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

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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

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

List of Attendees:

Juanita Bando

Jamie (by telephone)

Tony (by telephone)

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

Lisa (by telephone)

Toni (by telephone)

Jimontanae (Jae) McBride

Joyce Rex

Sarah McCoy (by videoconference)

Wesley (by videoconference)

Barbara (by videoconference)

Lasaunia Thompson, Treasurer, All Things PG (by videoconference)

Francesca Valentine, MSN, RN, Clinical Adviser for Sick Cells (by telephone)

Brindley Brooks, Founder and Executive Director of HS Connect (by telephone)

Lewis

Adrienne Shapiro

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

List of Attendees:

Alvin, in Toronto (by telephone)

Dan (by telephone)

Sarah Williams (by telephone)

Janet Frank (by videoconference)

Richard Frank (by videoconference)

Corlis Watkins-Nass, President and Co-Founder, All Things PG (by videoconference)

Chaquira Andrade

Laura K.S. Parnell, BS, MS, Board Member, Wound Healing Foundation (by videoconference)

Teresa Jones, MD, Program Director, Division of Diabetes, Endocrinology, & Metabolic Diseases, NIH

Mark (by telephone)

Carmen, FDA Staff

Jason, FDA Staff

Allison, FDA Staff

Karen, FDA Staff

Will, FDA Staff

C O N T E N T S

P R O C E E D I N G S

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

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

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

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

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

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

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

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

If you have any other medical related

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

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

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

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

generate a summary report from this meeting.

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

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

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

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

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

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

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

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

Dr. Tarver?

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

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

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

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

products that promote and protect their health and wellbeing.

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

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

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

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

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

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

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

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

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

technologies for healing wounds.

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

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

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

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

treatment outcomes are most meaningful.

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

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

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

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

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

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

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

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

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

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

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

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

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

treatments work or don't.

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

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

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

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

myalgic encephalomyelitis.

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

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

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

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

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

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

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

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

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

cover issues around trials or other aspects of drug development.

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

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

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

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

report called the "Voice of the Patient Report."

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

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

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

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

We work on behalf of the patient.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

have wound centers. We have training programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So critical to us that are providers,

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

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

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

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

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

of them. I need to come in."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the FDA meeting webpage.

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

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

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

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

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

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

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

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

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

living with nonhealing wounds and getting the support you need.

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

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

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

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

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

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

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

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

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

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

DR. DRIVER: You've already met me.

I'll pass it to Dr. Cole.

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

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

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

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

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

Please go to mentimeter.com or scan the QR code that is on the screen. We'll give everyone a moment to get it there before we read each question. And, hopefully, we will have a QR code that we are able to see in the room. If not, we'll work on that. Oops. There we go.

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

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

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

will have multiple answers.

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

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

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

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

wounds?"

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

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

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

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

All right. We have just a few more

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Brad, please go ahead.

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

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

I saw my primary care who gave me two

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

My number one issue is pain. I have

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

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

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

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

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

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

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

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

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

About a year after that, I had a major

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

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

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

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

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

anymore.

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

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

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

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

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

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

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

MS. BENT: Excellent. Thank you.

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

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

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

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

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

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

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

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

And not only was his left heel very

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

pharmaceuticals.

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

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

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

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

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

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

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

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

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

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

Amanda?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Cole, I think?

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

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

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

DR. COLE: Okay.

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

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

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

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

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

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

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

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

we took close notes.

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

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

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

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

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

to try that.

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

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

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

MS. BENT: Thank you.

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

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

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

have you had?"

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

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

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

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

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

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

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

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

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

So now as we move forward, I do want to

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

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

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

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

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

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

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

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

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

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

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

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

Peter, are you there?

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

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

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

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

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

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

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

My own personal experience comes bilaterally --

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

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

wounds that followed, obviously, were pretty severe.

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

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

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

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

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

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

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

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

So prosthetics is -- is an area that

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

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

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

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

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

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

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

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

Gabby, are you with us?

GABBY: Yes.

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

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

GABBY: Okay. First of all, I am a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

GABBY: Yeah.

MS. BENT: So thank you for sharing that.

GABBY: Thank you, again.

MS. BENT: Thank you.

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

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

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

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

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

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

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

share their experience?

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

Please go ahead, ma'am.

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

MS. BENT: Yes, we can.

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

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

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

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

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

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

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

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

So I'm walking around with a defective,

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

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

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

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

For two years I had been telling this

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

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

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

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

MS. BENT: Thank you so much.

MS. BANDO: Thank you.

MS. BENT: That was really inspiring.

All right. Let's go to one more person

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

Go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. BENT: Thanks, Ashley.

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

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

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

Jamie, are you there?

JAMIE: I am here.

MS. BENT: Wonderful.

JAMIE: Can you hear me?

MS. BENT: Please go ahead.

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

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

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

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

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

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

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

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

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

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

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

MS. BENT: Thank you.

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

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

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

maternal side, my grandfather and my mother.

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

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

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

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

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

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

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

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

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

And they came to the conclusion that it

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

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

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

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

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

And -- and then about a year later, I

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

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

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

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

TONY: Sure. Absolutely.

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

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

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

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

MS. BENT: Great. Thank you very much.

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

Please go ahead.

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

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

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

Happy to hear from anyone. Thanks.

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

So let's start with Laurie on line 8.

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

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

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

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

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

devastating to me, and way more serious.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So let's turn to line 6. Lisa?

LISA: Hi. Can you hear me?

MS. BENT: Yes, we can.

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

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

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

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

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

I used to have to drive over an hour --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Go ahead, Toni.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And I just want to thank you for giving

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Off the record.)

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

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

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

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

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

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

But in addition to that we are going to

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

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

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

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

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

then every month.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

it was a combination.

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

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

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

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

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

I can't say -- say Spectricept alone

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

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

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

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

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

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

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

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

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

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

healing started long before my mother's journey.

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

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

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

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

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

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

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

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

Thank you for allowing us to share our story.

MS. REX: Thank you.

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

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

Sarah, please go ahead.

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

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

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

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

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

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

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

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

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

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

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

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

On the outside of her hip, she had some

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

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

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

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

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

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

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

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

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

Jon will say that it was key to have a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Wes?

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

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

leg.

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

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

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

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

Additional absorption was generally

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you very much.

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

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

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

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

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

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

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

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

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

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

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

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

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

at all before it will approve that treatment.

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

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

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

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

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

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

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

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

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

Thank you very much.

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

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

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

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

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

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

My current wound management routine

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

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

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

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

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

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

wellbeing affects how I manage the condition.

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

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

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

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

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

your recovery.

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

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

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

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

I understand that treatments

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

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

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

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

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

Thank you for allowing me to share my

PG journey.

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

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

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

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

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

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

Sarah, go ahead.

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

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

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

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

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

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

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

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

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

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

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

MS. BENT: Great. Thank you.

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

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

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

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

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

MS. BENT: Thank you. That's really helpful information.

All right. We have a few more questions.

So I'm going to have -- Lasaunia, if you want to answer, if you can answer quickly.

