regimen does not affect the progression of my
20 scleroderma. The anti-diarrheal medication stops the
21 issue temporarily, but doesn't change the onset of

1 symptoms and activities of daily living are extremely
2 difficult due to the lack of my gut function.

3 My profusion is slightly better on
4 sildenafil. I was a failure on other treatments that
5 were given to me, such as calcium channel blockers.

6 I do want to spend a minute on pain
7 control. I do experience quite a bit of pain on a
8 daily basis and unfortunately, for someone like me who
9 has kidney disease, many options are not available to
10 me. And I am forced to end up taking opioids. And the
11 opioids are a very, very difficult medication to
12 obtain from a physician as well as you don't want to
13 be on it for long periods of time. So it is a
14 difficult thing to control my pain and I generally
15 have to try and grin and bear it.

16 Thankfully, I'm on mostly oral
17 medications, and that makes my life a lot easier. But
18 the down sides of my therapy include cumbersome
19 regimens, costs of my therapies, and pain control, as
20 I said before.

21 If I was to choose my ideal treatment

1 with scleroderma, it would include cost effective
2 therapies for disease and symptoms controls. The
3 therapies would have low or no toxicities. It would be
4 a simple regimen. Costs would be within reason, and
5 insurance coverage and peer coverage would be
6 acceptable to me. And I also would like to make sure
7 that it -- the therapy is easy to obtain.

8 Sometimes they make you go through
9 hoops to get medication or other modality, and it's
10 not always easy to obtain meds. The other thing I
11 consider before starting a therapy is the risk that
12 could fall back of the treatment.

13 I think about various things such as
14 potential value, comparison to other options and
15 therapies that are out there, cost, again, side
16 effects again, how severe are those side effects, how
17 is it going to impact my quality of life and what are
18 the effects on my family?

19 I also want to know what is the history
20 of the treatment? Has the drug been out for fifty
21 years, or has it been out for six months? That might

1 make a difference to me.

2 And lastly, if the drug is still
3 investigable. Did -- include patients like me? Did
4 they include patients who were in my age group, my co-
5 morbidities, treatment after the trial has ended? Will
6 there be a cost to me in a trial? Testing --

7 Lastly, is there confidentiality in a
8 trial? I was actually a participant in a
9 investigational study years ago and the data was
10 compromised, and my confidentiality was breached. And
11 so I just want to make sure that that never happens
12 again.

13 Now on a personal level, when treating
14 my disease, I would accept some side effects if the
15 gain was control of disease progression and increase
16 the overall quality of life. I would be willing to
17 accept some side effects if organ preservation
18 resulted. This is maybe the most debilitating issue to
19 me in the long run.

20 I'm also willing to accept different
21 treatments, depending on my disease state. When sicker

1 with life-threatening scleroderma systems, I might be
2 more willing to take riskier treatments if it improved
3 my chances of survival.

4 Now during the more prominent phase of
5 my illness, my present status, I would be less willing
6 to accept the more severe or lifelong debilitating
7 treatment. Having a slower, chronic decline for the
8 disease, to me, would be preferential to having an
9 acute life-threatening product which I would have to
10 take.

11 However, if I felt that I could live
12 satisfactorily with the risks that are incurred by the
13 medications, if they were acceptable or treatable
14 risks, I would be willing to take the medications or
15 treatment.

16 Thank you for allowing me to speak.

17 MS. BENT: Thanks so much, Anita. So
18 let's try and go back to -- to Demi and see if we've
19 resolved our audio issues.

20 Demi?

21 MS. TRICE: Can you hear me?

1 MS. BENT: It sounded like something we
2 are dealing with the same audio issues. I wonder if
3 maybe we could -- we could figure out a way to maybe
4 have you call in via the phone instead of -- instead
5 of online, because I think that might be one of -- one
6 of the -- the challenges.

7 So while --

8 MS. TRICE: Okay.

9 MS. BENT: Yeah. Sorry about that.

10 Let's move on to -- to Jackie as --
11 while we -- while we continue to work on -- on
12 Demi's -- Demi's audio issues and -- and we will come
13 back to her.

14 But Jackie, if you wouldn't mind
15 sharing your experiences with us, we really appreciate
16 it.

17 MS. LATKA: Sure. Okay. So my name is
18 Jackie Latka and I'm going to start with just a little
19 bit of background so you can understand my story.

20 I was diagnosed with systemic diffused
21 scleroderma in 2011 and I was put on a medication

1 called "CellCept" that I took for about six months
2 with my symptoms continuing to progress.

3 After six months, I started having some
4 breathing issues and was diagnosed with some secondary
5 issues; Raynaud's syndrome, interstitial lung disease,
6 and borderline pulmonary hypertension.

7 Not only did I have these secondary
8 issues, but the disease continued to progress and
9 started to make my mobility deteriorate. I could not
10 sit or stand for more than 15 minutes. I could not be
11 in a straight position. My body had to be bent for
12 more than 15 minutes, or it was very painful.

13 I could no longer go upstairs. I used a
14 walker. I was in a wheelchair. I needed assistance
15 with daily tasks that most people take for granted,
16 such as bathing, getting dressed, fixing something for
17 myself to eat, opening a bottle of water.

18 When the disease continued to progress
19 so rapidly, my doctors decided that I should take some
20 chemotherapy, Cytoxan infusions. However, nobody could
21 get the IV's in my arms because the skin was so tight.

1 So we moved to a daily, oral dose and I took it for
2 four months, until I started to get side effects of
3 the Cytoxan, with bladder issues.

4 So at this point, my doctors were kind
5 of at a loss for where to go with me because my
6 disease was progressing so rapidly. I did some
7 research on my own and found a rheumatologist very
8 well known in the scleroderma community, that I
9 traveled outside of my state to go and see what their
10 recommendation was.

11 And within 10 minutes of being in the
12 office, the recommendation -- and the only
13 recommendation she had for me was a stem cell
14 transplant. So in 2013, I went and had a stem cell
15 transplant as my treatment, and currently, continue to
16 be on medications to maintain a status quo of my
17 health and where it is from the transplant and the
18 medications that I've taken over the years.

19 I also take some non-prescriptions,
20 like calcium and Vitamin D and do exercises and stuff.
21 My treatment has changed a little bit because of the

1 transplant. Just different medications. I still take
2 an immunosuppressant. I still take something for my
3 lungs. I take something for my gastrointestinal, and
4 several other medications.

5 I did see improvement in my mobility
6 and in my lungs after my transplant. And I continue to
7 see what I call my baby steps and my new normal to
8 making more positive changes forward from the
9 transplant.

10 I was able to retire my -- some of my
11 medical equipment, but I still continue to use some
12 smaller equipment and gadget-type things like grippers
13 and door openers, et cetera.

14 So as I mentioned, my lungs did improve
15 from the transplant, however, they're still in a
16 compromised position and I do wish that they would get
17 better. And one of the things that I would say that
18 is, I guess, just annoying -- a little bit annoying to
19 me is all the medications that I continue to have to
20 take on a daily basis.

21 But in order for me to maintain my

1 status quo and not have to catch back up with the
2 disease, I continue to take medications. But I always
3 have the questions of worrying if another medication
4 is introduced, how it will affect me, making sure I
5 don't relapse, and worrying about any new symptoms.

6 In choosing treatments, I take into
7 consideration who's in charge of the treatment, how
8 knowledgeable are they about scleroderma, do I have
9 any other options that I need to research, and what
10 are my healthcare providers and my family recommending
11 to me.

12 And if the treatment were to make a big
13 difference in the -- and would improve my symptoms,
14 and preserve my organs, I would consider it. I would
15 have to outweigh the risks and the benefits, for
16 example, like I had to do with my transplant.

17 The risk of the transplant was very
18 high, however, in order to save my life and continue
19 living, I felt the option was to do the transplant.

20 In looking at bothersome symptoms and
21 things that are less important to me than are more

1 important, I look at, like, my hands. My hands are
2 curved like this, like a lot of scleroderma patients,
3 and I can't straighten them. But to me, they're
4 functioning hands. They're normal hands. I'm used to
5 these hands, and I can live my life with these hands.
6 So I wouldn't risk the possibility of doing a surgery
7 to straighten them out and go through the side
8 effects of that surgery.

9 However, if my lungs deteriorated, I
10 would consider a treatment that possibly has risks if
11 for the greater good of me and my lungs, it's going to
12 help and get the lungs better.

13 I think I've had a lot of high-risk
14 treatment in doing the scleroderma, and I've looked at
15 the benefits and risks and that's the main thing that
16 I look at when I look at my condition. If there's a
17 long-term factor, but my life will be much more
18 functioning, then it would be worth it to me.

19 You know, in a perfect world, our
20 treatment would be safe and we have positive results
21 or a cure, but I guess I look at all the treatments

1 and if my scleroderma symptoms started to decline, I
2 would have to weigh all of the options at the time
3 that I'm in, looking at the risk and benefits of them,
4 and what my healthcare providers would be
5 recommending.

6 So thank you to everyone. And that's a
7 bit about treatment and scleroderma.

8 MS. BENT: Thanks so much, Jackie. I
9 think that we -- I -- I appreciate that and I
10 appreciate kind of the unique perspective that you
11 bring, having -- having gone through the -- gone
12 through the transplant and also really kind of your
13 thoughts on -- on risk and benefits. That's really --
14 that's really helpful for us to hear.

15 And I think we're going to hear
16 hopefully from more of you on the line about your --
17 your thoughts and your experiences with treatment as
18 we move forward.

19 Right now, we are still working on
20 Demi's audio, so Susan, if you wouldn't mind us kind
21 of turning -- turning to you for -- for your -- your

1 thoughts and your -- your experiences, we would -- we
2 would really appreciate that.

3 MS. NYANZI: Definitely. Again, thank
4 you for having me. So I've had scleroderma for 45
5 years, and it took three years and three different
6 countries to finally get a diagnosis.

7 At the time, I didn't fit the standard
8 patient. I was a child, and I was African living in a
9 tropical country. For about 20 years, the scleroderma
10 was in remission, but three years ago, things changed,
11 and I had to figure out what I could do to go back to
12 a normal life.

13 Just to lead an ordinary life, all my
14 medications, prescriptions, and over-the-counter meds
15 must be compounded, because I have intolerances to the
16 binders and fillers that are now used to make all
17 medications. The food intolerances are a side effect
18 of SIBO, small intestinal bacterial overgrowth.

19 And because of this, I develop skin
20 rashes that won't go away, constant nausea, constant
21 aches and pains, and foggy-brain episodes. Once I

1 changed my diet and pulled that gluten, dairy colon
2 nightshades, all the symptoms disappeared, and my
3 energy levels skyrocketed.

4 To be able to function throughout the
5 day, I must put myself in TPN, total parenteral
6 nutrition at night for 10 hours, because 70 percent of
7 my nutrients come from TPN as I can't absorb
8 nutrients.

9 Although TPN has given me life, it also
10 has its downside. I get sepsis infections when the
11 PICC line gets infected. This usually results in a
12 nine-day stay in the hospital. The hospital stay is
13 gruesome, because many of the physician and nurses
14 don't know how to take care of scleroderma patients.

15 I have nutrition limitations; can only
16 eat four foods. I have medication limitations, so I
17 must bring my own medications and blood draws need to
18 be limited, otherwise I develop hospital-acquired
19 anemia that's treated with a blood transfusion.

20 Currently, there are minimal treatments
21 for patients with intestinal problems. Once you've

1 gone through the standard treatment, then your
2 rheumatologist and gastroenterologist have to become
3 creative in finding solutions that will work. We need
4 medications that treat the intestinal tract; those
5 that address SIBO, those that address lack of or
6 limited -- and those that address lack of absorption.

7 We additionally need medications that
8 address secondary Raynaud's that many of us develop.
9 Although nitroprusside is recommended, it has side
10 effects. A less aggressive medication is needed.

11 Many of us scleroderma patients are
12 usually in some type of pain most of the time. So a
13 medication that can lessen that pain and protect our
14 organs would be ideal. One hears of too many stories
15 where some scleroderma treatments result in rare
16 cancers. And we actually have a scleroderma warrior
17 that is currently going through this.

18 In the long term, aggressive treatments
19 that work well and have the potential to damage our
20 organs are not prolonging life or improving on quality
21 of life. They are causing more hardship.

1 We need treatments that work well,
2 protect our organs, and prolong life and quality of
3 life.

4 Thank you.

5 MS. BENT: Thank you so much, Susan. I
6 think that that was -- that was really very -- very
7 well said and I think that it is something that we
8 really -- we need -- we need to think about as a -- as
9 a whole and appreciate that.

10 Now we're going to turn back to Demi.
11 We believe we have fixed the audio issues, but of
12 course, on a live webcast, we can't test it. So we're
13 going to -- we're going to cross our fingers and hope
14 that third time is the charm. So Demi, if you want
15 to -- if you want to go ahead, we will -- we'll --
16 we'll cross our fingers.

17 MS. TRICE: Okay. Yeah. That's better.

18 The aspects of my systematic sclerosis
19 that impact my life the most is the tightening of my
20 skin. My skin on my arms, legs, hands, and face are
21 significant. The skin has tightened so much that it

1 causes me to have limited uses of my limbs.

2 I also have Raynaud's, making me
3 extremely sensitive to cold environments. I continue
4 to suffer from digital ulcers which cover many of the
5 areas of my body. I also have calcium deposits.

6 Due to all of these issues, I now
7 suffer from anxiety. Before being diagnosed in 2001, I
8 was a very active person. Now I'm unable to walk for
9 long periods of time. I no longer can put on socks,
10 comb my hair, or open up items. My left hand is
11 contracted, and my right hand has three partial
12 amputations. My feet hurt constantly and I have had
13 one toe removal.

14 All of this has greatly limited my
15 activities. On my best days, I'm still unable to
16 complete simple tasks like eating without adaptive
17 equipment. I still need a lot of assistance, which can
18 be very frustrating.

19 On my worst days, the fatigue is
20 overwhelming. I'm so tired I literally can't get up
21 and take care of my daughter. I'm forced to call

1 family in to make sure my child eats and to stay
2 entertained.

3 Over time, my scleroderma has gotten
4 worse. I now mainly focus on dealing with the
5 calcinosis, which is extremely painful and
6 uncomfortable. I don't have as many complications that
7 cause me to lose digits anymore. It seems my body is
8 at a point where it is adjusting to the trauma it has
9 experienced.

10 I have learned coping mechanisms that
11 seem to be working for me. I've had scleroderma since
12 2001, but I still can't define my sentence as being
13 well-managed. I just learn tricks to make it
14 tolerable.

15 The issue of premature death concerns
16 me the most about systematic sclerosis. If I could
17 change one aspect of the disease, it would be the loss
18 of my digits. I would like to have all my fingers and
19 toes. The loss of my fingers has been a traumatic
20 event for me and has caused me to suffer from
21 depression that I now have to be treated for.

1 To treat my scleroderma, I currently
2 use several medications that only are preventative.
3 For example, Lorvas. It's prescribed to me to make
4 sure my esophagus isn't damaged. I also use non-drug
5 therapies and over-the-counter products. One product
6 that I find the most helpful is Vaseline. I also use
7 chair yoga to relax and stretch my limbs.

8 My treatment regimen has changed over
9 time a lot. I used to take every medication a
10 physician prescribed. But I only found that my doctors
11 were experimenting and are not sure what can help me.
12 Some of the meds cause me to suffer so much that I
13 began picking and choosing which ones I -- that works
14 best for me. I no longer trust physicians as much. Now
15 I ask more questions and advocate for my healthcare
16 plan.

17 The symptoms I would like to be
18 improved or resolved by treatment is the skin
19 tightening. The severe lack of blood flow causes more
20 symptoms like the loss of my teeth.

21 Right now, the only treatment that

1 improves my abilities to do specific activities is
2 pain management. When I'm not in pain, I'm able to
3 function more normally in every-day activities. I'm
4 able to participate, which is more of an enjoyable
5 life.

6 The significant downsides are planning
7 my life around doctor's appointments, surgeries, and
8 home care visits. My ideal treatment would be to take
9 five or less prescription medications, to qualify for
10 more clinical trial opportunities. Also having one or
11 two physicians trained and capable of conducting the
12 majority of my care, instead of me having to see
13 several different doctors.

14 Facts I consider when selecting
15 treatment options are the physician's reviews, the
16 medication reviews, and the side effects. Also my
17 personal feelings of the results after treatment.

18 Another extremely important
19 consideration is the physician's bedside manners. When
20 I think about treatment risk, and treatment risk and
21 improving my symptoms, I would like to preserve my

1 organ functions. That would be worth the risk.

2 But I'm not willing to have a treatment
3 with cancerous-issue risk. If I had to chose between
4 two products, I would prefer a safe product that works
5 somewhat, giving me some levels of real relief.

6 On a lighter note, I'm surviving with a
7 smile on my face and a determination to be an
8 enjoyable person and have an enjoyable life. And I
9 want to thank you for listening and thank the FDA for
10 hosting a public meeting.

11 MS. BENT: Wow. Great. Thank you so
12 much, Demi, and thanks for your flexibility as we --
13 as we kind of trouble shot the -- the audio -- audio
14 issues.

15 So as you guys can hear, these are all
16 some really compelling and diverse experiences on both
17 the treatments and with the scleroderma and systemic
18 sclerosis. And I want to thank all of our panelists:
19 Monica, Anita, Jackie, Susan, and Demi for sharing
20 them.

21 And so as I mentioned before, the

1 discussion questions for this session are first --
2 first two questions are questions for the group. What
3 are you currently doing to treat your systemic
4 sclerosis, how has your treatment regimen changed
5 over -- over time, and why, and what symptoms would
6 you like to see most improved or resolved by -- by
7 treatment?

8 And so -- so right now, I -- I think
9 that -- I don't think we have anybody on the line, so
10 let me -- let me take a moment and turn to the FDA
11 panelists to see if they had any follow-up questions
12 for -- for our patient panelists.

13 Is there anything from the FDA
14 perspective that you wanted to clarify or -- or -- or
15 maybe follow up on?

16 DR. NIKOLOV: Robin, this is Nikolay --

17 MS. BENT: Hi.

18 DR. NIKOLOV: Hi.

19 MS. BENT: Yes.

20 DR. NIKOLOV: Thank everyone for
21 sharing your stories. Again, this pretty much what we

1 wanted to hear, and I think that the purpose of this
2 afternoon topic is mostly to think about how to think
3 about the benefits and the risks of therapies for
4 systemic sclerosis. And I wanted to probe a little
5 bit. Some of the comments that were shared and ask the
6 group, for new products that we may not know about the
7 long-term potential benefit, say for disease, for
8 educational, for slowing the progression of the
9 disease, but, you know, it's possible that based on
10 the mechanism of action and understanding, it may --
11 of action.

12 The question is, how much safety or
13 toxicity would you be willing to take with a product
14 like this? For example, if it causes cancer also, or
15 if it causes heart disease or, you know,
16 cardiovascular disease down the road, so these are
17 some of the uncertainties that we have that we would
18 want you to -- to share with us how you think about
19 products like this.

20 MS. BENT: Jackie, you want to kick it
21 off?

1 MS. LATKA: Sure. I can add that I --
2 it would depend on my health at the time. So for
3 instance, one of the things that my rheumatologist had
4 me take when my disease was progressing so
5 aggressively was the chemotherapy Cytoxan that does
6 have a side effect of cancer.

7 And in looking at the cancer, you know,
8 it's going to be a possibility and not necessarily a
9 yes, that you're going to for sure get it.

10 So I think I would, you know, at the
11 time of my disease and where I was sitting, it was
12 really more of a answer of if I don't try this, I'm
13 probably not going to live.

14 So at that point, the benefit of
15 possibly getting the cancer was a small side effect
16 for where I was at with my disease.

17 MS. BENT: All right. Thank you,
18 Jackie. Let's just kind of go in the order I see on my
19 screen with Susan and then Anita and then if Monica or
20 Demi wants to add anything, I'll -- I'll -- we'll go
21 there.

1 So go ahead.

2 MS. NYANZI: And so actually when I was
3 younger, my scleroderma was pretty bad and I was
4 diagnosed and treated in England. That's where I was
5 first diagnosed.

6 And so they did give me a medication
7 that was part of a cancer treatment. It was called
8 "chlorambucil" at the time. But they had to monitor me
9 very closely, because again, I was still a child and I
10 was still growing.

11 And so at that time, because, again, I
12 was progressing fast, that was the only option they
13 had at the time.

14 So I'm kind of conflicted with this
15 right now. So the scleroderma has kind of come back
16 now after 20 years and I think at this point in my
17 life, I wouldn't risk taking something that could
18 additionally cause cancer.

19 And you hear a lot of these worries
20 happening. As I had mentioned in my notes, we do have
21 someone who's going through that right now. But I

1 think with advances that have been taking place, I'm
2 confident scientists can find alternatives that are
3 less risky, and that will prolong life and give a
4 better quality of life.

5 MS. BENT: Great. Thank you. Anita?

6 MS. DEVINE: I would say that if the
7 treatment is going to cause me more problems, and more
8 severe problems, and mortality issues that I would be
9 reticent to take it.

10 Right now, living with scleroderma is
11 not easy, but I'm living. And so I think that, you
12 know, truly say that I might have such cardiac affects
13 that my heart might be severely compromised or that my
14 kidneys will completely fail, they're close to that
15 now, I don't know that I would be willing to accept
16 that. So now that's pretty much my personal feeling.

17 MS. BENT: Great. Thank you. The -- the
18 audio issue seems to be back a little bit. I'm sorry.

19 MS. TRICE: Can you hear me?

20 MS. BENT: Yes. Perfect.

21 MS. TRICE: Okay. I -- I would kind of

1 like to echo with Anita. I also wouldn't want to have
2 extra trauma done to me. I -- my body's already went
3 through enough. I don't feel like it would be
4 necessary to try something that would just make it
5 worse. So that's pretty much what I want to say.

6 MS. BENT: Okay. And Monica, I just --
7 I don't want to put you on the spot if you don't
8 want -- if you don't -- I mean, you kind of spoke
9 to -- spoke to this a little bit earlier, but if you
10 had anything else to add, I want to give you the
11 opportunity.

12 MS. CICCHETTI: Well, you know, when I
13 was recently diagnosed, I tried a couple of
14 medications and the side effects were horrible. And so
15 at that point, I -- I decided to try without and --
16 and thank God I'm still being able to do it. So I
17 really cannot agree with much in terms of medication.
18 Thank you.

19 MS. DEVINE: I would like to add one
20 thing, and that is if the side effects were treatable,
21 I think we're willing to take a risk. So I think

1 that's an important thing to say.

2 DR. NIKOLOV: Thank you, everyone, for
3 sharing your thoughts. I mean, we get the impression
4 that these are not easy decisions to make for patients
5 or for prescribers, but this is sort of a mutual
6 decision and I -- and I think we on our end also have
7 to think about how to incorporate these considerations
8 and how we assess the benefits and the risks of
9 treatments. Thank you so much for sharing.

10 MS. BENT: Great. Thank you. And let me
11 turn to Shannon to get -- I think we have one comment
12 in -- from the -- from the one who submitted a comment
13 online.

14 And so let me maybe have her -- have
15 her share that share that comment. And then -- and
16 then we'll -- we'll turn back -- we -- I think we
17 might have a few other questions from our FDA
18 panelists.

19 So Shannon, do you want to share
20 that -- that one comment that we got so far?

21 MS. COLE: Sure. Thanks, Robyn. So we

1 did receive one comment from a patient who was
2 describing the treatments that they're currently
3 using. So they are -- they're using a variety of
4 medications for GERD, high blood pressure, severe
5 Raynaud's, digital ulcers, and some neuropathy pain.
6 And they -- they try not to take some of these
7 medications because the side effects are not being
8 able to sleep, itching, and -- and -- but sometimes
9 the -- the side effects are better than being in pain.

10 They've also tried BOTOX and have also
11 used a hyperbaric chamber several times to help with
12 amputation peel, and some laser light therapy which
13 seems to also help the pain and ulcers to heal.

14 And they also stress that their
15 treatment regimen can change according to their
16 symptoms, so it may not be the same thing every day.

17 MS. BENT: Great. Thank you, Shannon. I
18 know that we do have some more questions from our FDA
19 panelists, but I'm going to get everybody kind of -- I
20 don't want to say up and moving, because answering a
21 polling question is not really aerobic activity, but

1 let's -- let's turn briefly to -- to the polling
2 questions to get some feedback from those of you who
3 are online.

4 Again, polling kind of remains limited
5 to the participants who have those experiences with
6 systemic sclerosis or scleroderma, either personal
7 experience or as a family member or -- or loved one.
8 And, too, our panelists who are participating still
9 for -- for the meeting, please feel free to pick up
10 your cell phones or your other -- and -- and share
11 your -- your responses with us as well.

12 And so this is where you're going to
13 find my embarrassing ability to pronounce medications.

14 So "Have you ever used any of the
15 following" -- sorry. I just want to make sure I'm --
16 all right.

17 "Have you ever used any of the
18 following interventions or medical products, drug
19 therapies, or medical devices to treat your systemic
20 sclerosis?"

21 And you can check all that applies for

1 this one. And so the the first are "Medications to
2 modify blood flow, such as Nifedipine." "B" is
3 "Medications that suppress the immune system to
4 prevent organ rejection or to treat arthritis such as
5 cyclosporine or Azathioprine." "C" is "antifibrotic
6 medications for interstitial lung disease such as
7 nintedanib." "D, course steroids for skin and
8 arthritis symptoms such as Prednisone." "E, Proton
9 pump inhibitors for digestive symptoms such as
10 omeprazole." "F, Pain killers such as Vicodin,
11 Percocet, oxycontin." "G, Bone marrow or solid organ
12 transplant." "H, Other medical products or
13 interventions not mentioned," or "I, I'm not using any
14 medical products or interventions."

15 So I'm going to be honest, that was the
16 question I was worried about all day for my
17 pronunciation. So apologies if I got those wrong.

18 All right. So looking at this -- and it
19 is -- it is a little bit difficult to see, which is
20 why you can see that we kind of shortened the --
21 the -- the answers on the survey question, so it looks

1 like the medications to modify blood flow is -- is
2 kind of 22 percent of people. Medications to suppress
3 the immune system, about 10 percent. Two percent are
4 using the antifibrotic medications for interstitial
5 lung disease. We have steroids at about 17 percent.
6 Proton pump inhibitors for digestive symptoms, the
7 omeprazole and such, at 19 percent. 14 percent for
8 pain killers. Not a huge number of people with bone
9 marrow or solid organ transplants. And we have 15
10 percent of people using others or -- other medical
11 products or interventions not -- not mentioned.

12 And that -- that is -- that is helpful
13 for us to know and we will get, in our next polling
14 question we're not going to quite yet, we will get to
15 kind of questions about all -- you know, about
16 physical therapy and diet modifications and counseling
17 and other therapies and -- and over-the-counter
18 medications and things like that.

19 So but right now, this is -- this is
20 just really to kind of give us -- give us an idea of
21 the -- of the treatments that -- that are being used.

1 And I think that that actually kind of leads us right
2 into -- into one of the questions that one of our FDA
3 panelists had about -- let me -- let me turn to
4 Dr. Glaser, because I think you had some questions
5 about -- about GI symptoms, and maybe meaningful
6 improvement?

7 DR. GLASER: -- get both audio and
8 video at the same time.

9 So I will echo my colleagues in
10 thanking all of you for taking the time to speak to us
11 today and describe your experiences living with
12 systemic sclerosis.

13 One thing that we've heard quite a bit
14 about today I think are the different GI
15 manifestations from different panel members.

16 I was wondering what GI manifestations
17 would be most important to develop treatments for? And
18 then sort of a Part B question to that is what would
19 be a meaningful improvement in those symptoms for you?

20 MS. DEVINE: Well, do you want me to
21 start?

1 MS. BENT: Oh, sorry. I was having a
2 great conversation that was deep and profound with
3 myself, because I forgot to unmute, so apologies for
4 that. Yes. If you want to -- Anita, if you want to
5 kick it off and then we'll move on to -- to Susan, who
6 I know touched on this during -- during her talk as
7 well. But go ahead. Thank you.

8 MS. DEVINE: I think, you know, a lot
9 of the issues that have been discussed are esophageal
10 reflux, difficulty swallowing. The problems with -- of
11 the gut and overgrowth of bacteria and all of those
12 resultant in, you know, diarrhea that is so severe
13 that it can be debilitating.

14 So all of those things would be of
15 interest to me, personally in finding some things that
16 would be beneficial. I would love that.

17 The musculature in the gut is some
18 impaired that, you know, that's another issue that
19 hopefully that could be alleviated as well. Thank you.

