

Hybrid Public Meeting on Patient-Focused Drug
Development for Nonhealing Chronic Wounds

Moderated by Robyn Bent, RN, MS

Tuesday, August 25, 2026

10:03 a.m.

U.S. Food and Drug Administration

White Oak Campus

10903 New Hampshire Avenue

Building 31, Room 1503

Silver Spring, MD 20993

Reported by: Richard Livengood

JOB NO: 8362211

A P P E A R A N C E S

List of Attendees:

Robyn Bent, RN, MS, Director of Patient-Focused
Drug Development, Office of the Center Director,
Center for Drug Evaluation and Research, FDA

Michelle Tarver, MD, PhD, Director of the Center
for Devices and Radiological Health, FDA

Ethan Gabbour, MS, Public Health Analyst,
Patient-Focused Drug Development, Office of the Center
Director, Center for Drug Evaluation and Research, FDA

Vickie R. Driver, DPM, MS, FACFAS, President and Board
Chair, Wound Care Collaborative Community, Professor,
Washington State University School of Medicine

Maryjoy Mejia, MD, Medical Officer, Division of
Dermatology and Dentistry, Office of New Drugs, Center
for Drug Evaluation and Research, FDA

Sarah Rosenberg, Clinical Outcome Assessment Reviewer,
Division of Clinical Outcome Assessments, Center for
Drug Evaluation and Research, FDA

Kathleen Young, PhD, Lead Reviewer, CDRH/OHT4 Plastic
and Reconstructive Surgeries Division

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

List of Attendees:

Anam Tariq, DO, MHS, FASN, Branch Chief, Office of
Cell and Gene Therapy, Center for Biologics Evaluation
and Research, FDA

Cynthia J. Chang, PhD, TAP Advisor, CDRH, Office of
the Center Director

Windy Cole, DPM, CWSP, Director, Wound Care Research,
Kent State University College of Podiatric Medicine
Robby

Brad (by videoconference)

Dave DePottie, IT Director, Secretary, and Chairman of
the Board, All Things PG (by videoconference)

Polly Cleveland

Kevin Wake, ICHOM Board Member (by videoconference)

Amanda (by videoconference)

Peter W. Thomas, JD, Independence Through Enhancement
of Medicare and Medicaid Coalition (by telephone)

Gabby (by telephone)

Ashley Valentine, Co-Founder, Chief Executive Officer,
Sick Cells

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

2 List of Attendees:

3 Juanita Bando

4 Jamie (by telephone)

5 Tony (by telephone)

6 Laurie M. Rappl PT, DPT, CWS (by telephone)

7 Lisa (by telephone)

8 Toni (by telephone)

9 Jimontanae (Jae) McBride

10 Joyce Rex

11 Sarah McCoy (by videoconference)

12 Wesley (by videoconference)

13 Barbara (by videoconference)

14 Lasaunia Thompson, Treasurer, All Things PG (by
15 videoconference)16 Francesca Valentine, MSN, RN, Clinical Adviser for
17 Sick Cells (by telephone)18 Brindley Brooks, Founder and Executive Director of
19 HS Connect (by telephone)

20 Lewis

21 Adrienne Shapiro

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

2 List of Attendees:

3 Alvin, in Toronto (by telephone)

4 Dan (by telephone)

5 Sarah Williams (by telephone)

6 Janet Frank (by videoconference)

7 Richard Frank (by videoconference)

8 Corlis Watkins-Nass, President and Co-Founder, All

9 Things PG (by videoconference)

10 Chaquira Andrade

11 Laura K.S. Parnell, BS, MS, Board Member, Wound

12 Healing Foundation (by videoconference)

13 Teresa Jones, MD, Program Director, Division of

14 Diabetes, Endocrinology, & Metabolic Diseases, NIH

15 Mark (by telephone)

16 Carmen, FDA Staff

17 Jason, FDA Staff

18 Allison, FDA Staff

19 Karen, FDA Staff

20 Will, FDA Staff

21

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

2 MS. BENT: All right. So we're going
3 to go ahead and get started, because we want to
4 reserve as much time as we can to hear from our
5 patient panelists and other patients both in person
6 and online. So we're going to go ahead and start the
7 meeting now.

8 So good morning, everyone. Thank you
9 so much for being here. Whether you joined us in
10 person here in the White Oak Campus or connecting with
11 us through the live webcast, welcome to FDA's Hybrid
12 Public Meeting on Patient-Focused Drug Development for
13 Nonhealing Chronic Wounds.

14 My name is Robyn Bent; I'm the Director
15 of Patient-Focused Drug Development in the Center for
16 Drug Evaluation and Research here at FDA, and I will
17 be serving as your discussion facilitator for today's
18 meeting.

19 A few housekeeping items. Mostly for
20 those of you who are in person, I want to take a few
21 minutes to go over some practical items.

1 Lunch -- pre-ordered lunch is available
2 from the kiosk until 10:30 a.m., so please place your
3 order before then if you'd like that option. I will
4 tell you that the lines do tend to get long at lunch,
5 so if you want to pre-order, I would recommend that
6 you do that.

7 You are also welcome to purchase some
8 lunch options during our designated lunch break, which
9 will begin around 12:15. The kiosk will be open for
10 coffee and breakfast until 10:30.

11 At that point, a water station will be
12 available throughout the day, including during our
13 lunch break and afternoon break, so please help
14 yourself at any time. Please use the cups that are
15 provided.

16 Restrooms -- as you leave the Great
17 Room, the nearest restrooms are located on the right,
18 past the tech desk, and down the hallway to the right.
19 If you need a private restroom, please let staff know,
20 and we will direct you.

21 If you have any other medical related

1 needs, we have two people identified to help with
2 that. We have Carmen, who is -- I believe you
3 probably saw as you entered into the campus through
4 security, and we have Jason, who is -- who moved and
5 is right here in front. So please let us know if you
6 have any needs related to that.

7 We also have three small conference
8 rooms reserved for your use today. Room 1404 is
9 available as a luggage room for storing personal
10 belongings, but I will note that it is not secured.

11 And then we have Rooms 1406 and 1408
12 available if you need a moment to kind of step away
13 for any reason, whether to decompress, to take a
14 private call, or simply collect yourself. We know
15 that some of the discussions can bring up a lot of
16 emotions, and we want you to have space for that.

17 For those of us joining us -- for those
18 of you joining us virtually, this meeting is being
19 webcast live and is open to the public. The webcast
20 recording and presentation slides will be made
21 publicly available after the meeting, and we will

1 generate a summary report from this meeting.

2 So now I'm going to walk you through
3 what we have planned for today. We'll start with
4 opening remarks from Dr. Michelle Tarver, Director of
5 FDA's Center for Devices and Radiological Health,
6 followed by Ethan Gabbour, who will give us an
7 overview of FDA's Patient-Focused Drug Development
8 Initiative.

9 Then Dr. Driver will provide us with a
10 clinical overview of nonhealing chronic wounds to set
11 the stage for our discussions. I will then return to
12 walk through our discussion format and ground rules
13 before we move on to our three discussion topics.

14 Topic 1 will be on health effects and
15 daily impacts. Topic 2 will be on current approaches
16 to treatment. And Topic 3 will be on patient
17 perspectives on clinical trials.

18 We'll break for lunch, as I mentioned,
19 at approximately 12:15 and have a shorter break in the
20 afternoon. We'll wrap up with the closing remarks
21 from Dr. Joy Mejia.

1 One thing that I do want to highlight
2 about today's meeting is that it is unlike some of our
3 more recent PFDD meetings, which have been fully
4 virtual. Today's meeting is hybrid, and we have an
5 in-person audience here with us, which is wonderful.

6 I also want to acknowledge that many
7 patients living with nonhealing chronic wounds are
8 joining us virtually today. Traveling with an open
9 wound, managing dressing changes, wound care supplies,
10 pain, and mobility challenges on the road can be a
11 significant challenge.

12 The fact that so many people are
13 joining us from home is, itself, a reflection of what
14 it means to live with this condition, and we are
15 grateful to every single person who is here today,
16 however they are able to join us.

17 And with that, it's my pleasure to
18 introduce Dr. Michelle Tarver, Director of FDA Center
19 for Devices and Radiologic Health, who will provide us
20 with our opening remarks.

21 Dr. Tarver?

1 DR. TARVER: So good morning, everyone,
2 and welcome. Thank you for joining us both in person
3 and online.

4 I'd like to begin, first, by thanking
5 all the patients who have joined us, the caregivers,
6 the family members, the industry, the researchers, the
7 regulatory and other government officials, who have
8 made time this morning to join in on this very
9 important topic.

10 We recognize that sharing all of your
11 experiences takes time, takes vulnerability, takes
12 openness, and also takes a commitment to advancing
13 regulatory science. And so for that, we are very
14 grateful for your participation and that you've chosen
15 to be here.

16 You know, patients are at the heart of
17 everything we do at the Agency. And our vision at the
18 Center for Devices and Radiological Health, which is
19 shared by many other medical product centers at this
20 Agency, is that patients in the United States have
21 access to high quality, safe, and effective medical

1 products that promote and protect their health and
2 wellbeing.

3 Achieving that vision requires not only
4 rigorous science, but also a very deep understanding
5 of the experiences of the people who live with these
6 conditions every day. That's why today's meeting is
7 so important. Patients are experts on what it's like
8 to live with their conditions.

9 You understand the daily realities that
10 cannot always be captured by traditional clinical
11 measures: the pain, the stigma, the impact on
12 mobility, sleep, work, relationships, mental health,
13 and overall quality of life. Your experience helps us
14 better understand what outcomes matter most, and what
15 meaningful improvement looks like.

16 CDRH, like the other medical product
17 centers, has made a very strong commitment to
18 incorporating patient perspectives throughout the
19 medical product lifecycle.

20 We have worked to encourage the
21 development of patient-reported outcomes, patient

1 preference information, and other tools that help
2 ensure medical product development and regulatory
3 decision-making reflects what matters most to
4 patients.

5 But these efforts are most successful
6 when patients are included, not just as participants
7 in the study, but as partners throughout the process.

8 The partnership extends beyond CDRH.
9 Meaningful progress depends on collaboration among
10 patients and caregivers, among clinicians and
11 researchers, among manufacturers, professional
12 societies, and regulators.

13 Each of us brings a unique perspective,
14 and when we work together with openness and with
15 trust, we can solve challenges that no single
16 organization could solve alone.

17 The Wound Care Collaborative Community
18 is an excellent example of this collaborative
19 approach. Its vision is to transform wound care by
20 breaking down barriers so that patients and healthcare
21 providers benefit from modern treatments and

1 technologies for healing wounds.

2 By bringing together patients alongside
3 experts from across the wound care ecosystem, the
4 Collaborative Community has helped advance patient-
5 centered science, develop better tools, and strengthen
6 the evidence needed to support innovation.

7 One example of the power of this
8 collaboration is the qualification of the WOUND-Q as a
9 FDA medical device development tool.

10 The WOUND-Q helps capture outcomes that
11 matter to patients. Not only whether a wound closes,
12 but also how the treatment affects symptoms, and
13 function, and quality of life. It represents an
14 important step towards ensuring that our evaluation of
15 medical products reflects the outcomes that patients
16 themselves care about and value.

17 Today's meeting continues that
18 important work. By listening directly to people
19 living with nonhealing chronic wounds, we have the
20 opportunity to better understand the burden of this
21 condition, identify unmet needs, and learn which

1 treatment outcomes are most meaningful.

2 Those insights can help inform future
3 research, clinical trial design, endpoint development,
4 and, ultimately, the development and evaluation of
5 medical products that better serve patients.

6 Thank you, again, for being here and
7 for sharing your experiences with us. Your voices are
8 essential to building a future where patients are true
9 partners to advancing innovation. We look forward to
10 listening, to learning, and to working together to
11 improve the lives of people living with chronic
12 wounds.

13 And with that, let's begin. I'll turn
14 it over to Ethan.

15 MR. GABBOUR: Hello? All right. Thank
16 you all for joining us today. It's great to have
17 people here both in the web and in person. Today, I'm
18 going to provide an overview of FDA's PFDD initiative.

19 To begin, what is FDA's role in medical
20 product development and evaluation? Well, FDA has a
21 broad portfolio, and part of our mission is to protect

1 and promote public health by evaluating the safety and
2 effectiveness of new drugs. And while we play a
3 critical role in oversight of drug development, that
4 is just one part of the process.

5 FDA does not develop drugs nor conduct
6 clinical trials. FDA provides regulatory oversight
7 during the drug development process, makes decisions
8 based on a review of evidence generated in clinical
9 studies, and on that basis makes decisions about the
10 approval of new drugs and devices and provides
11 guidance related to these matters.

12 So what is Patient-Focused Drug
13 Development or PFDD? PFDD is a systematic approach to
14 help ensure that patients' experiences, perspectives,
15 needs, and priorities are captured and meaningfully
16 incorporated into drug development and evaluation.

17 These meetings can be really important
18 to FDA's decision-making. Patients are uniquely
19 positioned to inform our understanding of the clinical
20 context for drug review and regulatory decision-
21 making.

1 And by that I mean, what is the
2 severity of this condition? What is it like to live
3 with this condition? And what treatments are
4 available, and how well are they working or not
5 working?

6 And prior to PFDD, the only mechanism
7 we really had available to us to gather patient inputs
8 were the sorts of discussions we might have about a
9 specific application in the context of an advisory
10 committee meeting.

11 But at those meetings only a few
12 patient representatives would speak, and there was a
13 screening process, so we didn't really have a good
14 opportunity in those settings to get the input from
15 the full community of people experiencing a particular
16 condition.

17 PFDD meetings, like the one today, give
18 us a better way to more systematically collect that
19 range of perspectives of the condition, its impact on
20 patients' daily lives, and their assessment of
21 available treatment options, including whether those

1 treatments work or don't.

2 This effort began almost 15 years ago.
3 In 2012 we established and set up the PFDD program,
4 and from 2013 to 2017, we really made it a bit of a
5 pilot effort and conducted 24 meetings in different
6 disease areas.

7 There was so much interest in these
8 meetings that we really wanted to expand our ability
9 to have them, and so we set up the externally led
10 option. This is where patient groups lead the effort
11 to set up and plan these meetings with the input from
12 our staff.

13 And FDA, we go to these meetings and
14 they have been extremely valuable to us. Both the
15 ones that FDA leads and the one patient groups have
16 led have given us a lot of important input.

17 This slide here shows the range of
18 conditions that FDA has conducted PFDD meetings for.
19 As you can see, the first Patient-Focused Drug
20 Development meeting was held 13 years ago, and that
21 meeting focused on chronic fatigue syndrome and

1 myalgic encephalomyelitis.

2 That first meeting, we found it so
3 powerful, and it made us realize how meetings like
4 this can really help us understand and hear directly
5 from patients. And so in addition to the 31 meetings
6 we've held already, there have been 128 meetings to
7 date that have been conducted externally.

8 And this has been a valuable
9 opportunity not just for FDA but our other key
10 stakeholders: our medical product developers, our
11 healthcare providers, our academic researchers, our
12 other government agencies to listen and learn and to
13 and for patients to be able to share their
14 perspectives.

15 The format of these meetings follow a
16 town hall style. We usually begin with an overview
17 provided by a clinician on the clinical background and
18 currently available treatments, and that's followed by
19 multiple topic sessions.

20 The first topic session will typically
21 focus on symptoms and daily impacts, and that begins

1 by having a panel of patients and care partners who
2 share their experiences and provide a range of
3 perspectives.

4 That sets the stage for a larger group
5 facilitated discussion where we hear from anyone with
6 that lived experience that wants to share their
7 perspectives on a given topic.

8 That is then followed by a similarly
9 structured session that looks at approaches to
10 management and treatment options. Again, this begins
11 with a panel of individuals' perspectives and what
12 they've experienced, and that sets the stage for a
13 larger group facilitated discussion.

14 And in some cases, like today, there's
15 a session that talks about patients' perspectives
16 about clinical trials that also follows a similar
17 format.

18 And so these meetings are tailored to
19 the needs of the specific disease area to try and
20 better understand how we can develop treatments that
21 are more effective and better for patients, and maybe

1 cover issues around trials or other aspects of drug
2 development.

3 And from our registration, we have a
4 wide range of participants, both in the room here
5 today and on the web. It's important that our drug
6 developers, our healthcare providers, our academics,
7 our clinicians are here with us.

8 But what we want everyone to remember
9 is that these meetings are really intended to hear
10 directly from the patients and their care partners.
11 So we ask that everyone else remain in listening mode
12 through these discussions so we can benefit from
13 hearing directly from the patients, patient
14 representatives, and patient care partners.

15 After this meeting -- or after these
16 meetings in general, we often have a docket that is
17 open where we can receive further public input and
18 comment, things people may not have been able to share
19 or thought of during the meeting.

20 We put that together with what we hear
21 during the meeting today to develop a comprehensive

1 report called the "Voice of the Patient Report."

2 And, in fact, if you were to go to your
3 favorite search engine and type in condition specific
4 Voice of the Patient Report, you'll find a repository
5 that we have in there. And that repository will allow
6 us to have the report following this meeting as a
7 resource for future reference for our reviewers and
8 for our drug developers, patient groups, and others.

9 And with that, I'll conclude and thank
10 you again for joining us. I look forward to listening
11 and learning today. Thank you. And I'll turn it over
12 to Dr. Driver.

13 DR. DRIVER: Good morning. It's a
14 pleasure to be here today. I'm representing the Wound
15 Care Collaborative Community, which is a behind-the-
16 scenes organization of volunteers.

17 We started this collaboration with the
18 FDA at the invitation of the FDA. In fact, it was
19 Dr. Michelle Tarver who actually called me five years
20 ago and asked us to start this collaboration.

21 We work on behalf of the patient.

1 Everything we do is to improve the care, the standards
2 of care, and also to help bring new diagnostics and
3 new advanced treatments to the bedside of the patient
4 to improve their lives.

5 I want to start with thanking the
6 patients who will be here today and the caregivers
7 who've taken the time out of their day and their lives
8 to help us understand this disease even better than we
9 can at the bedside with you.

10 We want to thank the FDA, because
11 without the FDA, in fact, we wouldn't be here. But
12 more than that, the FDA, if you don't know, works on
13 behalf of patients every single day. And I see this,
14 I know this, and I appreciate their effort.

15 They're sort of the unsung heroes. You
16 don't think of the FDA as patient advocates but they,
17 in fact, are, all of them. Just like Medicare and
18 Medicaid and the NIH, these people work day in and day
19 out for the lives of patients.

20 I want to thank the caregivers that are
21 here today, and they work hard every single day

1 improving the life of patients and giving a damn about
2 that patient that's in front of them at that moment.

3 That's what it's all about. Because of
4 you, the patient, we need to hear your voice directly,
5 and let it guide better diagnostics and treatments.

6 This is very personal to me. Both of
7 my parents died very young due to diabetes and
8 complications. And two of my sisters suffer today
9 with chronic diabetic disease and others, as well as
10 wounds all over their body that affect their lives in
11 horrendous ways.

12 We know that wounds often just don't
13 heal. There are lots of reasons why. But when we
14 think of a chronic wound, it's really a wound that
15 after four weeks of pretty good care, very good care,
16 they just don't heal; they stall.

17 Sometimes it's poor blood flow.
18 Sometimes these wounds get infected. Many times it's
19 because of pressure; it can be a wheelchair, it can be
20 a shoe. It could be a traumatic event, stepping on a
21 nail. It can be from a post mastectomy procedure. It

1 can be due to maybe diabetes and neuropathy, other
2 things.

3 But what we need to know and remember,
4 millions of patients in this country alone suffer with
5 this disease. Yeah, I'm calling it a disease. It's
6 not a boo-boo. These patients have real issues.

7 So when we talk about this disease, we
8 have often put it in stages. But, in fact, when we
9 think about it, every single wound goes through the
10 same mechanistic, much as the similar mechanism in
11 terms of it starts at the skin, it moves through the
12 superficial tissue where there's blood vessels, nerves
13 and hair follicles.

14 And then if we can't stop and the wound
15 progresses, it moves to deeper soft tissue, connective
16 tissue, the cushioning for insulation, and then onto
17 layers of muscle. And that, of course, causes many
18 patients to lose function, develop deep scars.

19 And then, unfortunately, some patients,
20 it moves into their bone, and they develop not only
21 infection of the soft tissue, but the deeper tissue.

1 Now, significant and very well
2 documented systemic flaws are now in modern medicine,
3 still in modern medicine.

4 Because we have found, through funding
5 research and specialized care, that when a condition
6 is primarily thought to be caused by diabetes, or
7 maybe a blood vessel that isn't working, or a venous
8 vessel that isn't working, then these primary diseases
9 get all the funding and all the attention. And the
10 secondary disease gets little, and the care gets
11 fragmented.

12 That's what's happened in the field of
13 wound care. Much like retinopathy of a diabetic,
14 early on we would just try to control the blood sugars
15 for patients with eye disease. And then we've
16 developed treatments -- through working with the FDA,
17 developed treatments that specifically address the
18 needs of these patients.

19 This is very important because medical
20 ownership of this disease has been short coming -- or,
21 I should say, long coming. Now we have experts. We

1 have wound centers. We have training programs.

2 We have some funding but, keep in mind,
3 while millions of patients suffer from this disease,
4 0.11 of the research funding actually goes to chronic
5 wound suffering patients. And so we need our industry
6 partners to help us move this disease forward.

7 Researchers and clinicians are
8 positioning to reclassify this problem, this condition
9 that we have. Maybe it will be a wound syndrome, a
10 chronic wound syndrome. Maybe it will be chronic
11 wound disease.

12 But these patients, ask any one of
13 them, it's a disease to them. It causes a lot of
14 harm. It often interferes with other diseases they
15 may have. But it's certainly, we know, most patients
16 or many patients start with wounds at mid 50s; some in
17 their 40s. They're still employed. They have to go
18 to work.

19 Or if you are retired, "I bought a van
20 to travel in. Guess what? It's been sitting there
21 for five years, because I can't leave my doctor. I

1 have to see them -- or clinician every single week."

2 These patients go into remission. Many
3 of them, they don't heal. They get a wound, we get it
4 healed, they have another.

5 We now know, through the work we're
6 doing with the Wound Care Collaborative Community, if
7 you have a diabetic foot ulcer, 50 percent of these
8 patients also have a venous leg ulcer. Likewise, the
9 other way around, VLU. So they don't just have one
10 wound. And this is really important to understand.

11 So we need a structural shift, and
12 that's what we're working on, is to understand
13 patients at the cellular level, treat them locally,
14 develop new drugs, not just devices.

15 We don't need more of the same
16 treatments that we have. We need new diagnostics. We
17 need help at the bedside. We need new treatment
18 options.

19 Think about -- here's a diagram, a
20 molecular diagram of a wound. But if you think of an
21 eye right next to a wound, they actually have very

1 similar problems. They're fighting the same problem
2 day in and day out.

3 And that, when we think about it, it's
4 much of the molecular part of any disease that is
5 ugly, that is difficult, and it's not just what you
6 see on the patient.

7 Chronic wound patients, as we will hear
8 today, I am sure it is not difficult for these
9 patients to -- it is difficult for these patients and
10 very difficult many times for them to even go out in
11 public.

12 So, yes, the wound is stalled. Lack of
13 oxygen can happen. We can find tissue death. And
14 these are the things that concern us the most.

15 But we are very focused in the research
16 community on developing signals. We're really working
17 very hard to understand pathways and different
18 responses that would be very helpful for patients
19 regardless of what disease actually caused the wound.

20 We have tremendous amounts, actually,
21 of FDA approved diagnostics and treatments. We've

1 gotten to precision diagnostics where tissue imaging
2 can be measured, perfusion mapping, molecular
3 bioburden. Now, this hasn't really transitioned yet
4 to new treatments, but we are working on this.

5 We have a comprehensive toolbox
6 utilizing multiple FDA approved advanced modalities,
7 not just one treatment option is what these patients
8 need. And then, of course, we have options for
9 debridement, ridding the wound of the necrosis or the
10 tissue that is no longer living.

11 But what we need are more and better
12 standards of care. And that is what the Wound Care
13 Collaborative Community is doing behind the scenes,
14 utilizing digital tracking tools to measure precise
15 healing.

16 Patient-centered endpoints -- we're
17 very, very interested in what the patient feels about
18 the treatment options we have today. What do they
19 think about the care? What's missing? These are key
20 pieces.

21 So critical to us that are providers,

1 and I think across the representatives here today, is
2 we need to develop home-based care.

3 Hauling the patient to clinic every
4 single week is not a great option. Traditional care
5 demands exhausting clinical visits, and patients have
6 to navigate the constraints; and this is just very
7 difficult. So that's where we're going in research
8 today.

9 Now, as a clinician, we have always
10 talked about red flags to patients. Patients with
11 chronic wounds know their disease.

12 Their clinician has trained them,
13 taught them, shared with them the bad things to look
14 for: sudden increase in localized pain or throbbing; a
15 foul odor; rapidly spreading redness, warmth; sudden
16 increase in uncontrolled fluid drainage; or feeling
17 sick like you have the flu.

18 Now, these things happen. And in wound
19 care centers and in practices today, patients call all
20 day long, "Oh, I need to speak to Lonnie because I --
21 she told me to look for these problems. I've got one

1 of them. I need to come in."

2 We are moving together forward. What's
3 coming next? Well, first, let's understand that
4 healing complex wounds is a complicated step-by-step
5 process. They don't go to a scratch to an infected
6 wound that incorporates bone. It's a step-by-step
7 process, as it is to bring them back to closure.

8 But most of the time we are treating
9 patients, coming in through the ER or coming in
10 emergently, with lots of problems that have already
11 been there because of the complications of their
12 disease.

13 We understand the burden. We
14 understand that patients can be exhausted. The toll
15 on their life is usually for years. If you start
16 developing wounds in your 50s, usually you're going to
17 get another one, unfortunately. And it becomes their
18 main disease.

19 But we want patients and caregivers to
20 know that they're not alone. We are working together
21 with researchers, the FDA, clinicians, Medicare and

1 Medicaid, and patients, working side-by-side to
2 understand the challenges.

3 Partnership is driving earlier more
4 precise diagnostics and more effective treatment.
5 This is a shared commitment. For those of you that
6 are suffering or treating these patients, every visit,
7 every measurement, every shared experience moves our
8 field forward.

9 And we're grateful for you, and we are
10 working on your behalf; and we will get there. And,
11 please, forgive us that it is taking us so long.
12 Thank you.

13 MS. BENT: Great. Thank you so much,
14 Dr. Driver. That's a really helpful foundation for
15 everything we're about to hear today. And it's
16 especially meaningful to hear from someone whose
17 personal connection to this condition has really
18 shaped their life's work. So thank you for sharing
19 that with us.

20 Now I want to share a little bit more
21 about how the rest of today's meeting will proceed.

1 And I want to start by saying that it's been truly an
2 honor to work with the panelists you are about to meet
3 as we have prepared for today.

4 If you are new to what FDA does in this
5 space, I hope that the last few presentations gave you
6 a little background on patient-focused medical product
7 development, because now we're going to kind of flip
8 the script. Most meetings involve medical
9 professionals giving presentations while you listen.
10 Today, we've reversed that.

11 Those of you who have lived experience
12 with nonhealing chronic wounds, whether as a patient,
13 a caregiver, or a patient representative, you are the
14 experts, and your expertise in what it's like to live
15 with these conditions is what we're here today to
16 hear.

17 Our three main topics for discussion
18 today are: one, health effects and daily impacts of
19 nonhealing chronic wounds; two, current approaches to
20 treatment and current management; and then, three,
21 patient perspectives on clinical trials.

1 We'll kick off each topic with a panel
2 of patients and caregivers who will share their
3 experiences. After the panel, we'll have some polling
4 questions.

5 And then we'll open the floor to a
6 broader group discussion. And that means everyone.
7 Those of you here in the room, those of you calling in
8 by phone, and those submitting comments online through
9 the webcast.

10 In fact, I did want to mention that
11 Ethan, who gave our recent presentation, will be with
12 us throughout the day. He and Allison, who are seated
13 here in our audience, are monitoring the webcast and
14 will be sharing comments from our virtual participants
15 in real time.

16 We also have Karen and Will covering
17 the phones, so if you join us online, please know that
18 you will have an opportunity for your voice to be
19 heard.

20 So for those of you in the room with
21 lived experience as patients or caregivers, we have

1 two microphone runners today. So you'll just raise
2 your hand. When we get to the open discussion parts
3 of the meeting, those of you with lived experience,
4 just raise your hand, and we will come to you to hear
5 your perspectives.

6 Again, for those of you joining us
7 virtually, you can share comments through the web
8 feature, or the chat feature in the webcast platform,
9 or by calling in.

10 We put the phone number on the screen
11 throughout the day. When you call in, you may give us
12 your first name or remain anonymous. We care about
13 your experience. We don't -- not as much your name.

14 If you do call in, it is helpful for us
15 to stay on topic -- stay on the topic that we're
16 discussing, and we do ask people, if you are making
17 comments, to keep them to two to three minutes just so
18 that we can hear from as many people as possible.

19 For transparency, if this is your first
20 comment today, we ask you to disclose whether you're
21 affiliated with any organization with an interest in

1 nonhealing chronic wounds or whether you have a
2 significant financial interest in wound product
3 development.

4 Throughout the day, as I mentioned, we
5 will have polling questions. You can participate
6 using your cell phone or any computer or tablet at
7 mentimeter.com.

8 Polling is anonymous. We only see
9 grouped responses, not individual answers. These
10 questions are a discussion aid, not a scientific
11 survey, but they help us to understand the range of
12 experiences represented in today's meeting.

13 Please also be aware that there is a
14 short delay between what is happening here live and
15 what you are seeing on your screen if you are joining
16 us virtually. So we'll do our best to give everyone a
17 moment to get to the polling questions as we read each
18 question.

19 We also have a public docket, which is
20 open through October 26, 2026, where anyone is welcome
21 to submit comments. The link is on the screen and on

1 the FDA meeting webpage.

2 You can also search "patient-focused
3 nonhealing chronic wounds" at regulations.gov.
4 Comments can be anonymous. We will incorporate
5 comments into the summary report that I mentioned
6 earlier.

7 Now I'd just like to turn to a few
8 ground rules. We encourage all individuals and family
9 members to contribute to the dialogue. Our
10 discussions will focus on health effects, treatment,
11 and clinical trials related to nonhealing chronic
12 wounds. The views expressed here today are personal
13 opinions and respect for one another is paramount.

14 We are glad to have representatives
15 from research, medical product development, and
16 clinical communities here with us. We believe the
17 input shared today will be important for you as well.
18 We do ask that you remain in listening mode throughout
19 the discussion.