And then we're going to go to Jae here on the panel, and then we're going to go to some of our panelists with a few more questions.

But we do want to get to the people on the phone and in the room, so we will try to keep things -- try to keep moving things along. Thank you.

Go ahead, Lasaunia.

MS. THOMPSON: Okay. So my treatment plan actually was based on four doctors and myself, because I live with May-Thurner syndrome, uveitis, PG, and rheumatoid -- rheumatoid arthritis.

My vascular surgeon, a ophthalmologist,

rheumatologist, and wound care all actually became a team and worked together, and they came up with a plan; and then we all collectively made the decision.

So it couldn't be just about the wound care. Because of everything else that was happening with my body, there had to be several people involved.

MS. BENT: Great. Thank you so much for -- and that -- I think that we've heard from so many people today about the fragmentation of care. So the fact that you have a care team that's working well together is really, really great to hear.

Let me turn now to Jae.

MS. MCBRIDE: Yes. We also were heavily involved in my mom's treatment plan. And not only do we have a great amazing team centered around her, they were open to suggestions that we had. We were -- we're up for using any cutting edge technology that was available out there.

They allowed me to bring my ideas. They looked at them. Sometimes they said no. Sometimes they did say yes, you know, to them, but

they -- they allow us to be heavily involved in her care.

MS. BENT: Wonderful. Wonderful.

Let me turn back to our panelists.

And, Kathleen, did you have a question that you wanted to ask?

DR. YOUNG: Yeah. So I also wanted to thank all of our panelists and the patients and their caretakers for presenting their stories today.

I think a through line for a lot of the things that we've heard today is that folks have tried a lot of different types of therapies until, for some of the lucky ones, that something finally did work.

I wanted to ask a general question to everyone who might have feedback to this. Like, when or -- when in treatment, or how, is that decision made that a current therapy or wound treatment is no longer working for the patient and that something new needs to be tried?

As it seems like this could affect the overall timeline and trajectory of treating that

wound. All right. Thank you.

MS. BENT: All right. Is there anyone who -- any of our panelists --

MS. MCCOY: I could answer.

MS. BENT: Oh, great. Go ahead.

MS. MCCOY: I could answer that question if you wanted me to. For -- for Morgan, like, trying a new treatment or once something was working or not working for her, sometimes it was PG rearing its ugly head.

That if you kept the inflammation down and the skin was continuing to grow without PG showing up, that was always a thing.

Sometimes when the skin stopped growing and you were seeing -- sometimes it's just more open for infection right -- usually, it was like a sign. Like, here comes PG.

We used to say that wounds are moody, and sometimes the mood would change. And when the wound got moody, that's sometimes when you had to look for other solutions, other options.

I mean a lot of her wound was a reflection of her gut, of the ulcerative colitis she had. Even with losing her colon, she still had a small piece of colon left. And so that sometimes was a big indicator.

Like, the wound told us other things about her body, but the wound just also had moods.

MS. BENT: Great. Thank you.

We probably have time for one more person to answer that question, if there is anyone who would like to answer the question. Otherwise, we can move on.

MS. MCBRIDE: I can answer.

MS. BENT: Okay. Jae?

MS. MCBRIDE: So for my mom, when things weren't working, we -- we needed a different skill set. You know, we were going to a traditional cardiologist, a surgeon, who was cutting. You know, surgeons like to cut.

But in my mom's situation, she has very small arteries and small vessels, so she needed more

of an interventional, you know, cardiologist, so who was able to utilize smaller tools.

So in -- in her -- her situation, that's where we -- we went. When -- when things weren't working, when wounds weren't healing, and her process wasn't getting better, they needed a new technique.

MS. BENT: Thank you.

And then we will go to Barbara, because I think you wanted to answer this as well.

BARBARA: Yes. My -- my caregivers have tried a lot to figure out how to get this wound to heal.

They've done -- I had venal ultrasounds done to see if there was a problem with the circulation there. There's not. Though the venal clinic doctor refused to do a second ultrasound a year later, which was surprising.

The other thing -- but one of the things that surprisingly worked is that switch from a general Vashe wash to using Hibiclens, a more -- what

I would say, a -- a stronger solution that will -- a stronger type of substance that will keep bacteria and such at bay. And that caused a dramatic shrinkage of the wound.

Still hasn't -- still got a couple of centimeters left to close, but it wouldn't be at this stage if we hadn't switched to that kind of topical treatment. Over.

MS. BENT: Thank you so much.

All right. So I think we have two more questions from our panelists. I think we have one from Sarah, and then one from some from Vickie, that we will get to before turning to the -- quickly to the polling questions and then to the phones.

MS. ROSENBERG: Thank you to all the patients who shared their stories. We really appreciate it.

I did have a question about did any of the treatments have any significant side effects that caused you to, maybe, stop the treatment or seek alternate treatment options? And are these relevant

to your treatment decision?

MS. BENT: All right. If -- for our panel --

MS. THOMPSON: I can --

MS. BENT: Okay. Great. Go ahead, Lasaunia. Thank you.

MS. THOMPSON: I was just going to say one of the medications that I was -- they wanted to give, I believe it was gabapentin. And it affects your eyes.

And, unfortunately, my eyes had already -- was doing what the gabapentin would've done. So that was a treatment that they had to take off the table.

And then we played around with the idea of methotrexate. And so, currently, I'm on it, but, initially, they had given me the higher dose and I should have got a lower dose.

So we had to keep going back and forth to figure that out. But, fortunate enough, they got to figure it out, and now I'm on methotrexate.

MS. BENT: Thank you.

Jae, did you want to say something?

MS. MCCOY: I was just going to say for Morgan, one of the things that -- that was -- had a side effect was doxycycline.

Like, it helps reduce the inflammation in the wound. It helps healing. But also the effects of just the -- like, burning easily in the sun.

When you're, you know, a -- a young college student, you want to be able to go to a football game or sit on a patio. So sometimes we had to take, you know, doxy off the -- off the list just because she wanted to live her life.

MS. BENT: I remember you -- in your -- you mentioned the brunch beforehand, and I think it is really important to try and figure out what we can do that allows people to reach their -- as much normalcy as possible.

Jae, let me turn to you.

And then we'll move on to Dr. Driver for our -- the final question.

MS. MCBRIDE: So my mom is very sensitive. She doesn't do well with pain meds or any -- some -- some antibiotics as well.

So those antibiotics or pain medicines that she was taking, like gabapentin and some of the antibiotics, made her just actually be a shell, and not be able to communicate or talk, and -- and just sleep all day.

So we had to, actually, change course when that happened. So she actually started to stop taking pain medicine, gabapentin and -- and things of that nature, and just -- you know, she decided to just deal with the pain.

Because she wanted to -- it was either be a vegetable in the bed all day, be loopy, be kind of just out of her mind, or be able to talk and communicate. So in her situation, you know, she's loopy and we monitor that very closely.

MS. BENT: Thank you.

Dr. Driver, did you have a question? I'm sorry.

DR. DRIVER: I have many, but I'll make it one. So I wrote down -- our panelists, patient and -- and daughter at the end of the table, thank you all so much for what you've contributed today.