20 MS. BENT: Great. And before --
21 before -- before I have Susan kind of launch into

1 that, so Anita, would you maybe tell us or maybe give
2 us an idea of what you think would be -- would be an
3 improvement? What would be a meaningful improvement
4 that would make it worth kind of taking -- taking a
5 medication maybe on a daily basis or -- or something
6 like that.

7 Obviously, absent the ability to stop
8 the checked problems altogether, would you -- what
9 would you think would kind of -- I'm meaning, like, a
10 decrease of like 50 percent in the reflux, or, like,
11 reflux only on 50% of days.

12 I don't want to put words in your
13 mouth, but just kind of -- kind of thinking about what
14 you -- what would be a -- a goal for treatment that
15 you would think, "Okay. This is worth -- worth kind of
16 taking."

17 MS. DEVINE: You know, we do have some
18 treatments now, but part of the problem is, you know,
19 the proton pump inhibitors to help a little bit with
20 the reflux, however, the side effects long term are
21 scaring me, and so we are -- we're taking very high

1 doses.

2 So, you know, when I step down therapy
3 and I try to decrease doses, the reflux is untenable.
4 So basically, I'd be looking for something -- even if
5 it was a 50 percent decrease as Robyn said, or 50
6 percent of daily episodes, that would be meaningful to
7 me. I'd be thrilled.

8 I'd be also looking for something that
9 doesn't have, you know, long-term side effects that,
10 you know, have been reporting most recently Type II
11 Diabetes. All these proton pump inhibitors and, you
12 know, all kinds of other issues that are being
13 reported in the literature over the years on high-dose
14 proton pump therapies.

15 So, yeah, I would -- I would love to
16 see some new therapies. Thank you.

17 MS. BENT: Thanks. Okay, Susan, go
18 ahead. Sorry. I -- I didn't mean to cut you off.

19 MS. NYANZI: No, no, no. That's okay. I
20 would definitely like to see treatments for the
21 intestinal tract. Currently there are really no

1 treatments for the intestinal tract. With SIBO,
2 there's a series of five antibiotics you can go
3 through to get the gas down due to the SIBO. But once
4 you've gone through those medications, you know,
5 several times and then they stop working, there really
6 isn't anything else that can be done. So your
7 rheumatologist and your gastroenterologist need to
8 work together to kind of finesse and figure out what
9 else can work for you.

10 So we definitely need medications for
11 the intestinal tract. Tablets or anything else that
12 can get that gas down, you know, 50 percent, that --
13 that would be great. And then also we have lack of
14 absorption.

15 So I have that. Seventy percent of my
16 nutrition is coming from TPN. TPN pretty much saved my
17 life. Other rheumatologists couldn't figure out what I
18 had, but my rheumatologist at UCLA, who is a
19 specialist in scleroderma, figured that out. And
20 that's how I ended up on TPN. Otherwise, I really
21 would have lost -- I had already lost 50 pounds. And I

1 don't think I would have been -- I would be here
2 telling you my story if he wasn't thinking about that.

3 So we also need medication that can
4 help with absorption for those of us who don't -- who
5 can't absorb any nutrients. So those are my points.

6 MS. BENT: Okay. Thank you. Did -- did
7 anybody else want to -- to comment?

8 MS. CICCHETTI: I would like to say
9 something about it. Thank you, Robyn.

10 My point of view is from the holistic
11 type of treatment. I -- I do see doctors regularly and
12 I make -- and I make sure that I'm doing all that
13 they're asking in turn, but at the same time, I --
14 my -- my focus is a lot on -- on lifestyle.

15 And it is interesting we have this
16 parasympathetic nervous system which is also called
17 "rest-and-digest system." And this is the part that
18 strengthens our immunity.

19 Before my diagnosis, I was working two
20 jobs and going to school. And I literally never
21 stopped Monday through Sunday. And so, you know, after

1 scleroderma, I started to value my sleep and to have
2 some more of a peaceful life. And my digestive
3 problems improved a lot.

4 And there's many tricks that I've
5 learned. Regarding diet, I am -- I observe my diet
6 very closely. But for instance, there are -- in foods
7 that I eat and give me heartburn. And I found out that
8 if I eat something that gives me heartburn in a empty
9 stomach or without any other food, then I have more
10 problems.

11 But I -- I got to understand more my --
12 my body and learned that if I have this together with
13 this other type of food, and usually try -- combining
14 protein and veggies and carbs. And if I get a balance
15 that my body likes of this food -- types of food, then
16 my heartburn goes way down almost to nothing. So that
17 -- that can also help.

18 Antibiotics. I did try antibiotics for
19 SIBO first. The problem with antibiotics is that
20 they -- they kill the bad guys and the good guys in
21 your -- so it's a double-edged sword and I -- I tried

1 another alternative.

2 MS. BENT: Great. Thank you -- thank
3 you so much. I think that that's -- that's helpful.
4 And I think that -- it sounds like you're going to
5 have a lot to kind of add to when we get to your next
6 polling question that those talk about kind of the
7 more -- the -- the non-medical -- or the non-
8 medication kind of based -- based treatment.

9 So at this point, I would like to --
10 I'd like to kind of turn to Shannon and see if she can
11 give us kind of a summary or a overview of the
12 comments that we're receiving from those of you who
13 are participating and providing comments through --
14 through the web comments.

15 Also, this would be a great opportunity
16 for me to put in a plug for those of you who would
17 like to give us a call and kind of share your thoughts
18 to -- to do so. So let me -- let me turn to -- to
19 Shannon. Shannon?

20 MS. COLE: Thank you, Robyn. So we are
21 getting several comments about treatment options

1 that -- that participants are using. One participant
2 said they're using Flolan and Veletri infusion for
3 Raynaud's and a high blood pressure medicine for blood
4 flow.

5 They're also using Cymbalta for nerve
6 pain and depression as well as Botox injections for
7 Raynaud's in their hands.

8 A few participants also mentioned
9 proton pump inhibitors and -- and one of them said
10 that the fact that proton pump inhibitors inhibit the
11 absorption of calcium is a huge issue for women. A way
12 to have a treatment with proton pump inhibitors
13 without the side effects of less calcium absorption
14 would be great.

15 We also received a comment from someone
16 who -- who was using GI systems and strategies to deal
17 with fecal incontinence. And some other recommended
18 lifestyle adaptations.

19 In addition to medication, one
20 participant listed they -- they did not eat late at
21 night. They have some dietary changes and are doing

1 their best to keep their core as well as extremities
2 warm for Raynaud's. And in -- in their current
3 condition, they would be wary of a long-term
4 medication that dramatically increased their chances
5 of cancer or cardiovascular issues. But if they're in
6 a bad situation, they're -- they're viewpoint on that
7 may change.

8 MS. BENT: Thanks so much, Shannon.
9 That was really -- that was -- that was helpful. And
10 thank you to all of you who are providing comments
11 via -- via the web.

12 At this point, I'd kind of like to --
13 we're going to -- we're going to take a little bit of
14 a turn. I'm going to go back to something we -- we
15 heard a little bit earlier in the day from -- from our
16 first panelist, which really, the challenges of
17 dealing with kind of fatigue.

18 And we heard it from you guys as -- as
19 well. There's -- there's a lot of -- lot of fatigue
20 that comes with it. And so let me turn to one of our
21 FDA panelists, Dr. Hull, to really kind of -- to

1 ask -- to ask his -- a question that I think we're
2 all -- we're all kind of interested in -- in hearing
3 your -- your thoughts on. So, Dr. Hull?

4 DR. HULL: Yeah. Hi. I would also like
5 to start by thanking all of the panelists for joining
6 today. This has been a -- very helpful from our point
7 of view for reviewing.

8 One thing that we commonly review in a
9 lot of different applications, including scleroderma,
10 is fatigue. And we hear a lot about patients with
11 fatigue.

12 One of the problems we have is how do
13 you assess it? Someone just saying it, so my question
14 to you -- and it's been a common theme for all the
15 patients, is how do you assess fatigue? For instance,
16 is it every day you're kind of running at half
17 battery, you know, half full, or does it come in
18 waves? It's only a couple days out of the week?

19 And if you were in a clinical trial,
20 how would you assess that? Would it be, you know,
21 questionnaires? How do you feel from day to day, and

1 do you think you benefit from how you feel looking
2 back at a week?

3 Just give us an idea so that if we
4 could do something as series as fatigue that we could
5 see that there was a clinical need for improvement in
6 it. Because --

7 MS. BENT: So if you -- Anita, I see
8 you unmuted, so -- so I'm assuming that means you'd
9 like to -- like to answer the question. So we would --
10 we really appreciate your thoughts on this.

11 MS. DEVINE: I -- you know, I do suffer
12 from chronic fatigue. It is a daily issue. I fight it
13 tooth and nail as best I can. I try to -- but you know
14 what, if the fatigue is scleroderma, it's like you hit
15 a brick wall.

16 I'm a Type A personality. I have always
17 been extremely busy. And there -- you know, the
18 scleroderma has caused such problems for me that just
19 about every -- I'm done.

20 And, you know, I would like to be able
21 to say that, you know, we had a longer day, not

1 fatigued. I would like to wake up not tired. I would
2 like to feel rested after a week. None of that occurs
3 for me and I -- I imagine it's probably --

4 MS. BENT: Okay. Thanks, Anita. I'm not
5 sure if you're still speaking. I'm finding there's
6 a -- I think you're having a little bit of an audio
7 issue and you're a little frozen. So -- so I'm going
8 to move on to -- I think Susan has unmuted and is
9 going to -- going to speak, and we'll come back to you
10 if you -- if you have anything else to say after Susan
11 is done. But Susan?

12 MS. NYANZI: Yes. So I go through bouts
13 of tiredness, so kind of go through what everybody is
14 saying. You know, you can sleep for 10 hours, but then
15 wake up tired. And you're dragging throughout the
16 whole day, from morning, lunch, dinner at night.
17 You're just dragging throughout the whole day.

18 And so I used to have this, most of the
19 time, for a whole week. And so it can come on and off.
20 For me, it used to be part of my diet, so I changed
21 that. But I know with scleroderma, you can have really

1 bad fatigue. And I've experienced that as well.

2 So I think, you know, you're talking
3 about in a clinical trial and how you can measure that
4 meaningfully, and I think assess it during a whole
5 week and see how people feel or have them describe
6 what they're going through when they're going through
7 the fatigue.

8 So it isn't just regular fatigue. I
9 mean, you are really drained. Your whole body is
10 drained. You know, even just going to get something to
11 eat from the kitchen, that is draining to do. So
12 everything you're doing is draining.

13 I hope that makes sense.

14 DR. HULL: I had one other question and
15 it's is there a symptomatic difference between fatigue
16 and the brain fog that you mentioned, or is that kind
17 of a combination of the two?

18 MS. NYANZI: Oh, no. It is different.
19 Brain fog, you can definitely see that one. That's
20 when you can't think what -- I didn't say that
21 correctly.

1 But you have difficulty thinking, so
2 cognitive function is going to be down, and then
3 trying to put concepts together, that is hard. Hard to
4 do. So, yeah, brain fog is definitely different from
5 fatigue.

6 And also with the brain fog, you can
7 forget what you were doing and don't remember why
8 you're doing what you're doing. So if you're working
9 in a work environment, that's very challenging to do,
10 to keep your work doing and -- and think appropriately
11 at the tasks that you are asked to do.

12 MS. BENT: Thank you, Susan. Anita, I
13 want to kind of circle back to you and see if you had
14 anything else to add or if you had completed your
15 thoughts when -- when I -- when I lost your audio.

16 MS. DEVINE: Did you say "Anita"?
17 Sorry.

18 MS. BENT: Yes.

19 MS. DEVINE: Okay. I guess the one
20 thing I would add for Dr. Hull is that when you're
21 trying to measure outcomes and -- and whether or not

1 some things actually helped, I guess I'd be looking at
2 the amount of fatigue experienced daily and are you
3 able to accomplish the things that you have set out to
4 accomplish.

5 In other words, quality of daily
6 living. Have you been able to have acceptable quality
7 of living, which was nearly rated because you had less
8 fatigue.

9 So that would be major to me.

10 MS. BENT: Thanks, Anita. Very helpful.
11 I -- did anybody else want to add -- add something?
12 Monica?

13 MS. CICCHETTI: Yes. In my case, I find
14 they both happen at the same time. Many times when I
15 wake up tired and I'm tired all day long, at night
16 it's unsustainable. I -- and that's when I -- I have
17 brain fog and I -- I can't talk. I can't find words. I
18 can't think clear. It's really bad. I -- I cannot
19 stand without holding myself on a chair or a table,
20 something -- a wall, because I get dizzy. So it's
21 really bad.

1 MS. BENT: Okay. Thank you. And Dr.
2 Hull, I don't know if you want to circle around,
3 or ...

4 DR. HULL: Thank you, all for those
5 answers. That was great.

6 MS. BENT: Great. Thank you. And so
7 Shannon, I wanted to turn to you because I think that
8 we're getting some comments from -- from our online --
9 I guess everybody's online, but from -- from our --
10 from our online comments about -- about this.

11 Did you want to share a little bit with
12 us?

13 MS. COLE: Yeah. So we are receiving
14 some comments online about the brain fog and fatigue
15 and one participant phrased it as "Brain fog is when
16 you know that you know the answer, but you can't
17 access it."

18 And another -- another participant
19 mentioned they measure fatigue in spoons -- so the
20 spoon theory. They never know until they wake up how
21 much energy they'll have for the entire day and their

1 energy can tank out at any time.

2 Sometimes it's just from physical
3 activity. Some of it is from over-stimulation. Some of
4 it is from emotional fatigue and some of it is anxiety
5 related.

6 And this person said they usually
7 expect that after doctors' appointments they will need
8 to rest. They said that anti-depressants can help
9 reduce fatigue and cut through brain fog a little bit,
10 but never completely.

11 MS. BENT: Great. Thank you. And so I
12 wanted now to -- to turn to the phone and I think we
13 have -- we have two callers on the phone who want to
14 share some experiences with us.

15 Let's start with Noel, and I'm not sure
16 whether you're from Los Angeles or Louisiana, but
17 we'll -- we'll get -- we'll start with you and then
18 we'll -- we'll move on. So thanks so much for calling
19 us.

20 NOELLE: Hi. My name is Noelle and I am
21 from Los Angeles. I went from diagnosis with diffused

1 systemic scleroderma to a oncologist told me about a
2 stem cell transplant in five months.

3 I was progressing aggressively and
4 about two and a half years after my transplant, I had
5 a severe allergic reaction to an injectable migraine
6 medicine that put me into kind of a tailspin that I'm
7 in right now, and I am progressing once again.

8 I am a young -- I am a mother with five
9 kids, four young kids still at home. I know -- I've
10 listened to the panelists and I know a lot of them
11 have talked about their -- their hesitance to have
12 more risk, but as a young mom with -- especially with
13 a child that I have that has a rare disease himself
14 with only about 355 cases in the U.S. I am -- I need
15 to be around for my kids. I need to be around for my
16 family.

17 And so, you know, I've had scleroderma
18 renal crisis. I have interstitial lung disease. I've
19 got -- pain now, that turns it on that is extremely
20 painful, making everyday living difficult. But I'm
21 willing to take risks if there is a medicine out there

1 or if there is something in the pipeline that's
2 coming, even if it has more risks than what others
3 might be able to -- to do.

4 So I'm just -- my question out there
5 is, besides, you know, CellCept, the Rituxan, the
6 Cytoxan, is there anything else out there that will
7 slow the progression of this disease?

8 Thank you for allowing me to share.

9 MS. BENT: Okay. And thank you -- thank
10 you for calling in, and I think that that's a --
11 that's a great question. And -- and so now we're going
12 to -- we're going to move on to a caller from San
13 Diego. Kristina? Yes. Kristina, so that she can -- she
14 can share some of her experiences as well. I think
15 we're -- we're talking about brain fog and -- and
16 pain. Right Kristina?

17 KRISTINA: Yeah. Yeah. So I -- I was
18 actually the one that sent in the comment about spoon
19 theory. And it's, like, you know, every day we -- we
20 would think that we would start the day with a certain
21 amount of energy. Unfortunately, we never know and so

1 someone actually stated this a while ago, where if
2 they, like, using up a certain amount of energy, we
3 call that a spoon.

4 And so there will be days that we get
5 to where we've used up all of our energy. It might
6 only be three o'clock. And that's it. You know, we are
7 down for the rest of the day.

8 But something else I -- that I say is
9 that like from brain fog, there's also pain fog and
10 pain somnia. So, you know, I've been -- last year,
11 I've been diagnosed for about 14 months now. I spent
12 most of last year with pericarditis. I have my
13 hospital stays. The medical bills are out of control.
14 That is one thing.

15 Like, we do need care that is not going
16 to bankrupt us all, you know, and that's -- that's
17 really what's hard and heartbreaking about living here
18 in the United States.

19 But, like, we -- you know, I was in and
20 out of the hospital for most of last year with cardiac
21 issues before we even found out that I had

1 scleroderma, before that diagnosis even came in.

2 And I didn't realize, because, you
3 know, I was trying so hard to keep up my life. Like, I
4 was an audiologist. I was trying so hard to make it to
5 work every day, that that's what your entire household
6 revolved around, was getting me to and from work for
7 those eight hours, and part of it is because that's
8 where my insurance was coming from.

9 And also because I loved my job, I
10 loved my patients. And -- and so, you know, I look
11 back and I honestly don't -- there's a lot of days
12 that are very -- I'll put it that way -- there are a
13 lot of days that that pain level is so high that if
14 you look back at it a year later, you're like, I don't
15 know. I -- I just don't know.

16 And -- and some of that comes from the
17 brain fog; some of that comes from the pain. I think
18 the pain also can result in mood changes. So you can
19 end up being a lot shorter with people and irritable
20 with people when normally that's not your personality
21 and that's not how you are and that's a really hard

1 thing to experience, too, because you don't want this
2 condition to change who you are as a person at your
3 core.

4 And I think, you know, spending that
5 time being mindful and meditating and being, you know,
6 outside as much as you're able or spending time with
7 friends and loved ones and your support group is
8 really important to keep those changes from happening.

9 The other problem is the insomnia. So
10 when you are in so much pain that it keeps you from
11 sleeping. And not something that, you know, it's --
12 it's really hard to regulate and now, it's -- it's not
13 very common that I get through a day without a nap,
14 you know.

15 And that's not something that's
16 conducive to working an eight-hour workday in most --
17 most jobs. Like, I'm 35, you know, and so the
18 expectation is, oh, yeah, you're going to be at work.
19 You know?

20 And that's not the reality. And
21 especially now with COVID. Like, I had to resign from

1 my job because of the high risk. And there were no
2 contingencies for those of us with scleroderma and
3 other high-risk conditions or how are we going to
4 support you and help you through this by the
5 government, and I think that part, for me, was really
6 upsetting.

7 Like, everybody that is high risk is
8 not necessarily over 65. There are high risk people
9 that they don't have diabetes, they don't have high
10 blood pressure. You know? There are other forms of
11 high risk, and I think more people need to recognize
12 that, and recognize that this is a disabling disease.

13 It's rare and it is very difficult to
14 live with, like all of our panelists have -- have
15 explained. And it -- just it can come on fast and hard
16 and you don't know what is going on until it's already
17 set in.

18 And that takes a while to wrap your
19 head around and accept, and so there needs to be a lot
20 more support. And I think doing things like this now
21 are wonderful so you all can understand our day-to-day

1 is extremely difficult. And we need more people to
2 know that and help accommodate that, because that is
3 going to keep us in more of the social model of
4 disability as opposed to just the medical model of
5 disability. Thank you.

6 MS. BENT: Thank you. And I think -- I
7 think what you're speaking to is really what -- what
8 we're all kind of -- I mean, for -- for those of us
9 who are not patients with systemic sclerosis and maybe
10 those of us who are -- are not experts in the field,
11 and I clearly put myself in -- in that. I'm not one of
12 the reviewers from the medical division.

13 I think what you're stating is really
14 what's becoming very clear to those of us who are not
15 experts, which is -- you guys are doing an amazing job
16 kind of getting through -- through the -- through the
17 days, trying to -- like, with -- not letting us see
18 all of the challenges of this disease, but it's really
19 becoming, I mean, it's -- it's obvious that this
20 has -- this disease has - this condition has -- has
21 huge implications for -- for -- for you and the -- the

1 quality of your life and how you're able to get
2 through -- through your days and so I -- I really -- I
3 really -- I really thank you guys all for -- all for
4 calling in and kind of sharing these experiences with
5 us as well as our -- our panelists who are really kind
6 of setting -- setting the stage for -- for everybody.

7 At this point, I would like to -- I
8 would like to turn to Dr. Schreiber from -- one of our
9 FDA panelists who I think she wanted to -- to ask us a
10 question. And so let me -- let me turn to her and --
11 and go ahead.

12 DR. SCHREIBER: All right. Thank you so
13 much. I want to echo what all of my colleagues have
14 said, which is to thank panelists for participating.
15 It's very informative.

16 So I know we heard from Noelle and
17 Jackie who had shared their experiences with stem cell
18 transplantation, but it didn't appear as though any of
19 the other responded to the poll has reported
20 transplant as a medication option they had undergone,
21 and I was curious as to the reason for this.

1 Is this because it hasn't come up in
2 discussions with your rheumatologists? Is it because
3 they didn't know that it was an option, or because
4 your disease state wasn't severe enough, or if it had
5 been presented to you as an option, is it something
6 that you didn't want to pursue or is it because the
7 benefit risk profile didn't seem sufficiently
8 favorable to you?

9 Thank you so much.

10 MS. BENT: So let me -- let me --
11 first, let me ask people who are online if you have
12 comments on this, please give us a call or -- or type
13 in -- type in your comments.

14 And now let me turn to our panelists
15 and see if any of you who have not undergone a
16 transplant have -- have any thoughts or want to --
17 want to share any of your -- your thoughts on -- on
18 that.

19 Again, you certainly don't have to
20 share thoughts if you don't -- don't want to, but if
21 you have thoughts, please let us know.

1 Demi, did you -- did you want to
2 unmute? Sorry. I didn't mean to put you on the spot.

3 MS. TRICE: Yeah. I unmuted.

4 MS. BENT: Okay. Good.

5 MS. TRICE: I have not undergone that
6 treatment. The reason why I didn't undergo that
7 treatment is because I've heard from other people it's
8 like a 50/50 where some people it helps, some people
9 it doesn't help, and because I'm already in enough
10 pain, I didn't want to risk putting myself in a
11 situation where I could have additional pain or
12 additional complications.

13 So I didn't even attempt to try to get
14 it.

15 MS. BENT: Okay. Thank you. Did anybody
16 else have -- have any thoughts?

17 MS. LATKA: Can I just add one thing
18 also on that, even though I've had one? So I had
19 mentioned -- so I have local doctors here, local
20 rheumatologists and they were very much against me
21 getting the transplant because I had mentioned it to

1 them as an option.

2 And then when I did go see the other
3 doctor in another state, and that was the only option
4 she gave me, they were a bit more open to it, but
5 very, very leery of it because of the mortality rate
6 at the time.

7 And one other thing, too, is I think
8 that -- or at least what I have been told and in my
9 research what I found out is there are certain
10 requirements that you have to have in order to get the
11 transplant. I don't know specifics on all of the
12 requirements, but at least one for myself was your --
13 your DLCO of your lungs could not go below 40 percent
14 in order for you to survive the transplant.

15 MS. BENT: Okay. Thank -- thank you,
16 Jackie. Before we move on to the polling questions,
17 let me just stop and say is there anything anyone else
18 would like to add or else we'll -- we'll move on to
19 our -- to our next set of -- of polling questions.

20 So all right. So it looks like for
21 those of you online who have thoughts on this, whether

1 it's why you chose a transplant and -- or why you
2 didn't chose a transplant, if you want to share those
3 with us in the comments or maybe if you feel open to
4 talking about as part of your submission to the
5 federal docket, we would -- we would really -- we
6 would appreciate that.

7 But now we're going to move on to
8 our -- our next polling question, so -- and we're
9 going to do two somewhat in -- in kind of rapid
10 succession because we are -- we are coming kind of up
11 on the -- the tail end of our meeting, and I want to
12 get through -- get -- get kind of everybody's thoughts
13 on these.

14 So the first -- the first question is
15 "For medical products or interventions that you
16 use" -- wait. Sorry. Okay. Sorry. I skipped -- I
17 skipped one. Sorry. Okay.

18 "Besides the medical products or
19 interventions mentioned previously, what else are you
20 doing to manage your systemic sclerosis?" And this is
21 also a check all that apply with "A" being "Over-the-

1 counter medications such as ibuprofen or
2 acetaminophen." "B, Lotions or moisturizers." "C,
3 Physical therapy and exercise." "D, Diet modification
4 such as the keto diet, the paleo diet, vegan diet, et
5 cetera." "E, Counseling or psychological treatment."
6 "F, Other therapies not mentioned." Or "G, I'm not
7 taking any therapies to manage my systemic sclerosis
8 or scleroderma."

9 And so let me see. Okay. And I think
10 that this kind of -- this looks to be pretty
11 consistent with what we -- we heard so far from --
12 from the -- from this -- from our panelists and from
13 our callers as far as most using over-the-counter
14 medications and moisturizers, physical therapy and
15 exercise as well as dietary modifications.

16 And I know we listed very specific
17 diets and I know that from what we heard today, it
18 sounds like everybody kind of has -- has found the
19 diet that works for them and it might be a hybrid of
20 multiple different diets that -- that really kind
21 of -- kind of work for them.

1 But it looks like we -- we are
2 seeing -- seeing a lot -- a lot of use of the over-
3 the-counter medications, moisturizing, physical
4 therapy, diet modifications. Some -- some counseling
5 or psychological treatment and then other -- other
6 therapies not mentioned.

7 And so let me turn to -- to Shannon and
8 see, Shannon, did -- do we have any comments about
9 kind of the other therapies?

10 MS. COLE: Yes. So we did receive one
11 comment from a participant who is using other
12 therapies and listed a few, such as the warm -- a warm
13 water therapy pool, massage, pelvic floor therapy,
14 water aerobics, building a strong support system,
15 having a different mental outlook, and kind of taking
16 quality over quantity. Asking for help when they need
17 it, learning to let things go, yoga and stretching,
18 and bible time.

19 MS. BENT: Excellent. Thank you. Thank
20 you. And so now let's move on just -- just kind of
21 to -- to the next polling question, which is "For the

1 medical products or interventions that you use, what
2 styles of treatment bothers you the most?"

3 And maybe this is kind of a leading
4 question because we're asking you what bothers you.
5 Obviously, there are benefits for the treatments, or
6 you would not be using them, but -- but in this case,
7 we're just trying to figure out what -- what are --
8 what are the things that are -- are the things that
9 bother you the most.

10 And you can choose up to three answers
11 for that with "A" being "How the medication is
12 administered, such as a topical cream, an injection,
13 or an oral medication." "B, The treatment only
14 provides minimal benefits." "C, The treatment is
15 effective only for a short term." "D, Bothersome side
16 effects of the treatment." "E, Concerns about serious
17 risks of the treatment." "F, Uncertainty about long-
18 term effects of treatment." "G, Difficulty in
19 accessing the treatment, such as insurance or
20 physician referral." Or "H, Other negative impacts not
21 mentioned."

1 Okay. And so -- so looking here, it
2 seems like the -- the majority of challenges are that
3 the treatment provides minimal benefits, the side
4 effects can be bothersome, and there's some concerns
5 about -- about the risk of -- of the treatment.

6 And, of course, we have heard from --
7 from people who have called in already today and from
8 our panelists about some of the challenges. Did we
9 lose a response? Okay.

10 So looks like maybe we lost one of the
11 responses, but -- but that's okay. This will -- this
12 will still give us a good -- good information. It
13 still looks like the treatment only provides minimal
14 benefit and the concerns about the serious side
15 effects are -- are helpful to -- helpful for us to
16 know.

17 And so I don't know if anybody wants to
18 give us a call and kind of share some thoughts with us
19 about -- about this or maybe share some comments
20 online. I know we are -- we are coming up to -- to the
21 end of -- of -- of the meeting, and I did want to kind

1 of move the -- into kind of our final -- our final
2 polling question, which is really a hypothetical
3 scenario.

4 And we've talked a lot about this, but
5 I think it would be helpful for us to just kind of put
6 this all into context and kind of wrap everything that
7 we've talked about during this session today into --
8 into this final hypothetical scenario, and I think
9 that I have to read the entire hypothetical scenario
10 to you -- oh, no. I don't. Excellent.

11 So I will read it, but it looks like --
12 we wanted to put a lot of checks in again, we found
13 out we had some technological challenges with that, so
14 here's the hypothetical scenario.