20 FDA staff is also here to listen. We
21 have FDA staff here in the room, here on the panel,

1 and online. We know that you may have questions about
2 drug development and drug review. If you have
3 specific questions, we encourage you to share them via
4 email with our FDA staff.

5 Our contact information is on the
6 meeting website. We'll get back to you with more
7 information following the meeting.

8 As has been described, our discussion
9 today is really focused, first, on the health effects
10 of nonhealing wounds and daily impacts, and then the
11 approaches to managing those health effects.

12 Our discussion may touch upon
13 scientific treatments. However, the discussion of any
14 specific treatments should really be done in a way
15 that helps to understand the broader issues, such as
16 what health effects are being addressed and how this
17 is meaningful to individuals with nonhealing wounds
18 and their loved ones.

19 We know that this is very complicated,
20 and there are many concerns and many questions and
21 things you have to think about with living -- when

1 living with nonhealing wounds and getting the support
2 you need.

3 While those are all important, today we
4 hope to focus on the topics that FDA and medical
5 product developers most need input on so that we can
6 do our best.

7 And so before we move on to our polling
8 questions, I just want to take a moment to introduce
9 the panel of colleagues who will be seated with us
10 today for the duration of the meeting. These are
11 representatives from the FDA, from the Wound Care
12 Collaborative Community, and from other partner
13 organizations.

14 As I mentioned, they are primarily here
15 to listen. This meeting is yours, the patients', but
16 from time to time I will turn to them to see if they
17 have any clarifying questions based on what they're
18 hearing.

19 And with that, I'd like to just ask my
20 colleagues -- we will hear from Polly and Robby very
21 shortly, so -- but I would like to ask my colleagues,

1 starting with Dr. Mejia, to just briefly introduce
2 themselves.

3 DR. MEJIA: Hi. I'm Joy Mejia; I'm a
4 Medical Officer in the Division of Dermatology and
5 Dentistry, the CDER.

6 MS. ROSENBERG: Hello, I'm Sarah
7 Rosenberg; I am a Clinical Outcome Assessment Reviewer
8 in the Division of Clinical Outcome Assessments in
9 CDER.

10 DR. TARIQ: Good morning. My name is
11 Anam Tariq; I'm a clinician as well as a branch chief
12 in the Office of Cell and Gene Therapy in CBER at the
13 FDA. Thank you.

14 DR. YOUNG: Hi. My name is Kathleen
15 Young; I'm an engineer and a lead reviewer in CDRH in
16 OHT4 in the Plastic and Reconstructive Surgeries
17 Division.

18 DR. CHANG: Hello. I'm Cynthia Chang,
19 and I am a TAP advisor in CDRH, the Office of the
20 Center Director. Thank you.

21 DR. DRIVER: You've already met me.

1 I'll pass it to Dr. Cole.

2 DR. COLE: Good morning. Dr. Windy
3 Cole; I'm a podiatrist wound care specialist, Director
4 of Wound Care Research, Kent State University College
5 of Podiatric Medicine, and proud member of the WCCC
6 where I had the Gaps Committee and the newly formed
7 Patient Advocacy Workstream. So thank you.

8 MS. BENT: Wonderful. Thank you, all.
9 And as I mentioned, we will check in with our panel
10 throughout the day to see if they heard something that
11 they would like to follow up on or ask a clarifying
12 question about. And they will just let me know and we
13 will give them the floor.

14 All right. So now, please, all get
15 your phones ready. This is -- we have two questions
16 that -- or one question for everybody and it's a
17 demographics question. And then we'll move on to
18 questions just for the -- for our patient population,
19 patient and caregivers.

20 So as we get -- before we get into our
21 first topic, let's do a quick polling question. These

1 are demographic questions. They'll also help you get
2 familiar with the polling platform and before we use
3 it during the discussions.

4 Please go to [mentimeter.com](https://www.mentimeter.com) or scan the
5 QR code that is on the screen. We'll give everyone a
6 moment to get it there before we read each question.
7 And, hopefully, we will have a QR code that we are
8 able to see in the room. If not, we'll work on that.
9 Oops. There we go.

10 So the first question -- we now have a
11 QR code. Thank you very much. The first question is
12 a pretty straightforward one: "Where do you live?"

13 And that -- we've just given you two
14 answers: "Within the Washington, D.C., metropolitan
15 area, which includes Virginia and Maryland suburbs; or
16 outside of the Washington, D.C., metropolitan area."

17 And as I mentioned, there is a little
18 bit of a delay, so we will expect that answers will
19 trickle in for a moment. While you are completing the
20 polling questions, I'm going to -- or for some of the
21 questions, you'll have one answer. For others, you

1 will have multiple answers.

2 These polling questions, again, are
3 just meant to be a discussion aid, and they are not a
4 scientific survey.

5 And so as we see, we have a majority of
6 people outside of the Washington, D.C., area, which is
7 what we would expect and what we are very excited to
8 see. It means that we are reaching people across the
9 country and perhaps even across the world. So we'll
10 give it one more minute 'cause we see a good number of
11 people responding.

12 All right. Excellent. So from this
13 point on, as I mentioned, we're going to ask that
14 polling be completed only by individuals who currently
15 have, or have had, a nonhealing chronic wound, or by a
16 family member or care partner of someone who has.

17 This helps us make sure that the data
18 we collect reflects the experiences of the people this
19 meeting is designed to serve. And so we will go to
20 the next question, which is: "Which statement best
21 describes your experience with nonhealing chronic

1 wounds?"

2 And you can select one answer for this
3 one. You are either "an individual who currently has
4 or has had a nonhealing chronic wound," or "a family
5 member or caregiver of an individual who currently has
6 or has had a nonhealing chronic wound.

7 We understand that for some of you, you
8 may be both. Choose the one that you feel applies
9 most at this time. And, again, we'll give everybody a
10 moment to answer.

11 All right. Great. So it looks like we
12 have a really nice breakdown of both people who have
13 had their own nonhealing chronic wound, and a really
14 good representation from family members or care
15 partners. And that is great.

16 We're hoping that those of you that are
17 answering these survey questions will really stay with
18 us throughout the day and take the time to call in and
19 share your experiences with us throughout the meeting.
20 So appreciate that.

21 All right. We have just a few more

1 questions before we get into hearing from the panel.
2 The first one is: "What is you or your loved one's
3 age?" If you're online and you answer that question,
4 feel free to move on to the next questions as well.

5 All right. So it looks like right now
6 we have a majority of people who are in that 45 to 65
7 age group, but good representation from the 18 to 45-
8 year-olds and the 65 to 75-year-olds, and a good
9 percentage in that 75 to 85-year range.

10 I think I might have -- it's the --
11 there might be the 85 and older range. I'll be
12 honest, the purples are a little difficult for me to
13 distinguish on this screen, so if I'm poorly
14 interpreting, please feel free to interpret yourself.
15 Very close colors.

16 All right. So we do have a great group
17 of people. And so now let's go to just the: "Do you
18 identify as male, female, other, or prefer not to
19 say?"

20 All right. We have a lot of women on
21 the line, but we do -- it does look like we're getting

1 more and more male input as well. So great to see
2 that we've managed to reach a really good group of
3 people, a lot of different age diversity, males and
4 females. This is really, really exciting for us. So
5 thank you everyone who is participating.

6 And then, finally, we'll move on to our
7 last polling question for this session, which is:
8 "Where is or was your or your loved one's chronic
9 wound located?" And this one you can select all that
10 apply. So you can select multiple options here.

11 And we're seeing a lot in the lower leg
12 area, the hip or buttock area, the foot or toe, looks
13 to be the majority. It also looks like there are a
14 good number of people who have had wounds in another
15 location that we did not list.

16 All right. Well, thank you. Thank
17 you, everyone. Those results give us a helpful
18 picture of who is with us today. We have a range of
19 people participating: patients, caregivers, people
20 from around the country. And, again, this is exactly
21 what we hoped for.

1 So thank you. And with that we're
2 going to move into our first topic.

3 So Topic 1, as I mentioned, focuses on
4 health effects and daily impacts of nonhealing chronic
5 wounds that matter most to patients. We have six
6 panelists who will start off the session by sharing
7 their experiences.

8 In about 30 minutes, we'll move to a
9 few more polling questions, and then open the floor
10 for a broader discussion. If there is something that
11 you hear from our panelists that really resonates with
12 you, or you want to share a bit of your experiences,
13 please consider sharing your comments via the web.

14 Or closer to the end of the 30-minute
15 period, maybe around 11:10, maybe a little bit earlier
16 Eastern Time, maybe give us a call. You could call
17 in. The phone number is 1-800-527-1401 to share.

18 You should know that if you do call in
19 and are placed on hold, the hold music will not
20 actually be music; it will be this meeting. So you
21 will be able to still hear from panelists if you call

1 in to speak. And so I think that's a really great
2 feature.

3 And with that, I would like to start by
4 inviting our panelists to share their experience.

5 And, Robby -- yes, would you like --
6 you can either sit there or come up here, whatever you
7 prefer. Excellent. Perfect. Thank you.

8 ROBBY: Good morning. Question for you
9 all. What if wound healing wounds didn't exist
10 anymore? That is my challenge to everyone in the room
11 and connected to us virtually. I want to talk about
12 my journey, the problem, the possibility, and my
13 story.

14 The problem -- in February 2025, I
15 found a small pinhole on my right toe. Smaller than
16 the tip of a needle. Didn't think much of it. All of
17 a sudden it started festering, and that pinhole took a
18 year of my life.

19 Before that pinhole, I was running five
20 days a week, going to the gym four days a week, and I
21 was walking at least 10,000 steps a day with my wife.

1 And this was time that my wife and the pups got out to
2 talk about our day, our stresses. And through the
3 wound, I had to stop doing that.

4 So within several weeks, I was on a
5 knee scooter. I couldn't put on a shoe on my right
6 foot, because the shoe was rubbing the toe, which was
7 causing the wound to constantly stay open. So I
8 couldn't take these walks with my wife or the puppy.

9 My wound never got bigger than an inch
10 and a half. You could cover it with your thumb. But
11 it was also deep. It was deep enough for several
12 months you could see the bones, or the bone.
13 Something that small ran all of me.

14 An open wound does not wait for you to
15 think about it. It is there when you put your foot
16 down, when the sheet touches it at night. I was not
17 sleeping more than several hours at a stretch for
18 months.

19 Every time I had to uncover it, get it
20 cleaned or covered again, a lot of it at home by
21 family members, no one was trained to kneel in front

1 of me and decide did it look worse or was it getting
2 better?

3 But the worst of it never turned off.
4 I dreaded started -- the dread started days before an
5 appointment. By the time they called my name, my
6 heart was already going. I was never going in for a
7 checkup. I was going in for a verdict. Is it
8 smaller? Is it deeper? Is the infection back? Do we
9 need to talk about amputation?

10 Your mind plays tricks on you. Some
11 days I would swear it looked smaller, until I looked
12 again and I knew I had been lying to myself. You
13 start believing whatever you need to believe.

14 Every night my mind would run the same
15 reel about amputation. Is it first the toe, then the
16 foot, then below the knee, then the leg? I would lie
17 there in the dark wondering where it stops.

18 And somewhere in that year, I noticed
19 that I started dreaming. And it wasn't about running
20 again, going to the gym; it was about shoes. Putting
21 on a pair of shoes and walking out the door like

1 everybody else. Who would've thought something so
2 routine could be taken from you. That was one of my
3 many problems.

4 And I want to talk about the
5 possibility. I was going to a wound care center and
6 they were doing great care, but I realized things were
7 really bad when my provider said, "I have used every
8 tool in my toolbox." And they sent me to MedStar
9 Georgetown.

10 I also reached out to the Global PAD
11 Association, and they were able to connect me with
12 Dr. Bernardo, who was able to restore blood flow to my
13 foot and save me from amputation.

14 My wound closed in August, but then it
15 reopened again, and I had my third surgery to close --
16 to get better blood flow, and it's been closed for
17 good in December. I'm standing here today on two feet
18 because a few people refused to give up on me.

19 Once it healed, people told me I looked
20 lighter, like a different person. I had been
21 disappearing for a year and never noticed.

1 I didn't get that year back, but I got
2 me back. And I can walk with my wife and pups again.
3 That is the possibility. It already exists. It just
4 took 10 months to reach me.

5 The plan forward -- I have volunteered
6 for many clinical trials but was never selected. The
7 criteria seemed so narrow that a man who spent a year
8 fighting to keep his foot could not qualify for
9 research meant to save it.

10 So take one thing from me today.
11 Measure what we actually live. Measure the pain.
12 Measure the lack of sleep. Measure the worry, because
13 it never lets up. Measure whether a man can put his
14 shoes on and walk out the door with his wife.

15 And measure whether it stopped growing
16 and how it kept my foot. But stopping it from getting
17 worse wouldn't give me my life back. My life came
18 back when the wound closed.

19 Make room in your studies for people
20 like me, because somewhere right now somebody is on
21 the edge of their bed at two in the morning looking at

1 their foot, doing the same math I did. A pinhole took
2 a year from me. I got mine back, but not everyone
3 does.

4 So I will leave you with where I
5 started. What if nonhealing wounds didn't exist
6 anymore? I believe it is possible, and I believe you
7 are the people who can do it. Thank you.

8 MS. BENT: Thanks, Robby. A pinhole
9 and yet a year. Thank you for trusting us with that
10 story and really for being here in person today.

11 We're now going to turn to Brad who is
12 joining us virtually.

13 Brad, please go ahead.

14 BRAD: All right. Thank you. That's
15 going to be a tough act to follow there.

16 I have wounds on both legs. It started
17 a little over six years ago. I had an injury to my
18 right heel, and being a typical tough guy, immortal, I
19 didn't really do much about it until it started
20 getting worse.

21 I saw my primary care who gave me two

1 options: go to the wound clinic or go to the hospital.
2 So I opted to go to the wound clinic, and have been
3 going there, off and on, now for seven years.

4 It's never really closed it. It --
5 it's on the top of my foot, the heel where the
6 original wound was, and also on the side. I've also
7 developed a wound on my left leg on the side of my
8 thigh.

9 About two and a half years ago, I
10 ruptured my meniscus in my right knee. I can't walk
11 now. No self-respecting orthopedist will do surgery
12 on a person -- on a person's knee when their foot is
13 covered in wounds.

14 So wearing shoes for me -- I'm happy
15 for the gentleman before me. Shoes have not been a
16 consideration for years now. I have my wounds -- or
17 my bandages changed three times a week, once at the
18 wound clinic and two by home healthcare. And this is
19 a continuing part of my life.

20 I sometimes have significant drainage,
21 which you end up leaving snail trails on the floor.

1 It gets to smell, especially if a dressing change is
2 missed.

3 I used to love surf fishing. I'm a
4 KCBS Certified Barbecue Judge. I don't do any of
5 those things anymore. I've worked from home ever
6 since, because I can't get into the office anymore.
7 The transportation methods that are available to me
8 now are pretty poor, and just leaving the house is
9 a -- is a huge hassle.

10 The drainage is bad enough that I can
11 no longer sleep in the same bed as my wife, and now
12 have to sleep in a different bed, and that has had
13 a -- a direct impact on our marriage.

14 I'm now stuck most of the time in the
15 basement where I work and sleep and eat, and it's just
16 really taken a huge chunk of my life now for years. I
17 don't know. I guess total healing for me would just
18 be able to go back to the beach, be able to walk, be
19 able to judge another barbecue contest.

20 Thanks to my current caregiver, Lonnie,
21 all I can say is I think we're on the right track, and

1 we're finally slowly making progress. And thank you
2 to the FDA for giving people like me time to speak,
3 and I'll turn it back over to you.

4 MS. BENT: Thank you so much, Brad.
5 The details you shared, the wet footprints, the
6 separate bed, those are the realities that tell us a
7 little bit about what life is actually like.

8 And so now we will turn from Dave, who
9 is also -- or to Dave, who is joining us virtually as
10 well. Thank you.

11 MR. DEPOTTIE: Hello, everyone. Thank
12 you for the opportunity to speak. I've had three
13 major wounds over the last 11 years on my leg, my bum,
14 and my arm. Each wound had its own complications.
15 Each wound changed my life in different ways beyond
16 what I could have imagined.

17 Overall, it affected my health and my
18 daily routine. And until you've experienced it
19 yourself, it's -- it's difficult to describe and
20 understand what it can do to you.

21 My number one issue is pain. I have

1 pyoderma gangrenosum, and when PG is active, it's not
2 a 10, it's -- it's a 14. That's what we say. And it
3 feels like a cigar being pressed against your skin and
4 they won't take it off.

5 My leg was my first wound. It was
6 misdiagnosed as a diabetic ulcer. They debrided it,
7 which made the wound explode in size and went deep,
8 exposing bone and tendon all the way down to the
9 tibia. And three different doctors wanted to
10 amputate.

11 My wife, who diagnosed my PG and did
12 all my wound care, she insisted that the bone was
13 still alive, and so we refused. And she was right.
14 The bone eventually grew skin, and I was able to keep
15 my leg, but it was a constant fear.

16 During this time, the hospital gave me
17 Remicade for PG, but they gave it to me during an
18 active infection. That resulted in five bouts of
19 sepsis over eight weeks, and I almost lost my life.

20 They used mass steroids to fight the
21 sepsis that destroyed all my muscles, and I became a

1 quadriplegic. My wife, my family, they all became my
2 caregivers 24/7, and they had to do everything for me.
3 It was traumatic for the entire family.

4 I developed bedsores on my bum that
5 turned into large, painful wounds. And this was,
6 actually, I think, the worst possible location for any
7 wound and had the biggest impact on my life. I could
8 no longer sit. I could no longer walk and go in my
9 wheelchair because I couldn't sit.

10 And you don't realize how much you rely
11 on sitting until you lose the ability. I became
12 completely bedridden, and at that point I was just a
13 head on a pillow. Those were very difficult days
14 mentally. I was in constant pain, and trying to
15 adjust to this new reality, thinking this was it.

16 We finally found a treatment that
17 worked for pyoderma, and both those wounds healed.
18 With physical therapy and my wife's help, I learned to
19 walk again, one baby step at a time. It took seven
20 years, but we finally put that wheelchair away.

21 About a year after that, I had a major

1 relapse, and I lost all that progress in a matter of
2 weeks. It was devastating to return to that severe
3 pain and to wound care, and to become permanently
4 disabled, losing my job, everything that goes with it.

5 Around that time I had spots appear on
6 my arm. They were misdiagnosed as MRSA. They took me
7 off my immune suppressants thinking that would help
8 fight the infection. All that did was allow these
9 wounds to grow over my entire arm.

10 We tried everything to stop the
11 progression. It ended up going from my wrist to my
12 shoulder. My entire arm was engulfed.

13 The pain was worse than anything I had
14 ever experienced before. I became very ill. I spent
15 weeks hospitalized. But whatever they did in the
16 hospital that time, my arm started to heal, and we're
17 not really sure why.

18 So right now, all three of my wounds
19 have healed. They've left terrible scars. My arm
20 looks like a burn victim. The skin won't stretch.
21 It's hard to stretch my arm. But I'm not in pain

1 anymore.

2 I lost my job, my mobility, my quality
3 of life, my relationships that I had, and the version
4 of myself that I had spent decades building. I was
5 very, very happy with life and how it had progressed,
6 and all of that was taken away.

7 This is what chronic wounds can do to
8 you. This is what pain can do. I now live with these
9 emotional scars and now in constant fear of relapse.
10 What if it happens again? I just don't know.

11 So chronic wounds does a lot more than
12 damage your skin. It damages your life. And I thank
13 you very much for listening to my story.

14 MS. BENT: Thanks so much, Dave. And I
15 think part of your story, or part of your experiences
16 really speak to what Dr. Driver was talking about
17 initially about that -- the importance of looking at
18 the whole person and the holistic nature of the care.
19 So thank you for that.

20 We're now going to hear from Polly, who
21 is here with us in the room.

1 And you can either speak from here or
2 from the podium, whichever you prefer.

3 MS. CLEVELAND: I guess the -- the
4 podium.

5 MS. BENT: Excellent. Thank you.

6 MS. CLEVELAND: Good morning. Is this
7 thing on? Yeah. Thanks you -- thanks so much for
8 inviting me. I'm going to talk about a -- another
9 aspect of nonhealing wounds, which is when you combine
10 nonhealing wounds with Alzheimer's.

11 I took care of my husband. My husband
12 was a very active guy. He went out and jogged every
13 day. But he got Alzheimer's, and, of course, that
14 meant he started to wander.

15 And after one night he went wandering
16 down the middle -- we live in Manhattan -- down the
17 middle of Columbus Avenue because he decided it was
18 going -- he was going to Mexico.

19 So I had to put him in assisted living.
20 It was very nice assisted living. He had his own
21 little room, a communal center, meals, other people to

1 chat with. He was a very outgoing person, so he
2 managed to have a good time.

3 And in case you wondered, there can be
4 life after Alzheimer's. Because I would visit him
5 every day, do some activities with him, have meals
6 with him, take him out for walks in the neighborhood.
7 And, you know, he was declining slowly. He didn't
8 really know quite what was going on.

9 At bedtime, I'd sort of -- we'd sit on
10 the bed and watch dance movies. And I should have
11 said he loved to dance. Not that he was a great
12 dancer, but he had his own special dance, the turtle.
13 And if anybody knows about turtles, a male turtle
14 courts the female by waving his -- his claws. So,
15 anyway, so Tom used to do the turtle.

16 Well, so in the beginning of June in
17 '23 -- Tom was close to 90 -- he got a light case of
18 pneumonia. And went to the hospital, came back three,
19 four days later, and he couldn't walk because his left
20 heel was very painful.

21 And not only was his left heel very

1 painful, but soon the skin broke and he had this
2 horrible nonhealing wound in his -- on his heel.

3 And can you imagine, he didn't
4 understand what was going on, but that heel had to be
5 treated. So -- so he -- he was now in a wheelchair
6 with this great big -- like a giant ski boot,
7 protective boot, on his left foot.

8 And, of course, this thing kind of
9 pulled him over to the left, and won't you -- you
10 wouldn't believe, as Vickie said, pretty soon he got
11 another nonhealing wound, this time on his left butt.

12 And at this point, can you imagine, the
13 poor guy was in tremendous pain from two wounds, and
14 he was now bedridden. He couldn't go out and join the
15 others for meals, join the activities.

16 He -- we had people around the clock,
17 you know, every two hours he had to be turned over.
18 You know, [makes sound], you know, 'cause it hurt
19 every time he was turned over.

20 So, you know, from being a very active
21 guy, and we were still enjoying life even with

1 Alzheimer's, he was kind of a bedridden zombie. And I
2 had to feed him purees in bed. So I brought him home.

3 And at home I had an aide, but I had to
4 help with -- with treating the wounds. And the wounds
5 were just, you know, as you've been hearing, icky,
6 stinky, leaky. You know, [makes sound].

7 And so I was helping treat the wounds.
8 But a bit of my history. As a kid, I was a bug lover.
9 I loved insects. I read everything I could get my
10 hands on about insects. So I knew that for thousands
11 of years, blowfly maggots had been used to treat
12 wounds. I knew that.

13 So I went online and, by golly, I was
14 able to order nonhealing -- order maggots online and
15 put them in my husband's wounds. And I'm sure we can
16 talk about this this afternoon because that's
17 treatment, but it was an absolutely amazing
18 experience.

19 Unfortunately -- and I really regret
20 this -- I had waited too long. I had one treatment
21 for his butt, one for his heel. I -- I can show you

1 photos of the results. But he was really too far
2 gone.

3 So, you know, imagine combining
4 Alzheimer's and nonhealing wounds and trying to treat
5 the person who screams when you turn him over. And it
6 was -- it was an experience. And I -- you know, I'm
7 sure many of you had similar.

8 But I want to thank the FDA for giving
9 me this opportunity. And for all of you who have
10 elderly relatives suffering with Alzheimer's and --
11 and nonhealing wounds, you know, more power to you.
12 Thank you.

13 MS. BENT: Thanks so much, Polly.
14 That -- the love in your story and the way you really
15 brought Tom to us is really unmistakable. And it
16 really reminds us of why we're here and why the work
17 that we do matters. So thank you for that.

18 We're now going to hear from Kevin, who
19 is joining us virtually.

20 MR. WAKE: Good morning, everyone, and
21 thank you for giving me this opportunity to speak

1 today. My name is Kevin, and I am a 58-year-old
2 patient living with sickle cell disease.

3 The hallmark symptom, of course, of
4 sickle cell is pain crisis. However, as I've gotten
5 older, I've realized that my disease presents itself
6 in multiple other complications. And one of those
7 complications for me has been recurrent leg ulcers at
8 my left ankle.

9 My first leg ulcer started back in
10 2010, and my last active wound was in 2024. This is
11 not something that I just experienced for a few weeks
12 or a few months. It became part of my life For years.

13 One of the hardest things for me was
14 never knowing when or if my wound was actually going
15 to heal. One week I'd go into wound care and I'd hear
16 the provider say, "Oh my God, this looks great. It
17 looks smaller. It's better." And I'd start thinking,
18 "We are finally getting somewhere."

19 And then the very next week I go in and
20 I hear, "Unfortunately, your wound is bigger" or "It's
21 infected." I've had wounds that have taken four

1 months to completely heal, and I've also had wounds
2 that have taken over two years to heal.

3 Leg ulcers were really controlling my
4 life. The pain was extreme. Debridement was near
5 intolerable, even with the numbing spray that they
6 used. There were days when the treatment itself
7 affected my ability to walk, and it meant taking
8 additional pain medication after treatment.

9 I'm dealing with wound pain. I'm
10 dealing now with infections. I am now adding both
11 pain medications and antibiotics to a regimen of
12 already eight medications that I take daily to control
13 my sickle cell.

14 My wound had great impact in the
15 management of my disease. For me, heat therapy is
16 crucial, and I use my hot tub nearly every day to
17 manage the pain from my sickle cell. But with an open
18 wound, even with the cast cover, I couldn't do that
19 anymore.

20 There was a lot of trial and error in
21 the treatment regimen for my ulcers as well. And at

1 one time, I was even taken off my hydroxyurea to make
2 sure that that drug that I take from my sickle cell
3 was not contributing to my leg ulcer or the healing of
4 that leg ulcer.

5 One problem from my health contributed
6 to the tools and took away management opportunities
7 for another disease, more pain, more stress, more
8 anxiety, and less sleep.

9 And then there was life. When this
10 first happened, I was working full-time. I was
11 traveling for my job. But suddenly my schedule had to
12 revolve around going to wound care three times a week,
13 not just for a week or two, but for months or years.

14 Add in dressing changes, elevating your
15 legs, limiting your walking, medications, pain
16 medicine, everything else that you're using to manage
17 your disease already is complicated.

18 I even had to add extra time into my
19 daily routine just to get ready in the morning to go
20 to work. At one time I even had to take a leave of
21 absence from my job, my career that I loved in

1 pharmaceuticals.

2 I ask you to focus on the healing of
3 wounds, but also look at the total impact on a
4 patient's life during therapy. Can a patient walk?
5 Can they work? Can they travel? Is their sleep
6 impacted? Can they spend time with their family?

7 Today, thank goodness, my wound is
8 healed, and I'm completely grateful. However, leg
9 ulcers are always top of mind for me. My ulcers have
10 occurred in the very same spot every single time, and
11 that skin is discovered -- discolored as well as
12 fragile.

13 When I walk outside, I'm always
14 thinking about are there sticks or things that can
15 actually hit my leg to contribute to that wound
16 opening again. My last leg ulcer started from a
17 simple mosquito bite and me scratching that skin, and
18 that wound opened up immediately.

19 The time before that, my leg ulcer
20 began from my dog simply playing and inadvertently
21 scratching my ankle.

1 I'm always thinking, is my wound going
2 to start again? And if it does, how quickly can I get
3 back into wound care?

4 So, yes, wound closure absolutely
5 matters, but please don't stop at just measuring the
6 pain and the time to heal. Also consider how the
7 treatments affect a patient's ability to walk, their
8 ability to work, sleep, travel, and manage other
9 health conditions that they have.

10 And remember that recurrence matters as
11 well. It's not just can we heal the wound, but can we
12 also give a patient part of their life back in the
13 process? Thank you.

14 MS. BENT: Thank you, Kevin. I think
15 that one of the things when we are having our prep
16 calls that really resonated with me the most was that
17 ongoing kind of fear and anxiety that you described
18 about needing to protect your legs at every moment for
19 fear that you would get a wound.

20 And really appreciate you sharing
21 this -- your experiences with us.

1 And so, as our final panelist, we
2 would -- we will be turning to Amanda, who is also
3 joining us virtually.

4 Amanda?

5 AMANDA: Good morning, everyone. My
6 name is Amanda; I am 43 years old. I work full-time
7 as a professor. I live in New York City, and I'm
8 married with an 8-year-old daughter.

9 Five years ago, when I was just 38, I
10 was diagnosed with a rare bone cancer on my sacrum and
11 tailbone, which metastasized a year later. I've been
12 living now with that for -- for four years.

13 The treatment I was given was heavy
14 radiation to the tailbone/sacrum area, and I was
15 always told that the skin was really delicate, and if
16 it opened, it would be hard to heal. And I took
17 really good care of the skin, but, nevertheless, one
18 year ago the skin on my tailbone began to open.

19 And it led to progressive skin
20 breakdown, a wound opening that's currently about the
21 size of a lemon, both in size and depth, and exposed

1 bone. And I now live with chronic osteomyelitis and
2 all the vagaries that that introduces, such as risk of
3 infection and that sort of thing.

4 Because there's no blood flow there due
5 to the radiation, I'm -- I'm being told that there are
6 really no definitive closure options and that I'll
7 basically be living with this wound, this life-
8 changing wound, for the rest of my life.

9 I was very surprised to find that there
10 was really no treatment plan. It was very hard for me
11 to find someone who would really partner with me on
12 this, and I -- I simply really wasn't prepared for
13 what this would entail.

14 Surprisingly, this has been far worse
15 for my quality of life than having stage 4 cancer.
16 That'll probably come as no surprise to the other
17 patients on the call.

18 It's also limited my treatment options
19 for cancer because I'm currently on a PICC line with
20 IV antibiotics, I can't do clinical trials while I
21 have osteomyelitis, and because all of these drugs

1 interact, it's -- it's really cut down on the kinds of
2 treatments I can do and explore.

3 There's also an enormous physical
4 burden in that area of the body.

5 I think, Dave, you said it's one of the
6 worst areas to have a wound, and I would certainly
7 agree.

8 There's drainage, there's smell.
9 There's daily wound care that my husband does, which,
10 of course, has had an enormous impact on our -- on our
11 marriage and my level of independence.