But you said measure these patients' treatments and -- and every day by quality of life, not the size of the wound. So could you articulate, explain to us -- we've been trying to capture that, but our clinical studies don't go long enough.

So what were these quality of life measures? What should they be?

MS. MCBRIDE: So my mom, basically, 12 months ago --

DR. DRIVER: Could you put the microphone a little closer?

MS. MCBRIDE: I'm sorry. Can you hear me? So 12 months ago, my mom could not walk. She -- I -- my husband and I literally had to pick her up and -- and move her.

She couldn't go to the restroom by herself. She could not put on her clothes. She could

not bathe. She couldn't do any of those things.

Today, you see she's walking. You know, she's walking. She's moving. She's -- she's able to put her clothes on. She's able to -- it -- it may be painful to walk, but she's able to walk.

I'm not carrying her anymore. I'm not -- I'm not putting her on the bedside pan. The -- literally, the first night -- we celebrate everything.

We like to -- like, we celebrate the minor things, because with these -- this disease and these wounds, you know, you have some very hard days, some very discouraging days. Some days we felt defeated, so we have to celebrate the small milestones when they come.

So the first night my mom was able to go to just simply the bedpan on her own -- own without waking me up to do it, we celebrated. You know, I did a little happy dance for her, and -- and we shouted.

Because that -- that was giving her some small part of her independence back. My mom is a

very active person. She likes to, like, just, you know, be vibrant. She's a -- a real estate broker. She needs to move.

And so for her to be able to start doing some of the things that she -- that makes her her, again, that's -- that's improving her quality of life.

DR. DRIVER: Thank you very much. You're very inspirational. To know that there are ways we can measure not just the size of the wound, but the quality of a life. Thank you very much.

MS. BENT: All right. So thank you all to our panelists. We really appreciate you both sharing your experiences and staying on with us to get some of our clarifying questions answered.

We are now going to turn back to everyone in the audience here and online, and to some polling questions.

So the polling questions for this session are focused on treatments and management approaches you have used, the challenges you have

faced, and the benefits that matter most to you when considering a new treatment.

So, again, please go to mentimeter.com or scan a QR code. And we'll move to the first question, which is: "Have you or your loved one ever used any of the following to manage your chronic wounds?"

And you can choose all that apply: "Topical wound care products; wound dressings; gauze; prescription topical medications; specialized wound therapies, such as negative pressure wound therapy or hyperbaric oxygen therapy; compression therapy, such as stockings, wraps, or bandages; clinical or surgical procedures, such as debridement or removal of dead tissue; support devices, such as shoes, casts, or cushions; diet or lifestyle modifications, such as nutritional supplements or elevation; other approaches that we haven't mentioned; or 'I am not using anything at the moment.'"

All right. I'm going to be honest, this is going to be a challenge for me to read.

All right. So it looks like we're seeing a lot -- about 20 percent of people using the topical wound care products.

We've got 17 percent using supportive devices. Others using approaches not mentioned. We see diet and lifestyle modifications. It's really kind of spreading out across the board.

All right. And it seems like -- I mean we heard a lot of these different approaches, but from our panelists as we talked about this earlier, and so it looks like we're about steady with a lot of the topical wound care products. Again, this is just to facilitate the discussion, not a scientific survey.

All right. Let's move on to polling question number 2, so: "What are the biggest challenges or barriers you face in managing your or your loved one's chronic wound?"

And you can choose up to three of these. So the top three: "Time or cost of maintenance, difficulty accessing specialized wound care, pain during treatment procedures, slow or no

improvement despite treatment, side effects from treatment, difficulty following treatment instructions, lack of information about treatment options, or other challenges that are not mentioned."

All right. And I think consistent with what we've heard already today, it looks like we are seeing the time or cost of maintenance is really a significant impact for people. Difficulty accessing that specialized care. Pain. Lack of improvement or slow improvement.

All of those things that are really consistent with what we've heard from our panelists today, and what I think we'll probably hear when we go to the phone in just a few minutes. So thank you for that. That was really helpful.

And so -- all right. Moving on to our final question for this session: "If you are considering a new treatment for chronic wounds, which of the following benefits would you consider to be the most meaningful?"

And this is choose up to three answers.

The options being: "Complete wound healing, faster healing time, reduced pain, improved mobility, reduced risk of infection, less frequent dressing changes, improved quality of life, prevention of wound recurrence, or other benefits not mentioned."

All right. And so faster healing time, improved quality of life, and then complete wound healing is bringing up the top three. Reduced pain is important.

I realize it's just kind of an unfair question, because it feels like all of these things are really important, so limiting you to three is probably not our -- not completely fair. But it is helpful for us to see what people are thinking, so thank you for sharing this.

Okay. We'll just give it another minute, but it looks like we've kind of stabilized in the responses with, again, the improved quality of life really being the largest priority. So thank you for that.

So now let's -- all right. I think

before we go to the phones -- and maybe we can take some answers from the phones as well.

Dr. Mejia, did you have a question that you wanted to ask?

DR. MEJIA: I did. And I know it's not fair for the last polling question. As you were saying, it's really hard to pinpoint this. But could any of the patients -- with some thought. And this isn't -- this maybe can be answered later on in the discussion.

But if there was one specific sign or symptom that you would consider equally important or more important than wound closure, that would -- you think it -- you would think would improve quality of life, what would that be?

MS. BENT: All right. That's a good question. And before I ask people to answer that question, I mean, please, if you're online and you have thoughts, please feel free to put that answer into the comments.

And for those of you who are going to

go to the phone now, and so if you have thoughts on that, please incorporate that into your response if you would like to.

I'm going to go to the phones. I would ask everybody to try to keep their answers brief, just so that we can make sure that we get through the number of callers that we have. We want to be able to hear from as many people as possible.

And so with that, I'm going to go to Francesca on line 1.

MS. FRANCESCA VALENTINE: Good afternoon.

MS. BENT: Good afternoon. Thanks so much for calling in.

MS. FRANCESCA VALENTINE: I'll avoid redundancy. I am -- my daughter, Ashley, led a segue into Marqus's history, but I will tell you his original wound -- by the way, I'm a mother of a winged warrior.

I'm a mother of a winged warrior. So Marqus is no longer with us, but his wounds were

extensive. Both legs, both limbs.

And it started in 2013 after a flood. He got scratched during a cleanup and that ankle proceeded to fester.

His first trip to the operating room for the surgical debridement put him into terrible crisis, and we soon learned that he would not be able to have OR debridement. So we went to clinic under the skill of our surgeon and did perineal nerve blocks in order to do sharp debridement.

We had all the treatments that were spoken about today that I was listening to, including portable hyperbaric chamber here in the home. And we also had grafts, and we had advanced dressing.

Wounds -- wounds are devastating because they do -- not everyone knows how to manage them. We soon learned that general wound clinic would not be acceptable because they did not have a good understanding of the pathophysiology of sickle cell disease.

It's an ebb and a tide. It is not

always circulation lost or gained. It's slow, ebb and tide. They don't understand that.