15 "So imagine that a new self-injectable
16 medication indicated to treat systemic sclerosis has
17 recently been approved by FDA. Your doctor believes
18 that you may be a good candidate for this medication.
19 IN the clinical trials that were conducted, the
20 medication was shown to reduce the symptom that most
21 significantly impact your daily life when injected

1 once weekly.

2 More common side effects of this
3 therapy may include headache, diarrhea, nausea,
4 stomach or abdominal pain, and weight loss. Rarer, but
5 it's more serious side effects may include infection,
6 seizures, trouble breathing, fever, general feeling of
7 discomfort or illness, and risk of bleeding.

8 And so given these risks, would you
9 take -- would you take this medication?"

10 And so your options are, "Yes, No," and
11 "Maybe."

12 And so -- so I think that one of the
13 things that we're going to -- that I -- I want to kind
14 of ask about is does your acceptance of potential
15 safety risks go up with potential effectiveness of the
16 product?

17 And so -- so, okay. So we're seeing
18 that about -- I'm just going to give it a second,
19 because I know there's a -- there is that 20 second
20 delay in -- in getting the responses. But we're
21 being -- I've had half of the people give or take are

1 on the yes side. Maybe about -- all right. So -- so
2 it's flip-flopping between yes and maybe. We don't
3 have some -- some absolute no's, and I think that
4 that -- that's really -- that's really helpful --
5 helpful for us -- us to -- to understand, and I think
6 that Susan really kind of touched on this earlier,
7 because I think we're talking about are we treating
8 symptoms or are -- or are we actually, you know, is
9 this -- is this going to -- is this going to work on
10 symptoms, or is this going to actually work on the
11 disease itself.

12 And so I think that that -- that --
13 that might -- that might kind of impact the -- the
14 decision as well. So let me -- let me kind of turn
15 to -- to our panelists and maybe ask a quick question
16 right as we're kind of wrapping up, which is like, can
17 you guys share with me any idea of what an ideal
18 treatment might look like for you?

19 What would -- what would an -- what
20 would -- what would an ideal treatment kind of be?
21 Would it be something oral? Would it be something IV?

1 Would it be something that you took once a month or
2 once a day? What would it treat? Maybe just give us a
3 little idea of -- absent a cure, which, of course,
4 would be -- would be wonderful, but what would -- what
5 would an ideal treatment kind of look like?

6 I don't know if any of you have -- have
7 any thoughts on that that you haven't already shared?
8 Demi, go ahead.

9 MS. TRICE: For me, once a week or once
10 a month treatment would be good. That would help. I
11 have a family, so I'm constantly on the move and
12 constantly have to be active, and I volunteer a lot.

13 So I would like something that would be
14 convenient. The easier, the better. If I could self-
15 administrate, it would be better. Going to the
16 doctor's office, having another appointment would not
17 be something that I'd be looking to do, but I would do
18 it as long as it didn't have anything that would be
19 like a fatal result from the treatment, I would be
20 willing to take it.

21 MS BENT: Okay. Thank you. Anita?

1 MS. DEVINE: I would be looking if
2 possible to an oral medication. I think that many of
3 us with scleroderma have very bad veins and IVs are
4 pretty traumatic for us, so that is an issue as well
5 as, you know, the fact that you have to go in to get
6 the IV. An inconvenience.

7 I'd also be looking at the regimen. Is
8 it multiple times a day, is it once a day, because
9 that does impact compliance and -- and ability to
10 really be successful. So that's my thought.

11 MS. BENT: Great. Thank you. Susan?

12 MS. NYANZI: I'm open to medication,
13 tablets and now that I've been with the PICC line for
14 four years, I'm open with infusion as well. Again, if
15 that can be self-administered at home, I have to clean
16 my PICC line every -- every day, twice a day. I would
17 be open to that.

18 MS. BENT: Great. Thank you. So can
19 I -- I'm going to go a little off script here, but it
20 would just be helpful for me, too, because I don't
21 know -- I didn't really -- I didn't talk about this,

1 but I'm -- I'm a nurse, and so I was wondering, when
2 you guys are -- have talked about the IVs and the
3 difficulty of getting IVs and things, do you -- do you
4 experience the same degree of difficulty of similar
5 degrees of difficulty when you're getting just a
6 regular blood draw, or is it really -- is it really
7 the -- or is the IV really the -- the more -- more
8 challenging? And so just -- go ahead.

9 MS. TRICE: Really, it's just any of
10 it. The blood draws, sometimes I have to get stuck
11 five times. Sometimes my veins won't allow the tubing
12 to go through because of the tightening, so it's any
13 of it. So it's not necessarily just one way; it's both
14 ways.

15 I don't even like to go get my blood
16 drawn anymore. I try to have them do all tests at one
17 time so that I don't have to be subject to that kind
18 of pain again.

19 MS. BENT: Okay. Thank you. And I think
20 that that's really something that we -- we -- you
21 know, as people are designing clinical trials, and

1 obviously we need -- there needs to be monitoring for
2 safety and things like that, but -- but your comment
3 about kind of trying to cluster the blood draws or --
4 so that they're -- they're really the -- you know,
5 it's as -- as few as possible, really, I mean, it kind
6 of -- it kind of resonates with me and so I hope that
7 it resonates with some of the -- the rest of -- of the
8 people watching as well because I think that this is
9 where we have the opportunity to hopefully do -- do
10 our -- do our best to make things as -- as simple as
11 possible for people who are -- are -- are
12 participating in -- in -- in research and things like
13 that.

14 So let me, as kind of my -- let me
15 first of all thank all of you so much for -- for your
16 thoughts and your -- your -- your feedback and I
17 just -- I want to turn in the last moments -- and I
18 know I've gone a few minutes over, so I apologize --
19 to Shannon, who has a few more comments from online,
20 and then we will turn to -- to Dr. Nair for -- for his
21 closing remarks. Shannon?

1 MS. COLE: Yeah. So we have received a
2 few comments about the hypothetical scenario and one
3 participant said that they are willing to try a new
4 drug as long as they can stop taking it if the side
5 effects outweigh the symptom management.

6 And another participant mentioned that
7 tablets are a challenge with sclerodactyly hands.

8 And then another -- another participant
9 mentioned that they -- they would appreciate if the
10 treatment decreased or minimized their fibrosis. And
11 that would be what they would look for in an ideal
12 treatment.

13 We actually just got another comment
14 about your question, Robyn, for the blood draw. And
15 this participant said a single blood draw for me is
16 fine, but when a longer term IV is needed, they have
17 had to have a guided wire IV, which is horrible, and
18 they ask for an ultrasound-guided usually from the IV
19 team.

20 MS. BENT: Excellent. Excellent. Thank
21 you so much, Shannon, and again, thank you -- thank

1 you to our FDA panelists who -- who are here and to
2 our -- of course, our patient panelists both for the
3 first and second sessions. And -- and to, again,
4 Shannon and Lyna who have done all the work behind --
5 behind the scenes while I've been on this camera.

6 So let me turn this over now to -- to
7 Dr. Nair who is going to provide us with some closing
8 remarks. Thank you.

9 DR. NAIR: Good afternoon, and thank
10 you for the opportunity to share closing remarks of
11 what we heard today. The perspectives and insights you
12 have shared allow me to approach my role with a better
13 idea of complex needs of the scleroderma patient
14 community.

15 We from the FDA are often tasked with
16 review of different measurements to assess scleroderma
17 disease activity and studies to evaluate treatments
18 for scleroderma. It is critical for us to better
19 understand the patient perspective when assessing the
20 outcomes for systemic sclerosis that appropriately
21 capture the patient's perspective.

1 Scleroderma is a complex medical
2 condition that affects so many organ systems, and
3 consequently can affect so many aspects of people's
4 lives. Thank you for participating today in this
5 meeting and for sharing your stories and experiences.

6 We heard the stories today of how
7 scleroderma can decrease the ability to participate in
8 activities such as the ability to play the piano or
9 participate in dancing. We heard how life plans have
10 to be changed, including stopping a business, losing a
11 job, or having to stop college in order to take care
12 of scleroderma.

13 We heard about how Raynaud's cold
14 intolerance and pain is severe and patients physically
15 have to relocate to warmer locations in hopes of
16 making the symptoms better, but knowing that the pain
17 will not completely go away. We heard about how
18 paralyzing the pain from calcinosis is and that there
19 are very few options in being able to alleviate the
20 pain.

21 Many activities that people take for

1 granted on a day-to-day basis have to be planned
2 carefully, including social activities, food to eat,
3 and planning for travel in order to avoid
4 complications of scleroderma.

5 We heard about using ingenuity to work
6 around the issues complicating scleroderma, including
7 straw and tape to pick up coins, modifications to door
8 knobs, and methods to extract calcinosis.

9 We heard about how the fears of
10 developing new symptoms and dying earlier are major
11 concerns with this disease and we heard about how
12 support groups and education about scleroderma have
13 been very helpful in coping with scleroderma.

14 Patients are experts in their
15 condition. The ability to hear what is most important
16 to patients with regards to symptoms, daily impacts,
17 and currently available treatments for scleroderma can
18 help FDA and other stakeholders to facilitate medical
19 product development as well as understand how patients
20 view the benefits and risks of therapies and devices
21 for scleroderma.

1 You all have identified a lot of key
2 issues today. Among them we heard that pain is a
3 significant issue with scleroderma, which can be from
4 multiple sources. These include muscle and/or bone
5 pain, excruciating pain caused by calcinosis and pain
6 caused by digital ulcers.

7 Digital ulcers have been a problem in
8 themselves because they can also lead to loss of
9 fingers and toes. We have heard about digestive
10 symptoms, which limit the types of food that can be
11 eaten and also the amount of food. We heard about only
12 being able to eat once a day. We heard about how
13 reflux requires significant medical intervention just
14 to keep under control. We heard about issues with
15 malabsorption and incontinence due to scleroderma
16 complications.

17 The fatigue is unpredictable and can be
18 severe leading to days where it is impossible to get
19 out of bed and can limit activities that were
20 previously routine.

21 Other key issues include shortness of

1 breath, requirement of oxygen, and damage that
2 scleroderma inflicts on organs like heart, kidneys,
3 and lung.

4 As FDA continues striving to
5 incorporate patient perspective more broadly into
6 medical product development, meetings such as this
7 scleroderma meeting you have participated in help
8 enhance our understanding of the patient perspective
9 and assist in moving the science of patient input
10 forward.

11 This input is valuable for FDA's drug
12 review because it helps provide the underlying
13 clinical context about the severity of the disease and
14 currently available treatments. This context is
15 necessary to take into account when assessing whether
16 drugs benefit outweighs its risk.

17 This kind of dialog is extremely
18 valuable, not only for FDA, but also industry,
19 academia, and other medical product developers in the
20 room and on the web. The perspective shared today can
21 help stakeholders identify areas of unmet need in the

1 patient population, identify or develop tools that
2 assess benefit of potential therapies, and also raise
3 awareness and channel engagement within the patient
4 community.

5 Involving patients through the direct
6 drug development process has the potential to
7 strengthen the process and improve the science.

8 Once again, thank you for your
9 participation and sharing your perspectives with us
10 today.

11 In addition, I would like to thank
12 everyone involved in planning this meeting. Thank you.

13 (Whereupon, the meeting concluded at
14 2:32 p.m.)

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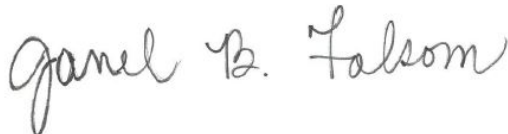
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1 CERTIFICATE OF NOTARY PUBLIC

2 I, JANEL FOLSOM, the officer before whom the
3 foregoing proceedings were taken, do hereby certify
4 that any witness(es) in the foregoing proceedings,
5 prior to testifying, were duly sworn; that the
6 proceedings were recorded by me and thereafter reduced
7 to typewriting by a qualified transcriptionist; that
8 said digital audio recording of said proceedings are a
9 true and accurate record to the best of my knowledge,
10 skills, and ability; that I am neither counsel for,
11 related to, nor employed by any of the parties to the
12 action in which this was taken; and, further, that I
13 am not a relative or employee of any counsel or
14 attorney employed by the parties hereto, nor
15 financially or otherwise interested in the outcome of
16 this action.

17 

18 JANEL FOLSOM

19 Notary Public in and for the

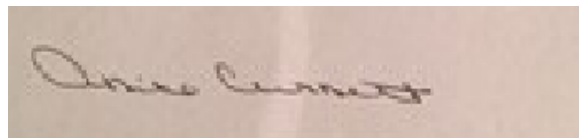
20 State of Maryland

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CERTIFICATE OF TRANSCRIBER

I, ANITA CURNETT, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

A rectangular area containing a handwritten signature in dark ink on a light-colored background. The signature appears to read "Anita Curnett".

ANITA CURNETT

1	200 37:6 45:2 200,000 17:20 2001 21:4 147:7 148:12 2011 136:21 2012 13:8 2013 13:9 138:14 2020 1:10 20993 1:17 20th 76:5 22 162:2 23 59:16 24 73:17 117:12 24/7 101:8 25 13:10 250,000 17:21 276 21:4 28 122:3 2:32 210:14	5	able 10:19 11:16 15:14 35:9,21 43:2,21 48:11 54:2 55:2,7,8 66:3 67:7,10 71:13 72:13 78:18 81:9 84:2,11 91:16 93:17 110:14 114:1 125:2 139:10 144:4 150:2,4 157:16 159:8 174:20 178:3,6 182:3 185:6 188:1 206:19 208:12 absent 165:7 200:3 absolute 199:3 absolutely 88:12 93:18 absorb 144:7 168:5 absorbing 125:4 absorption 145:6 167:14 168:4 171:11,13 academia 209:19 accept 134:14,17 134:20 135:6 156:15 186:19 acceptable 133:6 135:13 178:6 acceptance 198:14 access 42:12 102:10 179:17 accessing 195:19 accidentally 98:8 98:10 accidently 86:9 accommodate 37:5 187:2 accomplish 53:18 178:3,4	
1 25:9 43:12,15 52:5 109:1 123:14 1,400 62:19 1-800-527-1401 52:17 10 19:17 49:11 65:7 72:4 76:5 81:15 116:2 138:11 144:6 162:3 175:14 10903 1:16 10:00 1:11 11:15 52:17 11:20 52:17 12:15 120:17 12:45 122:7 13 1:10 14 129:19 162:7 183:11 145 68:2 14644 211:18 15 18:15 44:1 56:20 116:2 137:10,12 162:9 15th 35:15 16 56:20 100:5,6 160 21:7 17 162:5 17929 212:14 18 46:18,19 100:5 19 21:8 53:7 54:16 56:21 74:1 103:1 162:7 1998 69:16	3 3 46:1,3,14 30 14:11 20:19 46:19 47:4 48:21 52:9,16 106:14,16 122:2 123:11 31 46:19 328 21:11 35 62:6 68:17 185:17 355 181:14 38 96:9	6 6,000 21:13 60 23:2,13 46:19 47:2,4 101:2 61 46:19 65 186:8	7 70 46:19 47:5 144:6 71 46:20 75,000 18:6	
2	4 4 101:8 40 46:19 47:4 107:18 108:7 191:13 4080451 1:20 41 46:19 47:2 45 143:4 49 102:19	8 8 114:3 80,000 18:6 800-527-1401 123:15 80s 68:11 85 96:10 88 21:6	9 90 23:13 66:5 94 68:2	a a.m. 1:11 44:21 abate 131:4,12 abdominal 198:4 abilities 150:1 ability 77:20 160:13 165:7 201:9 206:7,8 207:15 211:10 212:7
2 45:8 46:4 122:14 122:15 20 19:17 28:18 44:1 48:21 56:11 56:11 100:2 143:9 155:16 198:19				

account 209:15 accurate 211:9 212:5 accurately 8:19 acetaminophen 193:2 ache 97:5 aches 143:21 achiness 96:13 aching 69:18 achy 97:2 acquired 144:18 act 127:2 acting 2:15 40:4 41:1 action 153:10,11 211:12,16 212:8 212:12 activated 25:17,18 active 26:7 54:13 147:8 200:12 actively 51:21 activities 59:9,19 66:19 132:1 147:15 150:1,3 206:8,21 207:2 208:19 activity 70:10 159:21 180:3 205:17 actual 95:10 acupuncture 60:19 acute 75:3 130:3 135:9 adaptations 171:18 adaptive 147:16 add 33:5 88:20 97:5,19 113:7 154:1,20 157:10 157:19 170:5 177:14,20 178:11 178:11 190:17	191:18 added 70:14 92:16 addition 14:10 67:20 171:19 210:11 additional 44:20 116:4 190:11,12 additionally 145:7 155:18 address 9:18 145:5,5,6,8 addressed 38:6 addressing 38:11 adequate 125:8 adjusting 148:8 administered 195:12 201:15 administrate 200:15 administration 1:14 admit 19:13 adults 110:5 advanced 2:18 40:9 advances 156:1 adverse 67:18 advisory 12:14 advocate 57:7,10 149:15 advocates 8:4 15:20 aerobic 159:21 aerobics 194:14 affect 20:1 22:11 52:5 88:15 131:19 140:4 206:3 affiliated 34:20 afraid 70:18 129:5 african 143:8 afternoon 153:2 205:9 age 20:19 46:14 46:16,16,21 74:10	101:1 134:4 agency 7:19 agenda 5:8 agents 131:2 aggressive 145:10 145:18 aggressively 76:16 154:5 181:3 ago 49:7,7,8,15 60:12 64:19 86:2 124:6 129:20 134:9 143:10 183:1 agony 78:8 agree 84:17 98:1 107:10 157:17 agreed 108:5 ahead 41:19 50:3 73:8 81:1,12 83:8 88:8 90:10 96:6 100:20 109:19 111:19 123:18 124:2 128:15,17 146:15 155:1 164:7 166:18 188:11 200:8 202:8 aid 42:20 130:14 aided 129:21 aids 94:16 air 77:11 96:21 116:16 alarmed 74:12 alive 78:12 101:21 allergic 67:14 181:5 allergies 64:4,4,4 65:11 90:19 91:14 allergy 90:20 91:14,19 alleviate 206:19 alleviated 164:19 allow 41:17 202:11 205:12	allowing 135:16 182:8 altering 17:17 107:9 alternative 58:16 170:1 alternatives 156:2 altogether 165:8 amazing 85:5 109:21 110:1 121:15 187:15 amazon 83:19 amount 93:8 98:18 178:2 182:21 183:2 208:11 amounts 118:8 amputation 19:7 159:12 amputations 83:21 147:12 amy 3:9,12 53:4,4 57:16 58:4 64:15 69:8 72:21 79:9 79:10 83:12 84:18 85:16 87:1 92:9 96:6 97:20 105:21 109:19 amy's 97:5 ana 76:3 analyst 3:8 anemia 144:19 angeles 180:16,21 anger 112:15 anita 3:19 128:13 129:3,8,16,18 135:17 151:19 154:19 156:5 157:1 164:4 165:1 174:7 175:4 177:12,16 178:10 200:21 212:2,15 annoying 139:18 139:18
---	---	---	--

<p>anonymity 47:21 anonymous 33:21 36:9,19,19 42:7 47:17 80:18 117:11 answer 42:18 46:16 76:7 154:12 174:9 179:16 answered 45:16 88:10 answering 45:18 46:15 85:8 159:20 answers 42:10,18 45:21 49:21 50:2 75:1 99:8 123:12 161:21 179:5 195:10 anti 26:17 131:2 131:20 180:8 antibiotics 86:4 167:2 169:18,18 169:19 antibodies 20:12 23:10 antifibrotic 161:5 162:4 antineoplastic 131:1 anxiety 126:14 127:9 147:7 180:4 anybody 80:13 109:17 113:3,3 152:9 168:7 178:11 190:15 196:17 anymore 55:4 59:17 64:13 148:7 202:16 anyway 87:12 114:12 anyways 106:12 108:8,14 apart 25:20 71:2 119:14</p>	<p>apologies 119:14 161:17 164:3 apologize 43:8 203:18 appear 188:18 applaud 28:11 applauding 80:2 application 42:5 44:7,8 applications 12:12 173:9 applies 160:21 apply 50:6 192:21 appointed 103:4 appointment 91:3 200:16 appointments 70:20,21 150:7 180:7 appreciate 10:10 38:10 93:12 136:15 142:9,10 143:2 146:9 174:10 192:6 204:9 appreciation 38:13 approach 11:21 205:12 approaches 6:7 32:3 38:1 122:16 appropriate 17:13 appropriately 177:10 205:20 approved 26:11 26:15 28:10 106:11 197:17 approximately 17:20 18:6 21:13 archived 7:3 area 13:7,16 14:5 15:19 30:13 43:16 44:14 47:2</p>	<p>areas 9:16 50:9 96:1,2 147:5 209:21 arizona 105:5 arm 98:13 arms 23:7 63:19 82:8 137:21 146:20 arounds 83:17 arterial 24:21 25:7 arthritis 21:1 28:6 50:11,14 51:2 99:14 115:5,15 161:4,8 arthrofibrosis 26:8 article 18:8 artificial 63:7 aside 32:13 asked 14:6 27:10 58:12,20 91:1 108:21 177:11 asking 52:11 89:19,20 92:5 109:14 114:7 115:18 168:13 194:16 195:4 aspect 22:6 103:13 148:17 aspects 22:3 58:14 128:18 146:18 206:3 aspirating 77:17 assault 78:2 assess 158:8 173:13,15,20 176:4 205:16 210:2 assessing 205:19 209:15 assessment 3:7 9:15 41:2</p>	<p>assessments 12:21 assist 209:9 assistance 137:14 147:17 assisted 83:16 associate 2:7 5:15 10:17 associated 28:15 97:15 assuming 174:8 assured 74:3 atrial 26:11 attack 111:6,7 attacked 76:16 attempt 190:13 attend 15:21 attendance 10:6 attended 126:13 attendees 2:2 29:21 attest 74:19 attorney 211:14 212:10 audience 22:19 audio 7:9 81:6 89:17 128:11,12 128:16 129:6,11 135:19 136:2,12 142:20 146:11 151:13,13 156:18 163:7 175:6 177:15 211:8 212:3 audiologist 184:4 authorities 9:17 auto 20:12 autoantibodies 22:10 25:4,4 autoimmune 19:14,19 20:21 21:2 107:8 126:7 autoimmunes 101:19</p>
---	---	--	--

autoimmunity 20:12 automatic 84:19 available 9:13 13:1 14:18 132:9 207:17 209:14 avenue 1:16 average 28:8 avoid 102:15 207:3 aware 24:8 25:11 71:4 89:2 awareness 210:3 awkward 92:6 azathioprine 161:5	bacterial 143:18 bad 55:11,17 60:8 62:21 65:15 75:14 82:10 86:21 90:18 97:10 155:3 169:20 172:6 176:1 178:18,21 201:3 balance 169:14 band 94:16 bandages 86:15 bankrupt 183:16 barely 121:4 based 21:12 76:4 92:19 93:7 114:11 153:9 170:8,8 basic 43:13 basically 166:4 basis 21:18 90:16 132:8 139:20 165:5 207:1 bathing 107:19 137:16 bathroom 67:11 67:11 bathtub 75:17 battery 173:17 battle 87:17 bear 132:15 beats 120:10 becoming 101:9 187:14,19 bed 55:7,14 64:8 65:19 125:12 208:19 bedding 64:7,8 bedridden 78:18 bedside 150:19 began 74:1,5 81:21 149:13 beginning 10:2 56:2 62:9 68:1 100:9	behalf 45:18 believe 37:9 89:13 95:2 105:21 106:9 106:10 146:11 believed 75:8 believes 81:16 197:17 belittled 74:16 bell 100:21 beloved 76:6 bend 53:16 87:7,8 bending 70:16 beneficial 164:16 benefit 9:15 153:7 154:14 174:1 189:7 196:14 209:16 210:2 benefits 44:11 140:15 141:15 142:3,13 153:3 158:8 195:5,14 196:3 207:20 bennett 3:13 73:10 84:17 94:9 97:4 113:6 bent 1:8 5:2,3 7:10 16:17 29:18 30:3 39:14 41:6 42:3 57:16 58:3 61:11 62:4 68:19 72:20 79:7 80:21 81:3 83:1 85:7 88:7,18 89:11,16 90:2,4,8 90:13 92:7 95:6 96:6 97:18 98:20 103:16 104:10 108:16 110:19 111:19 112:9 113:2,9,17 118:16 120:14 122:10,12 123:21 128:8,20 129:1,14,16 135:17 136:1,9 137:11 142:8	146:5 151:11 152:17,19 153:20 154:17 156:5,17 156:20 157:6 158:10 159:17 164:1,20 166:17 168:6 170:2 172:8 174:7 175:4 177:12,18 178:10 179:1,6 180:11 182:9 187:6 189:10 190:4,15 191:15 194:19 200:21 201:11,18 202:19 204:20 best 35:7 38:21 127:14 147:15 149:14 172:1 174:13 203:10 211:9 212:6 betray 77:4 better 6:9 8:11 9:15 14:9 69:6 74:3,5,21 83:18 86:17 96:4 98:16 111:15 121:19 122:19,20 127:19 132:3 139:17 141:12 146:17 156:4 159:9 200:14,15 205:12 205:18 206:16 biased 16:18 bible 194:18 big 27:5 51:18 55:5 61:10,10 65:20 86:19 87:21 88:2 120:7 140:12 biggest 44:10 55:1 58:19 59:10 65:6 65:6 72:12 bills 183:13 binders 143:16
b			
b 1:19 18:21 50:12 99:9,10 114:19,21 161:2 163:18 193:2 195:13 baby 139:7 back 37:17 41:7 56:20 59:21 64:15 77:2 87:3,16,16 89:4 91:3 94:8 98:21 109:12 122:7 128:14,14 129:2,10 133:12 135:18 136:13 140:1 143:11 146:10 155:15 156:18 158:16 172:14 174:2 175:9 177:13 184:11,14 background 5:20 14:17 30:15 136:19 backgrounds 10:13 backside 92:20 bacteria 164:11			

biologics 2:19 40:10 biopsy 25:15 birthday 76:6 bit 11:4 16:18 18:21 19:4 20:16 21:6 27:15 30:4 30:15,21 34:11 43:19 44:15 48:12 48:13 52:14 57:1 57:20 64:20 69:3 69:3 72:2 81:5 87:9 89:18,21 108:9 114:6,6 120:21 122:5,5 130:17 132:7 136:19 138:21 139:18 142:7 153:5 156:18 157:9 161:19 163:13 165:19 172:13,15 175:6 179:11 180:9 191:4 bite 118:8 bladder 101:13,14 138:3 blade 89:5,10 blame 87:10 blanket 66:1,2,6 blankets 65:21 bleeding 198:7 bleeds 68:5 blessed 104:12 108:14 blessings 128:7 bloating 99:13 115:5 116:19 blockers 26:10 132:5 blood 25:16 50:11 50:16 54:2 66:9 70:1 91:10 105:14 105:17 144:17,19	149:19 159:4 161:2 162:1 171:3 171:3 186:10 202:6,10,15 203:3 204:14,15 blow 96:21 blue 105:10 body 27:15 50:9 50:15 57:7,11 76:15 78:2 82:4 95:21 96:10 97:3 103:9 124:17 137:11 147:5 148:7 169:12,15 176:9 body's 78:20 96:14 157:2 bone 97:6,7 98:7 102:4 108:10,12 161:11 162:8 208:4 bones 98:6 117:9 book 127:6 borderline 137:6 bother 195:9 bothers 195:2,4 bothersome 53:21 114:8,11,16 115:10,10,14 119:2 140:20 195:15 196:4 botox 159:10 171:6 bottle 137:17 bottles 85:1 bottom 6:19 56:16 71:13 bouts 131:14 175:12 bowel 101:14 brain 59:5,11 60:5 67:21 112:8 143:21 176:16,19 177:4,6 178:17	179:14,15 180:9 182:15 183:9 184:17 branches 25:13 breached 134:10 break 70:19 122:2 122:3,5,12 breath 54:21 55:13 59:5 209:1 breathing 120:4,9 126:3 127:3 137:4 198:6 brick 174:15 brief 45:12,20 88:19 briefly 5:9 88:21 94:5,7,7 119:7 160:1 bring 15:6 79:1 142:11 144:17 bringing 13:5 brings 95:8 broad 100:12 broaden 32:7 broader 38:5 broadly 209:5 broken 107:3 brought 86:20 bruised 78:3 buddy 110:3 build 32:18,20 33:7 47:21 building 107:6 194:14 bulbs 63:10 bullet 77:2 bunch 65:21 110:6 115:18 burden 8:19 14:7 business 59:16,17 206:10 busy 174:17 buttonholes 84:7	buttons 64:21 84:7 buying 64:21 <hr/> c <hr/> c 2:1 3:1 4:1 5:1 18:20 50:17 99:10 115:1 161:5 193:2 195:14 caffeine 113:7 calcinosis 19:3,11 70:7 72:5,9 85:17 86:1,13 87:12 88:4,20 94:6 105:15,20 106:4 117:3,14 118:3 148:5 206:18 207:8 208:5 calcium 26:10 86:16 132:5 138:20 147:5 171:11,13 calculation 21:10 call 19:1 20:3 33:19 34:3 41:16 44:12 52:17,18 53:1 60:8 62:12 80:15 84:20 136:4 139:7 147:21 170:17 183:3 189:12 196:18 called 5:6 18:20 26:18 27:9 58:17 90:21 91:3 106:8 137:1 155:7 168:16 196:7 caller 80:16,18 81:1,4 100:17 182:12 callers 180:13 193:13 calling 6:20 93:12 101:11 123:14 180:18 182:10 188:4
---	---	---	---