12 I'm constantly taking antibiotics and
13 it's very, very hard for me to travel. Before this, I
14 would go to retreats, and I was very, very active and
15 independent. And now I'm really reliant on that --
16 that intimate person for wound care.

17 There's no more stretching, there's no
18 more yoga. And for me, there's no more swimming,
19 which has been a huge loss. I was a big, big swimmer.

20 What's really surprised me and what I
21 want to stress today is the sense of isolation and

1 depression that this -- these sorts of situations can
2 cause, particularly when there's radiation and there's
3 no hope for closure.

4 Whereas cancer, in a way, connected me
5 to everybody else -- I felt really like I was
6 connected to a much larger community -- this has cut
7 me off and I feel like I live on my own planet.

8 It's also been very hard to find a
9 medical provider who will really get in there with me
10 and partner with me.

11 Dr. Driver, your description of
12 treatment as "fractured" really resonates with me.
13 It's been like a little bit here, a little bit there.

14 I'm told, "Come when you want to come,"
15 you know, but nobody's really gotten in there to say,
16 "I'm going to hold your hand through this, and we're
17 at least going to make this as -- as tolerable as we
18 can."

19 So I really want to stress the
20 importance of -- for the providers in the room -- of
21 creating a consistent, comprehensive plan and making

1 it clear that you're not giving up on the patient even
2 if there's no hope for closure.

3 I finally found a doctor who -- after a
4 lot of searching, who can be a consistent source of
5 that support, and it's made all the difference.

6 And even if it will never heal, I'm at
7 least on a path to attempt it. And that -- that need
8 to continue to -- to live as if someday I can close
9 it, someday we might discover something. To not have
10 that hopeless despair has been life changing.

11 So I really want to stress that with
12 everybody listening. And thank you so much for
13 providing this space for -- for information and for
14 community support. Thank you.

15 MS. BENT: Thank you so much, Amanda.
16 That observation that your wound has been even more
17 burdensome and isolating than cancer is really
18 powerful, and your description of the fractured care
19 as well.

20 So I want to thank all of our Topic 1
21 panelists: Robby, Brad, Dave, Polly, Kevin, and

1 Amanda. You've given FDA researchers and clinicians
2 an extraordinary window into what it means to live
3 with a nonhealing chronic wound, and we are very
4 grateful.

5 So for our next steps, what we're going
6 to do is we're going to turn to our panelists here to
7 see if they have any clarifying question for our
8 patient and patient caregiver panelists.

9 And then as soon as we finish with the
10 clarifying questions, we're going to go to a few
11 discussion questions.

12 Then we have people on the line who are
13 interested in sharing their story. We'll also go to
14 people in the room who are interested in sharing their
15 experiences.

16 So with that, let me turn to my
17 colleagues and see if anyone has any clarifying
18 questions.

19 Dr. Cole, I think?

20 DR. COLE: Yeah, I have a question for
21 our first speaker. You mentioned that you had

1 attempted to get enrolled in clinical trials but were
2 not able to. Can you tell us why or what
3 qualifications you didn't meet?

4 ROBBY: Sorry about that. I -- when I
5 was connected with Dr. Bernardo at Washington Hospital
6 Center and his vein cardiac care group, he had a lot
7 of studies going on, and they were looking for
8 different inclusions that were a very small set, where
9 my blockage was a little larger.

10 DR. COLE: Okay.

11 ROBBY: I didn't qualify. And
12 then -- and there were -- there were three or four
13 trials he tried to put me into, but it was usually the
14 blockage was too large and wouldn't qualify.

15 Even though they were able to open it
16 up from being blocked a hundred percent to -- from
17 being blocked to a hundred percent to being actually
18 all the way open, it still didn't qualify for the
19 balloon having medication on it, that was having great
20 success in the upper part of the leg as opposed to the
21 lower part of the leg.

1 And they're seeing -- and according to
2 the researchers, there's a whole lot more studies
3 going on with the upper part of the leg as opposed to
4 at the foot.

5 DR. COLE: Thank you for sharing that.
6 It -- many of us in the room are involved in either
7 overseeing or participating or writing protocols for
8 trials, so it's really great to see what
9 inclusion/exclusion criteria are affecting the real
10 world patients that are dealing with these long-term
11 problems. So thank you for that input.

12 MS. BENT: And as a spoiler, that -- we
13 will get -- do a much deeper dive into that this
14 afternoon as well, so that -- yes.

15 Dr. Driver, and then I'm going to --
16 oh, okay. So we can do maybe two more questions, and
17 then we want to go to the polling.

18 So Dr. Driver, and then -- go ahead.

19 DR. DRIVER: First of all, thank you
20 very much for all of those that just shared your
21 experiences. We really needed to hear that, and I --

1 we took close notes.

2 Amanda, I wanted to ask you a question.
3 So your despair and hopelessness that you articulated
4 so very well really touched me, and I'm sure everyone.
5 We heard that from everyone that spoke.

6 Can you help us understand what we can
7 do as a field of medicine to help bridge that gap to
8 make it less fragmented? That would be helpful.

9 AMANDA: It starts with basic bedside
10 manner. It starts with not referring to the smell as
11 a stench, which has actually happened to me.

12 It starts with having really good
13 clinical behavior in the -- in the setting of the
14 appointment, and an awareness that we're still talking
15 about the patient's body and not something that's
16 separate from their body.

17 I think what's made the difference
18 with -- with the current provider has been a -- a
19 plan. A plan that we're going to meet at these
20 increments. We're going to measure it at these
21 increments. And we're going to try this, we're going

1 to try that.

2 And even if there's not necessarily a
3 sense that this method will -- will close it
4 completely, there's -- there's a hope that we can make
5 a little bit of progress on it.

6 That sense of just a regular timeline
7 has been really helpful. Even if the target won't
8 necessarily get met, just having that consistent
9 integrative approach with somebody.

10 DR. DRIVER: Thank you very much. That
11 was extraordinarily helpful.

12 MS. BENT: Thank you.

13 And, Sarah, did you want to ask a
14 question? Okay.

15 So then we will move on then to our
16 polling questions. And we will start with -- again,
17 this is for patients and their care partners.

18 And we will start with polling question
19 one: "What type of chronic wound or wounds" -- wait,
20 I -- okay, there we go. "What type of chronic wound
21 or wounds do you or your loved one currently have, or

1 have you had?"

2 And the options are -- you can select
3 all that applies. You can select more than one
4 option: "venous ulcer, arterial ulcer, pressure ulcer
5 or bedsore, diabetic ulcer, other type of chronic
6 wound, or I'm not sure."

7 It's always fascinating because we do
8 our best to kind of list the most common, but it's
9 interesting to see that "other type of chronic wound"
10 is really the one that we're seeing the most of on the
11 call today.

12 All right. All right. So, again, we
13 have that little 20-second delay, so we're just going
14 to give it a few more seconds to hear from people
15 before we move on to the next discussion or polling
16 question.

17 And this information will be included
18 as part of the Voice of the Patient Report, the
19 meeting summary that we put out. So if you -- if we
20 move on to the next discussion question or polling
21 question before we reach your -- before you're able to

1 fill this in, we'll still be able to get that
2 information.

3 So, again, it looks like we're -- we
4 have other type of chronic wound, followed by diabetic
5 ulcer, followed by pressure -- no, followed by venous
6 ulcer, followed by pressure ulcer.

7 All right. Let's move on to the next
8 question: "How long are you typically affected by a
9 wound episode from the time it develops to meaningful
10 improvement or closure?"

11 And you can select one option here:
12 "less than 3 months, 3 to 6 months, 6 to 12 months, 12
13 to 18 months, 18 to 24 months, more than 2 years, or
14 'my wound has never meaningfully improved or healed.'"

15 And it really does say a lot that what
16 is pulling ahead in this is "my wound has never
17 meaningfully improved or healed." And it really
18 speaks to one of the main reasons we're here today,
19 especially when the second most popular response is --
20 or most common response is "more than two years."

21 So now as we move forward, I do want to

1 remind everyone that these are polling questions to
2 aid as part of a discussion and not necessarily a
3 scientific survey, but they certainly are giving us a
4 really good idea of what people are living with and
5 how these are impacting people's lives. I think I
6 lost my script.

7 All right. And now we're going to move
8 on to our final polling question for this section,
9 which is: "What do you find to be the most bothersome
10 impact or impacts of nonhealing chronic wounds on your
11 daily life?"

12 And you can choose up to three answers
13 for this one: "It limits movement or walking, affects
14 ability to work, interferes with sleep, restricts
15 participation in social activities, impacts personal
16 hygiene routines, affects intimate relationships,
17 limits exercise or physical activity, mental health
18 impacts, other impacts not mentioned, or none of the
19 above."

20 So as we're waiting for the last
21 information to come in, I just want to give a heads up

1 that we are going to go to the callers that we have on
2 the line. We'll go to two or three callers on the
3 line.

4 And then if we have anyone in the room
5 who would like to share their experiences as a patient
6 or care partner, please, we will turn to you. You can
7 raise your hand and one of our microphone runners will
8 bring a microphone to you so you don't have to wander
9 the room looking for a microphone stand.

10 For those of you who are on the line,
11 please feel free to give us a call. Also, we have --
12 the chat is open and Ethan and Allison are working,
13 reviewing all of the chat comments.

14 And we will turn to them soon to hear
15 some of the experience of those of you who have shared
16 your experiences through the chat feature online. The
17 chat feature is named "Ask a Question." We could not
18 change that, but please feel free to share your
19 experiences through that "Ask a Question" bubble.

20 All right. Did we -- I missed seeing
21 the final results 'cause I was talking. I'm sorry.

1 All right. There we go. So it looks like -- let's
2 see. I need better glasses.

3 All right. So it looks like pain and
4 tenderness at the wound site is one of the largest
5 burdens, followed by other aspects that are not
6 mentioned, and drainage or discharge from the wound.

7 And so what we're going to do now is go
8 to line 5. I think we have Peter in Washington, D.C.,
9 who is going to share some experiences with us.

10 Peter, are you there?

11 MR. THOMAS: I am. Can you hear me?

12 MS. BENT: Yes, we can. Thank you very
13 much.

14 MR. THOMAS: Thank you so much for the
15 opportunity to testify on this very important issue,
16 and I -- I thank and appreciate the testimony of the
17 panel. It was excellent.

18 I am Peter Thomas; I'm with the ITEM
19 Coalition. That stands for the Independence Through
20 Enhancement of Medicare and Medicaid Coalition. It's
21 103 national nonprofit organizations all interested in

1 better access to assistive devices and knowledge of
2 people with disabilities.

3 And I do think there are opportunities
4 to -- to work with -- for FDA to work more closely
5 with CMS to accomplish some gains in this area.

6 I'm going to talk mainly about the
7 intersection between chronic wounds and pressure.
8 What I mean by that is limb prosthetics. There are
9 examples in wheelchair and -- wheelchairs and other
10 mobility devices for people with spinal cord injury
11 and other paralysis. And then diabetic shoes and
12 inserts.

13 My own personal experience comes
14 bilaterally --

15 MS. BENT: Thank you. Thank you,
16 Peter. I'm glad you're going to have your personal
17 experience. Thank you. That's what we would really
18 like to hear. Thank you.

19 MR. THOMAS: Yeah. I'm happy to do it.
20 When I was 10, I was in a car accident. Two
21 artificial limbs was the result. But the -- the

1 wounds that followed, obviously, were pretty severe.

2 And -- and as I spent about 25 years
3 dealing with what I was told was sebaceous cysts in
4 my -- on my residual limb, where the prosthetic limb
5 would impact the -- the residual -- they call it a
6 stump or a -- or a residual limb.

7 And those sebaceous cysts were
8 horrific. You'd, essentially, have to apply pressure
9 when you walk to a part of your body that had an -- a
10 boil, essentially, an active boil.

11 And what would happen is underneath the
12 skin, those walls would break down and they would --
13 over time, they would fuse together and create a canal
14 of -- essentially of -- of infection. This is caused
15 by -- my understanding was that it was caused by hair
16 follicles that became infected.

17 And when you are in a situation where
18 you have to apply pressure to the wound because
19 there's -- you just don't have a choice but to take
20 the limb off and sit around the house all day long.
21 You're going to school, you're going to work, you're

1 doing -- you're living your life. It's very difficult
2 to manage that kind of a ongoing wound.

3 I -- I wound up trying -- trying
4 Accutane. I wound up with all different types of
5 prosthetic socket designs and material applications.
6 And technology eventually began to catch up and -- and
7 did help.

8 But, ultimately, it -- it resulted in
9 two pretty significant surgeries, where, you know, a
10 plastic and neurosurgeon would go in and remove all of
11 those kind of -- all the residual tissue underneath
12 that area that was causing ongoing problems with --
13 you know, the snail trail issue is very, very clear to
14 me. I -- I know that very well.

15 Significant pain, and, really, I would
16 often get fevers, because some of that -- some of that
17 effluent would -- would wind up in my bloodstream
18 and -- and cause fevers. So I'd often get unexplained
19 fevers, and -- and only came to realize that after
20 years and years.

21 So prosthetics is -- is an area that

1 has significantly improved over time, and we are --
2 I've been very pleased not to have had these chronic
3 wounds for the past 15 years.

4 But talk to anyone who sits in a
5 wheelchair, and they need to figure out a way to
6 unweight the -- the lower part of their body. And you
7 can do that through standing, and there are
8 wheelchairs that allow individuals to move into a
9 standing position.

10 A national coverage determination has
11 been pending at CMS for six years, and they have not
12 yet opened it up. We strongly encourage FDA to work
13 with the CMS to -- to get that opened up.

14 And, finally, on diabetic shoes, only
15 1 percent of the need has been met with people with
16 diabetes who are suffering from wounds on -- chronic
17 wounds on their -- on their feet.

18 And we would strongly urge CMS to move
19 forward to accommodate that, figure out a better way
20 to meet the needs of that population, because that's
21 the most prevalent cause of limb loss in this country.

1 And so I'd just say that FDA has -- has
2 some leverage that it can use to try to address
3 chronic wounds, but it also can work with CMS to try
4 to use technology innovations and assistive devices to
5 improve the situation as well. Thank you very much
6 for your time.

7 MS. BENT: Thank you for sharing your
8 experiences with us.

9 Let us now turn to caller on line 1,
10 Gabby.

11 Gabby, are you with us?

12 GABBY: Yes.

13 MS. BENT: Thank you. Please go ahead
14 and share your experiences. Maybe if there's
15 something you want to talk about, or if there's -- if
16 you want to maybe share some specific activities that
17 are important to you that you cannot do.

18 Or maybe what a good day -- what the
19 wound looks like versus a bad day. Whatever you would
20 like to share with us. Please go ahead.

21 GABBY: Okay. First of all, I am a

1 stage 4 ovarian cancer survivor. I had debulking
2 surgery in November '24.

3 And when they closed -- when the doctor
4 took the staples out of my wound, instead of it
5 closing, it just went the other way and it went wide
6 open. So much so that the nurse was afraid to let me
7 leave the doctor's room because she was afraid my
8 insides were going to come out.

9 So, anyway, I had to go to a different
10 hospital, and they hooked me up to a wound vac from --
11 and I had daily bedside debris for three weeks.

12 And I went -- when I was released, I
13 was released to a Nova Wound Care Center. And they
14 had talked about, at the hospital, of doing a
15 bariatric chamber, but because of the cancer we
16 couldn't do that.

17 So the doctor -- I mean the PA at the
18 Wound Care Center, and Gaye Zingler, who was the -- he
19 was the -- I guess, the sales person for -- or the
20 contact for the Advanced Oxygen Therapy, they were
21 trying to find a candidate who they could use this

1 oxygen therapy to help the -- you know, to advance the
2 wound care and help my wound heal.

3 I had my doubts. The wound vac wasn't
4 working, and we started the oxygen therapy. A staple
5 patch was placed over my stomach and we did this for
6 90 minutes a day. Within the first ten days, there
7 was such an improvement. The wound did not need to be
8 debrided, anything like before.

9 And I used the oxygen -- the oxygen
10 therapy until June. And my wound had -- we couldn't
11 believe how much the wound had closed. So I'm
12 actually here for a -- as an advocate. This stuff
13 does work. Insurance companies need to pay for it
14 more.

15 Because I don't know how I would've
16 gotten through. I would -- I wouldn't go out of the
17 house. I wouldn't leave my house with the wound vac
18 on, because it was embarrassing. Who wants to see
19 that? And I felt like it gave me my life back.

20 So I thank Advanced Oxygen for
21 everything that they've done. I'm currently on

1 vacation with my sister. Still have cancer, still
2 have to go through treatment, but, you know, they gave
3 me a happy time that I probably wouldn't have gotten
4 otherwise. So thank you, guys, so much.

5 MS. BENT: It sounds like your
6 experience being able to identify a treatment that was
7 effective and allows you to now travel more and be out
8 has been really positively life changing. And that's
9 really great for us to hear. Thank you.

10 GABBY: It -- it took 14 months for my
11 wound to close.

12 MS. BENT: That's a long, long time.
13 Sorry.

14 GABBY: Yeah.

15 MS. BENT: So thank you for sharing
16 that.

17 GABBY: Thank you, again.

18 MS. BENT: Thank you.

19 Before we go to any other callers, let
20 me turn to Ethan and see do we have comments coming in
21 through the web?

1 MR. GABBOUR: Yes, we have a couple of
2 comments that reflect what we shared during the panel
3 and what we heard just now. People are talking about
4 the impact of these wounds causing pain and
5 discomfort.

6 The wounds -- there was somebody who
7 had wounds on their scalp and their throat and their
8 esophagus, cheeks, and lips, and that made it hard for
9 them to eat and drink.

10 We have a lot of patients that are
11 talking about the impact on mental health.

12 One patient said the difficulty and
13 frustration of being unable to work, especially as a
14 self-employed farmer, as well as the increased
15 workload to spouse and having to tend to them -- tend
16 to the farm and do wound care, leads to a loss of
17 independence and -- or leads to a loss of self-worth.

18 So that's what we're hearing so far.

19 MS. BENT: Great. Thanks, Ethan. Is
20 there anyone in the room who would like to -- any
21 patient or patient care partner who would like to

1 share their experience?

2 All right. I have one person over
3 here, and then I have one person over -- in the white,
4 over -- further over there.

5 Please go ahead, ma'am.

6 MS. BANDO: Hi. I'm sorry. Can you
7 hear me?

8 MS. BENT: Yes, we can.

9 MS. BANDO: Okay. My name is Nita, and
10 I am a partial amputee. I have peripheral artery
11 disease and I also have diabetes.

12 My wound started in 2015. It started
13 out as a little mosquito bite on the top of my left
14 foot, and it ended up -- mind you, I was still going
15 to my primary care, and they let it go until it turned
16 gangrene. So I had to get all five of my toes
17 amputated.

18 I stayed in the wound clinic for 38
19 weeks. I stayed in a hyperbaric chamber for eight
20 weeks, two hours a day every day. I had to leave
21 Maryland and go to Michigan to get my life saved. It

1 was a doctor by the name of Dr. Mustapha that actually
2 saved me.

3 I stayed in Maryland -- I mean Michigan
4 for seven years, getting my life back, or somewhat
5 like a life that I had, because before that I was very
6 active in entertainment. I own a couple of clubs. I
7 had a restaurant. I'm originally from Louisiana.

8 So this took away everything that meant
9 anything to me. And when I say that, I say that
10 because I have three grandkids that I missed out on
11 for seven years, and I see the lacking of me in them,
12 if that makes sense.

13 I still have issues with my leg. As a
14 matter of fact, I did have a ulcer on the back of my
15 ankle, so to speak. I'm still dealing with that.

16 My biggest issue right now is because
17 of my amputation and because I'm wearing a prosthesis,
18 I can't find anyone to fix it. The one that was
19 perfect for me was in Michigan. I can't find that
20 anymore and my insurance wouldn't cover it.

21 So I'm walking around with a defective,

1 if you think about it, prosthetic and still trying to
2 maintain life.

3 When I say those months and those weeks
4 in the hyperbaric and the wound clinic, it was
5 excruciating. Because every time I went in, they
6 would have to stick the measuring stick inside of
7 my -- to -- to measure the amount of healing that I
8 had.

9 But it wasn't much in the beginning,
10 until I learned how to live a different life, eating
11 differently, maintaining my mental health. That was
12 my biggest thing was my mental health. And I felt it
13 slipping away at times because of this illness that I
14 have.

15 And every now and then I'll get a flare
16 up. Right now it's hard to find someone to actually
17 go in and open up my arteries. The last time I had
18 this procedure done was two years ago, and I
19 mistakenly agreed to have a stent put in the back of
20 my knee. Now my -- I walk stiff.

21 For two years I had been telling this

1 doctor that we needed to go back in and -- and look at
2 the stent, and after two years he finally decided to
3 go back in and look at my stent. And guess what?
4 It's closed. Can't get through it.

5 The only way is through a bypass. So
6 that would be my second bypass surgery. Do you know
7 how long it takes to heal after a bypass surgery? My
8 first bypass surgery, my leg exploded from infection.

9 Okay. This is part of my story, but I
10 want everyone in this room to know with hard work,
11 prayer, mental stability, everything and anything is
12 possible. I stand here as a living testimony as to
13 the things that I have been through since 2015, and
14 I'm still here.

15 I'm still here. I'm still fighting.
16 And it -- it doesn't get easier as you age. I'm 61
17 but I'm still fighting.

18 MS. BENT: Thank you so much.

19 MS. BANDO: Thank you.

20 MS. BENT: That was really inspiring.

21 All right. Let's go to one more person

1 in the room and then we'll go back to the phones.

2 Go ahead.

3 MS. ASHLEY VALENTINE: I'm Ashley
4 Valentine; I lead an organization called Sick Cells
5 at -- I'm a co-founder but my other -- the other co-
6 founder is my brother, Marqus Valentine. So he lived
7 36 years with sickle cell disease.

8 He developed leg ulcers, as Kevin Wake
9 was sharing, in 2013, and we had never heard of leg
10 ulcers in sickle cell before this moment. And, I
11 guess, for a lot of us in the sickle cell community,
12 we don't know that leg ulcers exist until you develop
13 a leg ulcer.

14 The impacts of these leg ulcers, I
15 think that was probably one of the most damning parts
16 of sickle cell disease. And Marqus really started to
17 decline once the leg ulcers developed.

18 So how it impacted our daily life, no
19 one knew how to treat him. And so in my family, my
20 mom is a nurse. She worked at the VA for almost 40
21 years and she had done a stint in the wound clinic.

1 And so what she ended up doing was calling on some of
2 her colleagues to actually work on Marqus.

3 But they tried everything first, like
4 the Unna boot. They tried the diabetic care. They
5 tried all of these things, but it just made it worse
6 and worse and worse. And so what ended up working for
7 Marqus was doing complete apheresis blood exchanges.

8 So they'd -- he'd have to get the
9 catheter in his neck every six weeks and they'd do a
10 total blood exchange. And that started to heal the
11 wounds, but then Marqus needed a hip replacement. And
12 so I'm his sister, so I can say things like this.
13 Marqus decided to be Humpty Dumpty.

14 He was told he needed a hip
15 replacement, but he couldn't have the hip replacement
16 until his wounds closed. So they needed to put him on
17 the blood exchanges every six weeks.

18 So Marqus was stressed, and decided to
19 go take our 110 pound dog outside for a walk, and the
20 dog saw a coyote and bolted. And so Marqus fell and
21 broke his knee.

1 And so this is where the Humpty Dumpty
2 part comes in, because then, you know, we had to wait
3 for the knee to heal and the leg ulcers to heal before
4 they could do the hip replacement.

5 And so to me this is one of the most
6 profound moments with the leg ulcers because then, you
7 know, he had to go on complete and total bed rest for
8 a year. And so we moved him downstairs.

9 We were able to get visiting nurses to
10 come to the house, but, truly, we had to take Marqus -
11 - you know, bind him up and take him to wound clinic
12 almost three times a week so that they could be
13 debriding these wounds, and wrapping these wounds, and
14 doing the blood exchanges.

15 And sickle cell's an incredibly painful
16 disease. The debridements were more painful than the
17 sickle cell half the time, but like most people with
18 sickle cell, Marqus kind of got used to it.

19 So at first they would give him Valium
20 and dose him before he actually got to wound clinic
21 'cause they were taking a scalpel to these wounds.

1 But then they -- you know, he got used to it, so it --
2 he -- he started to debride the wounds sometimes
3 himself.

4 And, again, siblings, he'd be like,
5 "Come on in." "I'm not coming in there to help you
6 with this, Markus." Trying to make my mom's life a
7 little bit easier. But eventually they did close, and
8 he was able to get the hip replacement.

9 What I will say is that the mental
10 health aspect across the whole family is really,
11 really truth -- it -- it's hard on the family.

12 So you might hear from my mom later.
13 I've been trying to get her to participate in this,
14 but she's really had to step away because the wounds
15 were so impactful 'cause she is and was the primary
16 caregiver of my brother.

17 So having -- if you can imagine, her
18 child having to -- to take these -- these wrappings
19 off and his skin would come off, and the -- the pain,
20 the pain, the pain of having to do this over and over
21 and over again.

1 But, you know, she would talk to him,
2 or he would tell stories, or we would read books. It
3 just turned into this thing that they would do
4 nightly. And some of that was the reason why we were
5 able to heal those wounds.

6 The last thing I want to say is I know
7 this isn't about clinical trials, but I do have to
8 leave early. We did try to enroll him in some
9 clinical trials, but the washout period required to
10 enroll in the clinical trials for leg ulcer ended --
11 ended up putting Marqus in the hospital for sepsis.

12 So that was the barrier of why we
13 couldn't enroll in clinical trials because he needed
14 to stay on those compound creams. He needed to stay
15 on the antibiotics. He -- he had to maintain that,
16 because any change to that would set him up for repeat
17 infection. So thank you.

18 MS. BENT: Thanks, Ashley.

19 All right. We're going to now take a
20 turn back to the phones. And for those of you on the
21 phones, I'm going to ask if we can limit comments to

1 two to three minutes 'cause we have a good number of
2 people on the phone and we want to make sure that we
3 hear from as many as possible.

4 So we're going to start with Jamie, who
5 I believe is on line 6.

6 Jamie, are you there?

7 JAMIE: I am here.

8 MS. BENT: Wonderful.

9 JAMIE: Can you hear me?

10 MS. BENT: Please go ahead.

11 JAMIE: Okay. I'm going to be as brief
12 as possible 'cause I know a lot of people want to
13 talk.

14 Just a little background, I have a
15 degree in psychology. I was an emancipated minor
16 years ago. And my wound has had a bigger impact on my
17 overall mental health than any other obstacle I have
18 faced my whole life.

19 Having a wound that does not heal, that
20 requires, you know, daily changes and multiple moving
21 appointments, and infusions, it's a full-time job.

1 And every time -- I have a pyoderma
2 gangrenosum wound that started like the size of a 50
3 cent piece. But being in a small community, a lot of
4 doctors have never even seen a pyoderma wound, from
5 where I'm at.

6 So it did receive the wrong treatment
7 in the beginning, which is all a learning curve;
8 right? I didn't know what it was.

9 But as I've had this wound now for
10 almost two years, and it is the size of a softball,
11 and I continue to get more open wounds, I've
12 researched, you know, myself, and there's just not a
13 lot out there. And it's a lot of trial and error in
14 treatment.

15 I feel like that this has impacted my
16 older children's lives. You know, my -- my oldest
17 daughter, who's a chemo infusion RN, she takes --
18 she's on intermittent FMLA to take me to my
19 appointments.

20 I just feel that unless you've ever had
21 a wound or know somebody who's had a huge open wound,

1 your whole life, from your social life, your family
2 life, and your work life, is really impacted by these
3 wounds.

4 And I just think there needs to be just
5 more information, more resources, more training for
6 doctors. And, you know, I think having a support
7 group -- which first time in my life I'm in a pyoderma
8 support group, which is helpful.

9 So I think you need many different
10 resources in order to survive your wound. That's all
11 I have to say. Thank you.

12 MS. BENT: Thank you.

13 All right. Let's turn now to Tony on
14 line 7.

15 TONY: Hello, everyone. It is a
16 pleasure to speak to the group, and very impactful
17 statements from the other callers and speakers.

18 I'm a patient. I happen to be a
19 physician as well, and practiced for -- for over 25
20 years. And the -- the -- I'm a diabetic and developed
21 it over time. I have a history of diabetes on my

1 maternal side, my grandfather and my mother.

2 And, you know, during my training, I
3 didn't watch my diet very well. I gained some weight,
4 which I've lost since then, and, you know, developed
5 type 2 diabetes.

6 The importance of preventing things
7 before they occur, and, you know, the screening now
8 for pre-diabetes, I think, is very important.
9 Something I didn't screen for well enough.

10 My -- my regular glucose tests were not
11 significantly elevated, but over time, you know, my
12 lack of control contributed to developing type 2.

13 I thought everything would be fine. I
14 found an endocrinologist, a colleague, who is a
15 topnotch endocrinologist who got my glycohemoglobin
16 level down to 5.8 over 8, initially. And my
17 cholesterol is normal.

18 I, you know, was going around managing
19 my diet much better and staying away from sugary
20 foods, carbohydrates, and eating more protein, fruits,
21 and vegetables that were low in sugar content.

1 I was walking in the basement, and I
2 cut my foot. I was wearing socks and no slippers,
3 however. But I had never gotten any foot injuries
4 before. And the wound wouldn't heal.

5 And as a physician, I have access to
6 all my colleagues at academic medical centers in a
7 major metropolitan area. And in addition to my
8 endocrinologist, I saw a -- a podiatrist. I saw a
9 plastic surgeon who is a friend. And they weren't
10 able to heal the wound at all.

11 It was very frustrating. It was
12 causing pain. I was able to keep it infection free by
13 cleaning it religiously every day and putting a
14 bandage on it, but the wound wasn't closing.

15 I -- I went to a -- a wound healing
16 center, the Kimmel Center at NYU, and going there met
17 two extraordinary professionals, Dr. Iannuzzi and
18 Dr. Ross. And they evaluated the wound, you know,
19 both neurosurgeons and physical medicine physicians
20 and doctors.

21 And they came to the conclusion that it

1 was -- after evaluating -- and I went for Dopplers and
2 plethysmography. My general circulation was fine. I
3 had good arterial flows. I had good pulses.

4 It wasn't the fact that blood wasn't
5 getting there, but it was the years of microvascular
6 and peripheral neurologic damage that had occurred
7 that wasn't allowing it to heal properly.