So they would send him back home with a Unna boot. Well, that's compression. If he's in a VOC, why would you compress? So we soon learned that that would not be effective.

We got minimal results from the grafting. What worked -- the -- the trajectory of an infected wound is devastating. So then you have crisis, sepsis. He lost his portacath. I had a 480-hour FMLA all used up.

I had to discuss -- he was 26 at the time. I had to discuss with my 26-year-old, what does he want for his limb? So a mother having a discussion with their child, "Do you want amputation should we not be able to resolve this?" We had to have a frank discussion. If that doesn't cause PTSD, I don't know what would.

Then we went on to the cost. The cost -- every time the foot remodeled from poor circulation, open skin, nerve and tendon inflammation

and damage, you need a different shoe. You -- you can't wear the same shoes you wore possibly before your wound. We ended up with special shoes from a company that could make specialty shoes.

We had to fight the insurance company for medication, and for prosthetics, and for shoes. So there's that cost to fight.

The cost to the patient, their -- their humanity is part of this issue. How do you cover a foul smelling draining wound?

You need to put on shoes because you want to go outside. Marqus would put a plastic bag over, we'd wrap over that, and we'd be ready to put it down in the shoe because we had places to go and things to do.

Wounds -- what -- the question was how do you know you have a win when you're working on your wound? When you take that dressing off and you see those little bubbles and new skin come, and the pain is less, and infection free, that's a win.

It is not just the condition of the

wound. It is ongoing condition of the wound. You want to see that when you're doing the dressing.

I would get up at three, because I needed to be at work at seven, and we would do our dressing changes, hang our IVs, and do our IV piggyback, all before I left the house. And then when I got home from work, repeat.

Marqus learned to help his own wound, but not everyone can do that. It's really important that the caregiving is accessible.

I heard someone talk about having to go a hour and a half or two hours, three hours, every day. That is not accessible. That is accessible because you have to. What's the alternative?

But a lot of this goes right back to the core of sickle cell, lack of understanding of pathophysiology of the disease process. It happens with every organ system, including wounds and skin.

Marqus had to have chronic volume exchanges to close his limbs and prevent amputation and sepsis. He got his port put back in eventually.

Wounds did not take his life. Intracranial hemorrhage took his life. But --

MS. BENT: I'm going to -- I'm -- this is really helpful. I am going to ask you if you can make -- wrap it up so we can get to others, but are there any kind of final, like, points that you want to make before we move on?

MS. FRANCESCA VALENTINE: Wounds -- wounds last a long time. Thirteen years for him.

And I appreciate everyone's testimony. It was very impactful. Thank you.

MS. BENT: No, and thank you. And thanks to Ashley, who I know wasn't able to stay with us this afternoon, but your perspectives have been really helpful and really informative, so thank you.

All right. We're going to move on to our next caller on line 5, Brindley?

MS. BROOKS: Hi. Thank you so much for inviting me to be here today. My name is Brindley Brooks, and I'm the founder and CEO of HS Connect, which is a patient advocacy group for hidradenitis

suppurativa.

I have lived with HS for the last 37 years of my life, and I also have two daughters who have HS. I have a 19-year-old with stage 2 HS, and then I also have a 23-year-old stepdaughter who has stage 1 HS as well.

So HS has been a part of my life for a really, really long time, and moving into the advocacy realm and also, you know, raising children with HS has been quite interesting.

It's -- it's also been of note that many of the other conditions that have been discussed here today, we all share similarities, especially when it comes to wound healing.

Chronic wounds are part of the existence of someone with HS. A lot of times because of the draining tunnels that are formed for us, we have incessant, chronic draining wounds just like people with venous leg wounds as well.

So it's been -- I don't want to say heartwarming 'cause that's the wrong word -- but just

affirming to know that we all share something in common when it comes to chronic wounds.

There have not been many studies, if any, done on the nonhealing chronic wounds that are caused by HS.

And a lot of our patient population, because it is really expensive to care for these wounds with proper dressing, actually turn to things like toilet paper and paper towels to use as dressings to -- to soak up exudate, which is really unfortunate and has a huge impact on our quality of life.

I, personally, have had seven wide excision surgeries left to heal via secondary intention, so left to heel from the inside out. It's been traumatic, to say the least, but it absolutely changed my life for the best.

In fact, it changed my life personally so much that my 18-year-old -- well, 19 now, but 18 when she decided to have wide excisions of her bilateral inner thigh, which is the only way that we can hopefully accomplish wound healing completely with

hidradenitis suppurativa.

So I just really appreciate you guys bringing attention to this, and knowing that outside of your most obvious chronic nonhealing wounds, there are diseases like PG and HS that also have similarities that you don't think of offhand.

And I would love to change that landscape and that we have more research done on nonhealing HS chronic wounds as well.

Thank you so much.

MS. BENT: Thank you.

And I think that that was one of the goals that we had for this meeting was we -- you know, and one of the reasons FDA was hosting this meeting is because we know that nonhealing chronic wounds cross so many different conditions and wanted to really hear about that wound experience.

Obviously, it can't be separated from the causative experience, but it does give us an opportunity to talk about wounds themselves and the commonalities kind of across the different conditions.

Let me see. Let us go to one more caller on the phone, and then we will see if there is anyone in the room who would like to say anything. And then we'll go to the comments online, if we have any comments online.

So I think we're going to go to line 6, Laurie?

MS. RAPPL: Hi. I -- I spoke earlier today. This is Laurie Rappl; I'm a T-12 paraplegic in Greenville, South Carolina. I'm currently dealing with a sacral wound, a pressure injury, and -- due to treatment for two bouts of stage 4 breast cancer.

The current therapies are the same ones they've offered me for years. They start with negative pressure and will intersperse that with various wound dressings, the -- the dressing du jour, as I call it. You know, who -- who came in last and had some samples, and we'll try this and we'll try that.

But negative pressure is the overarching treatment that people give. And on me, it

doesn't work after a couple of weeks, couple three weeks; and we have to take a break from it, and then we can go back to it.

I also develop -- I -- I develop infections underneath that negative pressure, so we have to try various things for the -- for infections.

I've had three debridements on this wound. I had one in September, and then -- then I had to have one in April that went down to the sacrum. And then I just had one last Tuesday for more sacral debridement.

But my -- my problem with getting treatment for this wound and previous wounds is that I'm offered nothing in between negative pressure therapy and a flap surgery. And, unfortunately for them, I know that there's a lot of things in between there that -- that are available now on the market.

But I -- I know this is not a reimbursement call, but due to the fractured way that we reimburse different therapies, I'm not eligible for them. And as a previous caller said, a lot of

modalities and drugs and such are not studied on pressure injuries, and so they're not reimbursed.

So in my own words, what would healing, quote/unquote, mean to me?

MS. BENT: Yes.

MS. RAPPL: It would mean smaller measurements for sure. But measurements can be very subjective, because it depends on how you're laying and how -- how much they pull on the tissue, you know, to -- to get a good look at the wound. And they're so subjective that I just -- you can't compare them from one person to the next.