calls 93:16 camera 42:13 205:5 campus 1:15 cancer 102:4 153:14 154:6,7,15 155:7,18 172:5 cancerous 151:3 cancers 145:16 candidate 197:18 cannula 77:7 cans 84:5 capable 84:20 150:11 capacity 13:13 capillaries 22:7 capt 1:8 capture 205:21 captured 12:2 93:20 captures 46:12 carbs 169:14 cardiac 19:9,9 120:9 156:12 183:20 cardiovascular 153:16 172:5 care 28:2,2 34:2 36:16,16 72:13 91:8 92:18 96:17 104:20 144:14 147:21 150:8,12 183:15 206:11 career 82:7 102:18 103:13 carefully 207:2 caregivers 7:16 8:4,10 15:3,11 16:2,6,9 caring 101:5 carpal 69:20 case 87:20 178:13 195:6	cases 21:4,8,9 181:14 catch 140:1 catches 117:10 catching 48:21 cats 55:12 cause 28:13 77:13 87:17 97:8 108:7 113:8 148:7 149:12 155:18 156:7 caused 117:20 148:20 174:18 208:5,6 causes 53:13 67:15 78:2 96:11 118:5 147:1 149:19 153:14,15 causing 145:21 cautious 70:17 cell 26:18 33:2 42:8,13 43:5 94:4 99:17 138:13,14 160:10 181:2 188:17 cellcept 137:1 182:5 center 2:6,18 5:3,4 5:12 10:18 40:9 centers 102:11 certain 55:21 64:7 95:21 182:20 183:2 191:9 certainly 47:13 73:10 109:7 115:20 189:19 certificate 211:1 212:1 certify 211:3 212:2 cetera 139:13 193:5 chair 126:2 149:7 178:19	challenge 62:11 204:7 challenged 102:13 challenges 44:7 61:14 92:13,17 102:5 115:21 136:6 172:16 187:18 196:2,8 197:13 challenging 58:10 177:9 202:8 chamber 159:11 chance 128:16 chances 135:3 172:4 change 27:7 55:15 59:13 61:6 72:14 105:11 124:11 125:9 131:21 148:17 159:15 172:7 185:2 changed 60:11 74:8 84:9 123:7 130:6 138:21 143:10 144:1 149:8 152:4 175:20 206:10 changes 19:2 56:2 101:14 139:8 171:21 184:18 185:8 changing 64:14 channel 26:10 132:5 210:3 chapter 76:1 charge 140:7 charm 146:14 chat 6:18 33:4 119:4 check 160:21 192:21 checked 106:12 165:8	checks 197:12 chemotherapy 137:20 154:5 chest 27:14 91:10 chew 125:1 chewer 125:1 chi 125:21 chicago 91:17 child 143:8 148:1 155:9 181:13 child's 107:19 children 103:14 chinese 60:18 chlorambucil 155:8 choose 65:3 99:7 132:21 195:10 choosing 140:6 149:13 chore 126:10 choreography 64:17 chose 151:3 192:1 192:2 chosen 119:10 christopher 18:9 chronic 8:10 71:15 77:19 130:4 135:7 174:12 chronological 74:10 cicchetti 3:17 123:19 124:3 157:12 168:8 178:13 circle 177:13 179:2 circulation 54:1 clarify 22:19 152:14 clarifying 41:9 clasp 65:1 classification 21:21 22:15
--	--	--	--

classify 21:20 clean 201:15 cleaning 124:19 clear 121:4 125:14 178:18 187:14 clearly 44:17 130:3 187:11 clinic 28:10 clinical 2:11 3:6 8:17 9:5 11:10,15 12:8 14:17 22:1 28:18,21 39:17 41:2 150:10 173:19 174:5 176:3 197:19 202:21 209:13 clinician 19:5 21:16 22:12 24:6 24:10 25:6,19 26:5 28:17 clinicians 25:15 33:13 clinics 105:6 close 34:9,13 47:3 75:21 103:2 156:14 closed 64:9 closely 110:3,6 155:9 169:6 closer 52:15 127:12 closest 75:12 closing 203:21 205:7,10 clot 54:2 clothing 64:21 clouds 76:21 cluster 203:3 coast 44:21 code 42:14,16 43:2 cognitive 64:2 177:2	cohort 23:18 coin 85:4 coins 207:7 cold 62:17,18 66:2 66:8 70:5 99:10 111:8 112:10,13 112:21 115:2 147:3 206:13 cole 3:8 41:10,20 41:21 80:17 81:11 116:9 158:21 170:20 179:13 194:10 204:1 collagen 72:1 colleague 41:10,15 116:5 colleagues 39:6 83:5,8 163:9 188:13 collecting 12:10 13:18 college 55:2 74:2 206:11 colon 144:1 color 105:11 colors 112:17 comb 147:10 combination 24:20 176:17 combining 169:13 come 23:12 25:20 28:9 41:11 45:13 48:7 58:8 80:13 87:15 112:13 128:14,14 136:12 144:7 155:15 173:17 175:9,19 186:15 189:1 comes 17:17 78:13 172:20 184:16,17 comfortable 48:13 91:5 comforters 66:6	coming 44:3 46:1 86:9 93:15 167:16 182:2 184:8 192:10 196:20 comment 34:19 35:20 36:3 79:15 81:14,19 94:6 112:7 113:4 117:10 121:9 158:11,12,15,20 159:1 168:7 171:15 182:18 194:11 203:2 204:13 comments 33:3,20 35:3,5,7,10,10,18 36:8 39:5 41:11 41:13,16 42:1 52:15 79:16,20 81:9,12 82:19 83:3 93:15,16 113:20 114:1 116:6,11,14,18 121:1,2,8 153:5 170:12,13,14,21 172:10 179:8,10 179:14 189:12,13 192:3 194:8 196:19 203:19 204:2 committed 8:20 committee 12:14 common 48:1,2 91:21 173:14 185:13 198:2 commonly 173:8 communicated 75:5 community 7:19 10:4 29:5,6 48:1,7 102:10 138:8 205:14 210:4 comparison 133:14	compelling 151:16 complain 95:18 complaints 61:16 complete 147:16 completed 177:14 completely 103:12 129:10 156:14 180:10 206:17 complex 7:21 38:11 205:13 206:1 compliance 201:9 complicated 38:16 49:20 complicating 207:6 complication 25:1 complications 24:9 28:14 148:6 190:12 207:4 208:16 component 93:21 compounded 143:15 comprehensive 105:6 118:18 compromise 125:16 compromised 76:12 134:10 139:16 156:13 computer 33:2 69:21 computers 43:6 concentrate 58:20 59:13 concepts 177:3 concern 61:10 concerned 61:17 concerns 38:16 148:15 195:16 196:4,14 207:11 concluded 210:13
--	---	--	--

condition 12:20 12:21 15:1 91:5 92:12 117:18 126:7 141:16 172:3 185:2 187:20 206:2 207:15 conditioning 116:17 conditions 186:3 conducive 185:16 conduct 9:5 11:10 13:15 conducted 13:10 197:19 conducting 13:8 150:11 confident 156:2 confidentiality 134:7,10 confines 101:15 conflict 12:16 conflicted 155:14 connect 110:13 connected 48:12 73:14 connection 48:14 consequently 206:3 consider 52:15 99:4 114:8,15 119:5 120:12 123:13 133:11 140:14 141:10 150:14 consideration 110:17 140:7 150:19 considerations 158:7 consistent 100:8 193:11 constant 69:18 71:6 72:15 77:16	97:2 143:20,20 constantly 60:21 62:11 64:13 147:12 200:11,12 constipation 99:14 115:5 constitutional 27:20 consuming 124:19 cont'd 3:1 4:1 contact 37:16 context 12:8 30:11 95:7 197:6 209:13 209:14 contingencies 186:2 continue 69:6,6 136:11 138:15 139:6,11,19 140:2 140:18 147:3 continued 77:4 137:8,18 continues 81:17 209:4 continuing 45:4 137:2 contracted 18:13 147:11 contractures 24:3 24:18 56:17 81:17 82:10,20 contribute 36:2 93:20 control 78:9 125:10,11 130:9 132:7,14,19 134:15 183:13 208:14 controls 58:18 133:2 convenient 200:14 conversation 77:20 109:10 164:2	conversations 10:3 114:11 cooking 60:1 124:18 cooping 207:13 coordinating 41:14 coping 148:10 core 172:1 185:3 corner 6:19 correct 70:13 80:16 109:21 correctly 176:21 cost 133:1,15 134:6 costs 132:19 133:4 cough 77:19 78:4 90:18 coughing 77:16 78:2 couldn't 63:1 counsel 211:10,13 212:7,10 counseling 126:14 162:16 193:5 194:4 counter 143:14 149:5 162:17 193:1,13 194:3 counting 14:11 countries 143:6 country 143:9 couple 34:4 60:12 87:13 157:13 173:18 course 63:11 66:11,20 94:18 130:2 131:2 146:12 161:7 196:6 200:3 205:2 cover 147:4 coverage 133:5,5 covid 91:9 92:16 106:20 126:15	185:21 cramping 115:4 cramps 99:13 crazy 70:15 cream 195:12 create 33:8 creative 145:3 crest 18:20 50:15 crippling 105:12 crisis 19:10 25:10 130:3 181:18 criteria 12:17 22:15 critical 9:1 11:8 205:18 cross 146:13,16 culmination 75:9 cumbersome 132:18 cumulative 118:1 cupboard 98:9 cupping 60:19 curative 130:10 cure 72:11 141:21 200:3 curious 108:11 111:8 188:21 curnett 212:2,15 current 6:7 9:13 15:8 32:2 77:3 122:16 131:18 172:2 currently 14:18 123:6 130:8 138:15 144:20 145:17 149:1 152:3 159:2 166:21 207:17 209:14 curve 100:21 curved 76:11 141:2 cushion 98:6 117:7
--	---	---	--

<p>cushioning 94:17 cut 60:6 166:18 180:9 cutaneous 22:16 22:17 23:6 24:20 cycle 66:12 cyclosporine 161:5 cymbalta 171:5 cytoxan 137:20 138:3 154:5 182:6</p>	<p>daughter 147:21 day 6:16 8:14 33:1 44:19 53:9,10,11 54:5,5,8 55:6,11 55:12 58:9 62:14 62:15,16 65:2,13 65:14 72:17 73:16 73:18 74:6 78:11 79:1,2,6 83:18 92:2,2 94:12,12 97:11 106:18,19 108:14 112:4 118:9 121:6,6 125:14 144:5,12 150:3 159:16 161:16 172:15 173:16,21,21 174:21 175:16,17 178:15 179:21 182:19,20 183:7 184:5 185:13 186:21,21 200:2 201:8,8,16,16 207:1,1 208:12 days 55:16,17 60:3,4,6,8,8,9 65:4 66:14 71:10 71:14,16 76:5 78:5,9,15,17 101:16 106:21 111:13,14 130:20 147:15,19 165:11 173:18 183:4 184:11,13 187:17 188:2 208:18 deal 8:10 71:18 96:5 101:19 102:17 171:16 dealing 101:16 102:5 127:8 136:2 148:4 172:17 death 148:15 debilitating 130:4 134:18 135:6</p>	<p>164:13 december 35:15 decided 76:18 124:10 137:19 157:15 decision 12:9 39:2 158:6 199:14 decisions 62:15 158:4 decline 135:7 142:1 decrease 26:3 27:3 47:21 165:10 166:3,5 206:7 decreased 204:10 deep 78:20 164:2 deeper 127:8 deeply 127:3 defense 78:20 define 18:15 22:2 25:15 148:12 defined 50:8 definitely 35:12 112:13 143:3 166:20 167:10 176:19 177:4 deformed 101:9 degree 15:18 66:5 73:18 202:4 degrees 202:5 delay 43:20 44:1 48:21 198:20 delayed 118:10 demanding 82:7 demi 3:18 128:10 128:14,15 129:9 135:18,20 146:10 146:14 151:12,19 154:20 190:1 200:8 demi's 128:12 136:12,12 142:20 demographic 43:13</p>	<p>demonstrating 38:9 dental 70:20,21 82:14 dentist 71:4 91:21 92:11,11 dentistry 3:3,5 40:17,20 83:11 denton 18:9 department 103:5 depend 53:10 154:2 depending 134:21 depends 55:19 deposits 147:5 depressants 180:8 depressed 74:18 depression 28:14 71:14,15 148:21 171:6 derma 17:18 dermatology 3:3,5 40:16,20 83:11 describe 60:14 78:19 95:20 96:3 163:11 176:5 described 37:19 76:4 describing 159:2 design 9:17 designer 94:13,13 designing 94:20 202:21 desk 63:10 detect 78:6 detergent 64:7 deteriorate 137:9 deteriorated 117:8 141:9 determination 151:7 determine 124:9 detroit 21:3</p>
d			
<p>d 5:1 50:20 99:10 115:1 138:20 161:7 193:3 195:15 d.c 44:14 d.c. 43:16 dad 84:4 dad's 110:2 daily 6:4 9:12 12:21 15:4 21:18 32:1 34:8 37:21 52:5 53:18 59:20 62:12 69:13 71:7 71:7 80:19 83:13 90:16 95:7 99:5 109:2 121:5 132:1 132:8 137:15 138:1 139:20 165:5 166:6 174:12 178:2,5 197:21 207:16 dairy 144:1 damage 50:9 76:15 117:20 145:19 209:1 damaged 149:4 dancer 54:14 64:16 dancing 54:19 98:15 206:9 data 134:9</p>			

devastated 103:12	124:5 129:19	differentiate	dinesh 2:9 5:19
devastating 8:1	136:20 137:4	24:12	17:1
develop 9:5 11:10	147:7 155:4,5	differently 54:11	dinner 175:16
20:8 25:7,8,9	157:13 183:11	58:9	direct 210:5
143:19 144:18	diagnosis 49:5	differs 97:1	directly 9:10 16:1
145:8 163:17	56:11 68:1,8	difficult 29:3,5	16:5
210:1	76:17 101:1,4,6	53:7 54:19 56:18	director 2:3,7 5:3
developed 16:8	117:4 143:6	58:6,10 64:20,21	5:10,15 10:17
54:20 56:3,3	168:19 180:21	70:12 71:9,11	39:11
developers 9:7,17	184:1	82:5 115:19 117:7	disability 19:10
15:20 33:12 46:9	dialog 209:17	118:3 131:9 132:2	26:3 27:2 187:4,5
209:19	dialogue 10:2	132:11,14 161:19	disabled 82:7
developing 28:20	31:20 32:7,19	181:20 186:13	disabling 186:12
207:10	dialysis 131:10	187:1	disappeared
development 1:2	diarrhea 99:13	difficulties 59:4	144:2
5:7,17 7:13 8:18	115:5 164:12	difficulty 56:4	disclose 34:19
8:21 9:2,21 10:14	198:3	99:12 115:3	disclosures 17:13
11:1,5,9,11,14,17	diarrheal 131:20	116:14 118:7,10	discolored 76:10
11:20 12:3 13:5	diego 182:13	120:4 164:10	discomfort 96:2
13:12 14:3,13	diet 60:17 65:10	177:1 195:18	198:7
15:17 16:21 17:11	124:11,13 131:14	202:3,4,5	discount 115:20
30:14 35:2 37:8	131:15 144:1	diffuse 18:12,14	discuss 43:11
37:14 39:1 41:4	162:16 169:5,5	22:16 23:20 24:12	80:19
207:19 209:6	175:20 193:3,4,4	24:13,16 101:1	discussed 35:17
210:6	193:4,19 194:4	diffused 23:5 50:7	164:9
devices 160:19	dietary 171:21	51:8 129:19	discussing 34:6
207:20	193:15	136:20 180:21	51:21 82:19
devine 3:19	diets 124:16,16	digest 168:17	130:17
129:17,18 156:6	193:17,20	digestion 65:12	discussion 5:5,21
157:19 163:20	difference 114:6	125:3	10:11 14:15 15:6
164:8 165:17	124:20 134:1	digestive 99:12	15:13 31:19 32:1
174:11 177:16,19	140:13 176:15	100:6 115:4,14	33:18 37:2,19
201:1	differences 67:21	161:9 162:6 169:2	38:2,3,14 42:19
dexterity 76:11	different 14:15	208:9	49:18 52:1 69:11
diabetes 166:11	22:11 67:14 84:16	digital 19:6,6 20:8	80:10 123:1,4
186:9	88:14 108:20	24:4 26:7 42:16	152:1
diagnosed 21:14	117:17 124:15	70:4 72:3 96:18	discussions 12:11
27:18 45:9 49:10	130:6 134:20	99:10 115:1,9,12	16:4 31:12 189:2
49:13,15 50:6	139:1 143:5	117:19 147:4	disease 8:1,19
53:7 54:13,16	150:13 163:14,15	159:5 208:6,7	9:12 13:7,16,20
56:21 58:5,6,17	173:9 176:18	211:8 212:3	14:5 15:19 17:17
62:6 68:8 69:15	177:4 193:20	digits 148:7,18	19:12,14,18,19
69:17 76:7,14	194:15 205:16	diminished 75:2	21:2,14 22:10
82:3 102:3,14			23:16 24:2,13

25:8 26:4,21 27:4 28:15 29:4 50:18 55:2 56:1 57:2 58:8 72:4 92:4 101:7,21 102:7,16 102:20 103:15 106:18 107:8 108:3 129:21 130:2,5 131:3,3 132:9 133:2 134:14,15,21 135:8 137:5,8,18 138:6 140:2 148:17 153:7,9,15 153:16 154:4,11 154:16 161:6 162:5 181:13,18 182:7 186:12 187:18,20 189:4 199:11 205:17 207:11 209:13 diseases 14:2 20:21 21:19 51:1 102:2 103:2 dishes 71:9 107:3 107:4 dismissed 74:15 disorders 27:10 disparaging 75:8 distribution 23:17 diverse 48:19 102:7 151:16 diversity 46:21 divide 22:16 divided 18:2 division 2:3,11,13 2:15,21 3:2,4,6 5:11 39:11,18,21 40:4,13,16,19 41:1,3 187:12 divisions 11:12 dizzy 59:7 178:20 dlco 191:13	dna 20:2 dnas 19:21 docket 35:14,17 35:20 36:10 121:1 121:10,10 192:5 doctor 28:2,2 60:18 89:3 91:1 91:17,21 92:1 191:3 197:17 doctor's 88:10 90:21 150:7 200:16 doctorate 129:20 doctors 75:10 91:11 137:19 138:4 149:10 150:13 168:11 180:7 190:19 doing 13:4 28:18 54:11,18 57:13 58:8 68:4 71:5 123:6 126:9 141:6 141:14 152:3 168:12 171:21 176:12 177:7,8,8 177:10 186:20 187:15 192:20 dollars 64:6 91:11 don 78:17 don't 32:13 105:9 107:2 125:12 door 139:13 207:7 doors 84:10 dose 58:17 130:11 138:1 166:13 doses 166:1,3 double 169:21 doubling 94:17 doubt 75:10 downside 144:10 downsides 150:6 downtown 125:7 dr 5:10,14,15,19 6:2 7:6,8,11 10:13	16:18 17:1,4,5 29:19 30:2 35:13 39:7,9,20,20 40:15,21 83:10,15 85:9,10,10,12 88:12 95:17 98:19 100:8 104:21 111:3 113:15 127:5 152:16,18 152:20 158:2 163:4,7 172:21 173:3,4 176:14 177:20 179:1,4 188:8,12 203:20 205:7,9 dr.'s 30:9 dragging 125:13 175:15,17 drain 105:17,21 106:1 drained 176:9,10 draining 176:11 176:12 dramatically 101:14 172:4 draw 202:6 204:14,15 drawn 202:16 draws 144:17 202:10 203:3 dressed 67:8 137:16 drink 118:7 drive 54:8 59:7 driving 125:6 drug 1:2,14 2:6 5:4,7,13,17 7:13 8:21 9:1,17,20 10:14,18 11:1,8 11:14,19 12:3 13:5,12 14:3,12 15:20 35:2 37:8 37:13,14 41:3 58:16 133:20	134:2 149:4 160:18 204:4 209:11 210:6 drugs 9:5 11:7,10 11:11,17 12:5 209:16 dry 116:20 117:14 due 24:14 54:1 131:11 132:2 147:6 167:3 208:15 duly 211:5 duplications 15:15 duration 48:7 dying 72:14 207:10 dynamic 92:17 dysregulated 20:11
e			
e 2:1,1 3:1,1 4:1,1 5:1,1 18:20 51:4 99:11 115:3 161:8 193:5 195:16 eady 3:13 73:10 84:17 94:9 97:4 eager 10:5 earlier 35:14 92:10 104:21 116:10 157:9 172:15 199:6 207:10 early 18:12 23:16 26:1 27:11 45:1 117:4 ears 70:8 easier 126:19 132:17 200:14 eastern 122:7 easy 70:16 126:17 133:7,10 156:11 158:4			

<p>eat 65:13,13 67:2 67:3,3 71:8 77:15 82:13 118:8,9,11 137:17 144:16 169:7,8 171:20 176:11 207:2 208:12</p> <p>eaten 208:11</p> <p>eating 66:10 77:17 124:21 125:6 126:20 147:16</p> <p>eats 148:1</p> <p>echo 157:1 163:9 188:13</p> <p>echoes 92:8</p> <p>eday 113:6</p> <p>edged 169:21</p> <p>educate 8:8 24:8</p> <p>educated 57:13</p> <p>educating 92:3</p> <p>education 25:21 207:12</p> <p>educational 153:8</p> <p>effect 67:18 106:11 143:17 154:6,15</p> <p>effective 24:7 133:1 195:15</p> <p>effectively 27:1</p> <p>effectiveness 9:4 11:7,16 198:15</p> <p>effects 6:4 37:20 38:1,5,15 69:13 80:19 109:2 128:5 131:7 133:16,16 133:18 134:14,17 138:2 141:8 145:10 150:16 157:14,20 159:7,9 165:20 166:9 171:13 195:16,18 196:4,15 198:2,5 204:5</p>	<p>efficient 125:4</p> <p>effort 10:5</p> <p>efforts 5:17 10:14</p> <p>eight 184:7 185:16</p> <p>either 6:18 80:7 86:14,15 121:8 160:6</p> <p>elbows 56:5 70:7</p> <p>electric 66:1</p> <p>elements 8:17</p> <p>elevate 131:12</p> <p>email 36:5 37:15</p> <p>embarrassing 160:13</p> <p>emergency 65:14 91:6,9 112:14</p> <p>emotional 180:4</p> <p>emotions 126:13</p> <p>employed 211:11 211:14 212:8,11</p> <p>employee 211:13 212:10</p> <p>empowerment 33:10</p> <p>empty 36:21 169:8</p> <p>emptying 118:10</p> <p>enalapril 130:12</p> <p>encourage 15:19 33:19 35:15 36:2 37:15</p> <p>ended 66:2 88:3 124:16 134:5 167:20</p> <p>endpoints 8:18 29:12</p> <p>ends 59:3</p> <p>endure 78:21</p> <p>energy 103:9 126:6 144:3 179:21 180:1 182:21 183:2,5</p> <p>engaged 10:4</p> <p>engagement 210:3</p>	<p>engaging 77:20</p> <p>england 155:4</p> <p>enhance 209:8</p> <p>enjoy 55:9</p> <p>enjoyable 150:4 151:8,8</p> <p>enjoyed 54:18 103:11</p> <p>enlarged 50:16</p> <p>enormous 98:17 98:18</p> <p>ensure 11:16,21</p> <p>enter 42:16</p> <p>entertained 148:2</p> <p>enthusiasm 28:21</p> <p>entire 78:11 82:4 179:21 184:5 197:9</p> <p>entirely 92:17</p> <p>environment 19:21 63:8 177:9</p> <p>environmental 19:20</p> <p>environments 147:3</p> <p>epidemiological 22:1</p> <p>epidemiologists 21:21</p> <p>epidemiology 20:17</p> <p>epigenetics 19:21</p> <p>episodes 143:21 166:6</p> <p>equipment 139:11 139:12 147:17</p> <p>er 91:21 106:2</p> <p>erythematosus 21:1 51:2</p> <p>es 211:4</p> <p>esophageal 130:12 164:9</p> <p>esophagus 149:4</p>	<p>especially 27:14 30:16 56:5 96:18 181:12 185:21</p> <p>established 13:7 13:11</p> <p>estimate 18:5 21:11</p> <p>estimated 21:4</p> <p>et 139:13 193:4</p> <p>europe 21:6 106:10</p> <p>evaluate 11:7,13 205:17</p> <p>evaluating 9:3</p> <p>evaluation 2:6,19 5:4,13 10:18 11:5 12:3,5 40:10</p> <p>evened 68:4</p> <p>evening 66:5</p> <p>event 36:6 148:20</p> <p>eventually 82:8,13 86:16</p> <p>everybody 5:2 17:5 20:6 37:5 41:18 43:1 49:17 51:15 62:2 73:11 89:19 93:13 97:2 104:18 106:5 109:6 122:4,8 129:4 159:19 175:13 186:7 188:6 193:18</p> <p>everybody's 179:9 192:12</p> <p>everyday 181:20</p> <p>evidence 19:1</p> <p>evident 10:5</p> <p>exactly 87:18</p> <p>examination 73:19</p> <p>example 12:13 90:17 111:11,17 140:16 149:3 153:14</p>
---	--	--	--

<p>excellent 194:19 197:10 204:20,20</p> <p>excited 7:14 25:14 45:4 52:3,3 79:4</p> <p>excruciating 96:21 97:12 117:3 208:5</p> <p>exercise 60:18 124:12 125:19,20 126:8 131:15 193:3,15</p> <p>exercises 126:3 138:20</p> <p>exhausted 63:9</p> <p>exhaustion 28:13 66:12 71:6</p> <p>expand 13:13 35:16 121:10</p> <p>expanding 27:15 27:15</p> <p>expect 38:12 180:7</p> <p>expectation 185:18</p> <p>expense 91:11</p> <p>experience 15:4 34:3 36:17,19 52:14 53:6 58:1 62:1 72:3 75:17 93:4 108:10,13,20 113:12 132:7 160:7 185:1 202:4</p> <p>experienced 69:14 73:18 82:1 99:3 114:14 130:7 148:9 176:1 178:2</p> <p>experiences 6:15 6:18 9:13 12:1 15:12,13 30:1,19 31:6,20 32:15,20 35:16 48:10,14 51:16 52:8,10,12 52:19 53:4 57:19 69:2 73:8 79:9,11</p>	<p>79:19 80:7,14 82:18 89:14 93:3 94:7 100:18 104:7 109:8,13 119:18 119:20 122:17 123:2,3,17 128:9 129:5 136:15 142:17 143:1 151:16 160:5 163:11 180:14 182:14 188:4,17 206:5</p> <p>experiencing 51:19 75:7 121:6</p> <p>experimenting 149:11</p> <p>expertise 29:6 31:7</p> <p>experts 31:7,15,15 187:10,15 207:14</p> <p>explain 6:9 59:1 86:8 98:12,12</p> <p>explained 186:15</p> <p>explaining 74:16</p> <p>explore 73:3</p> <p>exploring 14:2</p> <p>expressed 38:8</p> <p>expressing 77:21</p> <p>expression 25:13</p> <p>extensive 108:19 109:7</p> <p>extent 75:6</p> <p>externally 13:12 14:12</p> <p>extra 70:14 120:10 157:2</p> <p>extract 207:8</p> <p>extracted 82:15</p> <p>extreme 65:10 112:14 117:5</p> <p>extremely 13:19 16:15 53:18 70:20 78:21 97:10 118:3 131:8 132:1 147:3</p>	<p>148:5 150:18 174:17 181:19 187:1 209:17</p> <p>extremities 172:1</p> <p>eye 41:11 92:1</p> <p>eyes 79:3 117:14 126:4</p> <hr/> <p style="text-align: center;">f</p> <hr/> <p>f 51:4 99:12 115:4 161:10 193:6 195:17</p> <p>fabric 64:3</p> <p>face 8:13 22:8 23:1 50:13 63:20 66:1,2 82:12 112:19,20 146:20 151:7</p> <p>facebook 58:7 107:16 110:10</p> <p>faces 93:8</p> <p>facilitate 207:18</p> <p>facilitated 15:6</p> <p>facilitator 5:5</p> <p>facilities 102:12</p> <p>facing 61:15</p> <p>fact 74:19 108:17 171:10 201:5</p> <p>factor 127:4 141:17</p> <p>factors 20:1</p> <p>facts 150:14</p> <p>fail 156:14</p> <p>failure 131:11 132:4</p> <p>fainting 66:18 67:20</p> <p>fall 15:15 70:18 90:18 133:12</p> <p>falling 119:13</p> <p>familiar 43:14</p> <p>families 8:2,9,13</p> <p>family 32:8,12 37:4 38:7 46:6 62:20 80:8 133:18</p>	<p>140:10 148:1 160:7 181:16 200:11</p> <p>fancy 84:20</p> <p>far 13:10 64:14 66:19 68:15 92:17 112:1 114:12 121:5 122:1 158:20 193:11,13</p> <p>farmington 104:11</p> <p>farmland 90:19</p> <p>fast 56:2 155:12 186:15</p> <p>fat 74:17</p> <p>fatal 200:19</p> <p>father 124:7</p> <p>fatigue 27:19 58:19,21 59:4,11 61:15 82:11,21 97:14 99:14 100:7 111:11,17 112:1 115:6 117:3,14 147:19 172:17,19 173:10,11,15 174:4,12,14 176:1 176:7,8,15 177:5 178:2,8 179:14,19 180:4,9 208:17</p> <p>fatigued 55:4 175:1</p> <p>favorable 189:8</p> <p>fda 2:6,8,12,14,16 3:8 5:4,6,13 7:14 8:15 9:1 10:18 11:9 13:10,19 14:16 15:19 26:15 26:18 28:10,11 30:13 33:11 37:12 37:16 38:21 39:6 39:6,19 41:7,19 83:5,8,8,11 95:14 95:15 106:11 109:15 110:20</p>
---	--	---	--