8 So they prescribed and administered
9 total contact casting, TCC. They casted my foot. Of
10 course, originally I didn't think -- I was trying with
11 orthotics and trying to limit pressure on it by, you
12 know, using a variety of devices.

13 But my compliance was not a hundred
14 percent because, you know, as a doctor I have -- I
15 also do research. I have many different obligations
16 and it's not always easy to not bear weight on my foot
17 or not drive.

18 But the total contact casting, in a
19 matter of four weeks, was able to totally heal the
20 wound on my foot.

21 And -- and then about a year later, I

1 developed another wound on the contralateral -- the
2 opposite foot. And they applied TCC, or total contact
3 casting, again, which unloaded the pressure from the
4 foot. And, again, a hundred percent healing.

5 The area where it heals is always going
6 to be a little bit weaker than the skin around the --
7 the normal skin where the area is not -- where there
8 was no wound, but it's closed and the risk of
9 infection has been reduced.

10 I want to remark on TCC as the method,
11 and I invited my providers to participate in the call
12 as well, my colleagues, and -- and my provider
13 physicians. But I also want to say --

14 MS. BENT: Great. I'm going to just
15 have to ask you to make your last few points so that
16 we can make sure we get everybody. Thank you.

17 TONY: Sure. Absolutely.

18 An ounce of prevention is worth a pound
19 of cure. So once it's healed, you need to moisturize
20 your feet, you need to have toenail clips and hygiene.
21 You know, you need to wear orthotics to make sure that

1 you distribute the pressure properly. And you need to
2 be very scrupulous about trying to prevent a
3 recurrence.

4 It's not always possible to do that,
5 but, you know, just religious follow-up is important
6 in terms of making sure that you try to avoid
7 recurrence. And finding the right wound center and
8 one that is able to apply TCC, or total contact
9 casting.

10 So thank you for the opportunity to
11 speak, but I -- I felt passionate about my journey
12 and, finally, the ability to have it healed by two
13 extraordinary professionals.

14 MS. BENT: Great. Thank you very much.

15 Before we go to our next caller -- and
16 our callers on the line, please, I think we're going
17 to ask -- one of our panelists has a question. I
18 wonder if while you're sharing your experience, you
19 could think about your response to the question that
20 one of our panelists is going to ask.

21 Please go ahead.

1 MS. TARIQ: Thank you. And this is a
2 general question, so anyone in the room or online, I'd
3 welcome to hear.

4 Thank you again for sharing your
5 perspectives. I think it's definitely powerful to
6 hear all the different stories. And not all the
7 stories are the same, so it's very important to
8 realize at the end of the day how different they are.

9 Just a general question. Many of you
10 mentioned that the wounds had relapsed or had
11 reopened. I'm just curious from, like, a clinician
12 perspective, but also somebody from the FDA side,
13 would like to understand does it fully close, or have
14 they not fully closed and then the end up reopening?

15 Happy to hear from anyone. Thanks.

16 MS. BENT: Okay. And so before we go
17 back to the room, we'll go to the -- one or two people
18 on the phone, and then we'll come back to two people
19 in the room.

20 So let's start with Laurie on line 8.

21 MS. RAPPL: Hi. I've got my clock on

1 so I'll try to keep my -- my comments just for the two
2 or three minutes requested. I really thank the FDA
3 for having this discussion. It's allowing me to
4 participate.

5 My name is Laurie Rappl; I'm a T-12
6 spinal cord injury from 1980. I'm also a physical
7 therapist and a wound specialist. And despite all
8 that knowledge, I have had my share of pressure
9 injuries over the years, probably four or five of them
10 on my ischium.

11 But recently I have -- I really
12 resonated with Amanda, because I -- my current ulcer
13 is on my sacrum. I've been in bed since July of last
14 year with this wound, and it developed due to -- I --
15 I have had two bouts with breast cancer. Had my one
16 mastectomy in 2024 and the second one in 2025.

17 And in the middle of that treatment for
18 the second stage 4 breast cancer is when the pressure
19 injury developed. And I will tell you that -- I told
20 my oncologist the same thing. I know the stage 4
21 cancer is important, but this wound is way more

1 devastating to me, and way more serious.

2 And isolating, as Amanda said. And
3 with the cancer treatment, you do have this whole
4 community that you're in, but when you have a pressure
5 injury, you don't.

6 Care for pressure injuries is
7 scattered. People knowledgeable on how to take care
8 of pressure injuries is scattered, because most of the
9 concentration in wound clinics is on diabetic and
10 venous wounds. So we're kind of the forgotten wound,
11 and it's hard to find an experienced clinician who's
12 competent.

13 But to speak to how this has imposed on
14 my life. I've been in bed for a year and a half
15 almost. It's an imposition on the whole family and on
16 my friends, and my family has rallied around me, but
17 it -- it's a big imposition on all of their lives.

18 And the wound itself takes so much time
19 every day that it -- it crowds out the ability to do a
20 lot of things socially, even if I could get out to do
21 those social things.

1 I've experienced personality changes
2 with this wound -- and this has been a -- much more
3 expansive than my previous wounds. I've experienced
4 personality changes, as my family will attest to.

5 I'm having trouble concentrating and
6 getting motivated, and that's usually -- either of
7 those is usually not a problem for me.

8 My overall condition has changed
9 significantly. I can only sit up for short periods of
10 time, if at all, and I've had blood pressure problems.
11 And I'm getting contractures in my shoulders, which is
12 going to affect -- when this thing finally heals -- is
13 going to affect my -- my mobility for pushing my own
14 wheelchair.

15 The long-term effects I'm concerned
16 about, or what concerns me most about living with the
17 wound, is the possibility of extensive surgery, like a
18 flap, which is what I've been trying to avoid my whole
19 life.

20 And these long term effects, as I said,
21 the loss of range of motion, the loss of my social

1 life. You know, a lot of people when you don't
2 contact them, they don't contact you anymore.

3 And that is my two minutes, and I will
4 go on to the next caller.

5 MS. BENT: Thank you. And I think what
6 you had just spoke about has really been echoed by a
7 lot of people that we've heard from today, that the
8 isolation, the mental health impacts, the fear of the
9 extensive surgeries, and so many other issues that are
10 more than just the wound itself.

11 Let me now turn to -- we have about six
12 or seven minutes left before we break for lunch. So
13 I'm going to turn to -- I think we'll probably -- I'm
14 going to ask callers on the line to again stick to
15 about two minutes if possible.

16 I think we'll probably get to two more
17 people on the line and then one person in the room if
18 everybody sticks close to that two minutes.

19 So let's turn to line 6. Lisa?

20 LISA: Hi. Can you hear me?

21 MS. BENT: Yes, we can.

1 LISA: Okay. I will -- I will give you
2 guys the Cliffs Notes version.

3 So in January of '22 -- of '24, I was
4 diagnosed with colorectal cancer. I went through
5 radiation. I went through chemo. And then in
6 September of '24, I went through major surgery where
7 they removed my rectum, my anus, and a portion of my
8 vagina.

9 I left the hospital with four drainage
10 tubes, two in my stomach, one on each side of my
11 abdomen, and two right below my buttocks on each side.

12 I was bedridden for a couple of months,
13 and then during that time, when the tubes came out,
14 one of the wounds on my right lower abdomen just never
15 healed. It never healed.

16 We did the wound vac. We did
17 everything. I'll call back and talk about treatment
18 but -- later, but -- so long story short, in the last
19 two years I've gone through incredible pain with this
20 wound. It's affected my life miserably.

21 I used to have to drive over an hour --

1 well, get a -- get a ride over an hour once a week to
2 the doctor that would -- was part of the surgery, who
3 would debride it each week. But no numbing, nothing,
4 so it was excruciatingly painful every time I went in
5 there.

6 I have been on pain meds regularly for
7 the last two years, pretty much once a day because the
8 pain is so excruciating. I went through -- again, I
9 won't talk too much about treatments, but I had done
10 several treatments. My wound was finally healing.

11 I developed -- I have a colostomy as
12 well -- I had developed a stoma hernia. So when they
13 did the surgery, they repaired that as well, which is
14 right next to where my open wound is. So there's not
15 a lot of real estate there, so to speak. So they're
16 very close together.

17 The wound was just about healed, and
18 then all of a sudden I developed a fistula, as well as
19 a hernia right where the wound is. So I had to go
20 back into surgery. I think -- I believe that was in
21 March of this year.

1 And now my wound is still open, but
2 it's healing. I -- fortunately, I was very lucky to
3 find, probably, the best wound doctor in the country
4 as far as I'm concerned. But she's been amazing,
5 and -- and it is healing again now, much faster than
6 it did the last time.

7 So yeah, it -- it's definitely affected
8 my life. Like, I -- I went through cancer treatments
9 like a breeze. Like, I had a very positive attitude
10 about everything. And it's difficult for my family
11 members, because I do keep a positive attitude all the
12 time.

13 So they don't really understand, like,
14 a lot of the isolation, the depression, the anxiety,
15 the things you feel going in public with -- like the
16 other caller said, going out in public with a wound
17 vac. It's humiliating and embarrassing and painful.
18 And the drainage and the smell.

19 And I developed bacteria. I ended up
20 with MRSA, and E. coli, and a couple of other
21 bacteria. And a doctor had wanted to just put a wound

1 vac on that, which would've sealed all that in, and
2 probably -- I probably wouldn't be able to talk about
3 it today.

4 So my heart goes out to all of the
5 callers and panelists and everybody and their -- and
6 their stories because I feel it too.

7 But we're not alone, you know. We're
8 not alone. We're still here. We're healing. It may
9 not be perfect. But everybody keep your heads up.
10 We -- we can -- we can do this.

11 So thank you very much for giving me
12 the opportunity to talk.

13 MS. BENT: Thanks so much, Lisa. And I
14 think what's really coming through is that a wound is
15 so much more than a wound. And so we really
16 appreciate you sharing that.

17 All right. So for the last phone
18 caller that we're going to get to during this session,
19 we'll go to Toni on line 10. And then we'll turn back
20 to the room for kind of the final remarks for this
21 session before we break.

1 Go ahead, Toni.

2 TONI: Hi. My name is Toni, and for
3 nearly 10 years I've stood by my husband, Derrick, as
4 he fought peripheral artery disease and chronic limb
5 threatening ischemia.

6 This disease has taken his toes. It
7 has led to a transmetatarsal amputation and repeated
8 battles with osteomyelitis. We have -- we have lived
9 wound by wound, surgery by surgery, and sometimes day
10 by day, never knowing what this disease might take
11 from him.

12 PAD didn't just change Derrick's life;
13 it changed mine. It changed our marriage and it
14 changed our entire future. I had a career that I'd
15 spent nearly 30 years building. Eventually, I was
16 faced with an impossible choice: continue my career or
17 fight for my husband's leg and his life. I chose
18 Derrick.

19 Walking away meant losing our insurance
20 and financial security at the very time that Derrick
21 needed medical care the most. And without that

1 insurance, this fight became even harder. But what
2 was I supposed to do? A career or the man that I
3 loved? A paycheck or his leg?

4 I became his caregiver, his wound care
5 partner, and his researcher, and his advocate. We
6 fought with everything available to us from advanced
7 vascular procedures to maggot debridement therapy.

8 Because when amputation is -- is
9 staring your family in the face, you don't care
10 whether a treatment sounds unconventional or not. You
11 care whether it gives someone that you love another
12 chance.

13 Dr. Jihad Mustapha and Dr. Fadi Saab
14 helped save Derrick's legs and fought with him all of
15 these years. And through it all, Kym McNicholas has
16 fought beside us through The Way to My Heart and the
17 Global PAD Association.

18 She taught me how to advocate, how
19 to -- how critical blood flow to the wound is -- is
20 imperative for healing. And she never
21 surrendered -- she -- she taught me to never surrender

1 Derrick's limb without knowing every reasonable option
2 that we -- was available to us.

3 I want the FDA to remember something
4 that can get lost in all the clinical data. There is
5 a human being behind every wound, an entire family
6 fighting behind that human being. Saving a limb means
7 saving mobility, independence, and a person's dignity.

8 Sometimes it means saving a marriage
9 from becoming nothing but caregiving and survival.
10 And sometimes saving a limb can help save a life.

11 PAD has already taken pieces of
12 Derrick. It has taken pieces of our financial
13 security, our freedom, and the life that we once knew,
14 but it has not taken away our hope. It has not taken
15 away our fight.

16 And nearly 10 years later, Derrick and
17 I are still here, still fighting this disease together
18 as a husband and wife. And as long as there is an
19 opportunity to save his limb and life and there are
20 options, I will be standing beside him.

21 And I just want to thank you for giving

1 me, and all of us, an opportunity to let you know what
2 a powerful fight we have to stand against amputation.
3 And I want to thank you for hearing my story and
4 Derrick's story. Thank you very much.

5 MS. BENT: Thank you so much, Toni.
6 That was really powerful. I don't know if you can
7 hear it, but there's applause in the audience for
8 really you sharing your experience as a caregiver and
9 all of the impacts it's had, not just on Derrick's
10 life, but on yours.

11 So before we break, I'm going to turn
12 back for very brief comments to one of our panelists
13 in the room. And I know you're going to be tempted,
14 but we're not focusing on specific healthcare
15 providers, so --

16 MS. BANDO: I'm going to answer her
17 question.

18 MS. BENT: Very good. Perfect. Feel
19 free.

20 MS. BANDO: Okay. First of all,
21 though, I do want to give a shout out to The Way to My

1 Heart. I'm a part of that organization as well with
2 Kym.

3 The opening, the reopening of a wound,
4 okay, for me, because they had to cut back my foot
5 twice because of the infection that had been
6 accumulated. So they had to cut back my foot twice,
7 so that meant they flipped the bottom of my foot onto
8 the top, if that makes sense.

9 So I still have an opening there. It
10 opens when -- when I have to go and get my feet
11 pedicured, my foot pedicured. It opens because they
12 cut so close, because it's a -- what they call a --
13 well, it's a big scab. It becomes a big thick scab
14 across your foot.

15 So once they cut it -- all that off,
16 it's a opening there. So you have to wait for it to,
17 you know, re-close up. So that's what my experience
18 has been with reopening wounds. Thank you.

19 MS. BENT: Wonderful. Thank you.
20 Thank you very much. We are now going to break for
21 lunch. We'll return at 1:15 Eastern Time. I want to

1 thank everybody, all of our panelists for sharing
2 their experiences.

3 For those of you who were not able
4 to -- we weren't able to take your call or your
5 comments during the first session, there will be
6 multiple opportunities during -- following the second
7 session and the third session for more input.

8 So thank you very much, and we'll see
9 you back in a little less than an hour. Thank you,
10 everyone. Also, we will work on the -- work on trying
11 to get the audio a little bit more clearer in the
12 room.

13 (Off the record.)

14 MS. BENT: All right. Everyone, we're
15 getting ready to start back up. All right. Great.
16 Thanks everyone. Welcome back. I hope you had a
17 chance to eat and to rest.

18 We are now -- I'm going to move
19 straight into Topic 2, which focuses on current
20 approaches to treatment and management of nonhealing
21 chronic wounds.

1 We'll hear from five panelists who will
2 share their treatment experiences. After they've
3 finished, once again, we'll go to polling, and then
4 open the floor for discussion. So if you are thinking
5 about something you want to share, please start
6 thinking about that now.

7 And so before lunch -- or before we
8 launch into our panelists' experiences, I want to let
9 you know that our first questions for the open
10 discussion session is: "What are you currently doing
11 to treat or manage your nonhealing chronic wounds?

12 "How has your treatment regimen changed
13 over time and why? And what symptoms would you most
14 like to see improved or resolved by treatment?"

15 So we're about 30 minutes away from the
16 panel discussion. I'd also like to let our panel --
17 or our participants in the room know that we know that
18 some of the phone calls came through a little muffled
19 in the earlier session. We are doing what we can to
20 kind of fix the audio.

21 But in addition to that we are going to

1 put the AI generated transcript on the screens when we
2 get to the phone callers, so that we can be sure not
3 to miss a single bit of what they're saying, because
4 we know that it's important and we want to be able to
5 hear it. So we are doing what we can to fix that
6 situation.

7 And so with that, I would like to
8 welcome our Topic 2 panelists. And we're going to
9 start with Jae and Joyce who are here today with us in
10 the room. And so with that, I'd like to turn over to
11 Jae and Joyce.

12 And you can stay right there or you're
13 welcome to get up to the podium.

14 MS. MCBRIDE: Thank you. Can everyone
15 hear me? Okay. Good afternoon. My name is
16 Jimontanae McBride, but everyone calls me Jae. And
17 this is my beautiful mom, Joyce Rex.

18 Before we talk about treatment, I want
19 you to imagine what my mom has been through. Imagine
20 living with peripheral artery disease and needing
21 angiograms every other year, then every few months,

1 then every month.

2 Imagine undergoing procedures after
3 procedures to restore blood flow, to have the surgical
4 incisions from those procedures fail to heal. With
5 the exception of one wound, all of my mother's wounds
6 began with surgical wounds that dehisced.

7 She developed 14 wounds on her right
8 leg, and, later, three massive wounds on her left leg,
9 so deep and extensive that at one point I was able to
10 put my fist in her wound.

11 She's had a successful fem-pop bypass
12 on her right leg, but the bypass on her left leg
13 failed. The graft ruptured nine times.

14 Eventually, my mother was in such
15 excruciating pain that she became essentially
16 bedridden and lost all of her independence. Then we
17 were told, "There's nothing more we can do. You need
18 an amputation."

19 MS. REX: That was me. I went from
20 being independent to needing help with almost
21 everything. I was in pain every day. And now I am

1 being told I was going to lose my leg. I was
2 devastated, but I wasn't ready to give up my leg.

3 MS. MCBRIDE: And neither was I. We
4 wanted another opinion, but my mother's -- mother
5 reminded me -- remained in the local hospital for
6 approximately three weeks while we struggled to get
7 her evaluated.

8 During that time, I watched her leg
9 deteriorate. Then the Global PAD Association stepped
10 in and helped us connect with an additional expertise.
11 We found a skilled interventional cardiologist,
12 Dr. Amit Amin in Lafayette, Louisiana, who approached
13 her circulation differently.

14 He accessed her circulation through her
15 arm, identified and treated the disease higher in her
16 vascular system, and restored blood flow to her leg,
17 the leg that we had been told we needed an amputation
18 on.

19 MS. REX: For me, that meant hope when
20 we met Dr. Amin. I still have terrible wounds for --
21 I still had terrible wounds for a long time, but after

1 being told there was nothing else that could be done,
2 someone was finally saying, "We're going to try to
3 save your leg." That meant everything to me.

4 MS. MCBRIDE: That experience taught me
5 one of the most important questions of this journey.
6 We can't only ask, "What can we put on the wound?" We
7 also have to ask, "Why isn't the wound healing?"

8 My mother needed blood flow to save her
9 leg, but she also needed blood flow to heal the
10 surgical wounds created while trying to save it.
11 Circulation didn't close her wounds. It gave her a
12 foundation for healing.

13 Then came the work of healing the
14 wounds. She underwent one extensive surgical
15 debridement, followed by a Veraflo wound vac therapy,
16 and later a traditional wound vac.

17 She received hyperbaric oxygen therapy,
18 followed by topical oxygen therapy. Her treatment
19 also included antimicrobial wound care, and advanced
20 therapies included matrix skin grafting. There
21 was -- there wasn't one treatment that did everything;

1 it was a combination.

2 However, one experience particularly
3 stood out to me with my mom's right leg. We
4 experienced multiple emergency room visits, multiple
5 surgical debridements.

6 When we later began outpatient
7 treatment of -- of a much more severe left leg,
8 Spectricept antimicrobial hypochlorous acid spray
9 became part of her wound care regimen.

10 I'm speaking as her daughter and a
11 caregiver, not a clinician, but I can tell you what
12 I've personally observed. There were areas that
13 appeared to be biofilm and non-viable tissue.

14 After Spectricept was applied, I
15 watched materials that appeared to be biofilm and
16 non-viable tissue wipe away from her wound.

17 And unlike our experience with the
18 right leg, we didn't experience the same pattern of
19 repeated emergency room visits, repeated surgical
20 debridements.

21 I can't say -- say Spectricept alone

1 was responsible, but by then her blood flow had been
2 restored and multiple therapies were working together.
3 But as the caregiver who saw those wounds every day, I
4 observed -- what I observed was meaningful.

5 MS. REX: From the patient side, all of
6 these treatments required commitment. There were
7 procedures, dressing changes, wound vac, oxygen
8 treatment, and appointments.

9 There were days when I was very tired.
10 There were days when I hurt, and there were days when
11 I didn't want to do any more, but I wanted my leg. I
12 wanted to walk again, and I wanted my independence
13 back, so I kept going.

14 It was really difficult a lot of days
15 that I just had to -- I just had to make my mind up to
16 just keep going, keep moving. We had to travel a long
17 ways for -- for treatment, but we just kept going.

18 MS. MCBRIDE: When I say commitment, we
19 mean it. We live in Alexandria, Louisiana. Much of
20 my mom's outpatient treatments was in Opelousas or
21 Lafayette. Opelousas is probably about an hour and a

1 half away. Lafayette is closer to two hours away. We
2 made that drive at one point every day.

3 She would have -- she -- we would drive
4 an hour and a half. She would have a two-hour
5 hyperbaric chamber therapy session. Then she would
6 have wound care. And then we would drive home, and
7 then to do it all over again the next day.

8 Getting her ready while she was
9 hurting, making the drive, completing treatment,
10 coming home to do it all over again the next day,
11 that's something I want people to -- who study, treat,
12 and develop therapies for chronic wounds to
13 understand.

14 The burden of treatment extends far
15 beyond the wound. There's pain and exhaustion, but
16 there's also transportation, time, caregiving, and the
17 emotional burden of wondering whether all of this is
18 going to actually even work.

19 Before this journey, I probably
20 would've identified healing as the wound is closed.
21 Of course, wound closure matters, but meaningful

1 healing started long before my mother's journey.

2 MS. REX: For me, healing started with
3 less pain, then being able to sit up comfortably, then
4 standing, then taking a few steps, then walking, and,
5 finally, doing more things for myself again.

6 Those things made look small to some,
7 and on a medical chart it may look small, but they
8 were -- weren't small to me. They were huge
9 improvements.

10 MS. MCBRIDE: They weren't small to me
11 either. When my mother's pain decreased, that was
12 healing. When she stood again, that was healing.
13 When she started walking, that was healing. When
14 wounds that once seemed impossible to heal became
15 smaller, that was healing. And when she started
16 getting her independence back, that was healing.

17 Today, after everything she's been
18 through, my mother has only one small wound left.
19 That's why I believe meaningful healing can't be
20 measured only in centimeters. It also has to be
21 measured in quality of life.

1 MS. REX: For me, healing meant getting
2 my life back. It meant less pain. It meant walking.
3 It meant doing things for myself again. And it means
4 enjoying my family instead of every day being about my
5 wounds.

6 I still want the last wound to
7 eventually heal, but when I look back where I've come
8 from and where I started from, I know how far I've
9 come.

10 MS. MCBRIDE: If there's one thing we
11 hope you take away from our story, it is healing is
12 not always one big moment. Sometimes it's restoring
13 blood flow. Sometimes it's getting through one
14 treatment. Sometimes it's less pain. Sometimes it's
15 standing, sometimes it's walking, and sometimes it's
16 getting your independence back.

17 Saving my mom's leg was incredibly
18 important, but her -- saving her leg was never the
19 final goal. The goal was giving my mom the
20 opportunity to get her life back. And to us, that is
21 what meaningful healing looks like.

1 Thank you for allowing us to share our
2 story.

3 MS. REX: Thank you.

4 MS. BENT: Thank you both. What a
5 journey you all have been on and walked together. So
6 thank you for sharing that with us today.

7 We're now going to hear from Sarah, who
8 is joining us virtually.

9 Sarah, please go ahead.

10 MS. MCCOY: Hi. I'm -- I'm Sarah
11 McCoy, and I'm here to talk about my brave and strong
12 28-year-old daughter. I -- I do have her permission.

13 I've always believed that this was her
14 story to tell, but I also believe that the medical
15 anxiety and the PTSD are real, so I spare her often
16 from retelling her story. But we share her hope that
17 maybe this will someday make someone else's medical
18 journey a bit better.

19 About seven years ago, in October of
20 2019, I went to Oklahoma because my daughter, Morgan,
21 was experiencing severe symptoms related to her sudden

1 onset ulcerative colitis diagnosis. She was 21, a
2 senior at the University of Oklahoma, and the
3 president of her sorority.

4 We decided she needed medical attention
5 from her physician, and we drove back to Houston. The
6 next morning, she awoke with her left leg being
7 gigantic.

8 She was hospitalized and in the ICU
9 with a pulmonary embolism sprayed throughout her lungs
10 and a huge blood clot that went up her left thigh and
11 across her abdomen.

12 About 72 hours later, her right
13 leg -- not where the blood clot was -- started to leak
14 and show concerning signs. Before she was rushed to
15 the OR for what they were thinking was possibly more
16 clotting, they ran her through a CT machine and
17 discovered that her colon had perforated.

18 She was septic. Necrotizing fasciitis
19 had dumped into her right leg. And in order to save
20 her life, they had to amputate her right leg above the
21 knee.

1 Multiple days and surgeries and many
2 discussions later about taking more of her leg even up
3 to her hip because there was no skin for coverage, a
4 new consult found us with a surgeon who said, "She is
5 young and she will grow skin."

6 "Rare" was what we kept hearing. A
7 rare medical emergency she experienced. She had
8 survived the perforation and the sepsis. That was
9 rare. Was it rare that she could grow skin?

10 She was in the hospital for two and a
11 half months. And, honestly, her wound care there was
12 basic maintenance, because they just wanted to
13 debride, debride, debride. And we were trying to save
14 every single cell we could for her to grow skin.

15 Once discharged, we saw Dr. Fife in
16 clinic, and she took on the task of helping us grow
17 skin. Because probably close to 75 percent of her
18 baby leg, of her stump, had wounds on it. Her entire
19 inner thigh, her groin, the end of her baby leg were
20 all necrotic.

21 On the outside of her hip, she had some

1 pink skin, but there were two single wounds. She was
2 a patient who named her wounds. Greg was kind of the
3 big one. Greg still exists today. Honestly, it kept
4 us focused on who we were caring for. We cared a lot
5 for Greg, and for Sadeep. He was very deep on the
6 side.

7 In an attempt to attempt to close the
8 single wounds on the outside of her thigh and her hip,
9 that's when the PG reared its ugly head.

10 I know you're discussing PG in a lot of
11 other sessions, but just know that swift action,
12 creative options, and the push to control the flare in
13 order not to worsen the condition were complicated and
14 key.

15 Morgan's situation was rare and
16 complicated. She needed a team who could think
17 outside the box. I felt strongly that a blend of art
18 and science was the only way that was going to improve
19 her outcomes.

20 She wasn't a typical 70-year-old with a
21 wound. Crazy enough, she was a healthy 21-year-old

1 who had experienced a major medical emergency. She
2 needed wound care that would get her back to college
3 and the opportunity to have a prosthetic.

4 We tried tons of things. We did honey,
5 PluroGel. That stuff is fascinating. Grinding
6 prednisone. Figuring out a possible topical
7 doxycycline, so she could get off the oral and enjoy
8 brunch on the patio with her friends in the sun.

9 We are incredibly fortunate that we
10 were able to find a prosthetist, Jon Holmes here in
11 Houston, who kindly looked her in the eye, a few
12 months post the emergency while wearing a huge wound
13 dressing, and said, "I'm throwing the book out the
14 window."

15 He said contrary to many physicians he
16 had followed for 30 plus years, that he felt a
17 prosthetic with constant compression on her wounds
18 might not only be beneficial for the wounds, but the
19 life offering opportunity to get her walking and back
20 to college.

21 Jon will say that it was key to have a

1 patient and a family who would follow directions and
2 do the right things. He noticed that we -- he noted
3 that we made and did lots of things in the beginning
4 that we had to pull off on our end.

5 We had to fly her back from Oklahoma to
6 Houston and back in one day so she could go to school,
7 see her wound care doctor, and see Jon. Jon was the
8 best.

9 Almost seven years later, he still
10 shares photos of Greg with his prosthetic students,
11 sharing that his case, specifically thinking, shows
12 long-term wound improvement and now independently and
13 walking, where traditional thinking would still have
14 her waiting seven years later for a prosthetic.

15 Even her wound vac journey had
16 challenges. Amputees use 40 percent more energy just
17 to walk, and a thick tube coming out of your wound and
18 up your leg doesn't mean that your prosthetic fits
19 well.

20 Then you're having to lug a heavy vac
21 in the backpack that you're wearing. She just

1 couldn't get approval for the mini vac with the small
2 tubes and the lighter machine.

3 Not everyone is the same, and each
4 situation needs specifics for that patient. Finding
5 dressings that would stay in place on a small baby leg
6 and not slide off were always challenging. Finding
7 materials that didn't irritate the little bit of good
8 skin she had.

9 Finding a dressing that would fit
10 inside the prosthetic and that could last all day when
11 she was in class and eventually in a job. Eventually,
12 we found, like, a KerraMax product which is thin and
13 absorbent, and it didn't expand, and it fits over
14 Greg, which is -- finally, Greg is, like, a half
15 dollar size now.

16 Of course, we wish there were more
17 options to, like, customize sizes and things that
18 would fit just to give her less dressing than what she
19 had.

20 My daughter's been fortunate enough
21 that she -- that we have advocated for her to have a

1 medical team who can think versus just doing what the
2 textbook says.

3 The evolution of the wound care world,
4 and finding providers who can meet the patients where
5 they are, with an arsenal of options, is really going
6 to be impactful to the future and to probably Morgan's
7 care.

8 MS. BENT: Okay. Thank you so much,
9 Sarah. The creativity and advocacy that you described
10 on behalf of your daughter is really amazing, and it
11 says everything about what patient-centered care
12 should look like.

13 We'll now turn to Wesley, who is also
14 joining us online.

15 Wes?

16 WESLEY: Yeah. My name -- hello, my
17 name is Wesley. I have a nonhealing venous leg ulcer
18 on my left lower leg, anterior side.

19 As a side note, I am a right-above-the-
20 knee amputee. This was due to necrotizing fasciitis.
21 So I'm trying to make sure I take care of my other

1 leg.

2 The wound began kind of fairly small at
3 the beginning of 2025 around January and slowly
4 started to weep intermittently, but stayed fairly
5 small, less than an inch long with minimal width and
6 depth.

7 It started to increase in size around
8 March or April when a home healthcare was called in.
9 I had moved to assisted living at that point.