So that's frustrating. And I wish there was a way to do volume instead of the four-point measurements, measurements at four points and then the depth at one point.

The -- the current treatments have been fair in helping me. The wound has decreased in size from 14 months ago till today. And yet it persists. And it -- it's very frustrating to lay here day after day, week after week, month after month, to watch the

impact on my family and to -- to see numbers not budge.

The -- the color of the tissue is one way you can document progress, but that's subjective as well.

The biggest downside I have found with my sickness is just what I would consider a lack of effectiveness, because of the extreme slowness of how this -- this wound has responded to these different treatments, and my lack of ability to access something other than what I've been offered so far.

I believe I found a provider now that's willing to try some different things and is pretty enthusiastic, but that -- that might remain to be seen because I'm -- I'm new with this provider.

And I think that that's plenty of time for my comments. I thank you for letting me speak again, and I will take you to the next speaker.

MS. BENT: Thank you so much, Laurie.

All right. Let me just turn to the room and see if there's anyone in the room that would

like to -- any patient with lived experience in the room that would like to speak.

Polly, I see you have your hand up. I will ask you -- because we do need to make sure we get to others -- to keep it pointed.

MS. CLEVELAND: Very -- very short and to the point. I was able to use medical maggots ordered from California to treat my husband's wounds. After five months of no progress, they were halfway cleaned out with one treatment. Unfortunately, he was dying. I should have started earlier.

The problem with medical magnets -- maggots -- okay -- is that they are not covered by insurance. If they were covered by insurance, which the AMA has so far refused to qualify, I think they would be much more widely used. And I would ask Lewis here to back me up. Yes?

LEWIS: Yes, indeed. It works.

MS. BENT: Thank you so much. And I think what we're hearing from you is similar to what we've heard from so many other people, which is a

frustration with accessing -- being able to access treatments.

And the desire as a family member or caregiver to not know exactly what the right path is in the beginning while you're learning this journey, and wanting the best for your family and not being able to completely understand what that is.

I think we can take one more comment over here, and then we will turn to Ethan for comments from the -- online. Thank you.

MS. SHAPIRO: Hi. I'm Adrienne. I -- one of the points -- I mean anybody that's lived with this can relate to everything that you've gone through, but the one thing I think we haven't talked about is the step therapy that -- they'll -- it doesn't matter; right?

They -- they'll say, "We know something doesn't work." And we'll say, "Well, you have this thing that somebody else experienced and it worked." And they're like, "Yeah, yeah, but we're going to try this first."

And so I think we really have to look at -- at how people are put through so many things until they get to the thing that has the better chance of working faster.

You know, that -- you know, it's -- it -- we end up spending a lot of money, a lot of time, until it fails. So it's try and fail as opposed to what would be the most effective treatment.

MS. BENT: Thank you.

Let me now turn to Ethan and see about the comments online.

And I don't know, Ethan, if you have a plan, but were we going to be able to share some thoughts related to the question that Kathleen asked? Okay. Perfect.

MR. GABBOUR: Yes. So we're getting a number of comments saying that treatment for them is a trial and error process like we've been hearing, and that there's no quick fix, especially because they are dealing with underlying conditions and that their providers aren't understanding their other conditions.

Some treatments mentioned are wound dressings, ozone boot and oil, stem cell treatments. And for one patient they would try something new if they went a couple of weeks without improvement and the wound got bigger.

There's also frustration that patients are being blamed for slow or no progress, even if a patient is being compliant with their treatment program.

One caregiver noted that they were disregarded when their dad underwent debridement and experienced a lot of pain, but their pain was just disregarded as neuropathy.

And to answer the question about what would be considered meaningful aside from wound closure would be less recurrence of infection.

And then one other quote was "Treatments or therapies that can reduce pain, reduce infection risk, and make life more normal, such as being able to walk, drive, and stand, would help improve quality of life."

MS. BENT: Great. Thank you. And I will note that Sarah, who was one of our panelists, mentioned that perhaps complete -- besides complete healing, maybe just living congruently with the wound and no dressing changes without a risk of deterioration.

So let me now go to -- back to the phone, and we will go to Alvin in Toronto.

Alvin?

ALVIN: Yeah. And, you know, thank you for allowing me to speak.

I would like to, you know, first and foremost say yes, I am calling in from Toronto where the healthcare may be a little bit different, but everything that I've heard from other panelists or other phone callers seem to be in line with what, you know, I've experienced.

So in terms of not being able to stay on my disease modifying treatment and also have my wound get better, or as someone just said, we're -- knowing what works for us, but then having to go

through all these other hoops and everything else just to get to where we knew we needed to get to.

And then, again, the -- the last person also spoke about, maybe, you know, quality of life improvement as long as the wound does not get any bigger. I had to go through everything from Vashe washes to Coban to -- Coban -- yeah, Coban treatments and compression socks.

So I -- I do think when you're thinking about things like wounds, which may have scent to them or leakage and all the rest of that, it does quite impact someone's life and the ability to enjoy it or to go out and to do any of those things.

And I do think, as many people at the table, to discuss what actually works. Like, you know, some people say, like, that -- that would be good enough. Or, like, the wound doesn't get better, but I can do this.

Where someone like me would be, like, no, I -- I absolutely need the wound to be closed because they always happened from my ankle down. So

if I can't put on shoes or socks, I can't do anything and I can't go anywhere. So that's not living life.

But I -- I would just say all of those things are -- are things that I would say to keep in top of mind when creating any kind of solutions that would affect such a big swath of the population.

Yeah. 'Cause I see it affecting from, you know, young to old and across the whole ethnic spectrum. So I think as many voices that are in the room when solutions are being created would be the most beneficial to everyone.

And as we know, nothing stays in one country forever. Solutions do travel.

Thank you.

MS. BENT: Thank you, Alvin. We really appreciate that and appreciate the perspective from a little bit outside of the United States as well.

So let me now turn to Dan on line 9.

Dan, good afternoon.

DAN: Thank you for -- for doing what you do. I'm a burn survivor going -- been 16 years

since I burned 85 percent of my body. So I had the luxury of dealing with a lot of wounds over the years, chronic wounds.

But I -- I've been listening for -- on and off for a while, and, yes, a lot of good information is coming forward.

And the patient -- what frustrates me is what frustrates a lot of people with chronic wounds is our providers know what can fix it, but the regulations and all that stuff kind of hinder the process.

I've been dealing with two wounds, one on my right leg, one on my left leg, and I've been -- veins and, you know, they did all that stuff. It -- it boiled down to I -- antibiotics I was on 'cause I had infections a few times.

But right now what, finally, is getting me moving in the right direction in closing these wounds up is my -- my doctor has put me on natural vitamins.

A bunch of natural -- you know, good

for your -- I guess, my body likes it because the -- whatever my doctor has prescribed me, I'm taking like eight or nine different things every morning and in the afternoon. So whatever it's doing to my blood flow, to the way my skin heals.

Because I -- I have scar tissues. And that just popped into my head. That's another problem. We go to these wound care centers, or I go to a wound care center.