124:4 151:9 152:10,13 158:17 159:18 163:2 172:21 188:9 197:17 205:1,15 207:18 209:4,18 fda's 5:17 8:20 10:14 11:1,4,5 12:8 209:11 fear 63:14,17 75:11 77:18 fearful 77:16,17 fearfulness 28:13 fears 207:9 feature 6:18 33:4 features 50:21 february 56:12 fecal 171:17 federal 9:8 121:10 192:5 feedback 80:4 116:4 119:3 160:2 203:16 feel 9:19 27:11 28:12 33:9,9 48:11,13 72:7 74:3,5 77:13 78:5 91:5 94:17 97:11 98:16 99:7 104:16 110:15 115:10 117:18 118:18 120:21 125:7,13 126:5 157:3 160:9 173:21 174:1 175:2 176:5 192:3 feeling 65:9 97:3 118:11 156:16 198:6 feelings 150:17 feels 27:12 96:13 97:4,7,17 105:16 117:8 126:9 feet 53:14 99:11 115:2 117:8	125:13 147:12 felt 74:4 75:7 135:11 140:19 female 20:20 47:11 females 48:15 fever 63:14,17 198:6 fevers 63:12 fibromyalgia 63:4 fibrosis 19:8,9 20:10,13 24:2 26:14,14,15 27:3 54:21 56:3 117:13 120:11 204:10 fibrotic 25:16 26:17 field 31:15,16 79:13 102:19 187:10 fifteen 131:7 fifty 133:20 fight 174:12 figure 71:11 136:3 143:11 167:8,17 195:7 figured 167:19 fillers 143:16 final 28:16 35:11 73:5 197:1,1,8 finally 29:11 75:18 127:20 143:6 financial 35:1 financially 211:15 212:11 find 29:3,5 36:4 54:9 60:21 64:12 68:13 70:17 75:1 76:2 84:5 85:18 92:3 94:14 102:9 107:9 108:4,4 110:9 115:13 124:14 149:6	156:2 160:13 178:13,17 finding 74:19 84:14 145:3 164:15 175:5 finds 108:11 fine 99:18,18 106:16 204:16 finesse 167:8 finger 22:21 62:21 69:18 74:14 105:11,16 106:2 fingers 27:21 50:13 53:14 56:5 62:18 70:7 76:11 82:2 85:5 86:9 87:7 94:11,12,15 95:2 104:17 117:21 118:4 146:13,16 148:18 148:19 208:9 fingertip 22:7 fingertips 53:20 105:15 finish 55:2 finishing 100:16 first 6:3,10,11 15:3 22:5,13 23:21 26:21 32:6 34:19 37:2,20 43:6 49:18 52:3 57:17 68:13 72:4 79:3 82:1 83:11 89:1,9 99:8 104:14 107:19 112:6 114:20 123:4 124:4,10 126:17 152:1,2 155:5 161:1 169:19 172:16 189:11 192:14,14 203:15 205:3 fish 77:11	fit 11:20 143:7 five 20:20 23:7,21 32:6 49:6,7,13,15 52:6 90:15 93:8 94:11 95:2 98:15 101:3 106:18 117:17 122:21 150:9 167:2 181:2 181:8 202:11 fixed 146:11 fixing 137:16 flare 81:17 105:19 flexibility 34:12 151:12 flip 199:2 flipped 31:9 flolan 106:9 171:2 floor 194:13 flopping 199:2 flow 105:15 149:19 161:2 162:1 171:4 flu 97:13 fluctuation 111:16 fluffy 65:20 focus 6:4,6 16:1 29:11 38:14,20 52:5 108:21 114:7 120:6 122:15 124:10 126:7 148:4 168:14 focused 1:2 5:7,17 6:14 7:13 10:14 11:1,19 13:5,12 14:3,12,20 15:17 17:11 37:20 108:21 focusing 20:17 109:1 fog 59:5,11 60:5 67:21 112:8 176:16,19 177:4,6 178:17 179:14,15 180:9 182:15
---	---	---	--

183:9,9 184:17 foggy 143:21 folding 78:19 folks 36:5 101:11 102:9 follow 32:21 41:8 83:6 109:16 110:21 111:5 113:14 152:11,15 followed 14:20 15:8 32:2 following 37:18 113:19 160:15,18 folsom 1:19 211:2 211:18 food 1:14 64:4 65:6,9,11 118:8 125:1,3,5,8,8 143:17 169:9,13 169:15,15 207:2 208:10,11 foods 144:16 169:6 force 77:15 forced 77:6 132:10 147:21 forearm 23:1 87:2 foregoing 211:3,4 212:4 foremost 37:3 forever 53:21 117:20 forget 107:4 177:7 forgot 164:3 format 6:9 9:14 14:15 18:2 forms 186:10 fortunately 71:3 forward 10:10 16:12,15 29:15 40:1 48:3 73:3 79:13 139:8 142:18 209:10	foster 31:19 found 84:6 127:5 127:8 138:7 149:10 169:7 183:21 191:9 193:18 197:12 foundation 10:3 110:4 four 49:14 67:7 101:3 138:2 144:16 181:9 201:14 free 56:9 99:7 160:9 frequency 111:12 frequent 117:19 131:13 friend 55:9 84:18 friendly 44:8,8 friends 185:7 frozen 175:7 frustrating 147:18 frustration 28:6 frustrations 118:20 fulfill 39:1 full 5:8 75:6 77:13 82:6 94:18 173:17 fully 6:14 34:11 125:10 129:2 fun 63:11 function 9:19 28:14 29:10 83:13 83:18 131:16 132:2 144:4 150:3 177:2 functioning 88:16 141:4,18 functions 151:1 further 22:15 75:11 211:12 212:9 future 10:3 122:19 127:2	g g 5:1 99:14 115:5 161:11 193:6 195:18 gadget 84:6 139:12 gadgets 54:11 83:13,16 84:5,18 gain 134:15 game 90:9 gamut 130:2 gap 57:1 gaps 7:21 gas 167:3,12 gasping 77:11 gastric 118:10 130:12 gastroenterologist 145:2 167:7 gastrointestinal 65:8 67:5 116:18 130:19 139:3 gazillion 97:16 gene 25:13 general 90:17 91:8 91:12 92:3 198:6 generally 132:14 gentleman 19:2 gerd 56:3 159:4 getting 29:3 38:18 53:8 58:16 64:10 86:5,13 87:11 102:14,14,20,21 105:14 119:3 125:18 127:12 137:16 154:15 170:21 179:8 184:6 187:16 190:21 198:20 202:3,5 gi 19:7 50:10 59:4 101:12 104:17 117:13 118:6 124:14 163:5,14	163:16 171:16 giant 66:11 gietzen 3:9 53:4,5 83:12,14,19 87:1 87:15,19 88:9 96:6,7 109:19,20 120:1 122:9 gift 76:7 79:6 give 9:9 10:21 15:3 30:10 34:1 41:18 44:1 45:20 51:17 81:5 107:11 126:8 128:15,15 155:6 156:3 157:10 162:20,20 165:1 169:7 170:11,17 174:3 189:12 196:12,18 198:18,21 200:2 given 13:7 77:21 94:11 106:14 120:20 132:5 144:9 198:8 gives 13:3 14:1 169:8 giving 13:19 23:13 26:21 31:11 124:5 151:5 glad 10:19 68:21 78:12 glaser 2:11 39:16 39:17 163:4,7 gloves 65:20 gluten 144:1 go 24:9 26:15 28:1 31:10 34:17 36:11 41:19 42:15 50:3 55:8 58:13 60:2 61:21 63:15 64:19 65:19 66:10 67:2 73:5 78:11 81:1 81:12 83:8 88:7 88:11 90:10,11 91:6,8,16,20 96:6
---	--	--	---

96:16 97:20 99:20 100:20 101:7 106:1,18 109:19 111:19 113:20 115:8 122:4 123:18 124:2 125:12,20 126:11 128:14,17,17 133:8 135:18 137:13 138:5,9 141:7 143:11,20 146:15 154:18,20 155:1 164:7 166:17 167:2 172:14 175:12,13 188:11 191:2,13 194:17 198:15 200:8 201:5,19 202:8,12,15 206:17 goal 31:18 39:1 48:2 165:14 god 78:16 127:10 157:16 goes 169:16 going 5:8 10:21 16:15 38:14 43:9 44:1 45:6,12,16 47:9 48:8,19 49:4 49:20 50:3 55:3 57:4,20,21 58:1 61:21 62:1 63:13 63:16 64:14 65:16 66:20,21 67:10,10 67:12 69:8 70:18 71:1 73:5,7 79:6 80:3 88:9 90:8 91:2 92:10 94:10 95:12 97:19 107:1 107:20 108:7 113:18,20,20 122:3,13 125:10 128:10,12 133:17 136:18 141:11	142:15 145:17 146:10,13,13 154:8,9,13 155:21 156:7 159:19 160:12 161:15 162:14 168:20 170:4 172:13,13 172:14 175:7,9,9 176:6,6,10 177:2 182:11,12 183:15 185:18 186:3,16 187:3 192:7,9 198:13,18 199:9,9 199:10 200:15 201:19 205:7 good 5:2 7:8,11 15:12 17:5,8 39:9 39:17 40:18 41:20 46:4 47:3 51:8,18 54:6 55:6,16 58:2 58:3,4 60:3,4,9 62:5,10 64:16 65:2 69:10 71:4 71:10,12,20 73:2 73:10 86:13 98:15 112:4 122:12 124:14 125:21 126:5 141:11 169:20 190:4 196:12,12 197:18 200:10 205:9 goodness 130:16 google 21:12 68:9 gosh 91:4 95:1 gotten 72:5 93:9 101:12 148:3 gout 88:1,2 government 186:5 governor 103:4 grab 84:19 85:4 grafting 108:12 grafts 108:11 granted 76:6 137:15 207:1	grateful 79:4 125:7 127:21 great 17:6,8 34:14 42:3 44:5,19 45:14 46:12,21 47:6,6,7,7 48:15 48:18,20 49:16 51:11 57:3 68:19 73:9 83:1 84:4 85:7,7 91:18 108:14 113:17 118:16 128:13 129:12 151:11 156:5,17 158:10 159:17 164:2,20 167:13 170:2,15 171:14 179:5,6 180:11 182:11 201:11,18 greater 46:20 141:11 greatly 129:21 147:14 greek 17:18 grin 132:15 grippers 139:12 grocery 60:1,2 gross 86:17 ground 37:1 85:4 group 17:11 48:19 62:6 107:16 134:4 152:2 153:6 185:7 grouped 42:11 groups 9:20 13:14 58:7 102:8 110:5 110:11 119:19 207:12 grow 45:4 87:16 growing 155:10 gruesome 144:13 guess 55:19 66:9 68:16 79:18 90:9 109:4 111:5 139:18 141:21	177:19 178:1 179:9 guided 204:17,18 gut 130:18 132:2 164:11,17 guys 47:8 79:14 85:8 90:1,6,7,12 100:15 109:12 111:7,8 119:15 121:2,6 151:15 169:20,20 172:18 187:15 188:3 199:17 202:2 h h 99:14 115:5 161:12 195:20 hair 147:10 half 66:15 75:17 91:4 173:16,17 181:4 198:21 hammer 105:17 hampshire 1:16 hand 15:3 18:13 89:6 126:11,12 131:6,7 147:10,11 handle 35:6 hands 50:13 55:5 56:17 63:19 69:18 70:2,11 71:8 81:18 82:2,8,10 82:20 83:20 86:2 86:14 96:2,12 98:5,5,13,16 99:11 101:8 112:17,18 113:1 115:2 118:4 141:1 141:1,4,4,5,5 146:20 171:7 204:7 happen 23:15,15 33:14 54:10 102:2 105:18 112:19 178:14
--	---	---	--

<p>happening 74:13 76:2 112:15,16,18 155:20 185:8</p> <p>happens 134:11</p> <p>happy 37:6 40:5 41:4 69:11 71:20 72:18</p> <p>hard 17:18 47:16 53:15,18 54:4,21 56:2 59:1,14,20 82:9,13 86:7 94:19 98:11 126:18 177:3,3 183:17 184:3,4,21 185:12 186:15</p> <p>hardening 63:19 99:9 114:19,20</p> <p>hardest 78:17</p> <p>harding 3:12 69:9 69:10 85:17,20 87:5,18,20 92:9 98:1</p> <p>hardship 145:21</p> <p>hate 104:16</p> <p>hates 105:21</p> <p>head 56:16 93:1,8 131:12 186:19</p> <p>headache 198:3</p> <p>heal 53:21 117:20 159:13</p> <p>health 1:9 6:4 9:3 11:6 32:1 37:20 38:1,5,15 52:5 69:12 80:19 103:5 103:19,21 104:3 105:4 109:2 126:11 138:17 154:2</p> <p>healthcare 9:7 15:20 101:4 105:2 140:10 142:4 149:15</p> <p>healthy 125:8</p>	<p>hear 5:15 7:15 9:10 13:6 16:5 29:21 31:8 37:9 51:14,14 52:3,4 52:13 61:13 62:3 69:8 81:4 88:13 89:16 90:2,6,7,12 93:12 104:9 105:3 107:15 123:20 128:21 129:5 135:21 142:14,15 151:15 153:1 155:19 156:19 173:10 207:15</p> <p>heard 16:9 31:14 33:11 41:9 73:13 74:17 79:19 83:7 100:8 101:18 103:19 109:18 110:15 121:11 124:5 163:13 172:15,18 188:16 190:7 193:11,17 196:6 205:11 206:6,9,13,17 207:5,9,11 208:2 208:9,11,12,14</p> <p>hearing 5:18 6:14 14:3,20 16:1,13 40:1 46:10 53:1 82:18,18 101:10 104:1 117:4 173:2</p> <p>hears 145:14</p> <p>heart 24:17 26:4 26:14 50:10 56:15 61:4,8 120:11 153:15 156:13 209:2</p> <p>heartbreaking 183:17</p> <p>heartbreaks 55:1</p> <p>heartburn 50:14 70:4 71:7,8 72:5 99:12 115:3</p>	<p>116:19 169:7,8,16</p> <p>heat 63:5,6 131:13</p> <p>heck 87:8</p> <p>hello 10:16 40:7 62:2 81:2,3 89:15 89:15 90:3 123:19</p> <p>help 9:16 11:21 22:15 25:5 31:1 33:14 34:4 54:7 60:16,17 61:1 75:21 78:21 79:13 83:13 84:6 85:1 102:15 121:19 129:11 141:12 149:11 159:11,13 165:19 168:4 169:17 180:8 186:4 187:2 190:9 194:16 200:10 207:18 209:7,21</p> <p>helped 84:5 103:14 118:19 178:1</p> <p>helpful 29:19 30:10 34:15 61:13 61:19 75:21 88:17 89:19 119:6 120:15 142:14 149:6 162:12 170:3 172:9 173:6 178:10 196:15,15 197:5 199:4,5 201:20 207:13</p> <p>helping 14:8 48:6</p> <p>helps 38:4 54:12 60:19,20 108:1 127:4 190:8 209:12</p> <p>hereto 211:14 212:11</p> <p>hesitance 181:11</p> <p>heterogeneity 29:7</p>	<p>heterogeneous 19:13 21:15</p> <p>hi 39:20 40:3,11 40:15,21 53:5 58:2 62:4 83:10 85:12 89:16 104:8 152:17,18 173:4 180:20</p> <p>hibernation 78:19</p> <p>high 21:18,18 50:11 84:8 130:11 140:18 141:13 159:4 165:21 166:13 171:3 184:13 186:1,3,7 186:8,9,11</p> <p>higher 24:14,14 24:21</p> <p>highlighting 22:3</p> <p>hikes 125:21</p> <p>history 23:18 133:19</p> <p>hit 86:10 98:10 105:16 174:14</p> <p>hits 112:5</p> <p>hitting 98:7</p> <p>hold 16:19 52:19 52:20</p> <p>holding 178:19</p> <p>holes 77:1</p> <p>holistic 168:10</p> <p>home 91:16 95:9 101:15 106:5 126:1 150:8 181:9 201:15</p> <p>honest 161:15</p> <p>honestly 184:11</p> <p>honey 107:4</p> <p>honor 30:6</p> <p>hood 65:20</p> <p>hoops 133:9</p> <p>hope 10:2 30:15 33:17 44:19 51:19 69:4,5 127:15</p>
---	---	---	--

146:13 176:13 203:6 hoped 50:2 hopeful 69:4 hopefully 48:13 122:5 130:14 142:16 164:19 203:9 hopes 206:15 hoping 44:6 46:13 72:10 horrible 78:12 157:14 204:17 horrific 82:1 hospital 106:13,20 144:12,12,18 183:13,20 hospitalized 86:2 hosted 7:14 hosting 151:10 hot 88:3 hour 67:6 75:17 91:4 106:14 185:16 hours 67:7 91:15 91:19 106:16,19 108:2 144:6 175:14 184:7 house 63:1,2 67:8 130:21 household 184:5 housekeeping 6:12 housework 59:20 65:2,3,5,5 huge 71:7 162:8 171:11 187:21 hugely 115:18 hull 2:13 39:20,20 172:21 173:3,4 176:14 177:20 179:2,4 hungry 77:14 118:11	hurt 59:21 86:21 89:3 147:12 hurts 55:13 59:21 60:1 89:10 96:18 97:14 98:2 husband 107:3 125:17 hybrid 193:19 hydrated 74:4 hyperbaric 159:11 hypertension 19:9 24:21 25:7 26:9 26:11 56:14 130:14 137:6 hypothetical 197:2,8,9,14 204:2	illoh 3:6 40:21 111:3 113:15 imagine 175:3 197:15 immediately 91:3 immune 20:11 107:8 127:4 130:3 161:3 162:3 immunity 168:18 immunology 2:5 5:12 immunosuppres... 26:16 139:2 impact 9:12,20 12:20 14:7 27:6 34:8 37:21 45:5 52:6 58:15 70:5 71:7 78:1 85:18 88:15 94:18 95:8 95:10 99:5 100:14 109:2 115:11 118:1 121:5 133:17 146:19 197:21 199:13 201:9 impacted 118:1 impactful 35:12 115:19 impacts 6:5 14:21 15:4 32:1 53:10 69:13 80:20 100:5 104:4 128:19 195:20 207:16 impaired 65:11 164:18 implications 103:20 187:21 importance 117:4 important 8:9,12 9:10 10:1,8 16:19 17:10 22:18 23:14 36:18 37:10 38:10 38:19 57:8 93:11 93:21 110:8,14,18	124:13 140:21 141:1 150:18 158:1 163:17 185:8 207:15 importantly 24:1 27:2 57:18 impossible 70:12 208:18 impression 158:3 impressive 10:6 improve 106:7 139:14 140:13 210:7 improved 123:9 135:2 149:18 152:6 169:3 improvement 139:5 163:6,19 165:3,3 174:5 improves 150:1 improving 145:20 150:21 incidence 22:2 incidents 21:7 include 32:7 93:18 132:18 133:1 134:3,4 198:3,5 208:4,21 included 130:8 131:6 includes 130:11 including 8:20 9:6 11:15 43:16 50:18 173:9 206:10 207:2,6 incontinence 101:13 107:17 171:17 208:15 inconvenience 201:6 incorporate 116:10 158:7 209:5
	i		
	ibuprofen 193:1 idea 47:15 51:18 116:6 162:20 165:2 174:3 199:17 200:3 205:13 ideal 122:18 132:21 145:14 150:8 199:17,20 200:5 204:11 identified 32:14 100:3 118:21 208:1 identifies 32:11 48:16 identify 9:16 47:10 119:4 209:21 210:1 identifying 8:17 ignored 74:16 ii 166:10 iii 25:10 illness 8:10 67:17 135:5 198:7		

<p>incorporated 12:3 35:11,18</p> <p>incorporating 16:20</p> <p>increase 126:3 130:13 134:15</p> <p>increased 74:10 172:4</p> <p>incredibly 58:6</p> <p>incurred 135:12</p> <p>independence 84:4,15</p> <p>independently 77:8 84:3</p> <p>indescribable 96:19</p> <p>indicated 197:16</p> <p>individual 42:10 106:18</p> <p>individuals 6:1,6 32:5,8 38:7 45:17</p> <p>industry 209:18</p> <p>infected 106:3 144:11</p> <p>infection 77:18 86:6 198:5</p> <p>infections 144:10</p> <p>inflamed 97:8</p> <p>inflammation 97:10 127:5</p> <p>inflammatory 25:17 131:2</p> <p>inflicts 209:2</p> <p>influence 9:15</p> <p>info 12:11</p> <p>inform 12:8</p> <p>information 2:5 5:12 9:14 13:17 30:21 36:13,15 37:16,18 39:4 50:2 196:12</p> <p>informative 111:5 188:15</p>	<p>informing 13:19</p> <p>infusion 106:8,13 106:14,19 171:2 201:14</p> <p>infusions 137:20</p> <p>ingenuity 85:2 207:5</p> <p>inhibit 171:10</p> <p>inhibitors 161:9 162:6 165:19 166:11 171:9,10 171:12</p> <p>initial 23:13 27:19 76:17</p> <p>initially 63:18 65:8 70:2</p> <p>initiative 5:6 11:1</p> <p>initiatives 2:8 5:16 10:18</p> <p>injectable 181:5 197:15</p> <p>injected 197:21</p> <p>injection 195:12</p> <p>injections 171:6</p> <p>injured 78:3</p> <p>innovative 85:6</p> <p>input 37:9 38:21 40:2 209:9,11</p> <p>inputs 111:4</p> <p>inside 67:1</p> <p>insights 13:19 205:11</p> <p>insomnia 185:9</p> <p>inspiration 104:19</p> <p>instance 98:2 154:3 169:6 173:15</p> <p>instructor 103:6</p> <p>insurance 133:5 184:8 195:19</p> <p>integrate 41:3</p> <p>integrity 11:17</p> <p>intense 78:8,21</p>	<p>intensified 74:9</p> <p>intentional 31:3</p> <p>intents 130:10</p> <p>interact 71:17</p> <p>interactive 52:11</p> <p>interest 12:16 34:20 35:1 164:15</p> <p>interested 46:9 123:12 173:2 211:15 212:12</p> <p>interesting 168:15</p> <p>internal 20:10,14 23:11 24:15 26:2 101:9</p> <p>internet 41:12 68:8 123:14</p> <p>interrupted 77:19</p> <p>interstitial 24:2 25:8 101:7 137:5 161:6 162:4 181:18</p> <p>intervention 208:13</p> <p>interventions 160:18 161:13,14 162:11 192:15,19 195:1</p> <p>intestinal 143:18 144:21 145:4 166:21 167:1,11</p> <p>intolerance 206:14</p> <p>intolerances 143:15,17</p> <p>intravenous 86:4</p> <p>introduce 7:6 39:7 41:10,18</p> <p>introduced 140:4</p> <p>introduction 129:18</p> <p>investigable 134:3</p> <p>investigational 134:9</p>	<p>invitation 33:7,18</p> <p>inviting 53:4 123:17</p> <p>involved 8:16 28:7 102:8 119:18 210:12</p> <p>involvement 19:5 19:6,7,9,13 20:6 22:4,9 23:1,11 24:3,3,4,5,15,17 24:18 26:1,2 61:5 61:8 117:13</p> <p>involving 70:11 116:20 210:5</p> <p>ironically 74:10</p> <p>irreparable 76:15</p> <p>irritable 125:15 184:19</p> <p>isa 3:14 89:13,15 90:1,3,6,10,12,14</p> <p>ischemia 24:4</p> <p>isolation 75:7</p> <p>issue 38:16 56:10 65:7 120:7 131:21 134:18 148:15 151:3 156:18 164:18 171:11 174:12 175:7 201:4 208:3</p> <p>issues 38:5 56:15 63:18 64:10 67:6 67:8 81:7 82:14 101:10,16 116:19 120:3,9 128:11 129:6 135:19 136:2,12 137:4,5 137:8 138:3 146:11 147:6 151:14 156:8 164:9 166:12 172:5 183:21 207:6 208:2,14,21</p> <p>it'll 16:14 98:14</p>
---	--	--	--

itching 66:9 159:8 itchy 76:10 items 112:11 147:10 iv 106:8,15 199:21 201:6 202:7 204:16,17,18 iv's 137:21 ivs 201:3 202:2,3 i'm 39:17 69:11 83:15	79:10 junction 77:3 junior 74:1	51:18 54:5,10 55:8,11,20 56:7 57:4 58:12 61:14 61:15,17,18 69:3 69:4 71:5 73:3 81:6,12 82:19 83:13 84:15 85:14 86:17 87:3 90:16 92:4,9,12,13,16 92:20 93:3,7,21 95:7,7,8,8,9 96:17 99:1,20 100:18 103:18,20,21 104:6 108:21 109:7,9,10 110:2 110:13 115:11,20 116:6 117:10 118:13,18 119:17 119:19 120:6,17 120:20 121:10,18 121:19 122:4 129:9,9 138:4 142:10,12,20 151:13 154:18 155:14,15 156:21 157:8 159:19 160:4 161:20 162:2,15,20 163:1 164:21 165:4,9,13 165:13,15 167:8 170:5,6,8,10,11 170:17 172:12,17 172:21 173:2,16 175:13 176:16 177:13 181:6 187:8,16 188:4,5 192:9,10,12 193:10,18,20,21 194:9,15,20 195:3 196:18,21 197:1,5 197:6 198:13 199:6,13,14,16,20 200:5 202:17 203:3,5,6,14	209:17 kinds 14:6 64:4 166:12 kitchen 84:10 98:16 176:11 kneel 53:16 knees 70:3,16 86:20 knew 74:12 75:16 87:11 90:18 91:8 knobs 84:10,12 207:8 know 16:14 23:12 25:14 29:14 31:16 33:9 34:10 35:21 37:13 38:15 52:18 53:8,10,12,16 54:4,6,10,13,15 54:16,20 55:1,6,9 55:10,14,18 56:1 56:8,9,10,10,11 56:12,17,21 57:2 57:12,12,14 58:8 59:19,21 60:3,17 60:20 63:13 67:1 68:5,16 69:5 70:13 71:4 74:7 74:18 78:7 79:1 83:17,18,20,21 84:7 86:3 87:8,13 87:17 88:6,10,12 88:13 89:2 94:14 96:9,16 98:3,14 98:15 100:16 105:1,7 106:3,11 107:1,2,7,14,20 107:21 109:5,11 110:8,12,17 111:12,15,16 119:2,21 120:5 123:3 124:13 133:19 141:19 144:14 153:6,9,15 154:7,10 156:12
j	keep 34:15 36:9 36:17 54:21 84:14 126:10 172:1 177:10 184:3 185:8 187:3 208:14 keeping 41:11 keeps 185:10 keith 2:13 39:20 kept 75:4,13 keto 193:4 key 8:17 30:16 75:21 116:13 117:11 208:1,21 khanna 2:9 5:19 6:2 17:2,4,5 29:19 30:2,9 100:8 104:21 kick 30:18 32:4 153:20 164:5 kicks 71:15 kidding 77:10 kidney 89:8 132:9 kidneys 50:10 102:5 131:15 156:14 209:2 kids 181:9,9,15 kill 169:20 killers 161:10 162:8 kimberley 113:9 kimberly 3:13 73:6,7 79:8,10 94:5,8 95:6 113:5 kind 31:1,9 32:15 33:7 43:13 44:10 44:20 46:12 47:1 47:16,16,17,19,20 47:21,21 48:2,5,6 48:18,21 51:15,16		
jackie 3:20 136:10 136:14,18 142:8 151:19 153:20 154:18 188:17 191:16 janel 1:19 211:2 211:18 jar 84:19 jars 70:12 84:6 jaw 71:3 jeffers 3:10 58:2,4 jewelry 64:20 job 1:20 58:5 118:2 184:9 186:1 187:15 206:11 jobs 168:20 185:17 join 10:19 48:6 joining 10:9 16:12 32:8 35:20 45:1 80:5 173:5 joint 24:18 96:11 117:15 joints 53:15 59:21 69:19 70:3 117:5 126:8 journal 27:9,9 journey 27:17 110:16 joy 78:13 83:10 julie 3:10 57:21 58:1 61:12 62:7			