10 In June of 2025, I started to go to a
11 wound clinic when the home healthcare suggested it.
12 Generally, they started by soaking the wound in Vashe.
13 The treatment usually involved covering the wound with
14 zinc, followed by various types of dressings,
15 including antimicrobial, alginate, collagen-based.

16 That care mitigated the leg swelling
17 and increased wound healing by experimenting with
18 various types of compression, including Unna boot,
19 Kerlix, Coban, ACE bandages, and other types of
20 compression bandages.

21 Additional absorption was generally

1 supplied with either ABD pads or Sofsorb, just kind of
2 experimenting with anything they could find; but they
3 were not satisfied.

4 It seemed like the wound clinic was
5 frustrated with my progress week to week, which would
6 ebb and flow. And they would switch the wraps and
7 dressings every week or two and blame either me or my
8 facility for the lack of progress.

9 They would do debridement every week,
10 which varied in pain, but usually it wasn't a big
11 deal. They would even -- resorted to ultrasonic
12 debridement a few times. This was kind of stressful,
13 which I will get to shortly.

14 The particular location on my leg was
15 the only place I really had trouble in healing. I cut
16 myself someplace else and that healed just fine, and
17 they didn't seem to pay any mind to that fact.

18 At the end of April, my current care
19 facility began treating my wound in house. After a
20 week or two they stuck by the same treatment and that
21 seemed to have yielded some result.

1 They used the application of iodine,
2 calcium alginate, ABD, Kerlix, followed by a bandage
3 wrapped to sort of keep everything compressed there.

4 They originally had two dressing
5 changes per day, and as of two weeks ago, I'm down to
6 one dressing change per day, after some skin growth
7 was noted and the wound has started filling in.

8 There were four major personal
9 consequences of this sort of chaotic treatment,
10 especially when I was using the wound clinic.

11 One thing I hated about this process
12 was the frequency and -- and unpredictability of the
13 dressing changes. This may have been just a matter of
14 some friction between who's directing the wound
15 treatment and who was doing the treatments between the
16 appointments.

17 Well, I didn't have a lot going on in
18 my life. I felt like I was scheduling my life around
19 my wound, including my sleep schedule. They wanted me
20 to lay down in order to elevate my leg. Normally,
21 this wouldn't be a problem, but I'm in a wheelchair

1 and I'm quite large, so this -- I like to limit
2 myself in transfers as -- as much as possible.

3 The transfer also affects my residual
4 limb as it tends to bump my leg as I'm getting in and
5 out of bed, causing a -- causing it to bump the rear
6 wheel on my wheelchair, causing damage to the rear
7 part of my residual limb.

8 I felt like I was disappointing the
9 staff if I -- my wound didn't get the results they
10 were hoping for.

11 Finally, in conclusion, this has been a
12 long process extending over a year and a half, and
13 I've seen a few different treatment providers.

14 While I'm starting to just see some
15 results, I feel like the various treatments have --
16 have upended my life some, and causing stress, and
17 perhaps extended the healing process.

18 Thank you very much.

19 MS. BENT: Thank you so much, Wesley.
20 That week-to-week variability and that sense of
21 feeling like you were responsible for the slow

1 progress and disappointing people, I know that that
2 has -- we heard that from several other panelists as
3 well.

4 And, obviously, that's something that
5 we don't want anyone to have to carry. But thank you
6 for sharing that with us.

7 We're now going to turn to Barbara, who
8 is also virtual.

9 BARBARA: Hello, everybody. I fully
10 admit I have not had the severity of symptoms or
11 disruptions in my life that many of the rest of you
12 have experienced. I'm fortunate that way.

13 But I do have chronic leg ulcers, two
14 of which healed, and a third that has not quite healed
15 after almost two years of treatment. Like many of
16 you, I'm aware of the risks posed by this wound
17 getting -- it could -- it's always been very shallow,
18 but it just doesn't heal.

19 And my brother had a similar type of
20 wound, was receiving medical treatment regularly, but
21 he -- that treatment actually was not competent, and

1 he died of sepsis related complications. So I know
2 what can happen.

3 I'm fortunate that my nonhealing wound,
4 it doesn't have much pain, if -- if any at all.
5 Has -- it doesn't have much drainage any at all -- at
6 all.

7 But it does require that constant care
8 that we all talk about: professional bandaging twice a
9 week, meetings with other healthcare professionals to
10 try to determine why it hasn't quite healed yet,
11 improved blood flow, et cetera.

12 I mean my wound sometimes shrinks; it
13 sometimes grows. Sometimes it gets infected. I take
14 another round of antibiotics.

15 Some treatments are effective for a
16 while, and then they stop being effective. And we try
17 either a new treatment, or one that previously worked
18 and stopped working, and that one works again for a
19 while.

20 Some treatments haven't been tried
21 because insurance requires that the wound not improve

1 at all before it will approve that treatment.

2 And when you have a cycle where it
3 improves and then doesn't improve and it just goes
4 back and forth, you don't get that duration of time
5 where it's -- that the insurance company requires
6 before a new treatment will be approved.

7 Like many of you, I work full time.
8 I've got healthcare benefits, including sick leave,
9 but that would not cover all of the -- the time that I
10 spend going to the wound care clinic and to the other
11 health professionals.

12 It also, of course, then ties me to the
13 area where I live, and all of my family lives out of
14 town, so I don't see them as much as I used to.

15 You know, talking about fully healed,
16 that -- to me that is having a stable layer of that
17 protective skin that will not require constant
18 professional care, so that I'm not tied to this area
19 every week.

20 And that gives me time to -- to travel,
21 and doesn't impact, you know -- you know, me having to

1 make up time at the wound care clinic, because sick
2 leave doesn't cover the amount of time I spend at the
3 doctors.

4 So this is -- this is -- to me, that's
5 what would be a benefit of trying -- trying to get
6 this wound to a -- a state where it doesn't need
7 healthcare professionals all the time.

8 And, of course, there's always that
9 risk that it will get seriously worse and, you know,
10 could be -- need to be amputated or kill me.

11 So I hope these experience helps --
12 help you understand that although I don't have the
13 severity of -- of complications that many of you have
14 experienced, it's still a constant issue in my life,
15 and I know it could get worse.

16 Thank you very much.

17 MS. BENT: Thank you, Barbara. And the
18 experience of treatments losing efficacy over time is
19 something I think we will -- we'll hear more about
20 later on, but I think we all hear you with your
21 frustrations around that.

1 And so right now we will finish up with
2 our panelists section. We'll hear from Lasaunia, who
3 is joining us virtually.

4 MS. THOMPSON: Good -- good afternoon
5 everyone. My name is Lasaunia Thompson, and today I'm
6 going to share with you my perspective on pyoderma
7 gangrenosum.

8 For seven years I lived with a disease
9 that didn't have a name. The pain was so unbearable
10 my sheets couldn't touch my skin. I went from doctor
11 to doctor searching for answers, but no one could tell
12 me what was wrong. Doctors called me a mystery.

13 In 2021 I received a diagnosis after
14 time and time again of "I don't know." Finally, for
15 the first time in seven years, my pain has a name.

16 PGS taught me that treatment is much
17 more than simply treating a wound. It's about
18 managing pain, protecting the wound, dealing with the
19 swelling, inflammation, and trying every day to live a
20 normal life during all the other uncertainties.

21 My current wound management routine

1 requires ongoing attention. I have to keep my wounds
2 clean, properly dressed, use the treatment recommended
3 for managing the inflammation and support the healing.

4 Wound care can become a regular part of
5 your daily routine. Unfortunately, physically and
6 emotionally, it's exhausting. Making the progress --
7 I'm sorry. It's exhausting.

8 One of the biggest challenges in the
9 healing, it's not always predictable. With chronic
10 nonhealing wounds, you can do everything you're
11 supposed to do and still feel like it's not enough,
12 and you don't make the progress.

13 There are times when the pain and
14 swelling and the discomfort can cause you to have
15 ordinary activities difficult.

16 Stress management is also important.
17 Living with a condition where you're constantly
18 thinking about whether the wound is going to be
19 healed, it can be stressful.

20 I have to be mindful that stress be --
21 be mindful of stress, because I know my overall

1 wellbeing affects how I manage the condition.

2 Some may ask me how do I deal -- what
3 does healing mean to me and how do I deal with it?

4 When I think about healing, I don't
5 just think about how the wound is closed. Healing
6 means being able to wake up immediately and not think
7 about pain, not think about wound care, not think
8 about what I have to wear that day because I have a
9 wound.

10 It means being able to wear comfortable
11 shoes, cute shoes, cute clothings, and things that
12 won't irritate my wounds. It means being able to move
13 around comfortable, participate in activities, go to
14 work, make plans, without constantly thinking, "What
15 happens if my wound flares up again?"

16 Most importantly, wound healing means
17 having some freedom, being able to focus on my life
18 instead of focus on the condition.

19 There's so many up and downsides to the
20 treatment. The treatments can reduce pain, the
21 swelling, the inflammation, and be very meaningful to

1 your recovery.

2 Being able to see some improvement,
3 less pain, less drainage, and the wound become smaller
4 can make a significant difference emotionally because
5 it gives the hope that the treatment was working.

6 I also believe that treatment success
7 should be measured not by -- by how the patient is
8 functioning and feeling, not only by how the -- how
9 the wound looks.

10 The downside is one of the difficult
11 parts of managing PG for the treatment can sometimes
12 become a burden. Frequent wound care, appointments,
13 procedures, ongoing medications, can take up a lot of
14 time and your energy.

15 There can also be concerns about the
16 effects of long-term medication. As a patient, I have
17 to think about the -- the potential benefits of
18 treatments, while also thinking about what may --
19 may -- what may I live with as a result of the
20 treatment.

21 I understand that treatments

1 without -- come with side effects and may cause risks,
2 but I also know that I am willing to accept some of
3 those side effects if the treatment gives me a
4 meaningful and pain-free life.

5 What I want healthcare professionals
6 and researchers to understand, PG affects the whole
7 person, not just the skin and the wounds. The
8 physical pain is one part of the experience.

9 There is emotional impact, the
10 uncertainty, the disruption of everyday life, the
11 frustration of dealing with conditions that can be
12 difficult to predict.

13 For me, the ideal treatment would not
14 only help heal my wound, it will help me get my life
15 back. It will have fewer limitations, less fear about
16 what's going to happen next.

17 I hope that future treatments will give
18 patients with PG more options, that they're effective,
19 sustainable, and focus on both healing the wounds and
20 improving a great quality of life.

21 Thank you for allowing me to share my

1 PG journey.

2 MS. BENT: Thank you so much, Lasaunia.
3 The emotional exhaustion of doing everything right
4 while still not knowing when -- whether healing is
5 coming, that's something that I think resonates with
6 so many people here.

7 So I'd like to now take this
8 opportunity to thank our Topic 2 panelists: Jae,
9 Joyce, Sarah, Wesley, Barbara, and Lasaunia.

10 I'm going to turn to my FDA colleagues
11 to see if they have any clarifying questions. And I
12 think I'd like to start with Dr. Chang.

13 DR. CHANG: Thank you, everyone, for
14 sharing these impactful stories about your
15 experiences.

16 I had a question for anyone who cares
17 to share regarding the involvement that you had in
18 participating in treatment or therapy decisions, and,
19 you know, whether you had a say in what treatments you
20 received, and how those decisions were made. Thank
21 you.

1 MS. BENT: Great. Thank you. And so
2 maybe we can go to Sarah, and then Wes, and then we'll
3 take it from there.

4 Sarah, go ahead.

5 MS. MCCOY: So regarding, like,
6 participating in treatment plans, Morgan was a young
7 adult when everything happened to her.

8 Sure, she was 21 and truly an adult,
9 but she was still a young adult; and she relied
10 heavily on me and my husband for us to guide her in a
11 lot of the decision-making.

12 And we very, very strongly felt that
13 for her to be a part of the decision, because she had
14 to participate in it. She had to be willing to trust
15 the physicians of what they were suggesting. We
16 discussed a lot about what was a suggestion that may
17 or may not work; what was a requirement.

18 She had to be willing to do the work,
19 sometimes a learning curve. And there were times that
20 sometimes she just said, "No, I'm not doing that. I'm
21 not going to -- I'm not going to do that twice a day."

1 Or I -- when she went back to school, she lived in the
2 sorority house. She's like, "I can't do that."

3 And so we just had to figure out what
4 worked best for her in the moment. And I felt very,
5 very strongly about that someone giving her the
6 guidance and able to make an opinion and a decision
7 based on what they had.

8 'Cause a lot of it was trial and error.
9 No one was really sure if something was going to work.
10 I mean she tried so many different things to help grow
11 skin from the Hydrofusion and to -- I think there was
12 a piece of, like, a -- a pig skin that she used,
13 'cause she'd never ever graft.

14 And there was a lot of discussion about
15 grafting from plastic surgeons, but a graft skin
16 underneath a prosthetic is really hard.

17 And so she participated a lot in that
18 decision. She did not want to risk the opportunity of
19 being able to be -- to wear a prosthetic and be active
20 if she really had the potential to grow skin.

21 So I just -- I feel that I had to,

1 like, let her trust her -- her gut and realize what
2 was a suggestion versus a requirement. If you have an
3 infection, the requirement is you need antibiotics.
4 If you're just trying something in hopes, you have to
5 feel like how you can live with that and do that.

6 MS. BENT: Great. Thank you.

7 Let me turn to Wes, and see if you have
8 thoughts you want to share as well?

9 WESLEY: Yeah. My -- my tendency is
10 just to let the medical professionals choose it,
11 because I -- I -- and then just do what I need to do.
12 'Cause so much of it was just done when I'm away from
13 them.

14 But, like, they wanted me to look --
15 you know, get in bed a few times a day, and I just --
16 I couldn't do that. It was just too difficult.

17 But when I was away from them -- I let
18 them experiment what they had to experiment,
19 especially at the wound clinic when -- but they --
20 when I was in my current place here, when they wanted
21 to do some skin grafting here, I -- I didn't want

1 them -- I didn't want them to do that, because it
2 just -- I just felt like that just wasn't necessary.
3 I -- I just didn't see any need for that.

4 MS. BENT: Thank you. That's really
5 helpful information.

6 All right. We have a few more
7 questions.

8 So I'm going to have -- Lasaunia, if
9 you want to answer, if you can answer quickly.

10 And then we're going to go to Jae here
11 on the panel, and then we're going to go to some of
12 our panelists with a few more questions.

13 But we do want to get to the people on
14 the phone and in the room, so we will try to keep
15 things -- try to keep moving things along. Thank you.

16 Go ahead, Lasaunia.

17 MS. THOMPSON: Okay. So my treatment
18 plan actually was based on four doctors and myself,
19 because I live with May-Thurner syndrome, uveitis, PG,
20 and rheumatoid -- rheumatoid arthritis.

21 My vascular surgeon, a ophthalmologist,

1 rheumatologist, and wound care all actually became a
2 team and worked together, and they came up with a
3 plan; and then we all collectively made the decision.

4 So it couldn't be just about the wound
5 care. Because of everything else that was happening
6 with my body, there had to be several people involved.

7 MS. BENT: Great. Thank you so much
8 for -- and that -- I think that we've heard from so
9 many people today about the fragmentation of care. So
10 the fact that you have a care team that's working well
11 together is really, really great to hear.

12 Let me turn now to Jae.

13 MS. MCBRIDE: Yes. We also were
14 heavily involved in my mom's treatment plan. And not
15 only do we have a great amazing team centered around
16 her, they were open to suggestions that we had. We
17 were -- we're up for using any cutting edge technology
18 that was available out there.

19 They allowed me to bring my ideas.
20 They looked at them. Sometimes they said no.
21 Sometimes they did say yes, you know, to them, but

1 they -- they allow us to be heavily involved in her
2 care.

3 MS. BENT: Wonderful. Wonderful.

4 Let me turn back to our panelists.

5 And, Kathleen, did you have a question
6 that you wanted to ask?

7 DR. YOUNG: Yeah. So I also wanted to
8 thank all of our panelists and the patients and their
9 caretakers for presenting their stories today.

10 I think a through line for a lot of the
11 things that we've heard today is that folks have tried
12 a lot of different types of therapies until, for some
13 of the lucky ones, that something finally did work.

14 I wanted to ask a general question to
15 everyone who might have feedback to this. Like, when
16 or -- when in treatment, or how, is that decision made
17 that a current therapy or wound treatment is no longer
18 working for the patient and that something new needs
19 to be tried?

20 As it seems like this could affect the
21 overall timeline and trajectory of treating that

1 wound. All right. Thank you.

2 MS. BENT: All right. Is there anyone
3 who -- any of our panelists --

4 MS. MCCOY: I could answer.

5 MS. BENT: Oh, great. Go ahead.

6 MS. MCCOY: I could answer that
7 question if you wanted me to. For -- for Morgan,
8 like, trying a new treatment or once something was
9 working or not working for her, sometimes it was PG
10 rearing its ugly head.

11 That if you kept the inflammation down
12 and the skin was continuing to grow without PG showing
13 up, that was always a thing.

14 Sometimes when the skin stopped growing
15 and you were seeing -- sometimes it's just more open
16 for infection right -- usually, it was like a sign.
17 Like, here comes PG.

18 We used to say that wounds are moody,
19 and sometimes the mood would change. And when the
20 wound got moody, that's sometimes when you had to look
21 for other solutions, other options.

1 I mean a lot of her wound was a
2 reflection of her gut, of the ulcerative colitis she
3 had. Even with losing her colon, she still had a
4 small piece of colon left. And so that sometimes was
5 a big indicator.

6 Like, the wound told us other things
7 about her body, but the wound just also had moods.

8 MS. BENT: Great. Thank you.

9 We probably have time for one more
10 person to answer that question, if there is anyone who
11 would like to answer the question. Otherwise, we can
12 move on.

13 MS. MCBRIDE: I can answer.

14 MS. BENT: Okay. Jae?

15 MS. MCBRIDE: So for my mom, when
16 things weren't working, we -- we needed a different
17 skill set. You know, we were going to a traditional
18 cardiologist, a surgeon, who was cutting. You know,
19 surgeons like to cut.

20 But in my mom's situation, she has very
21 small arteries and small vessels, so she needed more

1 of an interventional, you know, cardiologist, so who
2 was able to utilize smaller tools.

3 So in -- in her -- her situation,
4 that's where we -- we went. When -- when things
5 weren't working, when wounds weren't healing, and her
6 process wasn't getting better, they needed a new
7 technique.

8 MS. BENT: Thank you.

9 And then we will go to Barbara, because
10 I think you wanted to answer this as well.

11 BARBARA: Yes. My -- my caregivers
12 have tried a lot to figure out how to get this wound
13 to heal.

14 They've done -- I had venal ultrasounds
15 done to see if there was a problem with the
16 circulation there. There's not. Though the venal
17 clinic doctor refused to do a second ultrasound a year
18 later, which was surprising.

19 The other thing -- but one of the
20 things that surprisingly worked is that switch from a
21 general Vashe wash to using Hibiclens, a more -- what

1 I would say, a -- a stronger solution that will -- a
2 stronger type of substance that will keep bacteria and
3 such at bay. And that caused a dramatic shrinkage of
4 the wound.

5 Still hasn't -- still got a couple of
6 centimeters left to close, but it wouldn't be at this
7 stage if we hadn't switched to that kind of topical
8 treatment. Over.

9 MS. BENT: Thank you so much.

10 All right. So I think we have two more
11 questions from our panelists. I think we have one
12 from Sarah, and then one from some from Vickie, that
13 we will get to before turning to the -- quickly to the
14 polling questions and then to the phones.

15 MS. ROSENBERG: Thank you to all the
16 patients who shared their stories. We really
17 appreciate it.

18 I did have a question about did any of
19 the treatments have any significant side effects that
20 caused you to, maybe, stop the treatment or seek
21 alternate treatment options? And are these relevant

1 to your treatment decision?

2 MS. BENT: All right. If -- for our
3 panel --

4 MS. THOMPSON: I can --

5 MS. BENT: Okay. Great. Go ahead,
6 Lasaunia. Thank you.

7 MS. THOMPSON: I was just going to say
8 one of the medications that I was -- they wanted to
9 give, I believe it was gabapentin. And it affects
10 your eyes.

11 And, unfortunately, my eyes had
12 already -- was doing what the gabapentin would've
13 done. So that was a treatment that they had to take
14 off the table.

15 And then we played around with the idea
16 of methotrexate. And so, currently, I'm on it, but,
17 initially, they had given me the higher dose and I
18 should have got a lower dose.

19 So we had to keep going back and forth
20 to figure that out. But, fortunate enough, they got
21 to figure it out, and now I'm on methotrexate.

1 MS. BENT: Thank you.

2 Jae, did you want to say something?

3 MS. MCCOY: I was just going to say for
4 Morgan, one of the things that -- that was -- had a
5 side effect was doxycycline.

6 Like, it helps reduce the inflammation
7 in the wound. It helps healing. But also the effects
8 of just the -- like, burning easily in the sun.

9 When you're, you know, a -- a young
10 college student, you want to be able to go to a
11 football game or sit on a patio. So sometimes we had
12 to take, you know, doxy off the -- off the list just
13 because she wanted to live her life.

14 MS. BENT: I remember you -- in
15 your -- you mentioned the brunch beforehand, and I
16 think it is really important to try and figure out
17 what we can do that allows people to reach their -- as
18 much normalcy as possible.

19 Jae, let me turn to you.

20 And then we'll move on to Dr. Driver
21 for our -- the final question.

1 MS. MCBRIDE: So my mom is very
2 sensitive. She doesn't do well with pain meds or
3 any -- some -- some antibiotics as well.

4 So those antibiotics or pain medicines
5 that she was taking, like gabapentin and some of the
6 antibiotics, made her just actually be a shell, and
7 not be able to communicate or talk, and -- and just
8 sleep all day.

9 So we had to, actually, change course
10 when that happened. So she actually started to stop
11 taking pain medicine, gabapentin and -- and things of
12 that nature, and just -- you know, she decided to just
13 deal with the pain.

14 Because she wanted to -- it was either
15 be a vegetable in the bed all day, be loopy, be kind
16 of just out of her mind, or be able to talk and
17 communicate. So in her situation, you know, she's
18 loopy and we monitor that very closely.

19 MS. BENT: Thank you.

20 Dr. Driver, did you have a question?
21 I'm sorry.

1 DR. DRIVER: I have many, but I'll make
2 it one. So I wrote down -- our panelists, patient
3 and -- and daughter at the end of the table, thank you
4 all so much for what you've contributed today.

5 But you said measure these patients'
6 treatments and -- and every day by quality of life,
7 not the size of the wound. So could you articulate,
8 explain to us -- we've been trying to capture that,
9 but our clinical studies don't go long enough.

10 So what were these quality of life
11 measures? What should they be?

12 MS. MCBRIDE: So my mom, basically, 12
13 months ago --

14 DR. DRIVER: Could you put the
15 microphone a little closer?

16 MS. MCBRIDE: I'm sorry. Can you hear
17 me? So 12 months ago, my mom could not walk. She --
18 I -- my husband and I literally had to pick her up
19 and -- and move her.

20 She couldn't go to the restroom by
21 herself. She could not put on her clothes. She could

1 not bathe. She couldn't do any of those things.

2 Today, you see she's walking. You
3 know, she's walking. She's moving. She's -- she's
4 able to put her clothes on. She's able to -- it -- it
5 may be painful to walk, but she's able to walk.

6 I'm not carrying her anymore. I'm
7 not -- I'm not putting her on the bedside pan.
8 The -- literally, the first night -- we celebrate
9 everything.

10 We like to -- like, we celebrate the
11 minor things, because with these -- this disease and
12 these wounds, you know, you have some very hard days,
13 some very discouraging days. Some days we felt
14 defeated, so we have to celebrate the small milestones
15 when they come.

16 So the first night my mom was able to
17 go to just simply the bedpan on her own -- own without
18 waking me up to do it, we celebrated. You know, I did
19 a little happy dance for her, and -- and we shouted.

20 Because that -- that was giving her
21 some small part of her independence back. My mom is a

1 very active person. She likes to, like, just, you
2 know, be vibrant. She's a -- a real estate broker.
3 She needs to move.

4 And so for her to be able to start
5 doing some of the things that she -- that makes her
6 her, again, that's -- that's improving her quality of
7 life.

8 DR. DRIVER: Thank you very much.
9 You're very inspirational. To know that there are
10 ways we can measure not just the size of the wound,
11 but the quality of a life. Thank you very much.

12 MS. BENT: All right. So thank you all
13 to our panelists. We really appreciate you both
14 sharing your experiences and staying on with us to get
15 some of our clarifying questions answered.

16 We are now going to turn back to
17 everyone in the audience here and online, and to some
18 polling questions.

19 So the polling questions for this
20 session are focused on treatments and management
21 approaches you have used, the challenges you have

1 faced, and the benefits that matter most to you when
2 considering a new treatment.

3 So, again, please go to [mentimeter.com](https://www.mentimeter.com)
4 or scan a QR code. And we'll move to the first
5 question, which is: "Have you or your loved one ever
6 used any of the following to manage your chronic
7 wounds?"

8 And you can choose all that apply:
9 "Topical wound care products; wound dressings; gauze;
10 prescription topical medications; specialized wound
11 therapies, such as negative pressure wound therapy or
12 hyperbaric oxygen therapy; compression therapy, such
13 as stockings, wraps, or bandages; clinical or surgical
14 procedures, such as debridement or removal of dead
15 tissue; support devices, such as shoes, casts, or
16 cushions; diet or lifestyle modifications, such as
17 nutritional supplements or elevation; other approaches
18 that we haven't mentioned; or 'I am not using anything
19 at the moment.'"

20 All right. I'm going to be honest,
21 this is going to be a challenge for me to read.

1 All right. So it looks like we're
2 seeing a lot -- about 20 percent of people using the
3 topical wound care products.

4 We've got 17 percent using supportive
5 devices. Others using approaches not mentioned. We
6 see diet and lifestyle modifications. It's really
7 kind of spreading out across the board.

8 All right. And it seems like -- I mean
9 we heard a lot of these different approaches, but from
10 our panelists as we talked about this earlier, and so
11 it looks like we're about steady with a lot of the
12 topical wound care products. Again, this is just to
13 facilitate the discussion, not a scientific survey.

14 All right. Let's move on to polling
15 question number 2, so: "What are the biggest
16 challenges or barriers you face in managing your or
17 your loved one's chronic wound?"

18 And you can choose up to three of
19 these. So the top three: "Time or cost of
20 maintenance, difficulty accessing specialized wound
21 care, pain during treatment procedures, slow or no

1 improvement despite treatment, side effects from
2 treatment, difficulty following treatment
3 instructions, lack of information about treatment
4 options, or other challenges that are not mentioned."

5 All right. And I think consistent with
6 what we've heard already today, it looks like we are
7 seeing the time or cost of maintenance is really a
8 significant impact for people. Difficulty accessing
9 that specialized care. Pain. Lack of improvement or
10 slow improvement.

11 All of those things that are really
12 consistent with what we've heard from our panelists
13 today, and what I think we'll probably hear when we go
14 to the phone in just a few minutes. So thank you for
15 that. That was really helpful.

16 And so -- all right. Moving on to our
17 final question for this session: "If you are
18 considering a new treatment for chronic wounds, which
19 of the following benefits would you consider to be the
20 most meaningful?"

21 And this is choose up to three answers.

1 The options being: "Complete wound healing, faster
2 healing time, reduced pain, improved mobility, reduced
3 risk of infection, less frequent dressing changes,
4 improved quality of life, prevention of wound
5 recurrence, or other benefits not mentioned."

6 All right. And so faster healing time,
7 improved quality of life, and then complete wound
8 healing is bringing up the top three. Reduced pain is
9 important.

10 I realize it's just kind of an unfair
11 question, because it feels like all of these things
12 are really important, so limiting you to three is
13 probably not our -- not completely fair. But it is
14 helpful for us to see what people are thinking, so
15 thank you for sharing this.

16 Okay. We'll just give it another
17 minute, but it looks like we've kind of stabilized in
18 the responses with, again, the improved quality of
19 life really being the largest priority. So thank you
20 for that.

21 So now let's -- all right. I think

1 before we go to the phones -- and maybe we can take
2 some answers from the phones as well.

3 Dr. Mejia, did you have a question that
4 you wanted to ask?

5 DR. MEJIA: I did. And I know it's not
6 fair for the last polling question. As you were
7 saying, it's really hard to pinpoint this. But could
8 any of the patients -- with some thought. And this
9 isn't -- this maybe can be answered later on in the
10 discussion.

11 But if there was one specific sign or
12 symptom that you would consider equally important or
13 more important than wound closure, that would -- you
14 think it -- you would think would improve quality of
15 life, what would that be?

16 MS. BENT: All right. That's a good
17 question. And before I ask people to answer that
18 question, I mean, please, if you're online and you
19 have thoughts, please feel free to put that answer
20 into the comments.

21 And for those of you who are going to

1 go to the phone now, and so if you have thoughts on
2 that, please incorporate that into your response if
3 you would like to.

4 I'm going to go to the phones. I would
5 ask everybody to try to keep their answers brief, just
6 so that we can make sure that we get through the
7 number of callers that we have. We want to be able to
8 hear from as many people as possible.

9 And so with that, I'm going to go to
10 Francesca on line 1.

11 MS. FRANCESCA VALENTINE: Good
12 afternoon.

13 MS. BENT: Good afternoon. Thanks so
14 much for calling in.

15 MS. FRANCESCA VALENTINE: I'll avoid
16 redundancy. I am -- my daughter, Ashley, led a segue
17 into Marqus's history, but I will tell you his
18 original wound -- by the way, I'm a mother of a winged
19 warrior.

20 I'm a mother of a winged warrior. So
21 Marqus is no longer with us, but his wounds were

1 extensive. Both legs, both limbs.

2 And it started in 2013 after a flood.
3 He got scratched during a cleanup and that ankle
4 proceeded to fester.

5 His first trip to the operating room
6 for the surgical debridement put him into terrible
7 crisis, and we soon learned that he would not be able
8 to have OR debridement. So we went to clinic under
9 the skill of our surgeon and did perineal nerve blocks
10 in order to do sharp debridement.

11 We had all the treatments that were
12 spoken about today that I was listening to, including
13 portable hyperbaric chamber here in the home. And we
14 also had grafts, and we had advanced dressing.

15 Wounds -- wounds are devastating
16 because they do -- not everyone knows how to manage
17 them. We soon learned that general wound clinic would
18 not be acceptable because they did not have a good
19 understanding of the pathophysiology of sickle cell
20 disease.

21 It's an ebb and a tide. It is not

1 always circulation lost or gained. It's slow, ebb and
2 tide. They don't understand that.

3 So they would send him back home with a
4 Unna boot. Well, that's compression. If he's in a
5 VOC, why would you compress? So we soon learned that
6 that would not be effective.