But burn survivors aren't fortunate, because I've lost the top layer of my skin. I have third degree plus wounds where my both legs, you could basically take a knife and cut my legs and I won't feel it.

But with these wounds, I had one wound on my left leg and there was this tubular growth. They sent it out. It wasn't cancerous, thank God, but it just wouldn't go away.

So they kept cutting back, cutting back. And whatever that was, it was attached to a nerve, and oh my God, the pain.

And then the infections on and off. And another frustration, I don't get a high blood -- white blood count, I guess, when I'm infected, but I just get lethargic. I can't move.

And you go to a hospital and they have criteria. If you don't have a fever -- sometimes I don't have a fever and I'm infected.

Thank God for my primary care. I was in really bad shape 'cause I know I've been dealing with this for a long time. I was really not sleeping too much, out of it, 'cause my body's infected, but I don't have a fever. My -- my white blood count doesn't go up.

She put me on antibiotics, a couple of antibiotics. Within a day or two, bam, I recovered. So a lot of regulations are restricted and they're holding -- healthcare providers, you know, 'cause they -- they have the -- what is it, the -- when you have a lot of infection. Not chronic.

I'm trying to look for the -- the -- not the CDC. Who was the one that -- a doctor that --

I'm sorry. My mind is blank. But they -- they take care of when you're chronically infected and they make the decision in the hospital.

MS. BENT: Like, your infectious disease physician?

DAN: Yeah. Thank you so much. Yeah.

MS. BENT: No problem.

DAN: Infectious disease. Yeah. And if they -- if you don't meet the criteria -- I -- I'm pretty sturdy with pain and everything, 'cause you know, being -- I burned 85 percent of my body and I was -- thank God, they had me recovered with grafting in five months.

I have a wound that started out like a pencil tip, turned into about, I don't know, inch, inch and a half. One's a circular -- and about two and a half inches circular. And, finally, they're -- they're healing.

But I just watch my diet. I'm doing everything I can and I'm on these natural -- this natural stuff, and the -- you know, the antibiotics.

I know a lot of doctors are afraid to give you antibiotics, but, you know, my -- my leg was flaming red and it -- it was just horrible. It was just getting bigger and bigger and bigger 'cause it was infected. My wound grew --

MS. BENT: Thanks. Thanks, Dave -- or Dan. Would you --

DAN: Dan.

MS. BENT: Are there a few final points that you'd like to make?

DAN: The only thing is that I -- I appreciate everything you do. Thank you. And if we could do some way to give the healthcare providers a little more freedom where they can make decisions. 'Cause they -- they're right there on the front line. And that's my one suggestion.

But -- and vitamins. I -- it helped for me. I don't know if it's going to help everybody. And -- and keep your wounds clean.

MS. BENT: Thank you so much.

DAN: You know, that's one of the --

I'm constantly cleaning them. Thank you.

MS. BENT: All right. Let me now go to Lisa on line 8.

LISA: All right. Good afternoon. Can you hear me?

MS. BENT: Yes, we can.

LISA: All right. I am going to keep it as short as I can and stick on topic about treatments.

Obviously, all of us -- all of us with unhealing wounds have gone through the debridement and we've gone through different dressings and different changes and things like that, wound vacs, et cetera.

But I will -- I want to say is, for me, what finally worked after a year and a half of improper treatment from a doctor that wasn't just -- nothing wrong with him, he just -- he wasn't knowledgeable about proper wound care.

And I -- I did find a place that was, and eventually they did CTM -- CTM? Yeah. Which is biodegradable -- BTM -- biodegradable temporizing

matrix. And that started to work, because my wound wasn't ready for a skin graft yet.

So that worked, and my -- my wound finally started to close after a year and a half of excruciating pain. And -- which is great. It's an FDA approved product, but insurance fights it.

So I -- I know I'm not looking for any changes right now. I just want to put it out there that all of these things that the FDA approves are not being accepted by insurance, without peer-to-peer discussions between the doctor and the insurance company.

But the BTM worked for me, and then my doctor realized I was finally ready for an actual skin graft from my donor site. And she did that, and that was healing.

She also used RECELL when she did that, which is another FDA approved product that insurance fought her on, but she fought back and got it approved.

And my -- my wound finally healed for

the first time in a year and a half. Unfortunately, I did develop a fistula and, you know, I've been going on since then with an open wound again.

But I think it's important for you guys to hear that these products are approved, but insurance companies are making it very difficult for healthcare providers to use them on patients who desperately need it and it works.

So that's my perspective on that. I won't get into my whole story because I've -- I've been through it, a lot of it, a lot of stuff.

But most importantly, I think it's important to just recognize that there are products out there that help. Doctors are reluctant to use them because they get fight back from the insurance companies, but the FDA has approved them; so --

MS. BENT: Yeah. Thank you for that, Lisa. And I don't know -- I'm not sure what video they're showing on the webinar, but I will tell you that Dr. Driver's almost falling off her seat, like, nodding so vigorously.

And the rest of the room there was in agreement as well. So thank you for sharing that with us.

LISA: Yeah. No, and I know -- I know the medical bit. I -- I keep it -- on the -- on the screen right now is just the phone number.

But I know that medical providers understand this because I know their frustration. And I know that I -- I got very fortunate because I wasn't being treated properly, and I went through a lot of pain and a lot of suffering until I ended up with the doctor at -- so I go to South Shore Health Center for Wound Healing in Weymouth, Massachusetts.

And they have -- it's -- it's, like, a state of the art facility and they have the best doctors. And my doctor in particular has saved my life more than I can tell you. And I'm not kidding about that.

MS. BENT: Okay.

LISA: Like, there were -- there were times that I -- I probably shouldn't have made it

because of bad decisions from other doctors. But she treated it, and she treated it so well that if I hadn't gotten the fistula, I'd be fine. Nobody -- it's nobody's fault that I had the fistula.

So I did give Ethan my cell phone number. So if you guys -- I mean, I'm sorry, my email address. If you guys ever want to reach out to me, please feel free.

MS. BENT: Great. Thank you very much.

All right. And we have about two minutes before we go to -- before this session ends and we go to our break. And so I will be going to caller on line 1.

So, Williams, are you on line?

MS. WILLIAMS: Yes, I'm here.

MS. BENT: Great. Thank you.

MS. WILLIAMS: Thank you very much. My story is -- is probably a little bit different than the stories that I've heard all day today.

So I suffer from HS, hidradenitis suppurativa, which is very painful. It causes

abscesses and draining, and they are reoccurring, so it's like nonstop.

I have gone to so many doctors, tried so many things, and just last year I was introduced to copper dressing. And when I used the copper dressing, it literally changed my life.

So whether it was an active flare or a flare that was just beginning, as soon as I started to use those dressings, they would literally go away.

And usually one flare can last up to two to three weeks. And if it's really bad, it can last up to a month or more. And I have found significant relief in using these copper dressings.

Even going to the doctor -- and my -- my daughter has it as well, but I won't talk about her -- her situation. But she has it as well and it has helped her to -- to live a better quality of life as well.