156:15 157:12 159:18 162:13,15 164:6,8,12,18 165:17,18 166:2,9 166:10,12 167:4 167:12 168:21 173:17,20 174:11 174:13,17,20,21 175:14,21 176:2 176:10 179:2,16 179:16,20 181:9 181:10,17 182:5 182:19,21 183:6 183:10,16,19 184:3,10,15,15 185:4,5,11,14,17 185:19 186:10,16 187:2 188:16 189:3,21 191:11 193:16,17 196:16 196:17,20 198:19 199:8 200:6 201:5 201:21 202:21 203:4,18 knowing 65:3 76:7 206:16 knowledge 92:2 129:21 211:9 212:6 knowledgeable 140:8 known 24:2 138:8 kristina 4:3 182:13,13,16,17	large 21:17 24:18 50:9 102:10 115:13 largely 20:18 larger 115:13 118:12 laser 159:12 lastly 134:2,7 late 68:11 171:20 latka 3:20 136:17 136:18 154:1 190:17 launch 43:20 123:2 164:21 laura 3:15 100:17 100:19,21 103:17 105:3 107:16 lay 10:3 lead 103:21 143:13 208:8 leader 2:11,15,20 3:4 39:18 40:4,12 40:19 41:1 leading 92:4 195:3 208:18 leads 20:2 28:1 163:1 leaps 19:17 learn 148:13 learned 29:2 124:8 148:10 169:5,12 learning 85:14 194:17 leave 36:20 63:1,2 130:20 led 13:12 14:12 91:9 leery 191:5 left 18:18 19:2 20:5,9 22:20 25:5 26:6 112:13 131:17 147:10	legs 82:8 146:20 length 49:5 lessen 145:13 lessons 28:19 letter 70:15 letting 187:17 level 78:8 103:8 124:11 134:13 184:13 levels 144:3 151:5 levothyroxine 130:15 library 68:12 life 12:21 15:1 53:10 54:5 66:4 70:6 71:7 73:17 77:3 88:2,16 99:5 101:15 103:2 107:9 124:10 126:12 127:8,10 127:15 128:19 132:17 133:17 134:16 135:1,9 140:18 141:5,17 143:12,13 144:9 145:20,21 146:2,3 146:19 150:5,7 151:8 155:17 156:3,4 167:17 169:2 184:3 188:1 197:21 206:9 lifelong 135:6 lifestyle 118:2 124:10 125:9 128:3 168:14 171:18 lifting 66:17 light 63:7 159:12 lighter 151:6 lights 63:9 likes 169:15 limb 131:16 limbs 147:1 149:7	limit 59:12,12 60:5 208:10,19 limitations 50:1 103:21 144:15,16 limited 12:11 18:19 22:16,19,20 22:20 24:13,19 50:12,13 51:8 59:9 65:10 80:6 104:13,14,15,16 104:17 122:13 144:18 145:6 147:1,14 160:4 limiting 28:14 59:5 103:2 limits 71:8 line 89:13,14 90:5 93:14 100:17 104:6 142:16 144:11 152:9 201:13,16 link 36:4,5 lips 18:17 liquid 106:4 list 2:2 130:11 listed 171:20 193:16 194:12 listen 8:11 31:12 37:3,12 listened 181:10 listening 16:4 37:11 151:9 literally 55:13 86:12 95:2 125:13 147:20 168:20 literature 166:13 liters 101:8 little 11:4 18:20 20:16 21:6 30:15 34:11 43:19 44:15 44:21 47:17 48:5 48:11,13 49:19 57:1,20 64:20 69:3,3 81:5 84:5,6
I			
la. 125:7 lack 29:5,11 92:2 132:2 145:5,6 149:19 167:13 ladies 96:8 98:2 98:20 lag 34:11 laptop 42:8			

85:20 86:8 87:9 89:18,21 96:21 108:9 114:5,6 120:21 122:4,5 129:1 130:17 136:18 138:21 139:18 153:4 156:18 157:9 161:19 165:19 172:13,15 175:6,7 179:11 180:9 200:3 201:19 live 7:2 13:20 16:14 31:17 36:16 43:15 62:14 63:5 79:5,6 90:16 98:18 135:11 141:5 146:12 154:13 186:14 lived 30:1,19 31:5 65:19 75:18 80:7 lives 9:12 206:4 living 6:1 38:18 46:7 57:9,11 73:16,19 96:10 127:10 132:1 140:19 143:8 156:10,11 163:11 178:6,7 181:20 183:17 local 90:21 110:10 190:19,19 localized 18:2 131:13 locations 206:15 locking 75:17 log 43:2 129:2,2 logging 129:10,10 logistics 6:11 london 18:9 long 13:4 49:12 64:19 66:13,14,14 67:9,17,17 75:5 78:7 125:14	132:13 134:19 141:17 145:18 147:9 153:7 165:20 166:9 172:3 178:15 195:17 200:18 204:4 longer 73:19 77:8 77:14 79:5 98:6 137:13 147:9 149:14 174:21 204:16 longest 62:6 look 7:17 21:7 25:3 29:15 43:9 47:18 99:17 108:3 141:1,16,16,21 184:10,14 199:18 200:5 204:11 looked 141:14 looking 10:10 16:12 25:12 40:1 56:19 60:16 77:2 93:14,16 99:21 100:6 107:18 115:7,7,7 140:20 142:3 154:7 161:18 166:4,8 174:1 178:1 196:1 200:17 201:1,7 looks 44:5,6 45:3 46:3 48:20 49:9 51:6 100:1,1,11 106:3,4 115:8 116:1 161:21 191:20 193:10 194:1 196:10,13 197:11 loop 84:7 loperamide 130:18,21 lorvas 149:3 los 180:16,21	lose 62:21 126:7 148:7 196:9 losing 27:20 87:17 206:10 loss 138:5 148:17 148:19 149:20 198:4 208:8 lost 167:21,21 177:15 196:10 lot 12:10 23:6 28:4 28:5,6 31:11 44:15 46:8 47:3 48:9 53:13 55:4 56:15 57:14,19 66:16 68:6,15 69:21 77:17 79:8 83:21 87:8 93:1,1 93:5 96:1,15 98:4 101:15 106:5 107:15 108:18 110:4 114:1 116:13 124:9 130:18 132:17 141:2,13 147:17 149:9 155:19 164:8 168:14 169:3 170:5 172:19,19 173:9 173:10 181:10 184:11,13,19 186:19 194:2,2 197:4,12 200:12 208:1 lotions 193:2 lots 112:15 loud 35:10 louder 89:18 louisiana 180:16 lousy 71:12 love 74:19 104:14 164:16 166:15 loved 6:2 7:15 31:5 32:12 45:8 45:18 46:15 75:6	79:19 80:8 127:16 160:7 184:9,10 185:7 low 58:17 131:14 133:3 lower 18:18 19:2 19:10 lumps 97:12 lunch 55:10 109:10 122:5 175:16 lung 19:8 22:8 24:2,2 25:8 26:14 27:3,14 29:10 50:10 61:4,8 101:7 137:5 161:6 162:5 181:18 209:3 lungs 26:4 76:15 76:16,19,20 77:3 77:7,13,18 139:3 139:6,14 141:9,11 141:12 191:13 lupus 21:1 28:6 51:1 63:4,12 112:20 luxury 128:2 lyna 41:15 90:9 205:4 lyons 3:11 62:2,5 89:1 111:20 112:12
m			
m 70:14 107:14 m.b.b.s. 2:9 m.d. 2:3,11,13,15 2:17 3:2,4 ma'am 62:4 magazine 68:10 magnify 97:16 magnitude 74:8 main 31:21 120:6 141:15			

maintain 131:16 138:16 139:21	matter 6:5 9:11 33:9	102:11,19 105:20 139:11 160:18,19 161:12,14 162:10 170:7 183:13	40:14 91:14,19 96:15 171:3 181:6 181:21
major 131:6,6 178:9 207:10	maureen 21:3	187:4,12 192:15 192:18 195:1 206:1 207:18 208:13 209:6,19	meditating 185:5 meditation 127:11
majority 47:1 48:15 49:10 51:7 150:12 196:2	mayes 21:3	medically 102:20	meds 133:10 143:14 149:12
makeup 64:7	mayfield 80:18	medication 67:19 71:16 72:9 78:10 90:20 101:5 102:14 106:9 128:4 130:11 131:5,20 132:11 133:9 136:21 140:3 144:16 145:10,13 149:9 150:16 155:6 157:17 165:5 168:3 170:8 171:19 172:4 188:20 195:11,13 197:16,18,20 198:9 201:2,12	meet 12:16 15:18 30:7 107:19
making 12:9 39:2 53:15 124:17 139:8 140:4 147:2 181:20 206:16	maze 62:12	medications 26:9 26:12,15 57:6 67:13,15,18 70:10 101:20 108:5 117:17 128:1 130:9 132:17 135:13,14 138:16 138:18 139:1,4,19 140:2 143:14,17 144:17 145:4,7 149:2 150:9 157:14 159:4,7 160:13 161:1,3,6 162:1,2,4,18 167:4,10 193:1,14 194:3	meeting 1:1 5:6 6:9,13,19,21 7:1,3 7:12 8:6 9:9 10:1 10:7,8,20 11:2 12:14 13:13,16 14:16 15:7,18 16:7,10 17:11 28:12 29:11,16,21 30:4,8,11,19 31:2 31:10,19 32:10,16 33:4,10 35:14 36:6 37:9,17,18 38:12 39:13 41:7 41:13 42:2 44:18 45:1,5 46:5,13 48:8 52:11,20,21 69:1 85:15 92:20 93:18 94:1 116:11 151:10 160:9 192:11 196:21 206:5 209:7 210:12,13
malabsorption 208:15	meal 65:13,14 118:9,12	medicines 26:9	meetings 12:9,15 12:18 13:5,8,11 13:14,18 14:4,5 14:10,12,14 15:21 16:19 44:16 80:3 209:6
male 47:11,11	meals 60:1 124:18	medicines 26:9	mejia 3:2 40:15,15 83:10,15 85:9
males 48:16	mean 22:19 33:21 49:11 51:15 58:21 59:1 72:21 86:12 97:1 110:17 119:3 121:3 157:8 158:3 166:18 176:9 187:8,19 190:2 203:5	medicines 26:9	member 32:12 160:7
manage 24:10 60:16 63:6 192:20 193:7	meaning 17:18,18 165:9	medicines 26:9	members 32:8 37:4 38:7 46:6 80:8 163:15
manageable 70:9	meaningful 38:6 127:10 163:5,19 165:3 166:6	medicines 26:9	
managed 57:2 60:15 72:7,9 117:18 148:13	meaningfully 12:2 176:4	medicines 26:9	
management 126:14 150:2 204:5	means 12:6 174:8	medicines 26:9	
managing 6:7 38:1 128:3	meant 42:19 119:11	medicines 26:9	
manifestations 88:15 163:15,16	measure 176:3 177:21 179:19	medicines 26:9	
manners 150:19	measurements 205:16	medicines 26:9	
marked 18:12 20:9 26:7 29:7	measures 27:7 29:8	medicines 26:9	
marrow 102:4 161:11 162:9	mechanism 153:10	medicines 26:9	
maryjoy 3:2 40:15	mechanisms 12:10 148:10	medicines 26:9	
maryland 43:17 211:20	media 102:9	medicines 26:9	
mask 27:13 78:16	medical 2:17 3:2 9:7 11:4 14:19 16:20 30:14 31:11 33:12 39:1,21 40:8,16 46:8 92:3	medicines 26:9	
masked 78:6		medicines 26:9	
massage 60:19 103:1,6 194:13		medicines 26:9	
massive 64:3		medicines 26:9	

memorialized 93:21	142:20	mom 181:12	57:21 73:3 79:13
mental 126:11,12 194:15	mindful 126:16,19 185:5	moment 30:8 45:21 73:12 77:21	94:2 95:14 99:1 103:13 108:1
mentally 108:1	mindfulness 127:12	94:21 98:21 152:10	113:5,5,18 122:13 128:10,13 129:3,3
menti.com 42:7	mine 27:12 101:12	moments 203:17	129:8 136:10
mentimeter 42:6 42:12	minimal 144:20 195:14 196:3,13	monday 168:21	142:18 164:5
mentimeter's 42:7	minimized 204:10	money 91:13	175:8 180:18
mention 81:8	minor 131:7	monica 3:17 123:17,17 124:2	182:12 191:16,18 192:7 194:20
mentioned 33:2 35:13 41:21 52:4 73:1 83:12 85:17 99:15 115:6 116:10,16 117:6 122:15 139:14 151:21 155:20 161:13 162:11 171:8 176:16 179:19 190:19,21 192:19 193:6 194:6 195:21 204:6,9	minute 52:16 122:2,3 132:6	128:8 151:19 154:19 157:6 178:12	197:1 200:11
mentoring 107:13	minutes 23:13 52:9 98:15 123:11 137:10,12 138:11 203:18	monitor 155:8	moved 62:19 105:5 124:11 138:1
merzoug 41:15	misdiagnosis 28:5	monitoring 42:1 203:1	movements 76:10
methods 207:8	miserable 63:1	month 71:1 200:1 200:10	moving 30:3 37:1 44:11 85:13 114:3 126:10 159:20 209:9
methotrexate 26:17	misinformation 28:4	months 60:13 66:21 101:3 133:21 137:1,3 138:2 181:2 183:11	mullin 2:7 5:15 10:13,16,16 16:18 30:9 35:13
metropolitan 43:16 44:14	missed 76:14 114:9	montreal 110:7	multi 22:10 102:7 102:11
metzger 23:19	mission 11:5 41:2	mood 184:18	multiple 42:18 43:8,9 102:4 108:20 193:20 201:8 208:4
michigan 2:10 5:19 21:3 29:15 104:11,21	mobility 137:9 139:5	morbidity 21:18	multisystem 19:5 19:13
middle 18:13 19:8	modality 133:9	morbities 134:5	multitude 72:8
migraine 181:5	mode 16:4 37:11 79:5	morning 5:2 7:8 7:11 17:5,8 39:9 39:17 40:18 41:20 58:2,3 59:2 64:10 67:7 69:10 73:11 175:16	murky 76:21
mild 127:21	model 187:3,4	mortality 21:18 24:14 156:8 191:5	muscle 24:3 96:11 97:6,8 98:3 117:15 208:4
mile 66:15	moderated 1:8	mother 181:8	muscles 117:5
miles 62:19	modification 193:3	motility 65:11	musculature 164:17
million 21:5,9,11	modifications 162:16 193:15 194:4 207:7	mouth 56:5 71:1 108:12 116:20,21 117:14 126:4 165:13	musculoskeletal 20:14
mind 36:9,18 71:18 73:7 74:18 124:21 126:21 129:9 136:14	modify 161:2 162:1	move 43:6 45:6 46:1,2 47:9 48:2 49:4,18 52:10	music 52:20,21 mute 124:1 muted 39:15 97:20

mutual 158:5	110:12 118:7	newly 68:8	nose 18:16 68:5
mycophenolate	140:9 144:17	news 71:20	77:6
26:16	145:3,7 146:1,8,8	nice 15:5 48:11	notary 211:1,19
myeloma 102:4	147:17 167:7,10	nickel 77:1	note 42:9 69:4
myocardial 24:5	168:3 174:5 180:7	nifedipine 161:2	151:6
n	181:14,15 183:15	night 66:8 125:11	notes 155:20
n 2:1 3:1 4:1 5:1	186:11 187:1	125:17 131:12	noticed 95:18
70:14	194:16 203:1	144:6 171:21	numb 87:9
nail 19:2 174:13	209:21	175:16 178:15	number 6:20
nailfold 22:7	needed 76:3 84:2	nightshades 144:2	32:21 47:4 49:4
nails 105:16	90:20 91:8 124:14	nikolay 2:3 5:10	51:8 92:19 114:3
nair 2:15 40:3,3	137:14 145:10	7:6 39:7,10	123:15 162:8
203:20 205:7,9	204:16	152:16	numbness 53:13
naltrexone 58:17	needing 92:5	nikolov 2:3 5:10	nurse 55:3 202:1
name 34:1,1 35:4	103:14	7:6,8,11 30:9 39:8	nurses 144:13
36:16,20 39:10	needs 8:15 12:1	39:9,11 85:10,12	nutrients 125:5
40:3,7,18,21	38:21 186:19	88:12 152:16,18	144:7,8 168:5
41:21 104:8	203:1 205:13	152:20 158:2	nutrition 128:2
129:18 136:17	negative 195:20	nikolov's 5:14	144:6,15 167:16
180:20	neither 74:14	nine 76:1,13 82:14	nyanzi 3:21 143:3
nap 59:2 185:13	211:10 212:7	118:21 144:12	155:2 166:19
national 103:8	neospirin 86:15	nintedanib 26:18	175:12 176:18
natural 23:17	nerve 96:20 118:5	161:7	201:12
78:20	171:5	nitroprusside	o
nature 126:20	nervous 168:16	145:9	o 5:1
127:12	neuropathy 107:2	no's 199:3	o'clock 183:6
nausea 143:20	159:5	nodding 80:1 93:1	o.d. 3:6
198:3	never 54:9 55:18	93:9 113:10	oak 1:15
near 89:7	56:8,9,9 59:3	noel 180:15	observe 169:5
nearly 76:1,13	63:13 66:3 68:14	noelle 4:2 180:20	observing 126:20
178:7	71:12 74:4 75:2,5	180:20 188:16	obtain 12:19
necessarily 154:8	79:1 88:2 102:12	non 26:15 27:19	132:12 133:7,10
186:8 202:13	112:3 134:11	131:5 138:19	obvious 187:19
necessary 157:4	168:20 179:20	149:4 170:7,7	obviously 16:18
209:15	180:10 182:21	normal 105:18	34:10 104:17
neck 23:1	new 1:16 9:4,16	107:10 108:4	105:14 109:6
need 9:16 12:6,15	11:7 12:5 21:8,13	139:7 141:4	115:17 165:7
25:21 32:14 36:14	26:17 30:13 72:16	143:12	195:5 203:1
36:15 38:19 51:14	80:16,18 92:17	normally 150:3	occasional 117:15
51:14 57:9,11,13	107:10 108:4	184:20	occasionally 43:10
63:6 77:5 79:9	139:7 140:5 153:6	north 62:20 65:19	71:10
81:9 90:16 91:6	166:16 197:15	northwestern	occur 12:12 24:9
105:4,17 107:9,12	204:3 207:10	91:18	occurrence
107:17 108:4,5			111:13,16

<p>occurs 175:2 october 1:10 odd 106:17 office 2:5,17 5:3 5:12 25:20 40:8 63:8 90:21 119:13 138:12 200:16 officer 2:13 3:2 39:21 40:16 211:2 oh 78:15 91:4 95:1 112:12 164:1 176:18 185:18 197:10 okay 43:4 45:15 47:9 50:17 61:11 81:3 90:14 98:1 108:16 109:19 110:19 113:2,9 120:14 129:8,13 136:8,17 146:17 156:21 157:6 165:15 166:17,19 168:6 175:4 177:19 179:1 182:9 190:4,15 191:15 192:16,17 193:9 196:1,9,11 198:17 200:21 202:19 old 71:21 74:1 81:21 omeprazole 161:10 162:7 once 55:17 112:2 143:21 144:21 167:3 181:7 198:1 200:1,2,9,9 201:8 208:12 210:8 oncologist 181:1 ones 6:2 7:15 31:5 31:16 75:6 79:19 80:8 84:10,21 127:16 149:13 185:7</p>	<p>online 33:3 80:5,5 81:9,12 113:21 116:7 121:7 122:1 136:5 158:13 160:3 179:8,9,10 179:14 189:11 191:21 196:20 203:19 onset 20:19 28:9 73:21 81:20 131:21 onyeka 3:6 41:1 110:21 oop 119:13 open 31:20 32:19 33:8 35:15 71:3 79:3 84:5,11,21 85:1 121:18 123:4 147:10 191:4 192:3 201:12,14 201:17 openers 84:20 139:13 opening 5:9,14 7:7 31:14 70:12 75:20 137:17 operations 3:8 opinions 38:8,9 opioids 130:15 132:10,11 opportunities 150:10 opportunity 6:17 9:10,10 10:10 29:16 33:6,17 39:5 43:1 121:14 124:5 128:7 157:11 170:15 203:9 205:10 opposed 187:4 option 13:13 42:11 99:8 140:19 155:12 188:20 189:3,5 191:1,3</p>	<p>options 15:9 43:18 45:11 46:18 49:6 49:21 114:17 132:9 133:14 140:9 142:2 150:15 170:21 198:10 206:19 oral 132:16 138:1 195:13 199:21 201:2 order 32:16 58:12 122:4 139:21 140:18 154:18 191:10,14 206:11 207:3 ordinary 143:13 organ 23:11 24:15 26:1,2 50:9,17 101:9 134:17 151:1 161:4,11 162:9 206:2 organization 34:20 110:7 organizations 110:6 organizers 124:4 organs 20:14 22:11 26:4 140:14 145:14,20 146:2 209:2 orientation 31:1 orphan 21:14 29:4 orthopedist 28:3 outcome 3:6 27:7 29:8 41:2 211:15 212:12 outcomes 8:18 177:21 205:20 outlines 39:4 outlook 194:15 outside 29:6 67:1 138:9 185:6 outweigh 140:15 204:5</p>	<p>outweighs 209:16 overall 61:15 68:4 80:19 134:16 overgrowth 143:18 164:11 overhead 63:9 overlap 50:20,21 51:10 63:3 overlapping 57:1 overrepresentati... 44:16 oversee 11:13 overseeing 11:8 oversite 11:14,15 overtime 127:1 overuse 96:12 overview 10:21 14:17 17:3 170:11 overwhelmed 35:5 overwhelming 147:20 oxycontin 161:11 oxygen 77:5,6,12 101:7 209:1</p>
			p
			<p>p 2:1,1 3:1,1 4:1,1 5:1 p.m. 210:14 pa 91:2,2 pain 27:19 28:13 50:11,14 53:13,15 59:7,11 63:20 66:16 70:2 71:8 72:15 73:17,18,19 74:8,9,10 75:4,14 75:19 78:3,6,9,10 78:12,21 82:2,5 86:3,10 94:18,19 95:19,20,21 96:1 96:3,3,11,11,12 96:13,14,15,16,19 96:19,20 97:7,8 97:15 98:4,10,18</p>

106:2 111:17 113:8 117:3,5,15 118:5 130:15 131:13 132:6,7,14 132:19 145:12,13 150:2,2 159:5,9 159:13 161:10 162:8 171:6 181:19 182:16 183:9,10 184:13 184:17,18 185:10 190:10,11 198:4 202:18 206:14,16 206:18,20 208:2,5 208:5,5 painful 53:21 62:19 89:5 99:10 115:1 137:12 148:5 181:20 pains 74:16 97:6 98:3 143:21 painted 64:19 pajamas 65:19 paleo 193:4 palm 22:8 palpable 75:15 pandemic 63:14 panel 6:10 15:2,10 18:11,18,21 19:8 19:10 32:5,17,20 33:7 39:6 49:18 52:3,4,9 73:4 83:8 109:6,12 163:15 panelist 3:9,10,11 3:12,13,17,18,19 3:20,21 52:13 73:6 83:12,17 95:15 110:20 172:16 panelists 29:21 30:7 32:6,7,13 41:8,19 52:7 53:1 73:12 83:7 92:21 95:14 99:16 100:9	101:10 104:2 108:9,18 109:15 111:2,4 113:11 119:8 121:15 122:21 123:3 124:1 151:18 152:11,12 158:18 159:19 160:8 163:3 172:21 173:5 181:10 186:14 188:5,9,14 189:14 193:12 196:8 199:15 205:1,2 paralyzing 206:18 paramount 38:10 parasympathetic 168:16 parenteral 144:5 parents 110:1 part 5:6 8:5 9:2 11:2,6,9 30:11,18 36:20 62:21 69:11 70:10 74:21 93:17 93:17 107:13 112:6 155:7 163:18 165:18 168:17 175:20 184:7 186:5 192:4 partial 147:11 participant 116:16 117:6,12 134:8 171:1,20 179:15,18 194:11 204:3,6,8,15 participants 80:6 117:2 160:5 171:1 171:8 participate 10:5 12:15 32:13 33:18 36:1 39:13 51:21 58:7,12 66:21 99:17 150:4 206:7 206:9	participated 122:1 209:7 participating 15:7 47:15 51:13,20 116:7 160:8 170:13 188:14 203:12 206:4 participation 47:7 210:9 particularly 8:16 61:15 92:16 parties 211:11,14 212:8,11 partner 126:12 partners 9:6,8 parts 124:16 party 42:5 passed 124:7 passing 74:6 patches 99:9 114:19,21 pathogenesis 19:16,18 20:3,4 29:3 pathways 25:16 25:17 patient 1:2 3:14 3:15,16 4:2,3 5:7 5:17 7:13 9:20 10:14 11:1,19 12:11 13:4,12,14 14:3,12 15:17,19 16:6,8,20 17:11 18:18 23:20 27:11 30:7 90:15 93:19 110:13 126:15 143:8 152:12 159:1 205:2,13,19 209:5,8,9 210:1,3 patient's 12:6,19 13:6 205:21 patients 7:15 8:1,4 8:9,12,17,21 9:19 12:1,7,14 14:21	15:2,11 16:2,5,9 18:11,19 23:8,12 24:8,10,16,20 26:6,13 28:8 29:12 38:7 40:2 46:5 103:1 134:3 134:4 141:2 144:14,21 145:11 158:4 173:10,15 184:10 187:9 206:14 207:14,16 207:19 210:5 pause 42:21 45:13 pays 125:18 peace 127:10,13 peaceful 169:2 peak 20:19 peel 159:12 peer 107:13 133:5 pelvic 194:13 people 6:15 15:7 17:21 18:3,6 21:11,13 22:16,21 23:3 24:1,13 27:10 28:12 29:4 34:17 37:6 44:12 44:20,21 45:3 46:5 47:1,4,19 48:1,12 49:10,12 49:14 51:7,8,9,12 51:18,19 54:7 57:14 68:10 78:7 78:14 89:21 93:5 100:3,6 105:9 106:16 114:11 115:13 116:7 118:21 119:3 123:12 137:15 162:2,8,10 176:5 184:19,20 186:8 186:11 187:1 189:11 190:7,8,8 196:7 198:21 202:21 203:8,11
---	--	---	--