7 We got minimal results from the
8 grafting. What worked -- the -- the trajectory of an
9 infected wound is devastating. So then you have
10 crisis, sepsis. He lost his portacath. I had a
11 480-hour FMLA all used up.

12 I had to discuss -- he was 26 at the
13 time. I had to discuss with my 26-year-old, what does
14 he want for his limb? So a mother having a discussion
15 with their child, "Do you want amputation should we
16 not be able to resolve this?" We had to have a frank
17 discussion. If that doesn't cause PTSD, I don't know
18 what would.

19 Then we went on to the cost. The
20 cost -- every time the foot remodeled from poor
21 circulation, open skin, nerve and tendon inflammation

1 and damage, you need a different shoe. You -- you
2 can't wear the same shoes you wore possibly before
3 your wound. We ended up with special shoes from a
4 company that could make specialty shoes.

5 We had to fight the insurance company
6 for medication, and for prosthetics, and for shoes.
7 So there's that cost to fight.

8 The cost to the patient, their -- their
9 humanity is part of this issue. How do you cover a
10 foul smelling draining wound?

11 You need to put on shoes because you
12 want to go outside. Marqus would put a plastic bag
13 over, we'd wrap over that, and we'd be ready to put it
14 down in the shoe because we had places to go and
15 things to do.

16 Wounds -- what -- the question was how
17 do you know you have a win when you're working on your
18 wound? When you take that dressing off and you see
19 those little bubbles and new skin come, and the pain
20 is less, and infection free, that's a win.

21 It is not just the condition of the

1 wound. It is ongoing condition of the wound. You
2 want to see that when you're doing the dressing.

3 I would get up at three, because I
4 needed to be at work at seven, and we would do our
5 dressing changes, hang our IVs, and do our IV
6 piggyback, all before I left the house. And then when
7 I got home from work, repeat.

8 Marqus learned to help his own wound,
9 but not everyone can do that. It's really important
10 that the caregiving is accessible.

11 I heard someone talk about having to go
12 a hour and a half or two hours, three hours, every
13 day. That is not accessible. That is accessible
14 because you have to. What's the alternative?

15 But a lot of this goes right back to
16 the core of sickle cell, lack of understanding of
17 pathophysiology of the disease process. It happens
18 with every organ system, including wounds and skin.

19 Marqus had to have chronic volume
20 exchanges to close his limbs and prevent amputation
21 and sepsis. He got his port put back in eventually.

1 Wounds did not take his life. Intracranial hemorrhage
2 took his life. But --

3 MS. BENT: I'm going to -- I'm -- this
4 is really helpful. I am going to ask you if you can
5 make -- wrap it up so we can get to others, but are
6 there any kind of final, like, points that you want to
7 make before we move on?

8 MS. FRANCESCA VALENTINE: Wounds --
9 wounds last a long time. Thirteen years for him.

10 And I appreciate everyone's testimony.
11 It was very impactful. Thank you.

12 MS. BENT: No, and thank you. And
13 thanks to Ashley, who I know wasn't able to stay with
14 us this afternoon, but your perspectives have been
15 really helpful and really informative, so thank you.

16 All right. We're going to move on to
17 our next caller on line 5, Brindley?

18 MS. BROOKS: Hi. Thank you so much for
19 inviting me to be here today. My name is Brindley
20 Brooks, and I'm the founder and CEO of HS Connect,
21 which is a patient advocacy group for hidradenitis

1 suppurativa.

2 I have lived with HS for the last 37
3 years of my life, and I also have two daughters who
4 have HS. I have a 19-year-old with stage 2 HS, and
5 then I also have a 23-year-old stepdaughter who has
6 stage 1 HS as well.

7 So HS has been a part of my life for a
8 really, really long time, and moving into the advocacy
9 realm and also, you know, raising children with HS has
10 been quite interesting.

11 It's -- it's also been of note that
12 many of the other conditions that have been discussed
13 here today, we all share similarities, especially when
14 it comes to wound healing.

15 Chronic wounds are part of the
16 existence of someone with HS. A lot of times because
17 of the draining tunnels that are formed for us, we
18 have incessant, chronic draining wounds just like
19 people with venous leg wounds as well.

20 So it's been -- I don't want to say
21 heartwarming 'cause that's the wrong word -- but just

1 affirming to know that we all share something in
2 common when it comes to chronic wounds.

3 There have not been many studies, if
4 any, done on the nonhealing chronic wounds that are
5 caused by HS.

6 And a lot of our patient population,
7 because it is really expensive to care for these
8 wounds with proper dressing, actually turn to things
9 like toilet paper and paper towels to use as dressings
10 to -- to soak up exudate, which is really unfortunate
11 and has a huge impact on our quality of life.

12 I, personally, have had seven wide
13 excision surgeries left to heal via secondary
14 intention, so left to heel from the inside out. It's
15 been traumatic, to say the least, but it absolutely
16 changed my life for the best.

17 In fact, it changed my life personally
18 so much that my 18-year-old -- well, 19 now, but 18
19 when she decided to have wide excisions of her
20 bilateral inner thigh, which is the only way that we
21 can hopefully accomplish wound healing completely with

1 hidradenitis suppurativa.

2 So I just really appreciate you guys
3 bringing attention to this, and knowing that outside
4 of your most obvious chronic nonhealing wounds, there
5 are diseases like PG and HS that also have
6 similarities that you don't think of offhand.

7 And I would love to change that
8 landscape and that we have more research done on
9 nonhealing HS chronic wounds as well.

10 Thank you so much.

11 MS. BENT: Thank you.

12 And I think that that was one of the
13 goals that we had for this meeting was we -- you know,
14 and one of the reasons FDA was hosting this meeting is
15 because we know that nonhealing chronic wounds cross
16 so many different conditions and wanted to really hear
17 about that wound experience.

18 Obviously, it can't be separated from
19 the causative experience, but it does give us an
20 opportunity to talk about wounds themselves and the
21 commonalities kind of across the different conditions.

1 Let me see. Let us go to one more
2 caller on the phone, and then we will see if there is
3 anyone in the room who would like to say anything.
4 And then we'll go to the comments online, if we have
5 any comments online.

6 So I think we're going to go to line 6,
7 Laurie?

8 MS. RAPPL: Hi. I -- I spoke earlier
9 today. This is Laurie Rappl; I'm a T-12 paraplegic in
10 Greenville, South Carolina. I'm currently dealing
11 with a sacral wound, a pressure injury, and -- due to
12 treatment for two bouts of stage 4 breast cancer.

13 The current therapies are the same ones
14 they've offered me for years. They start with
15 negative pressure and will intersperse that with
16 various wound dressings, the -- the dressing du jour,
17 as I call it. You know, who -- who came in last and
18 had some samples, and we'll try this and we'll try
19 that.

20 But negative pressure is the
21 overarching treatment that people give. And on me, it

1 doesn't work after a couple of weeks, couple three
2 weeks; and we have to take a break from it, and then
3 we can go back to it.

4 I also develop -- I -- I develop
5 infections underneath that negative pressure, so we
6 have to try various things for the -- for infections.

7 I've had three debridements on this
8 wound. I had one in September, and then -- then I had
9 to have one in April that went down to the sacrum.
10 And then I just had one last Tuesday for more sacral
11 debridement.

12 But my -- my problem with getting
13 treatment for this wound and previous wounds is that
14 I'm offered nothing in between negative pressure
15 therapy and a flap surgery. And, unfortunately for
16 them, I know that there's a lot of things in between
17 there that -- that are available now on the market.

18 But I -- I know this is not a
19 reimbursement call, but due to the fractured way that
20 we reimburse different therapies, I'm not eligible for
21 them. And as a previous caller said, a lot of

1 modalities and drugs and such are not studied on
2 pressure injuries, and so they're not reimbursed.

3 So in my own words, what would healing,
4 quote/unquote, mean to me?

5 MS. BENT: Yes.

6 MS. RAPPL: It would mean smaller
7 measurements for sure. But measurements can be very
8 subjective, because it depends on how you're laying
9 and how -- how much they pull on the tissue, you know,
10 to -- to get a good look at the wound. And they're so
11 subjective that I just -- you can't compare them from
12 one person to the next.

13 So that's frustrating. And I wish
14 there was a way to do volume instead of the four-point
15 measurements, measurements at four points and then the
16 depth at one point.

17 The -- the current treatments have been
18 fair in helping me. The wound has decreased in size
19 from 14 months ago till today. And yet it persists.
20 And it -- it's very frustrating to lay here day after
21 day, week after week, month after month, to watch the

1 impact on my family and to -- to see numbers not
2 budge.

3 The -- the color of the tissue is one
4 way you can document progress, but that's subjective
5 as well.

6 The biggest downside I have found with
7 my sickness is just what I would consider a lack of
8 effectiveness, because of the extreme slowness of how
9 this -- this wound has responded to these different
10 treatments, and my lack of ability to access something
11 other than what I've been offered so far.

12 I believe I found a provider now that's
13 willing to try some different things and is pretty
14 enthusiastic, but that -- that might remain to be seen
15 because I'm -- I'm new with this provider.

16 And I think that that's plenty of time
17 for my comments. I thank you for letting me speak
18 again, and I will take you to the next speaker.

19 MS. BENT: Thank you so much, Laurie.

20 All right. Let me just turn to the
21 room and see if there's anyone in the room that would

1 like to -- any patient with lived experience in the
2 room that would like to speak.

3 Polly, I see you have your hand up. I
4 will ask you -- because we do need to make sure we get
5 to others -- to keep it pointed.

6 MS. CLEVELAND: Very -- very short and
7 to the point. I was able to use medical maggots
8 ordered from California to treat my husband's wounds.
9 After five months of no progress, they were halfway
10 cleaned out with one treatment. Unfortunately, he was
11 dying. I should have started earlier.

12 The problem with medical magnets --
13 maggots -- okay -- is that they are not covered by
14 insurance. If they were covered by insurance, which
15 the AMA has so far refused to qualify, I think they
16 would be much more widely used. And I would ask Lewis
17 here to back me up. Yes?

18 LEWIS: Yes, indeed. It works.

19 MS. BENT: Thank you so much. And I
20 think what we're hearing from you is similar to what
21 we've heard from so many other people, which is a

1 frustration with accessing -- being able to access
2 treatments.

3 And the desire as a family member or
4 caregiver to not know exactly what the right path is
5 in the beginning while you're learning this journey,
6 and wanting the best for your family and not being
7 able to completely understand what that is.

8 I think we can take one more comment
9 over here, and then we will turn to Ethan for comments
10 from the -- online. Thank you.

11 MS. SHAPIRO: Hi. I'm Adrienne. I --
12 one of the points -- I mean anybody that's lived with
13 this can relate to everything that you've gone
14 through, but the one thing I think we haven't talked
15 about is the step therapy that -- they'll -- it
16 doesn't matter; right?

17 They -- they'll say, "We know something
18 doesn't work." And we'll say, "Well, you have this
19 thing that somebody else experienced and it worked."
20 And they're like, "Yeah, yeah, but we're going to try
21 this first."

1 And so I think we really have to look
2 at -- at how people are put through so many things
3 until they get to the thing that has the better chance
4 of working faster.

5 You know, that -- you know, it's --
6 it -- we end up spending a lot of money, a lot of
7 time, until it fails. So it's try and fail as opposed
8 to what would be the most effective treatment.

9 MS. BENT: Thank you.

10 Let me now turn to Ethan and see about
11 the comments online.

12 And I don't know, Ethan, if you have a
13 plan, but were we going to be able to share some
14 thoughts related to the question that Kathleen asked?
15 Okay. Perfect.

16 MR. GABBOUR: Yes. So we're getting a
17 number of comments saying that treatment for them is a
18 trial and error process like we've been hearing, and
19 that there's no quick fix, especially because they are
20 dealing with underlying conditions and that their
21 providers aren't understanding their other conditions.

1 Some treatments mentioned are wound
2 dressings, ozone boot and oil, stem cell treatments.
3 And for one patient they would try something new if
4 they went a couple of weeks without improvement and
5 the wound got bigger.

6 There's also frustration that patients
7 are being blamed for slow or no progress, even if a
8 patient is being compliant with their treatment
9 program.

10 One caregiver noted that they were
11 disregarded when their dad underwent debridement and
12 experienced a lot of pain, but their pain was just
13 disregarded as neuropathy.

14 And to answer the question about what
15 would be considered meaningful aside from wound
16 closure would be less recurrence of infection.

17 And then one other quote was
18 "Treatments or therapies that can reduce pain, reduce
19 infection risk, and make life more normal, such as
20 being able to walk, drive, and stand, would help
21 improve quality of life."

1 MS. BENT: Great. Thank you. And I
2 will note that Sarah, who was one of our panelists,
3 mentioned that perhaps complete -- besides complete
4 healing, maybe just living congruently with the wound
5 and no dressing changes without a risk of
6 deterioration.

7 So let me now go to -- back to the
8 phone, and we will go to Alvin in Toronto.

9 Alvin?

10 ALVIN: Yeah. And, you know, thank you
11 for allowing me to speak.

12 I would like to, you know, first and
13 foremost say yes, I am calling in from Toronto where
14 the healthcare may be a little bit different, but
15 everything that I've heard from other panelists or
16 other phone callers seem to be in line with what, you
17 know, I've experienced.

18 So in terms of not being able to stay
19 on my disease modifying treatment and also have my
20 wound get better, or as someone just said, we're --
21 knowing what works for us, but then having to go

1 through all these other hoops and everything else just
2 to get to where we knew we needed to get to.

3 And then, again, the -- the last person
4 also spoke about, maybe, you know, quality of life
5 improvement as long as the wound does not get any
6 bigger. I had to go through everything from Vashe
7 washes to Coban to -- Coban -- yeah, Coban treatments
8 and compression socks.

9 So I -- I do think when you're thinking
10 about things like wounds, which may have scent to them
11 or leakage and all the rest of that, it does quite
12 impact someone's life and the ability to enjoy it or
13 to go out and to do any of those things.

14 And I do think, as many people at the
15 table, to discuss what actually works. Like, you
16 know, some people say, like, that -- that would be
17 good enough. Or, like, the wound doesn't get better,
18 but I can do this.

19 Where someone like me would be, like,
20 no, I -- I absolutely need the wound to be closed
21 because they always happened from my ankle down. So

1 if I can't put on shoes or socks, I can't do anything
2 and I can't go anywhere. So that's not living life.

3 But I -- I would just say all of those
4 things are -- are things that I would say to keep in
5 top of mind when creating any kind of solutions that
6 would affect such a big swath of the population.

7 Yeah. 'Cause I see it affecting from,
8 you know, young to old and across the whole ethnic
9 spectrum. So I think as many voices that are in the
10 room when solutions are being created would be the
11 most beneficial to everyone.

12 And as we know, nothing stays in one
13 country forever. Solutions do travel.

14 Thank you.

15 MS. BENT: Thank you, Alvin. We really
16 appreciate that and appreciate the perspective from a
17 little bit outside of the United States as well.

18 So let me now turn to Dan on line 9.

19 Dan, good afternoon.

20 DAN: Thank you for -- for doing what
21 you do. I'm a burn survivor going -- been 16 years

1 since I burned 85 percent of my body. So I had the
2 luxury of dealing with a lot of wounds over the years,
3 chronic wounds.

4 But I -- I've been listening for -- on
5 and off for a while, and, yes, a lot of good
6 information is coming forward.

7 And the patient -- what frustrates me
8 is what frustrates a lot of people with chronic wounds
9 is our providers know what can fix it, but the
10 regulations and all that stuff kind of hinder the
11 process.

12 I've been dealing with two wounds, one
13 on my right leg, one on my left leg, and I've been --
14 veins and, you know, they did all that stuff. It --
15 it boiled down to I -- antibiotics I was on 'cause I
16 had infections a few times.

17 But right now what, finally, is getting
18 me moving in the right direction in closing these
19 wounds up is my -- my doctor has put me on natural
20 vitamins.

21 A bunch of natural -- you know, good

1 for your -- I guess, my body likes it because the --
2 whatever my doctor has prescribed me, I'm taking like
3 eight or nine different things every morning and in
4 the afternoon. So whatever it's doing to my blood
5 flow, to the way my skin heals.

6 Because I -- I have scar tissues. And
7 that just popped into my head. That's another
8 problem. We go to these wound care centers, or I go
9 to a wound care center.

10 But burn survivors aren't fortunate,
11 because I've lost the top layer of my skin. I have
12 third degree plus wounds where my both legs, you could
13 basically take a knife and cut my legs and I won't
14 feel it.

15 But with these wounds, I had one wound
16 on my left leg and there was this tubular growth.
17 They sent it out. It wasn't cancerous, thank God, but
18 it just wouldn't go away.

19 So they kept cutting back, cutting
20 back. And whatever that was, it was attached to a
21 nerve, and oh my God, the pain.

1 And then the infections on and off.

2 And another frustration, I don't get a high blood --
3 white blood count, I guess, when I'm infected, but I
4 just get lethargic. I can't move.

5 And you go to a hospital and they have
6 criteria. If you don't have a fever -- sometimes I
7 don't have a fever and I'm infected.

8 Thank God for my primary care. I was
9 in really bad shape 'cause I know I've been dealing
10 with this for a long time. I was really not sleeping
11 too much, out of it, 'cause my body's infected, but I
12 don't have a fever. My -- my white blood count
13 doesn't go up.

14 She put me on antibiotics, a couple of
15 antibiotics. Within a day or two, bam, I recovered.
16 So a lot of regulations are restricted and they're
17 holding -- healthcare providers, you know, 'cause
18 they -- they have the -- what is it, the -- when you
19 have a lot of infection. Not chronic.

20 I'm trying to look for the -- the --
21 not the CDC. Who was the one that -- a doctor that --

1 I'm sorry. My mind is blank. But they -- they take
2 care of when you're chronically infected and they make
3 the decision in the hospital.

4 MS. BENT: Like, your infectious
5 disease physician?

6 DAN: Yeah. Thank you so much. Yeah.

7 MS. BENT: No problem.

8 DAN: Infectious disease. Yeah. And
9 if they -- if you don't meet the criteria -- I -- I'm
10 pretty sturdy with pain and everything, 'cause you
11 know, being -- I burned 85 percent of my body and I
12 was -- thank God, they had me recovered with grafting
13 in five months.

14 I have a wound that started out like a
15 pencil tip, turned into about, I don't know, inch,
16 inch and a half. One's a circular -- and about two
17 and a half inches circular. And, finally,
18 they're -- they're healing.

19 But I just watch my diet. I'm doing
20 everything I can and I'm on these natural -- this
21 natural stuff, and the -- you know, the antibiotics.

1 I know a lot of doctors are afraid to
2 give you antibiotics, but, you know, my -- my leg was
3 flaming red and it -- it was just horrible. It was
4 just getting bigger and bigger and bigger 'cause it
5 was infected. My wound grew --

6 MS. BENT: Thanks. Thanks, Dave -- or
7 Dan. Would you --

8 DAN: Dan.

9 MS. BENT: Are there a few final points
10 that you'd like to make?

11 DAN: The only thing is that I -- I
12 appreciate everything you do. Thank you. And if we
13 could do some way to give the healthcare providers a
14 little more freedom where they can make decisions.
15 'Cause they -- they're right there on the front line.
16 And that's my one suggestion.

17 But -- and vitamins. I -- it helped
18 for me. I don't know if it's going to help everybody.
19 And -- and keep your wounds clean.

20 MS. BENT: Thank you so much.

21 DAN: You know, that's one of the --

1 I'm constantly cleaning them. Thank you.

2 MS. BENT: All right. Let me now go to
3 Lisa on line 8.

4 LISA: All right. Good afternoon. Can
5 you hear me?

6 MS. BENT: Yes, we can.

7 LISA: All right. I am going to keep
8 it as short as I can and stick on topic about
9 treatments.

10 Obviously, all of us -- all of us with
11 unhealing wounds have gone through the debridement and
12 we've gone through different dressings and different
13 changes and things like that, wound vacs, et cetera.

14 But I will -- I want to say is, for me,
15 what finally worked after a year and a half of
16 improper treatment from a doctor that wasn't just --
17 nothing wrong with him, he just -- he wasn't
18 knowledgeable about proper wound care.

19 And I -- I did find a place that was,
20 and eventually they did CTM -- CTM? Yeah. Which is
21 biodegradable -- BTM -- biodegradable temporizing

1 matrix. And that started to work, because my wound
2 wasn't ready for a skin graft yet.

3 So that worked, and my -- my wound
4 finally started to close after a year and a half of
5 excruciating pain. And -- which is great. It's an
6 FDA approved product, but insurance fights it.

7 So I -- I know I'm not looking for any
8 changes right now. I just want to put it out there
9 that all of these things that the FDA approves are not
10 being accepted by insurance, without peer-to-peer
11 discussions between the doctor and the insurance
12 company.

13 But the BTM worked for me, and then my
14 doctor realized I was finally ready for an actual skin
15 graft from my donor site. And she did that, and that
16 was healing.

17 She also used RECELL when she did that,
18 which is another FDA approved product that insurance
19 fought her on, but she fought back and got it
20 approved.

21 And my -- my wound finally healed for

1 the first time in a year and a half. Unfortunately, I
2 did develop a fistula and, you know, I've been going
3 on since then with an open wound again.

4 But I think it's important for you guys
5 to hear that these products are approved, but
6 insurance companies are making it very difficult for
7 healthcare providers to use them on patients who
8 desperately need it and it works.

9 So that's my perspective on that. I
10 won't get into my whole story because I've -- I've
11 been through it, a lot of it, a lot of stuff.

12 But most importantly, I think it's
13 important to just recognize that there are products
14 out there that help. Doctors are reluctant to use
15 them because they get fight back from the insurance
16 companies, but the FDA has approved them; so --

17 MS. BENT: Yeah. Thank you for that,
18 Lisa. And I don't know -- I'm not sure what video
19 they're showing on the webinar, but I will tell you
20 that Dr. Driver's almost falling off her seat, like,
21 nodding so vigorously.

1 And the rest of the room there was in
2 agreement as well. So thank you for sharing that with
3 us.

4 LISA: Yeah. No, and I know -- I know
5 the medical bit. I -- I keep it -- on the -- on the
6 screen right now is just the phone number.

7 But I know that medical providers
8 understand this because I know their frustration. And
9 I know that I -- I got very fortunate because I wasn't
10 being treated properly, and I went through a lot of
11 pain and a lot of suffering until I ended up with the
12 doctor at -- so I go to South Shore Health Center for
13 Wound Healing in Weymouth, Massachusetts.

14 And they have -- it's -- it's, like, a
15 state of the art facility and they have the best
16 doctors. And my doctor in particular has saved my
17 life more than I can tell you. And I'm not kidding
18 about that.

19 MS. BENT: Okay.

20 LISA: Like, there were -- there were
21 times that I -- I probably shouldn't have made it

1 because of bad decisions from other doctors. But she
2 treated it, and she treated it so well that if I
3 hadn't gotten the fistula, I'd be fine. Nobody --
4 it's nobody's fault that I had the fistula.

5 So I did give Ethan my cell phone
6 number. So if you guys -- I mean, I'm sorry, my email
7 address. If you guys ever want to reach out to me,
8 please feel free.

9 MS. BENT: Great. Thank you very much.

10 All right. And we have about two
11 minutes before we go to -- before this session ends
12 and we go to our break. And so I will be going to
13 caller on line 1.

14 So, Williams, are you on line?

15 MS. WILLIAMS: Yes, I'm here.

16 MS. BENT: Great. Thank you.

17 MS. WILLIAMS: Thank you very much. My
18 story is -- is probably a little bit different than
19 the stories that I've heard all day today.

20 So I suffer from HS, hidradenitis
21 suppurativa, which is very painful. It causes

1 abscesses and draining, and they are reoccurring, so
2 it's like nonstop.

3 I have gone to so many doctors, tried
4 so many things, and just last year I was introduced to
5 copper dressing. And when I used the copper dressing,
6 it literally changed my life.

7 So whether it was an active flare or a
8 flare that was just beginning, as soon as I started to
9 use those dressings, they would literally go away.

10 And usually one flare can last up to
11 two to three weeks. And if it's really bad, it can
12 last up to a month or more. And I have found
13 significant relief in using these copper dressings.

14 Even going to the doctor -- and my --
15 my daughter has it as well, but I won't talk about
16 her -- her situation. But she has it as well and it
17 has helped her to -- to live a better quality of life
18 as well.

19 But we went to doctor after doctor, and
20 we were not able to get any relief until we actually
21 found these dressings.

1 So I just wanted to tell my story. I
2 haven't heard anybody say anything about copper
3 dressing treatment, but they have been a lifesaver for
4 my daughter and I.

5 MS. BENT: Thank you very much. That
6 was a really nice way to end the session.

7 And we really appreciate everybody who
8 participated in this version of this -- or in this
9 session. And so we're going to take a ten-minute
10 break. We will return in just a few minutes to hear a
11 discussion about clinical trials.

12 And we have another five exceptional
13 panelists who will be joining us, mostly virtually.
14 And so we'll see you in just a few minutes. Thank you
15 so much, everyone.

16 (Off the record.)

17 MS. BENT: All right, everyone. Thank
18 you so much. Welcome back. We are now headed into
19 our third and final discussion topic: patient
20 perspectives on clinical trials.

21 And so this session is going to focus

1 on what factors would or do people weigh in decisions
2 about whether to participate in a clinical trial, and
3 what outcomes are most important to measure.

4 After our panelists share, we'll go
5 back to the polling questions, and then open the floor
6 for discussion. So, again, if you want to call in,
7 please start thinking now about some of the topics
8 that you would like to speak to.

9 And so with that, I'm actually going to
10 turn to our Topic 3 panelists. And we are very
11 happily joined by Adrienne, who is here in person with
12 us today.

13 So with that, Adrienne, if you would
14 not mind taking it away. And do you want to be up
15 here at the podium? Okay. Perfect.

16 MS. SHAPIRO: Okay. First of all, I
17 want to say thank you so much for including me on
18 this. This has been an amazing -- an amazing session.
19 The sickle cell community is ever so grateful to the
20 FDA for looking out for us.

21 And, yeah, so let's talk about this.

1 So -- so I'm Adrienne. I am a lifelong sickle cell
2 advocate as the sister to a winged warrior named
3 Teddy, my eldest brother, and my daughter who was born
4 with sickle cell disease.

5 I -- I was in a bubble for a very long
6 time. My daughter got excellent care. My mom managed
7 to keep my brother alive for 51 years without all of
8 the great things that we had now. And I -- I just
9 thought everybody had what I had in my life.

10 And I was very excited about gene and
11 cell therapiesJ because I wanted to have my daughter
12 healed, and I truly, truly believed in science.

13 And when I was little, my mom would
14 say, you know, as we were going -- leaving the prayer
15 circles, "God is good, but science is going to fix
16 it." And at 7 years old, I told her I was going to
17 the FDA. Don't know where I got -- got that from, but
18 I was going to the FDA.

19 So I was going along, and all excited
20 about a cure, and I got a call to go look for someone
21 who was having a crisis and was at the hospital with

1 no care. And I got there and there was a young woman,
2 and she was in the ED, and she hadn't -- she had no
3 water, she had no -- you know, no IV bag. All the
4 things I expected to see.

5 And both her -- her ankles were wrapped
6 in, like, a kind of funky looking wrappings. At that
7 point I didn't even know about leg ulcers. And so I
8 didn't know really, really about them, but the
9 bandages were dirty. So I said to the doctor, "Look,
10 look, why haven't you guys done anything? Look at her
11 bandages."

12 And he said to me, "Oh, she's -- she's
13 just here for pain meds." I said, "No, no, look at
14 that." So he then, in front of me, ripped the bandage
15 off, and I could see the skin and the openness of the
16 wound.

17 And she screamed. And he looked at me
18 and said, "See, I told you. That's all dead tissue
19 and she's just play acting." So that was my
20 introduction to leg ulcers.

21 A while later my daughter developed

1 ulcers, an ulcer. It was the combination of
2 having -- they couldn't find any veins, so they used
3 her ankle.

4 Then she developed a -- an ulcer from
5 that, and I was like, "Whoa, this is my kid. She's
6 got an ulcer." And they were like, "Oh."

7 One person said, "There's nothing you
8 can do." And I said, "Of course there's something I
9 can do." Right? Of course. What do you mean there's
10 nothing?

11 So we went to her doctor and, of
12 course, I said, "What are -- what are you doing? What
13 can be done?" And he said, "Well there's this thing.
14 We can use a wound vac, but that requires that she be
15 hospitalized for six weeks."

16 I was like, "Good." So we had that,
17 and that was great. And that was my real kind of sort
18 of introduction.

19 Then I took in a friend of hers who had
20 a child who had leg ulcers, and lived with me for a
21 while, and I was the one who took her for wound care.

1 And it was the changing of the -- the
2 bandages. It was -- it was amazing, 'cause I kept
3 saying, "Well, we know that the wound vac works." And
4 they were like, "No, no, no, we have to do this first
5 and we have to do that first."

6 And she would get a little bit better,
7 and then she would -- it would open again. And I --
8 you know, I -- I was just amazed that I could not move
9 that any faster. I'm a master, master communicator,
10 but I couldn't move it faster.

11 And we would -- finally, we would sit
12 down and we would talk about things. And she wanted
13 to date. She was young, she was beautiful, but she
14 couldn't go anywhere. She couldn't do anything. She
15 had a 5-year-old child who said, "Mom, you smell."

16 And so it was kind of a -- how can I
17 say? It was such a sad time in my home, because she
18 was there with me and we were experiencing her getting
19 a little bit better, and then it would get worse, and
20 then I would fight.

21 And, finally, after close to eight

1 years, we did get a -- finally, we got a graft that
2 worked. But my question was why did it take us so
3 long to get it? Right?

4 So in -- in -- trying to figure out
5 what's the best part to -- to communicate.
6 Everybody's done a great job talking about how it
7 interferes with your life.

8 It interferes with how you're
9 perceived. I go back to that first person all the
10 time and I think about how the doctor just said, "Oh,
11 you're a drug addict 'cause you want pain -- and that,
12 and you've been on the streets and so now you have
13 open wounds. Oh well."

14 I guess it was for all of us, the lack
15 of really being educated about sickle cell and wounds;
16 right? So many people said, "Well, we can just cover
17 it up." But unless you do a deep dive like we've been
18 talking about today, you don't know everything that's
19 involved in it; right?

20 Not treating the underlying problem,
21 right, makes everything else we do moot. So we have

1 to do -- to do all of it. And I'm trying not to get
2 too teary here.