But we went to doctor after doctor, and we were not able to get any relief until we actually found these dressings.

So I just wanted to tell my story. I haven't heard anybody say anything about copper dressing treatment, but they have been a lifesaver for my daughter and I.

MS. BENT: Thank you very much. That was a really nice way to end the session.

And we really appreciate everybody who participated in this version of this -- or in this session. And so we're going to take a ten-minute break. We will return in just a few minutes to hear a discussion about clinical trials.

And we have another five exceptional panelists who will be joining us, mostly virtually. And so we'll see you in just a few minutes. Thank you so much, everyone.

(Off the record.)

MS. BENT: All right, everyone. Thank you so much. Welcome back. We are now headed into our third and final discussion topic: patient perspectives on clinical trials.

And so this session is going to focus

on what factors would or do people weigh in decisions about whether to participate in a clinical trial, and what outcomes are most important to measure.

After our panelists share, we'll go back to the polling questions, and then open the floor for discussion. So, again, if you want to call in, please start thinking now about some of the topics that you would like to speak to.

And so with that, I'm actually going to turn to our Topic 3 panelists. And we are very happily joined by Adrienne, who is here in person with us today.

So with that, Adrienne, if you would not mind taking it away. And do you want to be up here at the podium? Okay. Perfect.

MS. SHAPIRO: Okay. First of all, I want to say thank you so much for including me on this. This has been an amazing -- an amazing session. The sickle cell community is ever so grateful to the FDA for looking out for us.

And, yeah, so let's talk about this.

So -- so I'm Adrienne. I am a lifelong sickle cell advocate as the sister to a winged warrior named Teddy, my eldest brother, and my daughter who was born with sickle cell disease.

I -- I was in a bubble for a very long time. My daughter got excellent care. My mom managed to keep my brother alive for 51 years without all of the great things that we had now. And I -- I just thought everybody had what I had in my life.

And I was very excited about gene and cell therapiesJ because I wanted to have my daughter healed, and I truly, truly believed in science.

And when I was little, my mom would say, you know, as we were going -- leaving the prayer circles, "God is good, but science is going to fix it." And at 7 years old, I told her I was going to the FDA. Don't know where I got -- got that from, but I was going to the FDA.

So I was going along, and all excited about a cure, and I got a call to go look for someone who was having a crisis and was at the hospital with

no care. And I got there and there was a young woman, and she was in the ED, and she hadn't -- she had no water, she had no -- you know, no IV bag. All the things I expected to see.

And both her -- her ankles were wrapped in, like, a kind of funky looking wrappings. At that point I didn't even know about leg ulcers. And so I didn't know really, really about them, but the bandages were dirty. So I said to the doctor, "Look, look, why haven't you guys done anything? Look at her bandages."

And he said to me, "Oh, she's -- she's just here for pain meds." I said, "No, no, look at that." So he then, in front of me, ripped the bandage off, and I could see the skin and the openness of the wound.

And she screamed. And he looked at me and said, "See, I told you. That's all dead tissue and she's just play acting." So that was my introduction to leg ulcers.

A while later my daughter developed

ulcers, an ulcer. It was the combination of having -- they couldn't find any veins, so they used her ankle.

Then she developed a -- an ulcer from that, and I was like, "Whoa, this is my kid. She's got an ulcer." And they were like, "Oh."

One person said, "There's nothing you can do." And I said, "Of course there's something I can do." Right? Of course. What do you mean there's nothing?

So we went to her doctor and, of course, I said, "What are -- what are you doing? What can be done?" And he said, "Well there's this thing. We can use a wound vac, but that requires that she be hospitalized for six weeks."

I was like, "Good." So we had that, and that was great. And that was my real kind of sort of introduction.

Then I took in a friend of hers who had a child who had leg ulcers, and lived with me for a while, and I was the one who took her for wound care.

And it was the changing of the -- the bandages. It was -- it was amazing, 'cause I kept saying, "Well, we know that the wound vac works." And they were like, "No, no, no, we have to do this first and we have to do that first."

And she would get a little bit better, and then she would -- it would open again. And I -- you know, I -- I was just amazed that I could not move that any faster. I'm a master, master communicator, but I couldn't move it faster.

And we would -- finally, we would sit down and we would talk about things. And she wanted to date. She was young, she was beautiful, but she couldn't go anywhere. She couldn't do anything. She had a 5-year-old child who said, "Mom, you smell."

And so it was kind of a -- how can I say? It was such a sad time in my home, because she was there with me and we were experiencing her getting a little bit better, and then it would get worse, and then I would fight.

And, finally, after close to eight

years, we did get a -- finally, we got a graft that worked. But my question was why did it take us so long to get it? Right?

So in -- in -- trying to figure out what's the best part to -- to communicate. Everybody's done a great job talking about how it interferes with your life.

It interferes with how you're perceived. I go back to that first person all the time and I think about how the doctor just said, "Oh, you're a drug addict 'cause you want pain -- and that, and you've been on the streets and so now you have open wounds. Oh well."

I guess it was for all of us, the lack of really being educated about sickle cell and wounds; right? So many people said, "Well, we can just cover it up." But unless you do a deep dive like we've been talking about today, you don't know everything that's involved in it; right?

Not treating the underlying problem, right, makes everything else we do moot. So we have

to do -- to do all of it. And I'm trying not to get too teary here.

Anyway, so if we were to really, as a community, come to you, to the FDA, we would say, first, think of you -- thank you for what you're doing. Thank you for including us here. Thanks for looking at us as something other than a simple disease.

And hope that the whole thing that you're doing and trying with this -- this kind of thing is not dividing us from other humans by disease. That that whole focus is just amazing.

All right. So let's talk about clinical trials. For years, for us in sickle, clinical trials have been all based around only pain.

And unlike many of the things we talked about today, people with sickle cell are born with pain, born into pain. So we understand how pain works. We have a high tolerance for pain.

But it's the quality of our lives that are really, really most important to us. It is being

able to interact with the -- how can I put it -- the mechanism that's going to treat us, that we have to surrender our bodies to, and being treated by people who understand us, treat us with respect, and really, really listen to what's important to us.

The concept of measuring; right? Measuring what is life, what is a good life. Many people think -- and our doctors are trained to think that if you just extend life, that's what you're supposed to do. Not looking at the quality of life.

Given what happens with wound care, we've seen, we've talked already about all of the interruptions, the -- the -- I just remember them saying, "I can't go out. I can't go to the disco. I can't wear a short dress. I can't take my daughter to the beach."

All of those things that conflict and -- and minimize, right, their sense of being or having agency and control over their lives.

So in clinical trials, we would like for you to make sure that in the whole design of it,

right, that we're putting those types of -- of data points into the study, right, that have to do with quality of life.

Yes, I could take my kid to school. Yes, I could go to church. Yes, I could get out of bed. Yes, I feel better. And what is feeling better? It's not just a physical thing. It's a mental and an emotional thing.

I would ask that you also include in the trials, if you're collecting data, that we collect data again on quality of life, not just the physical mechanism of what having that treatment, doing that treatment, is doing for you disease wise.