<p>206:21 people's 42:10 82:18 206:3 percent 23:2,8 100:2,5,5,6 116:3 118:21 144:6 162:2,3,3,5,7,7,10 165:10 166:5,6 167:12,15 191:13 percentage 115:13 percocet 161:11 perfect 46:17 124:2 141:19 156:20 perfectly 99:18 perfusion 130:13 pericarditis 183:12 period 52:16 101:6 periods 62:10 132:13 147:9 permanent 117:20 person 18:14 22:12 27:18 32:11 44:16 51:9 54:14 55:20 57:9 62:6 105:18 127:19 147:8 151:8 180:6 185:2 personal 6:15 31:20 36:12,15 38:9,11 48:9,9 134:13 150:17 156:16 160:6 personality 174:16 184:20 personally 164:15 perspective 8:1,12 8:21 12:7 31:21 142:10 152:14 205:19,21 209:5,8 209:20</p>	<p>perspectives 12:1 12:19 122:17 205:11 210:9 pfdd 11:21 12:9 12:18 16:19 80:3 ph 17:17 130:13 ph.d. 2:7,20 pharmacy 129:20 phase 135:4 phenomenon 19:6 20:7 22:9 24:4 26:7 28:1 50:14 50:18 99:11 100:4 115:3,15 116:2,15 phone 6:20 33:2 33:20 41:16 42:8 42:13 80:11 93:16 99:17 136:4 180:12,13 phones 43:5 94:4 124:1 160:10 phrased 179:15 physical 124:11 126:11 131:14 162:16 180:2 193:3,14 194:3 physically 206:14 physician 90:17 132:12 144:13 149:10 195:20 physician's 150:15,19 physicians 22:1 68:13 102:12 149:14 150:11 piano 64:15 206:8 picc 144:11 201:13,16 pick 85:3 115:18 120:2 160:9 207:7 picked 120:2 picking 89:4 149:13</p>	<p>picks 103:18 picture 51:18 piece 75:21 pieces 86:19 pigment 18:13 pill 85:1 108:7 pin 17:6 pinch 29:9 pink 105:10 pinning 18:16,16 pipeline 182:1 pitting 117:21 pittsburgh 23:18 pj's 55:12 place 6:13 16:19 63:5 67:2 83:20 156:1 placed 52:19 places 107:14 plagued 75:2 plan 57:5 149:16 plane 63:15 67:11 planned 207:1 planning 116:10 124:18 150:6 207:3 210:12 plans 206:9 platform 35:8 43:14 play 11:8 90:8 206:8 played 64:15 playing 44:17 plays 9:1 please 11:2,18 12:4 13:2,21 14:13 15:16 16:10 25:2,18 27:4,16 33:16 36:2,12,17 42:9 43:5 46:15 52:14 80:10,21 81:1 83:9 97:20 99:7 100:20 123:13 160:9</p>	<p>189:12,21 pleasure 7:5 17:6 17:9 plug 121:1 170:16 plus 66:1 point 14:11 26:20 27:7 45:15 83:4 126:9 138:4 148:8 154:14 155:16 157:15 168:10 170:9 172:12 173:6 188:7 points 6:12 34:16 168:5 poll 42:12 188:19 polling 6:16 33:1 42:4,6,6,19 43:5,6 43:10,14 45:16 51:20 80:4,6 94:3 94:3 95:12 99:2,7 100:16 113:18,19 116:4 159:21 160:1,4 162:13 170:6 191:16,19 192:8 194:21 197:2 polymerase 25:10 polymyositis 51:2 pool 194:13 pooped 107:18 poor 54:1 pop 84:5 population 92:3 210:1 port 106:15 portable 77:12 portion 31:19 32:19 52:11 position 103:9 137:11 139:16 positioned 12:7 positions 103:7 positive 54:8 57:5 68:17 139:8</p>
--	--	--	---

<p>141:20 possibility 141:6 154:8 possible 26:2 34:9 34:13,18 35:7 80:1 131:16 153:9 201:2 203:5,11 possibly 141:10 154:15 post 109:10 potential 45:5 133:14 145:19 153:7 198:14,15 210:2,6 potentially 50:10 70:19 pounds 68:2,3 167:21 powerful 8:6 ppfd 16:7 practice 25:3 102:21 103:3 125:20 126:1,3,15 126:21 practicing 127:11 practitioner 103:1 practitioners 91:12 pray 125:7 prayer 127:12 praying 72:10 precious 126:6 predict 112:3,3 prednisone 161:8 predominance 20:20 predominantly 26:14 predominately 25:17 prefer 151:4 preferential 135:8 premature 148:15</p>	<p>prepare 121:17 prepared 30:8 212:3 prescribed 149:3 149:10 prescribers 158:5 prescription 91:15 150:9 prescriptions 138:19 143:14 present 9:8 72:17 135:5 presentation 17:3 29:20 30:10 presentations 31:11 32:18 presented 189:5 presenting 17:9 preservation 130:13 134:17 preserve 140:14 150:21 press 126:18 pressure 50:11 118:4 159:4 171:3 186:10 pretty 44:8 57:2 59:19 64:16 68:4 78:18 82:16 86:19 152:21 155:3 156:16 157:5 167:16 193:10 201:4 prevalence 21:4 22:2 prevent 26:1 27:1 161:4 preventative 149:2 previous 114:5,18 previously 33:3 65:18 131:1 192:19 208:20</p>	<p>primarily 86:1 primary 28:1,2 29:12 69:17 prior 12:9 70:8 211:5 priorities 12:2 private 102:21 privilege 17:9 prn 130:15 pro 107:5 probably 56:20 63:12 93:5 120:3 120:12 122:3 154:13 175:3 probe 153:4 problem 58:19 59:6,10 62:17 63:7 64:11 65:6 66:4 91:20 102:13 165:18 169:19 185:9 208:7 problems 55:5 66:11 74:20 125:4 144:21 156:7,8 164:10 165:8 169:3,10 173:12 174:18 proceed 30:5 proceeding 212:4 proceedings 211:3 211:4,6,8 212:6 process 6:10 9:2 11:9,17 16:21 61:18 102:1 210:6 210:7 producers 81:5 product 9:7 11:4 16:21 30:14 33:12 39:1 46:8 135:9 149:5 151:4 153:13 198:16 207:19 209:6,19 productive 10:11</p>	<p>products 149:5 151:4 153:6,19 160:18 161:12,14 162:11 192:15,18 195:1 professional 125:1 professionally 129:20 professionals 31:11 professor 2:9 18:9 21:3 23:19 profile 189:7 profound 164:2 profusion 132:3 prognosticate 25:5 program 13:7 21:17 107:14 programs 9:18 progress 137:2,8 137:18 progressed 56:13 progressing 23:21 138:6 154:4 155:12 181:3,7 progression 27:4 102:16 131:19 134:15 153:8 182:7 progressive 24:15 26:3 prolong 146:2 156:3 prolonging 145:20 prominent 135:4 promote 9:3 11:6 promotes 127:3 prompted 77:15 pronged 20:4 pronounce 160:13 pronunciation 161:17</p>
--	--	---	---

<p>protect 9:3 11:6 145:13 146:2</p> <p>protein 169:14</p> <p>proton 161:8 162:6 165:19 166:11,14 171:9 171:10,12</p> <p>provable 29:12</p> <p>proved 70:1</p> <p>provide 5:20 10:13 11:14 17:3 35:4 41:16 116:6 205:7 209:12</p> <p>provided 9:14 12:18 14:18 23:18</p> <p>providers 9:7 15:21 74:15 101:4 140:10 142:4</p> <p>provides 15:5,12 195:14 196:3,13</p> <p>providing 7:6 170:13 172:10</p>	<p>purple 108:6</p> <p>purpose 32:17,18 48:2 85:15 153:1</p> <p>purposeful 31:3</p> <p>purposes 22:2</p> <p>pursue 189:6</p> <p>push 84:11 94:20</p> <p>put 36:20 50:1 74:14 84:8 85:3 86:4,20 88:4 108:10 109:5 113:1 118:4 136:21 144:5 147:9 157:7 165:12 170:16 177:3 181:6 184:12 187:11 190:2 197:5,12</p> <p>puts 72:6</p> <p>putting 6:20 64:20 95:7 190:10</p> <p>puzzle 75:21</p>	<p>94:3 95:13,16 99:2,6,7 108:10 109:16 111:1,5,10 112:6 113:4,19,19 114:3,5,18 116:4 123:4,13 153:12 159:21 161:16,21 162:14 163:18 170:6 173:1,13 174:9 176:14 182:4,11 188:10 192:8,14 194:21 195:4 197:2 199:15 204:14</p> <p>questionnaires 173:21</p> <p>questions 6:17 14:6,8 32:21 37:13,15 38:17 41:8,9 42:4,17,19 43:10,13 47:12 48:5 58:11 80:4 80:10 83:6 85:10 94:4 95:12 100:16 113:14 114:12 123:5 140:3 149:15 152:1,2,2 152:11 158:17 159:18 160:2 162:15 163:2,4 191:16,19</p> <p>quick 73:11 105:4 121:1 199:15</p> <p>quickly 116:12</p> <p>quit 82:8</p> <p>quite 19:4 21:15 54:19 72:2 77:16 86:13 130:19 132:7 162:14 163:13</p> <p>quo 138:16 140:1</p>	<p>r</p> <p>r 2:1 3:1 4:1 5:1 18:20</p> <p>rachael 2:11 39:14 39:17</p> <p>radiates 98:13</p> <p>raise 210:2</p> <p>raised 72:21</p> <p>raises 97:9</p> <p>raj 2:15 40:3</p> <p>ran 49:21</p> <p>random 60:5 77:1</p> <p>range 14:2,4 46:17,21,21 47:4 47:5 51:12 100:12</p> <p>rapid 81:20 192:9</p> <p>rapidly 137:19 138:6</p> <p>rare 21:2 91:4 145:15 181:13 186:13</p> <p>rarely 130:16</p> <p>rarer 198:4</p> <p>rash 112:20</p> <p>rashes 143:20</p> <p>rate 191:5</p> <p>rated 178:7</p> <p>raw 98:7</p> <p>ray 76:18 91:10</p> <p>raynaud 111:7 112:9</p> <p>raynaud's 19:6 20:7 22:9 24:4 26:7 27:21 50:14 50:18 53:12 54:1 72:4 81:21 99:11 100:4 101:19 105:9,9,12 106:8 111:6 115:2,15 116:2,15,17 117:14,16 137:5 145:8 147:2 159:5 171:3,7 172:2 206:13</p>
<p>psychological 193:5 194:5</p> <p>public 1:1,9 7:12 9:3 11:6 14:16 35:14,17 36:10,11 38:12 121:10 151:10 211:1,19</p> <p>published 18:10 21:3 27:9</p> <p>puffy 27:21</p> <p>pull 86:16</p> <p>pulled 86:19 144:1</p> <p>pulmonary 19:8 24:21 25:7 26:8 26:11 54:20 56:3 56:14 117:13 120:3 130:14 137:6</p> <p>pump 161:9 162:6 165:19 166:11,14 171:9,10,12</p>	<p>q</p> <p>qr 42:14 43:1</p> <p>qualified 211:7</p> <p>qualify 29:4 150:9</p> <p>quality 88:16 101:15 124:9 133:17 134:16 145:20 146:2 156:4 178:5,6 188:1 194:16</p> <p>quantity 194:16</p> <p>quarantine 126:15</p> <p>quest 76:1</p> <p>question 22:13 43:5,7,12,15 45:7 45:8,16 46:1,3,4,4 46:14 47:10 49:4 49:18,19 50:4 59:8 60:10,14 61:3 66:17 85:8 85:11,16 88:10</p>		

reabsorbing 117:1 reach 53:16 84:8,9 98:9 reachers 84:18 reaching 56:11 reaction 181:5 read 35:10 49:20 50:3 117:9 197:9 197:11 ready 43:6 64:10 94:4 real 72:11 75:16 151:5 realities 71:19 reality 185:20 realize 54:17 94:21 112:16 184:2 really 10:9 11:16 12:6,10,11 13:13 13:15,17 16:12,19 24:7 27:12 28:11 29:19 30:10,12 31:19 32:13,18,19 33:6,8,19 34:2,2 36:15,18 37:12 39:12 44:10 45:4 45:4 46:4,9,11,12 47:2,13,14 48:6,6 49:17 51:13,17,17 52:13 53:6,8,9,17 53:19,20 54:4,13 54:17 55:4,11 57:3,3,5,6,8,10,13 58:4,10,10 59:11 59:13,17,20 61:5 61:5,9,13,13,17 61:19 65:13 69:2 71:10,14 73:2,2 79:9,12 80:1 82:18 84:4 86:7 88:2 90:18 92:6,8 92:11 93:5,11 94:21 95:8 96:16	96:17 103:18 105:3 107:11 109:1 110:3,8 115:11 118:17 119:2,6,6,17 120:6,15,15,19 121:3,4,15,16,17 121:18 125:1 129:4 136:15 142:12,13,14 143:2 146:6,8 151:16 154:12 157:17 159:21 162:20 166:21 167:5,20 172:9,16 172:21 174:10 175:21 176:9 178:18,21 183:17 184:21 185:8,12 186:5 187:7,13,18 188:2,3,3,5 192:5 193:20 197:2 199:4,4,6 201:10 201:21 202:6,6,7 202:9,20 203:4,5 reason 35:9 36:11 106:17 108:18 133:4 188:21 190:6 rebecca 2:20 40:11 recall 80:12,15 receive 35:8 159:1 194:10 received 75:9,21 76:7,17 81:8,11 81:14,19 113:21 113:21 171:15 204:1 receiving 75:11 92:18,18 101:1 170:12 179:13 recognize 186:11 186:12	recognized 7:20 8:15 recommendation 138:10,12,13 recommended 145:9 171:17 recommending 140:10 142:5 record 122:11 211:9 212:5 recorded 7:2 211:6 recording 211:8 212:4 recovery 65:4 red 50:15 88:3 reduce 26:2 27:2 180:9 197:20 reduced 24:18 211:6 reduces 127:4 referral 195:20 reflected 79:20 reflective 119:17 119:20 reflux 56:4 65:9 118:11 130:12 131:12 164:10 165:10,11,20 166:3 208:13 regard 12:12 regarding 75:19 88:20 169:5 regards 207:16 regimen 123:7 131:19 133:4 149:8 152:4 159:15 201:7 regimens 132:19 registered 36:6 37:8 regret 55:5 regular 118:9 176:8 202:6	regularly 126:8,16 168:11 regulate 185:12 regulators 46:8 regulatory 9:17 12:9 regurgitation 77:18 rejection 161:4 relapse 140:5 related 27:10 34:21 80:10 109:18 128:4 180:5 211:11 212:7 relationship 77:9 relative 211:13 212:10 relatively 94:15 relax 149:7 relaxed 124:21 relevant 9:18 reliant 77:10 relief 151:5 relocate 206:15 rely 94:16 remain 16:3 33:21 114:17 remains 160:4 remarkable 20:9 remarks 5:10,14 7:7 31:14 75:8,12 121:17 203:21 205:8,10 remember 46:15 73:16,21 177:7 reminded 21:17 reminder 79:16 121:1 126:8 remission 143:10 removal 147:13 removed 87:2,6 renal 19:10 24:17 25:10 130:12
--	---	---	---

<p>131:11 181:18 report 16:8 35:11 35:19 93:19 116:12 reported 1:19 166:13 188:19 reporting 166:10 represent 8:19 37:7 representations 8:3 representatives 16:6 33:11 representing 31:5 request 34:18 76:3 requirement 209:1 requirements 191:10,12 requires 208:13 reschedule 59:15 60:7 research 2:6,19 3:8 5:4,13 10:19 37:8 40:10 127:6 138:7 140:9 191:9 203:12 researchers 15:20 33:12 resembled 77:1 resign 103:7,8 185:21 resolved 123:9 135:19 149:18 152:6 resonates 52:13 93:5 203:6,7 resources 68:16 respect 8:20 38:9 responded 188:19 responding 123:13 response 78:21 113:4 196:9</p>	<p>responses 42:11 49:2 160:11 196:11 198:20 rest 61:1 168:17 180:8 183:7 203:7 rested 74:4 175:2 result 11:13 50:15 145:15 184:18 200:19 resultant 164:12 resulted 9:19 134:18 results 20:13 43:10,21 44:3 45:13 76:17 99:21 119:16,17 141:20 144:11 150:17 reticent 156:9 retire 102:20 139:10 retired 110:2 revealed 75:18 reverse 31:12 review 11:12 12:13 18:8 37:14 173:8 205:16 209:12 reviewer 2:17 40:8 reviewers 187:12 reviewing 173:7 reviews 150:15,16 revolved 184:6 rewarding 102:18 rheumatic 21:19 51:1 rheumatoid 21:1 28:5 51:2 rheumatologist 28:3,3 76:3,6,18 138:7 145:2 154:3 167:7,18 rheumatologists 167:17 189:2</p>	<p>190:20 rheumatology 2:4 2:12,13,16,21 5:11 39:12,18,21 40:5,13 ribs 78:4 rick 81:14 right 6:10,19 23:5 24:19 25:12 26:13 43:19 44:5 45:13 45:13 46:2 49:9,9 51:6,6 57:16 62:3 80:21 82:17 85:2 89:7 92:7 107:5,5 108:7 111:3 113:18 122:10 124:1 142:19 147:11 149:21 152:8 154:17 155:15,21 156:10 160:16 161:18 162:19 163:1 181:7 182:16 188:12 191:20 199:1,16 rip 71:2 risk 9:15 66:17 133:11 140:17 141:6,13 142:3,13 150:20,20 151:1,3 155:17 157:21 181:12 186:1,3,7 186:8,11 189:7 190:10 196:5 198:7 209:16 riskier 135:2 risks 128:4 135:12 135:14 140:15 141:10,15 153:3 158:8 181:21 182:2 195:17 198:8,15 207:20 risky 156:3</p>	<p>rituxan 182:5 rn 1:8 rna 25:10 road 153:16 robe 65:20 66:7 robin 152:16 robyn 1:8 5:3 41:21 53:5 58:20 94:10 116:9 122:9 124:3 158:21 166:5 168:9 170:20 204:14 rock 82:9 86:8 role 9:1 11:4,8 19:20 24:6 205:12 roof 86:11 room 65:14 91:6,9 209:20 roomful 47:18 roots 116:21 rosemary 3:11 61:21 62:1,4 68:20 79:10 88:18 89:11 111:19 rothwell 2:20 40:11,12 rough 129:1 roughly 20:3 routine 92:18 208:20 routines 125:20 row 22:5 rules 37:1 run 42:6 59:17 130:2 134:19 running 173:16 runs 21:16</p>
s			
<p>s 2:1 3:1 4:1 5:1 18:20 sadly 78:6 safe 141:20 151:4 safety 9:4 11:7,16 153:12 198:15</p>			

203:2	72:13 101:2,17	123:7 128:18	166:20 168:11
salivary 127:3	102:1 104:12,13	146:18 148:16	170:10 174:5,7
san 182:12	104:15 105:6,10	151:18 152:4	176:5,19 177:13
sander 127:5	105:11 110:4,10	153:4 160:6,20	187:17 189:15
satisfactorily	114:15 120:6	163:12 187:9	191:2 193:9 194:8
135:12	122:17 124:6,7	192:20 193:7	seeing 44:9 49:1,1
save 140:18	127:21 129:19	197:16 205:20	51:7 81:13 82:17
saved 167:16	130:4,7 131:11,20	scratch 124:19	100:2 103:1
saves 106:5	133:1 135:1	scratched 121:4	110:11 116:2,7,13
saw 68:13 108:3	136:21 138:8	scream 98:11	116:18 118:14
saying 11:3 49:15	140:8 141:2,14	screen 6:19,21	194:2,2 198:17
64:15 97:5 104:18	142:1,7 143:4,9	25:21 27:1 80:10	seen 29:9,10 39:10
105:4 106:1	144:14 145:11,15	154:19	68:14 91:1 102:13
107:15 109:21	145:16 148:3,11	screening 12:16	sees 112:17
173:13 175:14	149:1 151:17	screens 43:9	seizures 67:21
scar 117:21	155:3,15 156:10	script 31:9 201:19	198:6
scaring 165:21	160:6 167:19	search 21:12	select 50:6
scenario 197:3,8,9	169:1 173:9	searching 76:1	selecting 150:14
197:14 204:2	174:14,18 175:21	second 6:6 44:1,2	self 73:18 83:21
scenes 205:5	181:1,17 184:1	48:21 109:3	127:4 197:15
school 168:20	186:2 193:8 201:3	198:18,19 205:3	200:14 201:15
schreiber 2:17	205:13,16,18	secondary 137:4,7	sell 59:16
40:7,8 188:8,12	206:1,7,12 207:4	145:8	send 28:4
science 209:9	207:6,12,13,17,21	secretion 127:3	sends 28:2 86:10
210:7	208:3,15 209:2,7	see 14:4 18:12,13	senior 14:19
scientific 7:19	sclerosis 1:3 5:21	18:14,16,20 19:1	sense 14:1 77:14
38:2 42:20 47:13	6:1,5,8,16 7:14,17	22:12 28:12 33:14	176:13
scientists 156:2	7:17 8:13 10:4	37:6 41:8 42:10	sensitive 64:1
sclero 17:18	16:14 17:4,10,12	43:1,10,21 44:2,3	147:3
sclerodactyly	18:3,7 20:7,17	44:3 46:3 47:1,19	sensitivity 53:13
204:7	22:4,14 23:3,4,15	47:19 48:15,15,16	70:5 99:11 115:2
scleroderma 6:2	25:1 30:20 31:6	60:18 76:3 78:14	sent 182:18
17:9,16 18:1,1,4	31:17,21 32:2,5	80:1,2 83:5 84:1	sentence 148:12
18:12,14,19 19:16	32:12 33:13,15	90:17 91:2,17,21	sepsis 144:10
20:2,12 21:13,17	34:21 35:1 37:4	92:21 93:8 95:15	sequence 20:2
22:9,13,17 23:8	37:21 38:18 45:9	97:9 99:21 109:13	series 167:2 174:4
23:10 24:16 25:4	45:17,19 46:7	112:15,17 113:10	serious 102:2
25:10 27:9,11,18	50:5,20 51:10	113:10 119:8	125:4 195:16
29:1,5,6 30:1,20	52:6 54:15 58:14	122:8,18 128:12	196:14 198:5
31:6 32:2,11 37:3	60:11,15 61:4,7	129:10 131:7	serve 5:5
45:10,19 46:7	69:13 72:15 76:8	135:18 138:9	service 1:9
50:5 53:6,9 54:3	79:13 80:7 81:15	139:5,7 150:12	session 6:4,6,11
57:9,14 69:15	99:4 114:14	152:6,11 154:18	14:20 15:8 32:4
70:1 71:19 72:7	117:12 122:16	161:19,20 166:16	52:7 73:6 109:1,3

<p>120:19 123:5 152:1 197:7 sessions 6:3 205:3 set 14:14 29:20 31:2 94:3 113:1 178:3 186:17 191:19 sets 123:5 setting 6:14 34:11 44:11,18 47:18 79:21 118:20 188:6,6 seven 44:21 56:8 66:20 seventy 167:15 severe 101:12 130:11,19 133:16 135:6 149:19 156:8 159:4 164:12 181:5 189:4 206:14 208:18 severely 156:13 severity 12:20 75:4 111:14 209:13 shake 98:16 shannon 3:8 41:10 41:17,19,21 80:12 81:7 83:1 116:5,8 118:17 158:11,19 159:17 170:10,19 170:19 172:8 179:7 194:7,8 203:19,21 204:21 205:4 shape 27:14 share 6:17 8:6 30:4,21 32:15 33:20 35:7,16 36:13 37:15 38:12 52:14,17,19 53:4 58:1,1 62:1 69:12 80:9,14,14 81:10</p>	<p>89:14 94:6,10 100:18 104:6 108:9,13 114:1 123:17 127:20 153:18 158:15,15 158:19 160:10 170:17 179:11 180:14 182:8,14 189:17,20 192:2 196:18,19 199:17 205:10 shared 32:20 79:16,20,20 113:12 153:5 188:17 200:7 205:12 209:20 sharing 41:12 48:13 52:7,10,15 57:18,18 69:2,3 73:8,13 79:11 83:2 93:10 111:4 123:1,12,14 128:9 136:15 151:19 152:21 158:3,9 188:4 206:5 210:9 shelf 98:10 shell 76:9 shera 2:17 40:7 sheri 3:16 104:5,8 104:8,11 109:14 109:18 shiny 76:10 shoes 64:9,9 84:8 88:4 shopping 55:9 60:1,2 124:18 short 15:15 101:6 195:15 shortened 161:20 shorter 184:19 shortly 122:8 shortness 59:5 208:21</p>	<p>shot 151:13 shoulder 89:5,9 shouldered 75:11 shoulders 70:3 show 18:1 30:21 76:18 showed 21:15 showing 20:5 23:20 81:4 shown 20:9 22:20 25:5 197:20 shows 22:5 24:16 shrinking 116:21 shuts 71:18 sibo 143:18 145:5 167:1,3 169:19 sick 108:3 sicker 134:21 side 19:2 20:5,9 22:20 23:5 24:19 25:5,12 26:6,13 43:9 128:5 133:15 133:16 134:14,17 138:2 141:7 143:17 145:9 150:16 154:6,15 157:14,20 159:7,9 165:20 166:9 171:13 195:15 196:3,14 198:2,5 199:1 204:4 sides 132:18 signature 211:18 212:14 significant 7:20 9:20 35:1 58:15 59:4 69:12 99:5 100:4,13,14 115:16 146:21 150:6 208:3,13 significantly 197:21 sildenafil 130:13 132:4</p>	<p>silence 75:11 silent 16:3 silver 1:17 similar 14:6 20:21 114:4 202:4 simple 71:9 91:7 127:2 133:4 147:16 203:10 sine 23:8 50:17 51:9 single 73:17 114:7 114:15 204:15 sip 122:6,6 sit 66:13 67:2 137:10 site 42:7 sitting 63:8 154:11 situation 67:4 71:5 92:6 172:6 190:11 six 51:9 75:1 106:19 133:21 137:1,3 sized 77:1 118:9 sjogren's 51:3 101:20 skills 211:10 212:6 skin 17:19 18:12 18:21 20:13 22:4 22:5,20 23:6,9,20 25:15 26:14 27:21 29:9 50:8,12,18 56:5 58:18 63:18 63:19,21 64:3,4 64:10 70:4 72:1,1 76:10 82:4 97:9 98:5 99:9,9 101:8 114:19,20,21,21 117:15 120:5,7 137:21 143:19 146:20,20,21 149:18 161:7 skipped 192:16,17</p>
---	--	--	---

<p>skyrocketed 144:3 sleep 61:1,2 64:7 66:3,4 71:18 78:20 124:11 125:9,12,18 159:8 169:1 175:14 sleeping 65:18 66:10 116:14 185:11 slide 11:2,18 12:4 13:2,3,20 14:13 15:15 16:10 17:12 17:15 18:7,8,10 19:14,15 20:15 21:16,19,20 22:3 22:11,21 23:11 24:11,15,19 25:2 25:12,19 27:4,16 28:15,16 29:14 36:4 39:4 42:14 42:16 slides 17:7 27:5 28:20 slightly 132:3 slippers 65:21 66:7 slow 182:7 slowed 57:3 slower 135:7 slowing 153:8 small 15:10 89:8 108:6 118:8 143:18 154:15 smaller 71:2 139:12 smile 78:7,8 151:7 snezan 3:4 40:19 95:17 soak 86:14 soap 64:6,6 social 66:19 102:9 107:6 187:3 207:2 socks 65:20 147:9</p>	<p>soda 84:21 sodium 131:15 solid 161:11 162:9 solutions 74:20 145:3 somebody 48:16 55:10 68:10 89:12 89:12 107:6 108:11 110:12,15 112:16 somebody's 96:10 someplace 63:15 somewhat 114:4 151:5 192:9 somnia 183:10 son 89:4 soon 72:11 74:4 sooner 102:15 sores 53:19 83:21 sorry 39:16 47:11 73:15 85:20 88:7 90:14 97:21 99:21 100:5 104:10 111:20 113:13,13 114:20 115:9 119:13 129:14 136:9 156:18 160:15 164:1 166:18 177:17 190:2 192:16,16 192:17 sort 13:3 14:14 72:10 86:4 158:5 163:18 sounded 136:1 sounds 86:17 92:15,15 100:7 105:13 170:4 193:18 sources 208:4 south 62:20 66:5 spasm 66:10 113:1 spasm 66:10 113:1 speak 32:14 34:17 37:5 41:15 53:2</p>	<p>57:10,17 96:8 108:18 135:16 163:10 175:9 speaker 62:7 81:2 speakers 79:21 speaking 33:20 75:20 80:3 117:2 175:5 187:7 specialist 167:19 specialists 91:18 specialty 102:11 specific 12:12 15:19 27:19 37:14 38:3 59:9 92:11 150:1 193:16 specifics 191:11 speech 125:14 spend 5:18 23:13 132:6 spending 125:16 185:4,6 spent 64:5 74:21 91:13 183:11 spike 111:14 spikes 112:1 spin 110:7 spirit 78:13 spiritual 127:8 spoke 104:21 157:8,9 spoken 65:17 sponsors 28:21 spoon 179:20 182:18 183:3 spoons 179:19 spot 157:7 190:2 spots 50:15 89:8 spread 47:7 spring 1:17 springboard 15:5 15:13 staff 14:19 37:12 37:16 105:20</p>	<p>stage 29:20 188:6 stakeholders 7:20 8:16 9:6 13:6 207:18 209:21 stamina 54:21 103:10 stand 66:13 137:10 178:19 standard 143:7 145:1 stars 30:20 start 5:9 11:3 27:20 31:18 45:1 52:2,7 53:3 54:16 123:1,16 127:1 136:18 163:21 173:5 180:15,17 182:20 started 56:19 60:12 62:21 69:16 74:2 75:10 97:20 101:2 137:3,9 138:2 142:1 169:1 starting 39:7 43:12 69:17 133:11 starts 112:2 126:21 state 19:16 34:1 103:5 134:21 138:9 189:4 191:3 211:20 stated 183:1 states 20:18 21:11 183:18 stating 187:13 statistician 2:20 40:12 status 135:5 138:16 140:1 stay 16:4 34:5,9 34:13 37:11 57:5 67:17 78:17 98:14 101:21 108:21</p>
---	--	--	---