3 Anyway, so if we were to really, as a
4 community, come to you, to the FDA, we would say,
5 first, think of you -- thank you for what you're
6 doing. Thank you for including us here. Thanks for
7 looking at us as something other than a simple
8 disease.

9 And hope that the whole thing that
10 you're doing and trying with this -- this kind of
11 thing is not dividing us from other humans by disease.
12 That that whole focus is just amazing.

13 All right. So let's talk about
14 clinical trials. For years, for us in sickle,
15 clinical trials have been all based around only pain.

16 And unlike many of the things we talked
17 about today, people with sickle cell are born with
18 pain, born into pain. So we understand how pain
19 works. We have a high tolerance for pain.

20 But it's the quality of our lives that
21 are really, really most important to us. It is being

1 able to interact with the -- how can I put it -- the
2 mechanism that's going to treat us, that we have to
3 surrender our bodies to, and being treated by people
4 who understand us, treat us with respect, and really,
5 really listen to what's important to us.

6 The concept of measuring; right?
7 Measuring what is life, what is a good life. Many
8 people think -- and our doctors are trained to think
9 that if you just extend life, that's what you're
10 supposed to do. Not looking at the quality of life.

11 Given what happens with wound care,
12 we've seen, we've talked already about all of the
13 interruptions, the -- the -- I just remember them
14 saying, "I can't go out. I can't go to the disco. I
15 can't wear a short dress. I can't take my daughter to
16 the beach."

17 All of those things that conflict
18 and -- and minimize, right, their sense of being or
19 having agency and control over their lives.

20 So in clinical trials, we would like
21 for you to make sure that in the whole design of it,

1 right, that we're putting those types of -- of data
2 points into the study, right, that have to do with
3 quality of life.

4 Yes, I could take my kid to school.
5 Yes, I could go to church. Yes, I could get out of
6 bed. Yes, I feel better. And what is feeling better?
7 It's not just a physical thing. It's a mental and an
8 emotional thing.

9 I would ask that you also include in
10 the trials, if you're collecting data, that we collect
11 data again on quality of life, not just the physical
12 mechanism of what having that treatment, doing that
13 treatment, is doing for you disease wise.

14 And, again, I want to thank you. I've
15 cut my speech -- my talk short because every -- I
16 didn't want to be redundant. So, again, I just want
17 to thank you.

18 MS. BENT: No, and thank you. I think
19 that -- so no, thank you. And I think that that
20 was -- you made some really good points about
21 minimizing the burden of the clinical trial, as well

1 as thinking about endpoints that really are meaningful
2 to the patients. So thank you for that.

3 So now we're going to turn to Janet and
4 Richard on -- who are participating virtually.

5 MS. FRANK: Okay. Hello?

6 MS. BENT: Hello.

7 MR. FRANK: Hello. All right. Yes.

8 I -- I'm here, Richard Frank, and my wife Janet. I
9 want to thank you for the opportunity to speak here.

10 I've been diagnosed with pancreatic
11 cancer stage 4 in August 1923 --

12 MS. FRANK: No, 2000.

13 MR. FRANK: 2023. Excuse me, not quite
14 that old. I also, incidentally, had a misfortune of
15 having a ruptured left Achilles tendon, which led to
16 significant issues with respect to wounds and wound
17 care.

18 And I certainly was an enormous
19 beneficiary of having dedicated wound care with
20 respect to my situation, particularly because the
21 interaction between the chemotherapy I was receiving

1 and the wound care treatment was very much something
2 that had to be negotiated.

3 I had, initially, a clinical trial in
4 the fall of 19 -- 2024 -- 20 -- yeah, 2024. However,
5 I was in a control group in a clinical trial for that,
6 which meant that I wasn't receiving any actual therapy
7 at that time.

8 My oncologist recommended leaving that
9 initial trial in favor of a second trial, which is
10 where we've ended up with, and very, very fortunately
11 this has been a -- a real life changing event for
12 myself.

13 In respect to the mission here is to
14 talk about some practicalities with respect to
15 clinical trials. And for those of you who are
16 involved in this or examining this, I think what's
17 important to understand is, first of all, there's
18 enough practicalities that have to be considered.

19 If you're in a clinical trial, it's
20 very helpful to be -- and you're going to be in any
21 location, whether it's paid parking or transportation

1 to a trial -- trial site location, a meal card if
2 you're -- overlaps your -- a meal card if you're
3 overlapping the meal time.

4 There's also a question of cost for
5 drugs, devices, or medication, supplies, and whether
6 that's being paid for by the sponsor for the clinical
7 trial.

8 You also have to have -- a really
9 important facet of this is to have a trusted contact
10 for the clinical trial, which you're able to go to and
11 get direct answers to many questions that may be
12 raised in your mind with respect to dealing with that
13 trial.

14 When these trial visits are scheduled,
15 it's important that the trial team consults with the
16 patient, and this should not be on your responsibility
17 simply to schedule the trials -- visits itself.

18 There's also, you know, lab work
19 required, and this is important that you have a lab in
20 some close proximity to you and your trial site in
21 order to facilitate doing that. And there are some

1 remotes but most should be in person to the trial
2 site.

3 There's tremendous personal
4 satisfaction in that -- involved in doing this,
5 because what you do may potentially have the
6 benefit -- be the benefit, literally, for millions of
7 others in terms of the developments that are conducted
8 in these trial drugs. And that certainly has been my
9 experience.

10 And I can't say too -- enough about how
11 important the wound clinic has been. We didn't know
12 about that at all before we started this.

13 We found it absolutely invaluable with
14 respect to what I was dealing with in terms of the
15 synergy between the clinical trials I was involved in
16 and -- and the wound on my left leg due to the
17 Achilles tendon injury. Thank you.

18 MS. FRANK: Okay. And I'll continue,
19 because I want to focus on some of the general
20 concerns and pieces that need to be in place, we found
21 with the clinical trial, to make it really palatable

1 for the participants.

2 We understand how stressful it can be
3 in a clinical trial, and, of course, the trial team is
4 collecting data all the time.

5 So I -- I will just quote the nurse
6 practitioner who said to us at one point, "Are you
7 living for the clinical trial or are you using the
8 clinical trial to live?"

9 And I think that gets to what kind of
10 quality of life do I have while I'm in this clinical
11 trial?

12 Okay. So general concerns -- will the
13 intervention help? Of course, nobody knows because
14 it's a clinical trial.

15 And what is the duration of the trial?
16 Now, for Rich, he's still in the clinical trial having
17 started it in the end of January of 2025. He's been
18 told he can continue it as long as he wants, and then
19 there's a certain time period past the last enrollee.
20 So he will continue to stay in the trial. In fact, we
21 have a visit tomorrow for the protocols for him.

1 Also, is there a capable and reliable
2 caregiver available to follow the protocols of the
3 home requirements for treatment in the trial? We know
4 with wound care, I have been the -- the wound care
5 giver at home, and it's time consuming.

6 And so you can expect probably in a
7 clinical trial to follow the protocols for a long
8 time. It can be exhausting for both the patient and
9 the caregiver.

10 What are the possible side effects, and
11 are protocols in place for managing these? Now, we'll
12 speak to that because we have had side effects from
13 the existing clinical trial we're in.

14 And the question was is there a 24/7
15 triage number available to the participant? In our
16 case we're fortunate to have that, so we can have our
17 condition -- Rich's condition or side effect triaged
18 by phone.

19 And then if he needs to be seen in
20 person, that is, in fact, facilitated and expedited
21 through the clinical trial team, whether it's

1 emergency care or whatever. So you don't have to get
2 in line at the emergency room.

3 If there are complications, are
4 there -- are all the relevant practitioners able to
5 communicate with each other in a timely fashion? Are
6 they in the same system or on the same electronic
7 medical records platform?

8 This has been kind of a pet peeve for
9 me and for Rich, just because we did have an instance
10 where we had a very major emergency situation that
11 landed us in one emergency room at an academic center.

12 The problem was the communications --
13 even though they were on the same platforms, the
14 communication was just very difficult between the
15 clinical trial team and this other academic center.

16 The decision was made that we transfer
17 up to the clinical trial academic center, because
18 that's where everybody could see everybody else's
19 emails and communicate there, and that we think is
20 really, really important.

21 And I'll add this aside, why is it --

1 to the FDA and whoever else might be listening, why is
2 it -- as we contemplate fragmented healthcare, why do
3 we have health systems across this country that are
4 not on a same or similar EMR platform? It sure would
5 make communication easier.

6 And I will say -- when it comes to
7 emergency healthcare and whatnot, I will say that Rich
8 carries an info sheet, that was provided by the
9 clinical trial, with him when he travels that details
10 the trial he is in, the medications he is on, and the
11 contact numbers. This is so helpful when we leave the
12 immediate DMV.

13 Okay. So next is assuming trial meds
14 and supplies are paid for by the sponsor, what role
15 does health insurance play? Does the sponsor pick up
16 any difference in cost between insurance and what is
17 not covered? Can the trial team make certain there
18 are no out-of-pocket costs billed to the participant?

19 This is important because we know that
20 not everybody is as fortunate as we are to have two
21 coverages. So we are able to get by with zero cost

1 for most -- most everything except some prescriptions.

2 How much time will be needed for
3 visits? Can the clinical team stay on schedule?
4 We've had to juggle our work schedules to accommodate
5 the clinical trial team, and sometimes visits with the
6 clinical trial director kind of throw a wrench in the
7 schedule.

8 So that's something that needs to be
9 considered, and participants, you know, can -- can
10 look at this also before considering whether they
11 participate or not. Of course, participants are
12 screened before joining the clinical trial and we
13 understand that.

14 MS. BENT: Thanks, Janet. I can -- we
15 have about one minute left. Is that --

16 MS. FRANK: Okay.

17 MS. BENT: Are we good?

18 MS. FRANK: Yep.

19 MS. BENT: Okay. Thank you.

20 MS. FRANK: The takeaway is -- the
21 takeaway is it -- it is important to advocate for a

1 loved one and yourself to get what you need in a
2 clinical trial. Patient, caregiver, clinical trial
3 professionals are one team.

4 We would recommend keeping a notebook
5 and taking down info at each and every medical trial
6 visit. Share all your concerns. Ask questions. And
7 it's so much easier to refer back to the information
8 that is contemporaneous, easier to share with PCP, PA,
9 PT, as well as other doctors or nurses who may not be
10 part of the trial.

11 Of course, people have talked about
12 outcomes that they're looking for. I don't need to go
13 over that in a clinical trial.

14 And one last point I will make. It
15 sure would be nice to have a clinical trial
16 clearinghouse for wound care.

17 It is done with pancreatic cancer
18 through PanCAN, and I will say that our oncologist has
19 developed a network of navigators, nationwide
20 navigators, who help patients navigate clinical
21 trial -- the clinical trial maze.

1 I think that would be very helpful for
2 wound care as well. Thank you.

3 MS. BENT: Thanks so much, both Janet
4 and Richard. That was really helpful and really gave
5 us some very concrete things that could be done to
6 make clinical trial participation just more realistic
7 for people. And I think we'll definitely take some of
8 that back.

9 And so now we are going to hear from
10 Corlis, who is also joining us virtually.

11 MS. WATKINS-NASS: Hello. My name is
12 Corlis Watkins-Nass, and I am the co-founder and
13 president of All Things PG, a nonprofit organization
14 dedicated to supporting individuals affected by
15 pyoderma gangrenosum.

16 I am also the administrator of All
17 Things Pyoderma, a Facebook based patients'
18 community -- support community.

19 I have personally lived with PG for
20 eight years. I had chronic wounds for four of those
21 years. So I understand firsthand that this disease

1 affects far more than the skin. It -- it impacts
2 every aspect of a person's life, socially,
3 economically, physically, mentally, and spiritually.

4 I am -- I am incredibly grateful to say
5 that on August 8th I celebrated eight years in
6 remission with no flares.

7 That experience has given me not only a
8 personal perspective, but also a deep understanding of
9 how important effective treatments and clinical trials
10 are to patients and their families.

11 When I think about participating in
12 clinical trials, one of the first concerns that comes
13 to mind is the financial burden of living with -- with
14 chronic wounds.

15 Compensation for trial participation is
16 important, because patients may have to take time away
17 from work, travel significant distances, arrange
18 transportation, and potentially make childcare or
19 other arrangements. These expenses can add up
20 quickly.

21 For patients managing open wounds,

1 there is another layer of preparation. Before
2 traveling, we have to make sure we have an adequate
3 supply of wound care materials available, not only for
4 the duration of the trip, but also in case an
5 unexpected issue or emergency occurs.

6 These are practical realities that can
7 determine whether a patient is able to participate in
8 a clinical trial at all.

9 Another significant concern is the lack
10 of rescue medication, particularly for patients with
11 chronic wounds. For many, the medications they are
12 currently taking may be working. They may finally see
13 their wounds heal, their pain decrease, and their
14 quality of life improve.

15 Asking them to discontinue a treatment
16 that is working in order to participate in a trial can
17 be an extremely difficult decision. One day without a
18 medication that is controlling the wound can
19 potentially result in weeks or even months of
20 setbacks.

21 Having a rescue medication available

1 during a clinical trial could make a significant
2 difference. It could give patients greater confidence
3 that if their wound worsens, there is an established
4 option to intervene.

5 More importantly, it would also allow
6 patients to make a truly informed decision about
7 participation, knowing there is a safety net if the
8 investigational treatment or placebo does not
9 adequately control their wound.

10 The logistics of a clinical trial are
11 also extremely important. Patients want to know how
12 long the trial will last, how frequently they will
13 need to travel, how many in-person visits will be
14 required, and what happens if they experience
15 worsening of the wound while participating?

16 For some living with a chronic wound,
17 frequent travel can be physically exhausting. Extreme
18 fatigue is something many patients experience on a
19 daily basis.

20 If virtual appointments could be
21 offered when medication is not being administered or

1 when an in-person examination is not medically
2 necessary, I believe more patients would be willing
3 and able to participate.

4 Reducing unnecessary travel could also
5 make clinical trials more accessible to patients who
6 are already physically, emotionally, and financially
7 exhausted.

8 Ultimately, I believe patients with
9 chronic wounds would want better treatment options.
10 We want to participate in research. We want to help
11 advance science and make sure future patients do not
12 have to experience what we have experienced.

13 But in order to participate, patients
14 need to feel that the clinical trial recognizes the
15 realities of living with chronic wounds.

16 Financial support, reasonable travel
17 requirements, rescue medication, flexibility in trial
18 visits, and clear communication about what happens if
19 the wound worsens are not luxuries.

20 For many patients, they are the
21 difference between being able to participate and

1 having to say no.

2 Thank you for this opportunity to speak
3 to you.

4 MS. BENT: Thank you, Corlis. The
5 concept -- that was really helpful and really, really
6 informative. So thank you for taking your time with
7 us.

8 We are now going to turn to Chaquira
9 for -- to hear from your experiences and thoughts.
10 Please go ahead.

11 MS. ANDRADE: Hello, everyone. My name
12 is Chaquira Andrade; I'm currently a hidradenitis
13 suppurativa patient, and I've been a patient for the
14 last 16 years. I would like to be able to speak about
15 my experience as an HS warrior going through clinical
16 trials.

17 Clinical trials, one of the top
18 difficult things that can be experienced, as other
19 patients mentioned, was the -- the frequency of having
20 these visits, being able to figure out what you're
21 going to do with your transportation, and making sure

1 that you understand the balance of work and also your
2 personal life.

3 Living with HS, you deal with a lot of
4 different underlying problems that may be able to make
5 these appointments limited to you, but also can be an
6 experience that you have where it can be life
7 changing, just like mine.

8 So, for example, something that can
9 make it easier is definitely a flexible schedule.
10 Being able to either have virtual visits, being able
11 to have transportation assistance.

12 And, also, I would like to highlight --
13 as a social worker for the Department of Homeless
14 Services in New York City, I would like to even
15 discuss the social determinants of somebody's life.

16 And being able to analyze them for
17 everything that's going in their life, based on their
18 housing, their transportation, their means of dieting,
19 how are they -- whether they're participating in
20 government assistance.

21 To be able to make sure that you're

1 just not focusing on how to better somebody's quality
2 of life, but you're able to give them the tools and
3 the resources that's needed to maintain this quality
4 of life.

5 Another logistic that I know that it's
6 very important to be able to understand is patients
7 being able to participate in research and managing
8 those everyday life to life, whether it's a physical
9 aspect, emotional aspect, or even a mental capacity
10 that could play a role in you living with a chronic
11 skin condition.

12 So such as going to wound care, being
13 able to have those unnecessary burdens such as
14 transportation or trying to figure out how you're
15 going to be able to better your health taken off of
16 your shoulder can be able to be a great deal for
17 patients.

18 Another improvement that can be done is
19 the importance of being able to understand that while
20 living with this condition, there is something more
21 than just the physical side of it.

1 We all often deal with severe pain,
2 drainage, odor, and there are multiple things that can
3 be able to play a factor in our mobility.

4 So exercising, walking, socializing, or
5 even wearing comfortable clothes, or being in a
6 setting where you can be able to have that, can be
7 dramatic to the quality of life of an HS patient.

8 Also, considering measuring these
9 outcomes, another additional thing to be able to
10 understand about wound healing is the quality of life
11 and the frustration and the functions that go into it
12 every single day.

13 So, for example, besides the pain being
14 impactful, we deal with mobility issues, sleep,
15 dressing changes, and the ability to participate in
16 daily activities.

17 Lastly, I would like to speak about the
18 research and the understanding and the biggest lesson
19 of being part of a clinical trial. Patients are able
20 to shine a light on their voices and enhance their
21 quality of life with successful treatment.

1 Clinical trials is an outcome that is
2 very important, because research also is considered,
3 whether the treatment helps a person live that better
4 quality of life, or whether it's managing and healing
5 their wounds.

6 Me being able to participate in
7 clinical trials for the last five years, from '20 to
8 '25 -- from 2020 to 2025, and being able to gain my
9 quality of life back, also with a treatment drug, has
10 been the greatest blessing of my life.

11 But most importantly, I don't want to
12 forget to mention my community that gave me the
13 support I needed to be able to have the opportunity to
14 thrive.

15 And thank you so much to the FDA for
16 giving me this opportunity, as an hidradenitis
17 suppurativa warrior, to be able to amplify the voices
18 of my community.

19 MS. BENT: Thank you so much, Chaquira.

20 And so our last panelist today is
21 Laura. We're going to turn to Laura, and then we're

1 going to turn back to our panelists for a few
2 clarifying questions.

3 So please go ahead, Laura.

4 MS. PARNELL: Thank you. I appreciate
5 it so much, Robyn. And thank you for organizing the
6 chronic wound listening session.

7 I'm Laura Parnell. Most -- many of you
8 will know me from my work in the Wound Healing
9 Foundation, but my most important work has been being
10 there for my daddy and my mama as they dealt with my
11 dad's diabetic foot ulcers.

12 There's -- there's a real lack of
13 education and understanding and practicing of the
14 chronic wound care clinicians, and it's a real burden
15 for the wound patients. And almost every single
16 patient all day today has -- has led back to that.

17 What I'm going to talk about now is in
18 the rural areas, this becomes an even bigger burden
19 for rural wound patients.

20 In rural areas, it's not unusual to
21 travel more than six hours, or even go out of the

1 country, in order to receive good wound care by
2 experienced wound clinicians who can think outside the
3 box and realize that this is not going specifically
4 the way it should be.

5 Additionally, the lack of cell phone
6 service and internet access can be a real limitation
7 to your treatment options as well.

8 Until we got the Starlink, we had to
9 drive 30 minutes into town to use the computers at the
10 library in order to access the internet to search for
11 potential answers or look for new clinicians. And,
12 believe me, we went through a lot of clinicians before
13 we found some that could actually listen.

14 When you're dealing with a wound, a
15 chronic wound of any kind -- but in my dad's case, it
16 was a diabetic foot ulcer -- combating wound infection
17 such as MRSA in a rural area was fraught with a lot of
18 difficulties.

19 We had to try to find a hospital that
20 had capabilities and had the antibiotics it needed.
21 And for us, that ended up being about two and a half

1 or three hours away.

2 Also, side effects, such as
3 C. difficile that came after the MRSA antibiotics,
4 having deep vein thrombosis and pulmonary emboli
5 because of too tight casting, these things all became
6 nightmares and were life threatening.

7 And you add the -- the additional
8 trying to figure out what was wrong and go to find the
9 hospital, it was not a situation you want to have
10 anybody to have to go through or repeat.

11 I'll reemphasize what several patients
12 have said that not all caregivers and not all
13 clinicians are created equal. Your wound care will
14 not necessarily be adequate between clinicians. This
15 seems to be even more so in the rural areas.

16 How a clinical trial is broached with a
17 wound patient and their families impacts their
18 willingness to consider participating in a clinical
19 trial. Considering the potential adverse effects can
20 alarm patients.

21 But really the possibility of being in

1 the placebo-only group, which can delay the treatment.
2 It can delay healing. It could possibly increase
3 further deterioration, no improvement. What about the
4 risk of infection? What's the protocol if it becomes
5 infected?

6 Things of that -- those things have to
7 be seriously considered by the family and the patient,
8 because each of these little wins are so hard won, and
9 it does not take very long at all to flip back into a
10 bad setback.

11 Several people have mentioned about the
12 logistics, and, again, speaking from the rural
13 perspective, the logistics of coming and going from a
14 clinical trial can be a huge issue for rural patients.

15 You're asking them to travel, which is
16 not always easy. You're asking them to schedule yet
17 another visit, which can disrupt their week. Try to
18 fit it around all the other doctor's appointments.
19 Everything takes longer to do.

20 It requires more effort and often
21 there's more pain whenever you're going somewhere or

1 doing something new. All of these things have to be
2 taken in consideration as part of that willingness to
3 participate in the study.

4 Travel compensation is needed,
5 especially if you're driving four to six hours away.
6 But if it's that far, I'd encourage sponsors to
7 consider compensation for a hotel too, since it can
8 take all day or two partial days just to get there, to
9 go to the appointment, and then get back home again.

10 This -- this can be done and it has
11 been done. My dad's been in a couple of different
12 clinical trials, and it's doable. But you have to
13 have the right staff and the right mindset, and the
14 patient has to decide that it is the option for them.

15 Patients like my daddy and my mama want
16 to feel valued, and their opinions valued. They don't
17 want to just be another body in a clinical trial.

18 When this is done well, the wound
19 patients that become study subjects can enjoy or even
20 look forward to participating in follow-up evals.
21 They form bonds with the study staff and the

1 investigators.

2 These are things that even now, even
3 after Daddy's been out of the study for a couple of
4 years, they still go back and bring Christmas presents
5 to the study staff. These person-to-person bonds are
6 important, as -- as important as anything else.

7 In remote studies, these person-to-
8 person bonds can be lacking and -- because it -- it
9 forms over time. How easy or how well a coordinator
10 or a doctor can connect with others over the internet
11 or over the phone is an important consideration for
12 remote evaluations.

13 And just, lastly, I'll wrap up and say
14 that in addition to improvement of wound measurements
15 and wound characteristics, a reduction in pain and
16 improved mobility are excellent secondary
17 measurements.

18 To my family, the healing
19 durability -- that is, to not break down and become a
20 wound again -- is a better characteristic to measure
21 than faster healing.

1 This is, obviously, a complicated
2 dynamic. And, certainly, healing faster has some
3 benefits, such as lower colonization and infection
4 risks, but so does durability. And this allows the
5 body to remodel and strengthen the wound scar and not
6 break down over and over again.

7 I want to thank everybody for their
8 time today and letting me share our family's wound
9 experiences with you. And I'd be more than happy to
10 take any questions you might have.

11 Thank you very much for this
12 opportunity.

13 MS. BENT: Thank you so much, Laura.
14 That rural dimension of the experience, the six hour
15 drives, the internet access or lack of internet access
16 until you had -- able to access Starlink, and other
17 things are really -- just kind of put things in
18 perspective for those of us who are living in the
19 metropolitan Washington, D.C., area. So really
20 appreciate that.

21 And so thank you to all of our Topic 3

1 panelists: Adrienne, Janet and Richard, Corlis, Laura,
2 Chaquira. Your perspectives were really -- will
3 really directly inform how we think about clinical
4 designs for -- or clinical trial designs for
5 nonhealing chronic wounds.

6 I would like now to turn to our
7 panelists, our FDA panelists, our -- and WCCC
8 panelists, and our newly arrived NIH panelists, and
9 just see if you have any clarifying questions.

10 I think, Sarah, did we want to
11 start or -- okay. We're going to start with
12 Dr. Mejia. Then I know Dr. Driver has a question.

13 And I know, Sarah, you have a question.

14 So we'll just work the way down. And
15 for our panelists, if you -- who are online, if you
16 would like to answer the question, any of the
17 questions, clarifying questions, please feel free to
18 just turn on your camera and we'll come to you one at
19 a time.

20 And if anyone in the room who is a
21 patient or caregiver would like to respond to some of

1 the questions, please raise your hand and we will have
2 one of our mic runners bring it on over to you.

3 So please go ahead, Dr. Mejia.

4 DR. MEJIA: Sure. Thanks.

5 So this question is first directed
6 towards Corlis, but if anybody else wants add
7 clarification, that would be great.

8 So most of the clinical trials we see
9 involve standard of care in the control arm to ensure
10 that participants are still getting high quality care
11 even if they don't get the investigational product.

12 Can you explain or tell us a little bit
13 more about your concerns around not receiving
14 treatment or needing rescue medication?

15 MS. WATKINS-NASS: So I can speak from
16 the perspective of having lived with pyoderma
17 gangrenosum.

18 What I am receiving from many of the
19 folks that are in the support group is they are so
20 scared because the medications that they are currently
21 on seem to be working, and so when they are being

1 asked to participate in a clinical trial and
2 everything is taken away from them, that in itself is
3 more than enough for them to say no.

4 But what they are telling me is -- is
5 if there is a rescue drug that's available, just in
6 case they happen to start flaring, then they would be
7 more willing to be able to actually participate in a
8 trial.

9 MS. BENT: Okay. Thank you.

10 All right. Was there anyone else who
11 wanted to speak to that a little? All right. So I
12 see -- so let me go to Adrienne, then Laura, then
13 Chaquira. And go ahead.

14 MS. SHAPIRO: So one of -- one of the
15 things we found that's been really helpful for this is
16 that in -- as part of your clinical trial design, you
17 have a -- a process for interacting with the -- the
18 care provider of that person.

19 So that you've already worked out how
20 things are going to -- how you're going to communicate
21 and -- and I -- I guess, increase the comfort level of

1 not feeling like your care is -- is going to -- to
2 drop out.

3 The other thing is we found that in the
4 actual design of the trial, that it's really important
5 that you have a person that's there from the very
6 beginning of the design, who is either a patient or
7 caregiver, but someone who has lived with the disease.

8 So you can make sure that in the whole
9 design, from the very beginning, you're capturing all
10 the things you need in order to -- to ensure a more
11 effective and -- and successful trial.

12 MS. BENT: Thank you.

13 Let me think. I think I said Laura
14 next; right?

15 MS. PARNELL: So I would just mention
16 that, at least for diabetic foot ulcers, whenever we
17 discussed it as a family, it was not something that we
18 wanted to do as far as standard of care, because you
19 can actually lose some progress.

20 For some people -- 20 percent of people
21 will improve on standard of care, but we just did not

1 feel that the risk was worth the benefit.

2 Studies that my dad has participated
3 in, it was for ophthalmology. It was actually one of
4 those things, the standard of care was a already
5 approved treatment versus a treatment that was more of
6 an advancement potentially.

7 So for us, it was just a -- going back
8 to the standard of care was just a no go starter.

9 MS. BENT: Great. Thank you.

10 And Chaquira?

11 MS. ANDRADE: Yes. Hi. I would just
12 like to mention being able to live with HS, sometimes
13 it can be a very invisible disease.

14 And sometimes we don't have the actual,
15 you know, caretakers or caregivers surrounded by a
16 warrior, just for the fact that this is something we
17 try to hide for a long period of time, especially the
18 fact that it comes with so much embarrassment, so much
19 of the unknown.

20 So I just wanted to make sure that I
21 just shared my experience on how I was actually one of

1 those patients that didn't have anyone. And I leaned
2 on my medical team and leaned on my dermatologist to
3 be able to help me.

4 And understand that, going back to
5 the -- the social determinants of life, there can be
6 things that can be put into place for me to be able to
7 be understood and have that support system.

8 Along with being able to speak about,
9 like, the step therapy act where you have to try all
10 these medication drugs to be able to get the one that
11 your doctor knows is right.

12 So just being able to have someone on
13 the back end that can be able to understand your
14 journey and know what you have encountered, and what
15 may work, and what's available to you can also be able
16 to help your quality of life, and comfort somebody to
17 be able to participate in clinical trials. Because it
18 gave me so much hope.

19 MS. FRANK: I -- if I could -- if I
20 could add, also, that, you know, when Rich was in a
21 clinical trial, he was -- the first one was watch and

1 wait or immunotherapy. And the watch and wait is when
2 he developed problems based on CT scans and -- and
3 blood testing.

4 Trial number two compared two different
5 standards of care in combination with the clinical
6 trial drug. And so there was a way to really layer
7 this, so that both cohorts could be evaluated on the
8 clinical trial drug with a given standard of care.
9 It's just there were two different standards of care.

10 Okay. And then the second thing is
11 that I -- I agree with everyone who said it's
12 important to have a support person.

13 And in our case it was an oncologist
14 who was kind of keeping watch over things. He
15 happened to know all the clinical trials, and he was
16 in contact with the clinical trial team.

17 And I think that by doing that, he
18 could guide us in separate visits and whatever else he
19 chose to do outside of the clinical trial to guide us
20 and say, "Yeah, I think this is a good path. Yeah,
21 I'm going to talk to the clinical trial team about

1 this."

2 And he even gave us some additional
3 information about resistance to the clinical trial
4 drug based on his journeys to talk to other
5 researchers.

6 So I think that piece of having a
7 support person, not only somebody who is outside the
8 trial who is supporting you and monitoring things, but
9 also that -- Rich alluded to the clinical trial nurse
10 who is there for logistics and questions and
11 coordination and guidance.

12 That is so important. Because I think
13 I communicate with the clinical trial nurse once a
14 week, and she does check in on us. So I think that's
15 so important for making the patients really, really
16 feel comfortable in the clinical trial.

17 MS. BENT: Great. Thank you very much.

18 All right. Sarah, did you have a
19 question you wanted to ask?

20 MS. ROSENBERG: I -- I do. Thank you.

21 So I've heard a lot about quality of

1 life, but there's a lot that goes into that, and we've
2 heard from a lot of different experiences with
3 underlying diseases that quality of life can look very
4 different for each person.