<p>126:1 144:12,12 148:1 stays 183:13 stem 26:18 131:2 138:13,14 181:2 188:17 step 166:2 steps 139:7 steroids 161:7 162:5 stiff 76:11 stiffness 53:15 96:11 97:3 stimulation 180:3 stitch 87:3 stomach 82:8 169:9 198:4 stooping 66:17 stop 27:3 126:21 128:20 165:7 167:5 191:17 204:4 206:11 stopped 63:21 168:21 stopping 206:10 stops 131:20 stories 8:6 85:13 145:14 152:21 206:5,6 story 15:12 65:18 73:13 129:5 136:19 168:2 straight 122:13 137:11 straighten 81:6,6 141:3,7 strategic 2:8 5:16 10:17 strategies 171:16 straw 85:3 207:7 strength 103:10 strengthen 210:7 strengthens 168:18</p>	<p>stress 112:14 116:17 126:14 127:4,9 159:14 stressful 70:21 stressors 111:6,9 112:21 stretch 53:16 60:18 149:7 stretched 27:13 stretching 194:17 striving 209:4 strong 67:12 194:14 structure 31:2 struggles 8:13 stuck 202:10 studies 205:17 studio 89:21 study 27:8 47:14 134:9 stuff 84:2,7,19 86:5 101:20 138:20 style 14:15 styles 195:2 subject 33:8 202:17 submission 192:4 submit 36:3,8,10 39:4 79:16 80:11 121:8,9 submitted 158:12 submitting 35:3 121:2 subtle 77:7 subtype 50:4 suburbs 43:17 successful 32:16 129:7 201:10 succession 192:10 suddenly 78:1 suffer 17:21 18:7 71:15 147:4,7 148:20 149:12</p>	<p>174:11 sufficiently 189:7 sugar 113:7 suit 107:19 summarize 16:8 35:6 81:13 116:12 summary 35:11 35:19 116:12 170:11 summer 102:3 sun 63:5,6 sunday 168:21 super 79:4 supplemental 77:5 supplements 128:1 support 38:19 54:6 102:8 107:7 107:11 108:4 110:1,5,9,10 119:19 128:2 185:7 186:4,20 194:14 207:12 supports 40:13 127:3 suppress 161:3 162:2 sure 7:9 42:21 43:2 49:8 51:5 57:4 83:19 86:5 88:1 103:17 127:16 129:4,15 133:6 134:11 136:17 140:4 148:1 149:4,11 154:1,9 158:21 160:15 168:12 175:5 180:15 surface 86:14 121:5 surgeon 87:10 surgeries 131:7 150:7</p>	<p>surgery 131:6,9 141:6,8 surgically 87:2,6 survey 42:15,16 42:20 43:3,20 93:7 161:21 survival 24:19 79:5 135:3 survive 191:14 surviving 151:6 susan 3:21 81:19 142:20 146:5 151:19 154:19 164:5,21 166:17 175:8,10,11 177:12 199:6 201:11 suspect 92:19 93:4 98:21 114:9 sustenance 77:12 swallow 65:9 82:13 125:2 swallowing 56:4 99:12 115:4 118:7 164:10 swam 54:14 swear 78:3 95:11 swelling 66:16 69:18 82:2 swim 107:19 swollen 88:3 sword 169:21 sworn 211:5 symbiotic 77:9 symptom 56:9 72:16 114:8,15 115:10 117:16 197:20 204:5 symptomatic 176:15 symptoms 9:11 14:21 15:4 27:19 27:20 28:9 34:7 50:17 56:12,19</p>
---	---	--	--

58:18 60:16 69:16 69:17 70:8,9 72:8 73:1,21 75:1 76:4 81:16 82:19 88:14 99:3,13,15 100:13 101:3 103:19,21 111:11,13,14,17 114:10,13 115:4,6 115:14,19,21 116:20 118:6 119:1 123:8 124:15 125:11 127:9 128:3 130:9 130:19 131:12 132:1 133:2 137:2 140:5,13,20 142:1 144:2 149:17,20 150:21 152:5 159:16 161:8,9 162:6 163:5,19 199:8,10 206:16 207:10,16 208:10 syndrome 18:20 50:15,21 51:3,10 63:3 112:10 137:5 system 20:11,14 22:10 45:18 54:6 100:6 107:7,11 110:1 127:4 161:3 162:3 168:16,17 194:14 systematic 11:21 12:19 146:18 148:16 systemic 1:3 5:20 6:1,5,7,15 7:13,16 7:17 8:12 10:4 16:14 17:4,10,12 18:3,3,7 19:14 20:7,17 22:4,14 23:3,3,15 25:1 30:20 31:6,17,21 32:2,5,11 33:13 33:14 34:21 35:1	37:3,21 38:18 45:9,17 46:7 50:5 50:20 51:1,1,10 52:6 54:15 58:14 60:11,15 61:4,7 69:13 72:15 74:3 76:8 79:13 80:7 81:15 99:3 101:2 101:17 114:14 117:12 122:16 123:6 129:19 136:20 151:17 152:3 153:4 160:6 160:19 163:12 181:1 187:9 192:20 193:7 197:16 205:20 systems 135:1 171:16 206:2 t t 18:20 table 125:8 178:19 tablet 42:8 tablets 167:11 201:13 204:7 tachycardia 120:11 tai 125:21 tail 192:11 tailored 15:18 tailspin 181:6 take 28:8 33:16 39:3,5 42:14 45:12 53:21 59:2 62:18 63:4,10 71:16 72:13 73:11 78:10 87:3 101:21 108:6 117:20 121:13 122:4 128:1,1,4 130:16 130:18,21 135:2 135:10,14 137:15 137:19 138:19 139:1,2,3,20	140:2,6 144:14 147:21 149:9 150:8 152:10 153:13 154:4 156:9 157:21 159:6 172:13 181:21 198:9,9,21 200:20 206:11,21 209:15 taken 138:18 211:3,12 212:9 takes 67:5 186:18 talk 5:16 19:12 20:16 27:17 57:20 65:17 105:8 108:2 110:12 118:6 127:7 164:6 170:6 178:17 201:21 talked 181:11 197:4,7 202:2 talking 15:11 17:14 26:21 34:6 34:7,7 48:8,12 62:7,13 92:10 100:10 107:7 176:2 182:15 192:4 199:7 tangible 75:15 tan glasia 19:1 tank 180:1 tape 85:3 207:7 tapered 72:2 tasked 205:15 tasks 53:18 59:20 137:15 147:16 177:11 taut 76:10 team 2:11,15,20 3:4 39:17 40:4,12 40:13,19 41:1 57:3 204:19 tears 86:21 technical 50:1	technological 197:13 teeth 82:14 116:21 149:20 telangiectasia 56:15 telangiectasias 22:8 telephone 33:4 90:9 tell 16:13 27:6 68:14 107:17 165:1 telling 13:15 93:3 168:2 tells 25:6 temperature 62:13 temporarily 131:21 ten 23:7 49:7,7,15 tend 26:9 53:19 78:14 tendon 24:3 term 104:14 141:17 145:18 153:7 165:20 166:9 172:3 195:15,18 204:16 terminologies 18:15 terms 30:16 31:1 103:5 111:6,12 157:17 terrible 53:19 62:17 65:8 66:9 74:13 107:2 test 76:4 91:9 146:12 testifying 211:5 testing 134:6 tests 29:10 202:16 tethered 75:15
---	--	--	--

<p>thank 8:4 10:9,14 16:11,16,17 29:13 29:16,18 30:2,3,9 41:4,6 45:6 47:8 53:5 57:15,16 61:10,11,11,20 68:19 69:1,1,7 72:18,20,20 73:9 73:12,14 79:6,7,9 79:14 83:1,2 85:7 85:12 89:1,11 92:7 93:9,10 94:9 95:6 98:19,20 103:16,16 104:4 104:10 108:8,16 110:19,19 111:3 111:18 113:2,12 113:15,16 116:9 120:14 121:14,21 122:2,7,8 124:2,3 124:4 128:6,8 129:13,14,17 130:16 135:16 142:6 143:3 146:4 146:5 151:9,9,11 151:18 152:20 154:17 156:5,17 157:16,18 158:2,9 158:10 159:17 164:7,19 166:16 168:6,9 170:2,2 170:20 172:10 177:12 179:1,4,6 180:11 182:8,9,9 187:5,6 188:3,12 188:14 189:9 190:15 191:15,15 194:19,19 200:21 201:11,18 202:19 203:15 204:20,21 204:21 205:8,9 206:4 210:8,11,12 thankfully 132:16</p>	<p>thanking 29:14 163:10 173:5 thanks 39:16 40:14 42:3 49:16 49:16,17 97:18 108:15 113:9,17 118:16 122:9 129:16 135:17 142:8 151:12 158:21 166:17 172:8 175:4 178:10 180:18 theme 173:14 themes 116:13 theory 179:20 182:19 therapeutics 17:14 therapies 2:18 9:4 9:16 24:7 26:16 26:17 40:9 132:19 133:2,3,15 149:5 153:3 160:19 162:17 166:14,16 193:6,7 194:6,9 194:12 207:20 210:2 therapist 110:11 therapy 26:18 131:14 132:18 133:7,11 159:12 162:16 166:2 193:3,14 194:4,13 194:13 198:3 theresa 2:7 5:15 10:13,16 thickening 18:21 23:6,9,21 27:21 50:8,13,19 99:10 114:19 115:1 thighs 23:7 thing 22:18 59:6 61:6,9 63:20 65:16 67:9,13,16</p>	<p>68:17 77:10 91:21 103:18 106:7 132:14 133:10 141:15 157:20 158:1 159:16 163:13 173:8 177:20 183:14 185:1 190:17 191:7 things 8:8 23:15 34:4,16 38:17 48:9 53:16,17 54:10,11,17 55:7 55:17,18,21 56:18 59:18 60:6,7,16 60:17 61:1,16 62:14 64:5,14 67:14 68:6 69:5 71:9 72:9 74:17 84:3,8,15 90:15 90:17 100:18 103:11 112:15,18 112:19 117:11 118:14 120:4 127:14 133:13 139:12,17 140:21 143:10 154:3 162:18 164:14,15 178:1,3 186:20 194:17 195:8,8 198:13 202:3 203:2,10,12 think 7:16 16:18 17:10 18:5 19:19 19:20 21:16 27:6 28:11,20 29:10,19 30:11 34:8 36:1 36:12 38:18 39:10 39:14 44:9 46:12 48:20 51:13 54:6 54:12 55:14 56:12 57:8,19 61:12,12 68:3,9 73:2 78:13 79:9 80:12,15</p>	<p>84:13,15 85:13,16 87:7 88:7,18 89:8 89:18 91:14 92:8 92:8 94:5 95:4,7 95:11,13 96:7 97:1,2,13 100:7 103:17 107:8,10 109:15,20 110:8 110:11,17 118:17 119:16 120:1,1,15 121:3,17 130:5 133:13 136:5 141:13 142:9,15 146:6,7,8 150:20 152:8,9 153:1,2,2 153:18 154:10 155:16 156:1,11 157:21,21 158:6,7 158:11,16 163:1,4 163:14 164:8 165:2,9,15 168:1 170:3,4 173:1 174:1 175:6,8 176:2,4,20 177:10 178:18 179:7 180:12 182:10,14 182:20 184:17 185:4 186:5,11,20 187:6,7,13 188:9 191:7 193:9 197:5 197:8 198:12 199:3,5,7,12 201:2 202:19 203:8 thinking 25:21 26:5 125:14 165:13 168:2 177:1 third 42:5 146:14 thoroughly 103:11 thought 28:19 44:21 54:9 71:1 74:2 79:3 88:1</p>
--	--	---	---

89:3 201:10 thoughts 6:7 80:9 104:7 109:7,17 119:8,9,16 123:2 128:9 142:13,17 143:1 158:3 170:17 173:3 174:10 177:15 189:16,17,20,21 190:16 191:21 192:12 196:18 200:7 203:16 thousands 64:6 91:10 threatening 135:1 135:9 three 20:4,20 65:4 67:6,7 87:14 89:7 91:19 99:8 123:5 124:6 143:5,5,10 147:11 183:6 195:10 thrilled 39:13 166:7 thumb 87:5,12 89:7 tight 82:12 137:21 tightened 146:21 tightening 22:6 50:8,12 70:4 72:2 82:4 99:9 101:8 114:21 117:15 146:19 149:19 202:12 tightest 27:16 tightness 56:4 time 5:18 27:13 29:1,13 34:12,19 41:6,6 49:5,12 55:15 60:11 63:21 64:19 65:14 72:18 77:17 81:5 82:4,6 83:4 89:1,9 94:11 95:1 97:15 99:1	101:6 106:6 117:17,19 118:15 120:21 121:15,16 122:7,13 123:8 124:8,19 125:12 125:17 126:5,10 126:19 132:13 142:2 143:7 145:12 146:14 147:9 148:3 149:9 152:5 154:2,11 155:8,11,13 163:8 163:10 168:13 175:19 178:14 180:1 185:5,6 191:6 194:18 202:17 timeline 13:4 times 44:15 70:13 159:11 167:5 178:14 201:8 202:11 tire 55:4 tired 58:21 59:1,2 59:3,14 60:2,4 125:15 147:20 175:1,15 178:15 178:15 tiredness 175:13 tissue 97:12 117:21 tissues 2:18 40:9 today 7:15 8:5,7,8 9:8 10:11,20 16:12 17:14 30:17 31:12,18 33:10 35:10,17 36:1 37:2,7,10,20 38:20 40:2 42:5 42:20 44:13,13 46:5 47:7,15 51:13 57:1 69:11 71:12 72:17 104:18 121:15	163:11,14 173:6 193:17 196:7 197:7 205:11 206:4,6 208:2 209:20 210:10 today's 5:5 7:3 9:9 10:1 30:8 42:1 toe 88:1,2,4 147:13 toes 53:20 56:17 70:8 148:19 208:9 told 76:2 181:1 191:8 tolerable 148:14 tolerate 64:8 tom 23:19 tomorrow 72:17 tools 84:20 210:1 tooth 174:13 toothpaste 106:4 top 56:16 57:5 72:6 topic 32:6 34:5,6,8 34:9 52:5 109:1 122:14,15 153:2 topical 195:12 topics 31:21 38:11 38:20 topoisomerase 25:9 tops 70:8 torment 75:7 total 113:1 144:5 touch 6:11 38:2 86:10 97:11 106:2 108:17 111:1 touched 27:12 164:6 199:6 touching 64:3 92:9 tough 33:8 townhall 14:15 toxicities 133:3	toxicity 153:13 tpn 144:5,7,9 167:16,16,20 tracking 42:9 tract 50:10 101:13 104:17 130:20 145:4 166:21 167:1,11 traditional 29:7 77:14 trained 150:11 trajkovic 95:17 98:19 trajovic 3:4 40:18 40:19 95:18 transcriber 212:1 transcript 212:3,5 transcriptionist 211:7 transcripts 7:3 transfusion 144:19 transparency 34:18 transplant 2:4,12 2:14,16,21 5:11 39:12,18 40:1,5 40:14 138:14,15 138:17 139:1,6,9 139:15 140:16,17 140:19 142:12 161:12 181:2,4 188:20 189:16 190:21 191:11,14 192:1,2 transplantation 26:19 188:18 transplants 162:9 trauma 148:8 157:2 traumatic 75:16 148:19 201:4 travel 67:9 110:2 207:3
---	--	---	--

traveled 138:9	140:6 141:21	126:18 131:2	66:6 70:6,14,21
travesty 74:7	144:20 145:15,18	132:15 135:18	76:21 86:2 87:13
treat 92:1 123:6	146:1 151:17	154:12 157:4,15	98:2 103:5 124:6
145:4 149:1 152:3	158:9 159:2	159:6 166:3	150:11 151:4
160:19 161:4	162:21 163:17	169:13,18 174:13	152:2 162:3
197:16 200:2	165:18 166:20	190:13 202:16	168:19 176:17
treatable 135:13	167:1 195:5	204:3	180:13 181:4
157:20	205:17 207:17	trying 47:20 58:6	192:9
treated 144:19	209:14	59:16 60:21 64:6	type 31:10 63:20
148:21 155:4	trial 11:15 22:1	75:1 76:2 98:16	64:2 78:20 94:13
treating 91:5,12	134:5,6,8 150:10	124:15 177:3,21	96:14 102:13
134:13 199:7	173:19 176:3	184:3,4 187:17	119:4 127:21
treatment 14:18	trialist 28:17	195:7 203:3	139:12 145:12
15:8 28:10 32:3	trials 9:5 11:10,13	tubing 202:11	166:10 168:11
38:3 72:10 108:19	28:18 29:1 197:19	tuesday 1:10	169:13 174:16
109:4 122:16,18	202:21	tunnel 69:21	189:12,13
123:7,10 128:4	trice 3:18 128:18	turn 10:12 17:2	types 101:16
130:5 131:18	128:21 129:13,15	39:6 41:7,17 78:2	103:10 112:21
132:21 133:12,20	135:21 136:8	83:5 88:21 94:5,8	124:15 130:7
134:5 135:7,15	146:17 156:19,21	95:15 100:19	169:15 208:10
138:15,21 140:7	190:3,5 200:9	104:5 109:12	typewriting 211:7
140:12 141:10,14	202:9	110:20 116:5	typical 14:16 53:9
141:20 142:7,17	tricks 148:13	119:7,13,15	101:19
145:1 149:8,18,21	169:4	146:10 152:10	typically 14:18
150:8,15,17,20,20	tried 96:15 157:13	158:11,16 160:1	typing 70:12
151:2 152:4,7	159:10 169:21	163:3 168:13	u
155:7 156:7	trigger 19:20	170:10,18 172:14	u 107:14
159:15 165:14	111:7,9 116:17	172:20 179:7	u.s. 1:9 17:21 18:6
168:11 170:8,21	triggered 112:10	180:12 188:8,10	23:4 181:14
171:12 190:6,7	112:11	189:14 194:7	ucla 167:18
193:5 194:5 195:2	tripartite 20:3	199:14 203:17,20	ulcer 20:8
195:13,14,16,17	trivializing 75:12	205:6	ulcerated 53:19
195:18,19 196:3,5	tropical 112:14	turning 84:12	ulcers 19:7 26:7
196:13 199:18,20	143:9	112:17 142:21,21	62:18 70:4 72:3
200:5,10,19	trouble 58:16	turns 120:16	96:18 99:10 115:1
204:10,12	151:13 198:6	181:19	115:9,12 117:19
treatments 7:18	true 211:9 212:5	tv 55:12 125:17	147:4 159:5,13
9:13 13:1,1 14:7	truly 21:14 22:10	twelve 60:13	208:6,7
15:14,14 38:2,15	30:6 156:12	twenty 70:6 124:6	ultrasound 204:18
57:6 76:14 92:5	trust 57:12 149:14	twice 86:2 201:16	umbrella 105:5
108:20 109:9	truth 75:19	two 6:3 17:17	unable 59:10
122:19 130:1,6,8	110:16	18:19 23:21 27:5	147:8,15
131:5 132:4	try 8:11 34:8 35:6	31:21 34:16 42:13	unassuming 78:7
134:21 135:2	37:4 60:17 85:3	43:18 44:2 45:10	

unbelievable 88:5	unmute 17:2	vascular 20:6 26:8	voices 15:6
uncertainties 153:17	111:20 128:16	vasculopathy 20:6	volume 65:12
uncertainty 72:16	164:3 190:2	vaseline 86:15	volunteer 200:12
195:17	unmuted 85:21	149:6	w
uncomfortable	174:8 175:8 190:3	vasodilators 26:10	waging 87:17
91:12 148:6	unpack 79:8	vegan 193:4	wait 91:19 192:16
undergo 12:16	unpredictable	veggies 169:14	waiting 116:3
190:6	28:13 208:17	veins 22:21 201:3	wake 59:2 125:11
undergone 188:20	unsustainable	202:11	175:1,15 178:15
189:15 190:5	178:16	veletri 171:2	179:20
underlying 209:12	untenable 166:3	veritable 20:1	walk 5:9 18:10
understand 8:3,11	unveiled 78:16	vessels 20:10	66:14,14,15 88:5
12:6 31:2 38:4	uphill 125:13	50:16 66:9	125:21 147:8
45:2 51:15 82:1	upper 18:11 23:7	vicodin 161:10	walker 137:14
89:12 95:5 96:1	ups 81:17	video 7:9 17:2	walking 117:7,9
115:17 118:19	upsetting 186:6	39:6 163:8	126:19
136:19 169:11	upstairs 137:13	videoconference	wall 174:15
186:21 199:5	use 22:14 26:9	1:1 2:2	178:20
205:19 207:19	29:8 42:13,15	videos 92:21	want 6:11 7:9 11:3
understanding	58:15 60:15,17,17	view 26:20 27:7	16:11 25:11 27:17
7:21 12:8 14:9	64:5 67:10 70:11	42:13 168:10	30:21 34:2,17
19:18 121:19	80:3 83:12 84:19	173:7 207:20	36:9,13 38:20
153:10 209:8	94:11,14 118:4	viewpoint 24:10	41:10 52:14 55:20
understatement	131:13 139:11	25:20 172:6	58:5,13 60:3
115:11	149:2,4,6 192:16	views 14:21	63:15 68:17 71:17
understood 92:12	194:2 195:1	violent 78:1	71:17 73:11,14
92:12	user 44:8	virginia 43:17	84:21 88:13 92:1
unfortunately	users 80:8	virtual 6:14 7:12	98:11 99:1,16
19:7 20:8 60:11	uses 147:1	10:6 34:11 44:11	107:20 111:21
130:10 131:3,18	usually 18:2 44:8	44:18 47:17 79:21	114:1 120:18,21
132:8 182:21	77:15 80:2 144:11	110:4 118:20	121:8,9 122:2
unidentified 81:2	145:12 169:13	virus 74:3	123:3 128:16
unique 142:10	180:6 204:18	visible 76:20	129:4 132:6,12
uniquely 12:7	v	vision 41:3	133:19 134:11
united 20:18	valuable 16:15	visit 23:13 76:16	146:14,15 151:9
21:11 183:18	120:19 209:11,18	visited 74:15	151:18 153:18,20
university 2:9	value 13:17	visits 75:10 150:8	157:1,5,7,8,10
5:19 23:18 29:14	133:14 169:1	visual 94:12 95:9	158:19 159:20
102:11 104:20	variety 46:5 47:6	95:9	160:15 163:20
105:1	125:19 159:3	vital 76:14	164:4,4 165:12
unmet 9:16	various 133:13	vitamin 138:20	168:7 177:13
209:21	vary 97:6	vitamins 130:21	178:11 179:2,11
	varying 73:18	voice 13:6 16:7,20	180:13 185:1
		29:12 41:3 93:19	188:13 189:6,16

189:17,20 190:1 190:10 192:2,11 196:21 198:13 203:17 wanted 13:15 54:18 80:13 84:3 85:18 94:5,6 105:8 108:8,9 109:4 111:1,15 113:3,6 116:12 117:9 152:14 153:1,4 179:7 180:12 188:9 197:12 wants 106:2,20 154:20 196:17 warm 172:2 194:12,12 warmer 206:15 warrior 145:16 wary 172:3 washing 71:9 washington 43:16 103:6 watching 32:10 55:12 203:8 water 77:11 122:6 137:17 194:13,14 wave 41:19 waves 173:18 way 12:19 31:3 38:4 67:12 77:19 80:2 84:16 85:19 89:17 119:2 127:8 127:9 136:3 169:16 171:11 184:12 202:13 ways 42:13 54:9 83:18 84:14 94:14 202:14 we've 13:4,8,18 14:2,11 30:8 31:14 48:19,19 93:9 113:21 121:4	135:18 163:13 183:5 197:4,7 weak 126:1 weakness 53:14 weather 125:21 web 35:8,21 52:15 80:11 82:17 83:3 121:3 170:14 172:11 209:20 webcast 7:1,2,2 32:9 35:4 37:7 42:1 116:11 118:14 121:8 146:12 webchat 116:8 webinar 44:13 45:3 47:16 website 7:4 36:7 36:12 37:17 week 28:19 173:18 174:2 175:2,19 176:5 200:9 weekly 198:1 weeks 121:16 weigh 142:2 weight 27:20 67:21 68:1 198:4 weird 48:5 welcome 7:12 32:12 35:19 wellbeing 126:13 went 68:2,12 76:13 89:3 92:13 92:13 138:14 157:2 180:21 west 44:20 wheelchair 137:14 white 1:15 105:10 wide 14:4 71:3 125:19 wild 67:21 willing 54:7 134:16,20 135:2,5 135:14 151:2	153:13 156:15 157:21 181:21 200:20 204:3 wire 204:17 wise 101:1 wish 120:20 139:16 witness 211:4 women 171:11 wonder 136:2 wonderful 29:1,16 49:3 83:20 91:18 121:12 131:8 186:21 200:4 wondering 83:15 89:20 127:1 163:16 202:1 word 17:17 36:10 70:13 104:16 words 17:18 23:9 30:16 98:12 165:12 178:5,17 wore 65:19 work 16:15 21:2 29:15 30:6 59:10 59:12,12,13,14,15 60:5 61:18,18 64:13 70:1 71:5 77:8 82:5 83:17 84:13 85:21 89:21 91:10 95:3 103:4 110:3,5 111:21 136:11 145:3,19 146:1 167:8,9 177:9,10 184:5,6 185:18 193:21 199:9,10 205:4 207:5 workday 185:16 worked 14:8 69:21 102:19 103:8 working 13:2 44:4 44:6 82:6 94:15	142:19 148:11 167:5 168:19 177:8 185:16 works 64:12 106:12 127:1 149:13 151:4 193:19 workshops 126:13 world 112:13,14 141:19 worn 96:14 97:3 worried 161:16 worries 61:3 72:12 155:19 worrisome 61:5 worry 19:4 35:5 61:9 65:1 127:1 worrying 140:3,5 worse 60:12 62:8 62:8,8,9 66:8 67:15 72:5 74:5,6 74:6 96:4 148:4 157:5 worsen 60:13 worst 60:6 61:9 71:14,16 81:16 87:20 117:16 147:19 worth 141:18 151:1 165:4,15,15 wounds 77:2 wow 79:3,7 103:16 151:11 wrap 86:14 186:18 197:6 wrapping 199:16 wrinkles 71:21 wrists 56:6 69:19 writhe 78:3 wrong 161:17 www.menti.com 42:15
--	---	---	---

[x - younger]

Page 43

x	yesterday 71:11 yoga 126:1,2,2,3 149:7 194:17 york 80:16,18 young 18:3 53:8 72:14 110:5 181:8 181:9,12 younger 46:18 155:3
x 76:18 91:10 94:13	
y	
yeah 48:4 54:12 61:9 65:15 83:14 83:19 87:5,15,19 88:5,18 89:9 90:6 90:14 91:13 95:17 97:18,20 109:20 110:3 113:6 120:1 120:8 128:16 136:9 146:17 166:15 173:4 177:4 179:13 182:17,17 185:18 190:3 204:1 year 21:8,9,14 26:21 28:9 49:6,6 56:11 69:16 76:1 82:3 183:10,12,20 184:14 years 9:21 18:15 19:17 20:19 24:1 28:18 49:7,7,7,8 49:11,14,15 54:14 54:15 56:8,11 59:16 60:12 62:7 65:7 68:17 70:6 71:21 72:4 73:17 74:1,9 75:1 76:13 81:15,20 86:2 87:14 90:15 102:19 103:1 108:7 117:13 124:6,6 129:19 133:21 134:9 138:18 143:5,5,9 143:10 155:16 166:13 181:4 201:14 yep 90:4	