5 So I'd like to get a little more nitty
6 gritty about it. As a measurement scientist, it's
7 very hard to measure quality of life. But I was just
8 curious as to what specific signs or symptoms most
9 affect your quality of life?

10 So for example, if you have pain, is it
11 pain reduction during dressing changes that is
12 meaningful? And I was just hoping one of the patients
13 could actually just elaborate a little bit more about
14 what that looks like to them.

15 MS. SHAPIRO: Well, I know from our --
16 in the sickle cell community, if the wound is causing
17 lots of pain, then that will have you -- will many
18 times throw you into crisis.

19 So then you have the VOC happening at
20 the same time that you're -- you're having an eruption
21 from your ulcer. So, absolutely, calming that down

1 and keeping it under control would make a big
2 difference.

3 MS. BENT: Thank you.

4 Chaquira, did you have something you
5 wanted to say?

6 MS. ANDRADE: Yeah. I was just going
7 to say specifically for an HS patient dealing with
8 wound care, you say that you can't measure the quality
9 of life or you don't know how it may look if, you
10 know -- for -- for us specifically dealing with the
11 skin and dealing with drainage and the odor, I feel
12 like you can see the improvements within what we're
13 able to do in the improvement.

14 So, for example, mobility. If somebody
15 was not able to lift their arms up all the way or
16 extend it to a certain point, if you're measuring how
17 far and how better they're going with their mobility
18 to be able to extend their arm.

19 Or if the drainage is -- is -- used to
20 fill up a whole bandage and now it's just a dot or
21 two. The odor, if -- if she's using a specific body

1 wash or -- or a product that is available for an HS
2 patient and she's seeing better results and -- and
3 less odor.

4 So it's those kind of things that we
5 would like to measure, and we would like other people
6 to understand. With those measurements we could be
7 able to understand if we are improving a condition or
8 if it's getting worse.

9 And especially with the nodule count, I
10 remember participating in clinical trials and being
11 able to know that my treatment drug was working for me
12 because my diagram of my body figure, my lesions, and
13 my nodules, and my boils, and the flares that was
14 occurring was decreasing and was actually healing.

15 And that's how I was able to understand
16 that my quality of life was being improved.
17 Especially that we deal with surgeries and think that
18 we need wound care to be such a factor of and be
19 measured to the best ability to see the improvements.

20 MS. BENT: Thank you.

21 And then we'll go to Corlis, and then

1 over to Dr. Driver for the next question.

2 Corlis, go ahead.

3 MS. WATKINS-NASS: All right. As a
4 person living and have lived with PG, the pain
5 perspective is -- is -- it's most important.

6 What we know about PG is the pain is
7 oftentimes unbearable, especially if you are in the
8 midst of having an infection, it literally feels like
9 your body is on fire.

10 Oftentimes when I know -- I knew that I
11 had an infection by the level of pain that I was in at
12 that particular time. There was always pain but there
13 were different levels of it.

14 And when it got to the point where I
15 could no longer take the pain -- because I -- you
16 know, having the disease, you already have a high
17 tolerance for a pain level.

18 But when I got to the point where I
19 could no longer take the pain, I knew at that
20 particular point that that was time for me to get
21 myself to the hospital because I had an infection.

1 And once that infection was able to be
2 able to gotten under control, then we were able to
3 start the healing process again.

4 So that and also the smell. It is
5 quite embarrassing when you are out. I was still
6 trying to teach at the time, and just the odor that
7 goes along with you wherever you go, it's -- it's
8 embarrassing and it just makes you want to retreat and
9 not go out to see anyone.

10 And you just want to stay at home
11 because, you know, just having that was just so
12 embarrassing. So those two things are of utmost
13 importance for those of us with PG.

14 MS. BENT: Thanks so much. And I can
15 only imagine trying to teach in the best of times, let
16 alone with dealing with nonhealing wounds. So thank
17 you for sharing that.

18 So I'm going to turn to Dr. Driver
19 who -- because I think you had a question.

20 And then I know Dr. Jones has a
21 question as well. So let me come to you.

1 DR. DRIVER: Yeah. So my question
2 is -- so we know, because we've been studying, the
3 percent of patients that are actually allowed in
4 clinical trials to be very low. Some people say
5 10 percent. It's actually more like 2 or 3 percent.

6 So I'd like to know from the patients
7 and caregivers, in your experience, what has excluded
8 you from clinical trials?

9 Because we are moving, actually, fairly
10 quickly on redesigning clinical trials to include more
11 patients that are representative of everyday patients
12 seen in our clinics.

13 MS. SHAPIRO: So I can say that in the
14 last 10 years -- 'cause it was 10 years ago, I had my
15 first clinical trial where I was an advisor -- that
16 trials that have put in support for the patients,
17 the -- the psych social support and the financial
18 part, those really are an incentive to know that
19 you're going to have that -- not have that burden;
20 right?

21 Because the other thing is when -- how

1 can I put it? Okay. The doctors are the other thing
2 that happens; right? So many times you don't know
3 about the trial, and your doctor has to decide whether
4 or not you are, like, trial worthy; right?

5 And not understanding that you may miss
6 doctor's appointments because you're not well.
7 There's -- there's -- one doc said to me, "Well, they
8 didn't keep their appointments."

9 And I'm like, "Well, you're having them
10 come, and they have to pay \$22 for parking, and gas
11 for coming for 45 miles." And, initially, the doctor
12 didn't think -- well, that's no big deal; right?

13 So having those sorts of things in
14 place. And I think we're -- you know, again, these
15 kind of conversations are driving us towards that.

16 MS. BENT: Thanks, Adrienne. Is there
17 anyone -- any of our panelists online who want to
18 speak to what -- kind of what barriers have you
19 encountered as far as not being able to be eligible
20 for clinical trials?

21 I'll also turn to the people in the

1 room and see if there's anyone who had wanted to
2 participate in a clinical trial but had been not
3 eligible, and who wanted to share that information.

4 I'm not seeing anyone, so I'm going to
5 appeal to our online community.

6 MS. WATKINS-NASS: Yes.

7 MS. BENT: Oh, wait, suddenly I see
8 three people. Excellent. All right. Let me go
9 Laura, Chaquira, Corlis. I'm not sure what order you
10 went in, so I apologize if that's not the correct
11 order.

12 MS. WATKINS-NASS: That's okay.

13 MS. PARNELL: I was actually last, but
14 I'll be really brief.

15 For us, it was the weekly -- needing to
16 come in weekly. And that just was not realistic for
17 us in -- in where we were, particularly given that we
18 were going to have to drive, you know, five hours just
19 one way and then five hours back. On a weekly basis,
20 that just didn't work.

21 MS. BENT: Great. So it was more of a

1 logistics issue then that kept you from being eligible
2 in, like -- from your -- because of your life, and not
3 as much of a -- like, a lab value or a concomitant
4 medication or anything like that?

5 MS. PARNELL: It -- It was both the in-
6 person evaluation as well as the lab draws.

7 MS. BENT: Great.

8 MS. PARNELL: Because the nearest lab
9 is, like, two hours away. So we just couldn't comply
10 with their protocol.

11 MS. BENT: Yeah. That feels like a
12 significant burden. So no, thank you.

13 All right. Chaquira?

14 MS. ANDRADE: For me, I could be able
15 to just speak on how when you're living with
16 hidradenitis suppurativa, a lot of, like, the outcome
17 to be able to remove the tunneling and the flare is
18 surgery.

19 And I did find that while on clinical
20 trials I was exempt from, like, having deroofings, any
21 surgeries, or in-site steroid injections.

1 So just those limitations -- you know,
2 my doctor had to plan accordingly before me going on
3 clinical trials to be able to get my mobility and be
4 able to have these procedures scheduled in a matter of
5 time for me to still be able to have the opportunity
6 to go into clinical trials.

7 So also just highlighting when you know
8 that there's a different option for your warrior to be
9 able to take during the matter if you're still trying
10 to find her the hope of the treatment drug. So that
11 was one of my limitations and barriers that I faced.

12 So I'm just grateful that I had the
13 time and my body had the strength to be able to allow
14 me to have those surgeries and then participate in
15 clinical trials, because I couldn't do two things at
16 the same time that I knew was going to be effective to
17 me being able to have my quality of life.

18 MS. BENT: Thank you. I think that was
19 really good information. We really appreciate it.

20 Corlis?

21 MS. WATKINS-NASS: One of the things

1 that we are concerned about is the lack of awareness
2 of the trials themselves.

3 The dermatologists not knowing that the
4 trials are out there to be able to let their patients
5 know that there are the trials, that they hopefully
6 will be able to get into them.

7 So if we had a way of communicating
8 that information, you know, that would be most
9 helpful. If there was a -- a website -- and I know
10 there -- there are.

11 But most of the patients don't know
12 exactly where to go to see what trial that they would
13 be able to participate in. So just lack of awareness.

14 MS. BENT: Thank you. And I know Janet
15 mentioned that earlier as well, so that is a recurring
16 theme as well.

17 Janet, please go ahead.

18 MS. FRANK: Yeah. Yeah. I just wanted
19 to say I think that if you go to the websites and look
20 at the clinical trials -- because we did in the hunt
21 for a clinical trial that would help Rich -- it's

1 really hard to understand. They're not user friendly.

2 And I think that's why it's really
3 important for this idea of navigators or a -- a
4 physician or nurse who has expertise in this area to
5 guide -- guide us.

6 And -- and let me just say one other
7 thing. You know one of the issues that has come up
8 repeatedly is that if there's a complication -- and
9 comorbidities plays a huge part in clinical trials;
10 right?

11 Because some clinical trials will allow
12 you in with certain comorbidities and others will not.
13 Some will allow you to continue in the clinical trial,
14 even though you have developed new comorbidities,
15 because you entered the clinical trial without them.

16 And so one of the issues that has come
17 up repeatedly is we have to talk -- if something comes
18 up, we have to talk to the clinical trial team to see
19 if medication X is under the protocols.

20 And that necessitates a call to the
21 sponsor by the clinical trial team. And that can

1 delay treatment some. Because sometimes it takes a
2 day or so to get a response from the sponsor.

3 So there are all kinds of logistics
4 that -- you know, when I've heard multiple people say,
5 you know, that they -- they are reluctant because they
6 have made progress with their wound care.

7 And we've had two. Fortunately, we --
8 we've had good coordination between the clinical trial
9 team and the wound care specialist. So we're working
10 in tandem.

11 But it's a balance, and I think getting
12 that -- finding that balance, whereby you can still
13 participate in a clinical trial team while also
14 dealing with other comorbidities or other issues,
15 wound care or whatever, is so important for patients.

16 And I just want to say that it is -- it
17 is something that has come up repeatedly.

18 MS. BENT: Thanks so much, Janet.

19 So I'm going to make an appeal --
20 because we've heard from a variety of our panelists
21 about their thoughts. We realize that we don't

1 have -- we have some from Laura.

2 But if there's anyone who is listening
3 to the meeting who has thoughts on this, particularly
4 if you have a diabetic foot ulcer or something like
5 that, if you wouldn't mind sharing -- like, calling in
6 to share your perspectives on what would be meaningful
7 improvement, especially from a quality of life
8 standpoint, that would be really helpful.

9 The number 1-800-527-1401. That would
10 be -- we would be appreciative to kind of hear your
11 perspectives as well, because we're noticing that
12 there are slightly different things that matter to
13 people with different conditions, and just want to
14 kind of cast a wide net to get a broader
15 understanding.

16 While we're waiting on -- while we're
17 waiting to hear from others, I would like to turn to
18 Dr. Jones.

19 I think you had a question that you
20 wanted to ask.

21 And then we will move to polling

1 questions. Very exciting.

2 DR. JONES: Okay. Well, thank you.

3 And I want to -- I really want to thank all the
4 participants for sharing their stories, and I'd also
5 like to thank the FDA for sponsoring this in this
6 format of listening. I've listened and hope we can
7 really include that in the research we do at NIH.

8 So I have a question about the duration
9 of clinical trials. We've gotten a lot of good
10 feedback about what people like and don't like about
11 trials.

12 So this is about how you weigh the
13 duration, how long a trial will last. I mean there's
14 a time commitment, which would be a negative.

15 On the other side, a longer trial, you
16 might really then understand the full course of the
17 disease, the quality of life, and for diabetic foot
18 ulcers, you know, the durability of healing.

19 But there's a kind of balance there.
20 So I'd like to hear from our participants on this
21 question. Thank you.

1 MS. BENT: And as a spoiler, we will
2 also ask that as a polling question after, but I think
3 the details -- that would give us just a very blunt
4 tool.

5 I think hearing from you all about your
6 thoughts about trial duration and being able to dig
7 deeper into kind of your rationale for what you're
8 thinking would be very helpful.

9 So do we have anyone who would like to
10 talk to us?

11 All right. Go ahead, Janet.

12 MS. FRANK: Okay. So what I would say
13 is -- and I know that in wound care it's different
14 than in cancer; right? In cancer you can have CT
15 scans, you can have blood measurements, and whatnot.

16 But as long as there is some sort of
17 feedback to the patient as to what is improving or
18 what is changing, I think that's so important.

19 And I mean, you know, feedback every
20 single visit. That is helpful for a patient to know
21 that -- that their participation in the clinical trial

1 is making headway. Okay? I think the -- the hardest
2 thing is to not know.

3 And I think as -- as clinical trial
4 patients, we want to know -- I know my husband wants
5 to know -- how am I doing compared to last week, last
6 month? Is there progress? Is there change, positive
7 change? Is there negative change? And that really
8 makes a difference for a patient.

9 MS. BENT: Great. Thank you. And I
10 think to your point, it feels like one of the main
11 things that we're hearing today is the importance of
12 communication in so many different realms. And so I
13 think that's really -- that's -- we hear you.

14 Laura, did you have something? You
15 disappeared from my screen, but --

16 MS. PARSELL: No, I just wanted to
17 mention that whenever we were looking at duration, as
18 long as the -- the visits, the evaluations and things
19 of that nature weren't excessive in our mind, so
20 maybe, like, a once a month visit.

21 But we would be happy to sign up for

1 two years, a once a month visit, as opposed to weekly
2 for six weeks. It -- it just fits into our lives
3 better that way.

4 So, you know, it's not always about get
5 as much information as you can in six weeks.
6 Sometimes that -- that longer course is the better way
7 of going about for patients. And certainly you would
8 get -- you capture different data, but sometimes we
9 want to see more of what's going on.

10 With wounds, you know, sometimes a
11 month can be a whole lifetime in the span of a wound,
12 at least to the patients. So that doesn't work for
13 everybody, but from a rural perspective, it would.

14 The other thing I would mention is the
15 communication that Janet had mentioned. Whenever you
16 hear, "Hey, you know, your -- this is looking a lot
17 better. You've improved this much. These things --
18 you know, everything's looking really good. There's
19 no infection."

20 Those are the types of things that not
21 only make you feel good, the fact that you're doing

1 that, but it gives you that hope that normalcy is on
2 the horizon. You haven't gotten there yet.

3 It's almost like trying to chase a -- a
4 pot of gold at the end of the rainbow. It -- the
5 rainbow just keeps moving, but eventually you can
6 capture that pot of gold. And, fortunately, for my
7 dad, he was able to get both of his DFUs healed.

8 But I would say duration, you know,
9 setting a -- an expectation of X amount of weeks isn't
10 always necessarily an endpoint that -- that patients
11 would agree with.

12 MS. BENT: Thanks so much. And that
13 feedback that you mentioned, and Janet mentioned, and
14 Jae mentioned earlier with them saying that they
15 celebrate everything, celebrate every success, is
16 really, I think, so important.

17 So let's see. Maybe it's time for
18 us -- and I know we've exhausted everybody, but we're
19 going to go to polling questions and see how many
20 people are still hanging with us.

21 We've got just about 20 minutes left,

1 so we'll go through the polling questions. Please be
2 ready for them, and we will -- there's three of them,
3 just to give you some context. And then we will turn
4 to some of our callers on the phone.

5 So let's start with polling question
6 number 1, which is: "Would you join a study testing a
7 treatment that improved symptoms; for example,
8 improves odor, reduces itchiness, or increases
9 movement, but did not always close the wounds?"

10 And the answers options are: "yes, no,
11 or not sure." I will remind you that there is a bit
12 of delay, but, hopefully, more than one person will
13 respond. Woo hoo.

14 All right. Right now we've got a
15 "yes," "no," and "not sure." And I can appreciate the
16 "not sure." There needs to be a few more details,
17 perhaps, before you could really make a significant
18 commitment to something like that.

19 All right. But it does look like
20 there's openness from at least a good number of people
21 to something that is really working on those symptoms.

1 And so that is really helpful information.

2 All right. All right. Let's move on
3 to the next question: "How long" -- and I kind of lied
4 about there being a clinical trial duration polling
5 question. Apologies. I'm about to be outed by
6 myself.

7 "How long would you be willing to wait
8 to see results from a wound treatment before you would
9 consider it not working?"

10 Would that be: "2 to 4 weeks, 6 to 8
11 weeks, 10 to 12 weeks, 16 to 20 weeks, or 'it depends
12 on the wound type and severity?'"

13 All right. So right now we're seeing a
14 majority of the people saying six to eight weeks as a
15 time to give it a chance to work.

16 All right. And let's now move to our
17 final polling question before we go to our callers on
18 the phone: "What is the biggest barrier to joining a
19 clinical trial for wound care?"

20 And please select one answer,
21 understanding that all of these probably apply, but

1 what is the most significant: "transportation to the
2 trial site, eligibility criteria, mistrust, time
3 constraints, lack of information, fear of side
4 effects, fear of receiving inactive treatment, other
5 barriers not noted -- not mentioned."

6 All right. So what we're seeing is the
7 concern over receiving an inactive treatment is really
8 what people are saying. It seems to be the largest
9 barrier or concern.

10 We're also seeing fear of side effects
11 as our second -- oh wait, no, eligibility criteria.
12 Sorry, the letters are very small. Eligibility
13 criteria being the most significant, followed by fear
14 of inactive treatment, and then fear of side effects.

15 So thank you, everyone. This was
16 really helpful and it helps us to -- kind of, again,
17 it's to help with our discussion. It's not a
18 scientific survey, but it does give us an idea of what
19 people are thinking; and we do really appreciate that.

20 And so with, that I'd like to turn to
21 our callers. We have two callers on the line, and so

1 we'll take -- I'm going to ask you -- I know you've
2 been waiting for a while. I'm going to ask you to be
3 brief so that we are able to end on time and we can
4 get both of you in.

5 And then we'll turn to Ethan for the
6 comments online, and then we will go to closing
7 remarks. So with that, I'd like to go to our caller
8 on line one.

9 UNIDENTIFIED SPEAKER: Hi.

10 MS. BENT: Hello. Please go ahead.

11 UNIDENTIFIED SPEAKER: Oh, am I
12 supposed -- am I supposed to respond to a particular
13 prompt or --

14 MS. BENT: So if you have thoughts on
15 anything that we've been talking about, please feel
16 free to answer questions, especially around what would
17 be a meaningful improvement to you related to your
18 wound.

19 But if there's anything that you would
20 like us to specifically hear from you, an aspect of
21 your experience living with a wound or caring for

1 someone with a wound, please feel free to share that
2 as well.

3 UNIDENTIFIED SPEAKER: Thank you for
4 the clarification. I will make it brief.

5 I am speaking on behalf of both my
6 mother who is 79 with lupus and comorbidities, my aunt
7 who is 91 recently placed on hospice care in a nursing
8 home.

9 My mother's wounds come from what has
10 turned into acute kidney disease. They include
11 excessive scratching to the point of breaking skin
12 throughout the body, and legs were weeping
13 uncontrollably.

14 It took some time to get it controlled.
15 It took three specialists. If there was something
16 that could have helped her, she -- she would have
17 absolutely done a clinical trial.

18 What she would need to know would be
19 would she be able to maintain her lupus medication,
20 her heart medication, her blood pressure medication,
21 et cetera? Because she's not able to go off of

1 those -- those pills.

2 And what would the time frame look
3 like? Because she has macular degeneration, so
4 she -- she depends on my husband and me for transport,
5 and to be there with her, and her eyes.

6 Then going to my aunt who is 91. Right
7 now, they're not really looking to heal her, per se.
8 She has a wound that does not heal. She has Factor V
9 Leiden, and it has left her in bed immobile.

10 And because of hospice's guidelines --
11 she's in Arizona -- she's not able to try to achieve
12 healing, rather comfort. And she is able to pull
13 herself off of hospice if she chooses, but she'll lose
14 certain aspects of her care.

15 So she can't move because of that
16 wound, the debridging is a terrible process for her,
17 and she would like to be able to move but she cannot
18 do anything until that wound is healed.

19 And we would like to see some
20 improvements for my aunt in that end as well, just to
21 help her live out the rest of her life without the

1 pain that she's experiencing, to be able to at least
2 go through physical therapy for comfort.

3 And I -- I think that's -- that pretty
4 much covers. Thank you.

5 MS. BENT: No, thank you. I think
6 the -- this is a perspective that we hadn't heard
7 before, and it is really helpful to hear that. So
8 thank you for taking the time to speak with us.

9 All right. We are going to go to our
10 last online caller, Mark.

11 MARK: Hi. Thanks for taking my
12 comments today. So as someone living with pemphigoid,
13 I would consider participating in a clinical trial if
14 I believe that the treatment could actually improve my
15 daily life, not just my disease score.

16 So I think what would motivate me most
17 would be the possibility of healing my wounds faster,
18 preventing new blisters, reducing the pain and
19 itching, and spending less time every day on wound
20 care.

21 I would really want to understand how

1 the treatment works, how it is given, and the
2 potential side effects, and how quickly it might -- I
3 might expect to see some benefit.

4 I would say that the logistics of a
5 trial would also matter enormously. You know, the
6 frequency of the visits, how long they last, distance
7 to travel. Because, you know, having to travel when
8 my skin is painful or I have difficulty walking can
9 really make participation very difficult.

10 So flexible scheduling, remote visits
11 when possible, maybe local testing, and assistance
12 with travel would make participation much easier.

13 And I'd also want the study team to
14 understand that pemphigoid can be very unpredictable,
15 and that a flare or difficult wound should not
16 automatically make it impossible for me to
17 participate.

18 I would say one of my biggest concerns
19 would be having to stop a treatment that is helping
20 me, or go through a period of where my disease could
21 get worse, just to participate in the trial.

1 And I think most importantly, I would
2 want the clinical trial to measure what matters to me
3 as a patient. Did my wounds actually heal? Did I
4 have fewer new blisters? Did my pain and itching
5 improve? Could I sleep better or walk more easily?

6 Be able to just take a shower or dress
7 without fear putting clothes on, and spend less time
8 changing dressings.

9 And I really would also like to know
10 whether I could return to normal activities, like
11 eating, working, socializing, and spending time with
12 my family without constantly thinking about my skin as
13 an issue.

14 So for me, successful treatment is not
15 simply an improved disease score. It means healing,
16 regaining my independence, and getting my life back.
17 Thank you.

18 MS. BENT: Thank you. Thank you very
19 much. And that is, I think, a theme that we have been
20 hearing from a lot of people.

21 So now before we head into our closing

1 remarks, I'm going to turn to Ethan to hear the
2 comments that you all have shared with us online, and
3 thank you so much for that.

4 So please go ahead, Ethan.

5 MR. GABBOUR: Yes. Thank you. So we
6 received a couple of comments that answer some of the
7 questions the panel had posed.

8 One person reiterated that receiving
9 standard of care does not ensure high quality care for
10 the control arm. The fear of going backwards if you
11 get into a control arm is a real concern.

12 And something that can impact
13 participation is access to clinical trials and limited
14 options, especially being in a rural area.

15 Additionally, allergies, like
16 medication and food, can limit participation.

17 And specifically for someone with a
18 diabetic foot ulcer, meaningful improvement is closing
19 the wound for good and not opening it every single
20 time. The patient noted they are willing to take
21 risks in a trial if the therapy will help close the

1 wound for good.

2 And then another caregiver of somebody
3 with a DFU said, "If the study allowed current or
4 similar treatment of the wound while studying the
5 symptom -- while studying the symptoms, especially for
6 reduction in itch or pain, I'd be open to it."

7 Thank you.

8 MS. BENT: Yes, go ahead.

9 Can somebody run a mic -- oh, there we
10 go. Ethan's going to run a microphone to Joyce.

11 MS. REX: First of all, I would like to
12 thank y'all so much for inviting us. I've truly
13 enjoyed it. And a lot of that just gave me an
14 understanding of what my wounds are really about, too.
15 And I just really enjoyed it.

16 And -- and one thing I want to say,
17 it's so important to have an advocate. My daughter is
18 my advocate. I'm sure y'all could tell that.

19 She spoke -- she -- I said I wanted
20 to -- when -- when my doctors, my local doctors, said
21 they had to amputate, they would not let me out of the

1 hospital for three weeks with no blood flow to my
2 legs.

3 All along they were telling her she was
4 delusional because I was so sick that I couldn't stand
5 to travel anywhere. She was insistent. Then they
6 said, "Well, we" -- she said, "I want -- my mother
7 wants a second opinion, so we're going to do
8 everything we can to get her a second opinion."

9 They said, "You've had second, third,
10 and fourth." Because this was the doctors on the same
11 team. She said, "The doctors on the same team is not
12 a second opinion. A second opinion is outside of your
13 team."

14 So -- so for some reason she -- she got
15 in touch with Kym McNicholas -- I think that's her
16 last name -- with the Global PAD Association. They
17 worked hard and tried to help her get a second
18 opinion. And we got another second opinion, but this
19 doctor was just so amazing.

20 So now it's good to have a good
21 cardiologist on -- a cardiologist on your team, a good

1 wound care doctor, and a good family doctor on your
2 team. And I'm blessed to have all three.

3 And one thing, I had hyperbaric oxygen
4 and I've had topical oxygen, but the topical oxygen is
5 not paid by FDA for a person that's not in the VA.
6 They told me the only way they could pay me if I was a
7 veteran.

8 I'm not a veteran, so my cost was,
9 like, about \$4,000 a month that I had to pay out of my
10 pocket for -- I think it was, like, four or five
11 months we had to pay this. And I'm sure y'all know
12 I -- all my credit cards are just to the top because I
13 had to pay that.

14 But if FDA can find some kind of way to
15 help with the topical oxygen for individuals that's
16 not the veterans, that would be greatly appreciated.

17 So that's what I had to say. And,
18 again, thank y'all so much.

19 MS. BENT: Thank you. Thank you so
20 much.

21 And so now we're going to move into our

1 wrap up session. And so I just want to thank all of
2 you who are here today, both virtually and in person.

3 To our panelists who have been with us
4 throughout the day, you came here and you gave us
5 something that no data set can: the truth about what
6 it's like to live with this condition. Thank you.

7 To everyone who shared a comment today,
8 in person or on the phone or through the webcast, your
9 voice is in this room and it will be in our report.

10 If we did not get to your comment
11 today, it is not lost. Please submit to the public
12 docket, which remains open again through October 26,
13 2026. The link is on the screen, and we will send it
14 to all registered participants following the meeting.

15 And before we move to closing remarks,
16 I just want to take a moment to express my sincere
17 gratitude to the team that made this meeting possible.
18 Putting together a meeting like this one takes an
19 enormous amount of work.

20 And I'm proud and tearful and grateful
21 to the PFDD and Medical Product Review Centers' review

1 staff who have worked tirelessly on the details of
2 this meeting, from panelist outreach to logistics.

3 To our Great Room and FDA studio staff
4 who have managed the audio and video, thank you for
5 your patience and for your technical expertise.

6 To our colleagues and the Patient
7 Engagement Staff in the Office of the Commissioner who
8 helped us out today, we couldn't have done it without
9 you.

10 And I also want to extend a heartfelt
11 thank you to the Wound Care Collaborative Community,
12 the WCCC, for their partnership, their clinical
13 expertise, and their dedication to making sure that
14 patients with nonhealing chronic wounds have a seat at
15 the table. As well as our colleague at NIH.

16 None of this happens without all of
17 this. Thank you so much.

18 And I'm going to turn over to Dr. Mejia
19 to give us our closing remarks.

20 DR. MEJIA: All right. I'll be brief.

21 But, again, thank you to all patients

1 and care partners for sharing your experiences and
2 perspectives today. We want you to know that we're
3 listening.

4 We heard from most of you, who shared
5 your stories or participated in polling, that your
6 wounds have never meaningfully improved or healed
7 despite multiple therapeutic interventions.

8 We heard a pinhole-size lesion took
9 away an entire year of one patient's life, and a
10 mosquito bite led to a partial foot amputation for
11 another patient. We heard impacts of a chronic wound
12 are worse than stage 4 cancer.

13 We heard nonhealing chronic wounds
14 directly and adversely affect marital and other family
15 relationships. We heard these wounds damage lives.
16 They lead to isolation, loss of independence, physical
17 and emotional scarring. They make patients feel as if
18 they're disappearing.

19 We heard that the response of wounds to
20 treatment is often variable and unpredictable even in
21 the same patient. And, therefore, care plans require

1 a combination of therapies and differing approaches,
2 as well as multiple changes in the course of
3 treatment.

4 We heard that wound healing means
5 freedom. Freedom from pain, infection, and burdensome
6 dressing changes. Freedom to wear shoes and
7 comfortable, cute clothing. Freedom to engage at
8 work, school, and in social situations.

9 And we were reminded that there's more
10 to the clinical data that's collected and analyzed.
11 There are people and their families suffering and
12 struggling from the effects of chronic wounds.

13 These insights and feedback are
14 extremely valuable. They directly support the
15 development of new therapies to improve daily function
16 and quality of life for individuals with chronic
17 wounds.

18 It's clear that wounds impact every
19 aspect of patients' and caregivers' lives, and that
20 addressing chronic wounds needs a holistic approach
21 and a comprehensive empathic effort.

1 Today's dialogue and ongoing
2 conversations are important, not only to us here at
3 FDA, but also for the pharmaceutical companies,
4 researchers, and other medical device and product
5 developers.

6 Thank you, again, to all the patients
7 and care partners for helping advance the development
8 of new therapies and approaches that will improve how
9 you and others with chronic wounds feel and function
10 each day.

11 And, as Robyn said, thank you to
12 everyone who made today's discussion possible. Thank
13 you.

14 (Whereupon, the meeting concluded at
15 4:30 p.m.)

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21

1 CERTIFICATE

2 I, RICHARD LIVENGOOD, the officer before
3 whom the foregoing proceedings were taken, do hereby
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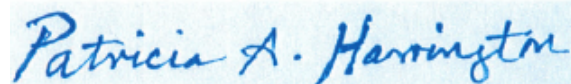
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PATRICIA A. HARRINGTON

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