And, again, I want to thank you. I've cut my speech -- my talk short because every -- I didn't want to be redundant. So, again, I just want to thank you.

MS. BENT: No, and thank you. I think that -- so no, thank you. And I think that that was -- you made some really good points about minimizing the burden of the clinical trial, as well

as thinking about endpoints that really are meaningful to the patients. So thank you for that.

So now we're going to turn to Janet and Richard on -- who are participating virtually.

MS. FRANK: Okay. Hello?

MS. BENT: Hello.

MR. FRANK: Hello. All right. Yes. I -- I'm here, Richard Frank, and my wife Janet. I want to thank you for the opportunity to speak here.

I've been diagnosed with pancreatic cancer stage 4 in August 1923 --

MS. FRANK: No, 2000.

MR. FRANK: 2023. Excuse me, not quite that old. I also, incidentally, had a misfortune of having a ruptured left Achilles tendon, which led to significant issues with respect to wounds and wound care.

And I certainly was an enormous beneficiary of having dedicated wound care with respect to my situation, particularly because the interaction between the chemotherapy I was receiving

and the wound care treatment was very much something that had to be negotiated.

I had, initially, a clinical trial in the fall of 19 -- 2024 -- 20 -- yeah, 2024. However, I was in a control group in a clinical trial for that, which meant that I wasn't receiving any actual therapy at that time.

My oncologist recommended leaving that initial trial in favor of a second trial, which is where we've ended up with, and very, very fortunately this has been a -- a real life changing event for myself.

In respect to the mission here is to talk about some practicalities with respect to clinical trials. And for those of you who are involved in this or examining this, I think what's important to understand is, first of all, there's enough practicalities that have to be considered.

If you're in a clinical trial, it's very helpful to be -- and you're going to be in any location, whether it's paid parking or transportation

to a trial -- trial site location, a meal card if you're -- overlaps your -- a meal card if you're overlapping the meal time.

There's also a question of cost for drugs, devices, or medication, supplies, and whether that's being paid for by the sponsor for the clinical trial.

You also have to have -- a really important facet of this is to have a trusted contact for the clinical trial, which you're able to go to and get direct answers to many questions that may be raised in your mind with respect to dealing with that trial.

When these trial visits are scheduled, it's important that the trial team consults with the patient, and this should not be on your responsibility simply to schedule the trials -- visits itself.

There's also, you know, lab work required, and this is important that you have a lab in some close proximity to you and your trial site in order to facilitate doing that. And there are some

remotes but most should be in person to the trial site.

There's tremendous personal satisfaction in that -- involved in doing this, because what you do may potentially have the benefit -- be the benefit, literally, for millions of others in terms of the developments that are conducted in these trial drugs. And that certainly has been my experience.

And I can't say too -- enough about how important the wound clinic has been. We didn't know about that at all before we started this.

We found it absolutely invaluable with respect to what I was dealing with in terms of the synergy between the clinical trials I was involved in and -- and the wound on my left leg due to the Achilles tendon injury. Thank you.

MS. FRANK: Okay. And I'll continue, because I want to focus on some of the general concerns and pieces that need to be in place, we found with the clinical trial, to make it really palatable

for the participants.

We understand how stressful it can be in a clinical trial, and, of course, the trial team is collecting data all the time.

So I -- I will just quote the nurse practitioner who said to us at one point, "Are you living for the clinical trial or are you using the clinical trial to live?"

And I think that gets to what kind of quality of life do I have while I'm in this clinical trial?

Okay. So general concerns -- will the intervention help? Of course, nobody knows because it's a clinical trial.

And what is the duration of the trial? Now, for Rich, he's still in the clinical trial having started it in the end of January of 2025. He's been told he can continue it as long as he wants, and then there's a certain time period past the last enrollee. So he will continue to stay in the trial. In fact, we have a visit tomorrow for the protocols for him.

Also, is there a capable and reliable caregiver available to follow the protocols of the home requirements for treatment in the trial? We know with wound care, I have been the -- the wound care giver at home, and it's time consuming.

And so you can expect probably in a clinical trial to follow the protocols for a long time. It can be exhausting for both the patient and the caregiver.

What are the possible side effects, and are protocols in place for managing these? Now, we'll speak to that because we have had side effects from the existing clinical trial we're in.

And the question was is there a 24/7 triage number available to the participant? In our case we're fortunate to have that, so we can have our condition -- Rich's condition or side effect triaged by phone.

And then if he needs to be seen in person, that is, in fact, facilitated and expedited through the clinical trial team, whether it's

emergency care or whatever. So you don't have to get in line at the emergency room.

If there are complications, are there -- are all the relevant practitioners able to communicate with each other in a timely fashion? Are they in the same system or on the same electronic medical records platform?

This has been kind of a pet peeve for me and for Rich, just because we did have an instance where we had a very major emergency situation that landed us in one emergency room at an academic center.

The problem was the communications -- even though they were on the same platforms, the communication was just very difficult between the clinical trial team and this other academic center.

The decision was made that we transfer up to the clinical trial academic center, because that's where everybody could see everybody else's emails and communicate there, and that we think is really, really important.

And I'll add this aside, why is it --

to the FDA and whoever else might be listening, why is it -- as we contemplate fragmented healthcare, why do we have health systems across this country that are not on a same or similar EMR platform? It sure would make communication easier.

And I will say -- when it comes to emergency healthcare and whatnot, I will say that Rich carries an info sheet, that was provided by the clinical trial, with him when he travels that details the trial he is in, the medications he is on, and the contact numbers. This is so helpful when we leave the immediate DMV.

Okay. So next is assuming trial meds and supplies are paid for by the sponsor, what role does health insurance play? Does the sponsor pick up any difference in cost between insurance and what is not covered? Can the trial team make certain there are no out-of-pocket costs billed to the participant?

This is important because we know that not everybody is as fortunate as we are to have two coverages. So we are able to get by with zero cost

for most -- most everything except some prescriptions.

How much time will be needed for visits? Can the clinical team stay on schedule? We've had to juggle our work schedules to accommodate the clinical trial team, and sometimes visits with the clinical trial director kind of throw a wrench in the schedule.

So that's something that needs to be considered, and participants, you know, can -- can look at this also before considering whether they participate or not. Of course, participants are screened before joining the clinical trial and we understand that.

MS. BENT: Thanks, Janet. I can -- we have about one minute left. Is that --

MS. FRANK: Okay.

MS. BENT: Are we good?

MS. FRANK: Yep.

MS. BENT: Okay. Thank you.

MS. FRANK: The takeaway is -- the takeaway is it -- it is important to advocate for a

loved one and yourself to get what you need in a clinical trial. Patient, caregiver, clinical trial professionals are one team.

We would recommend keeping a notebook and taking down info at each and every medical trial visit. Share all your concerns. Ask questions. And it's so much easier to refer back to the information that is contemporaneous, easier to share with PCP, PA, PT, as well as other doctors or nurses who may not be part of the trial.

Of course, people have talked about outcomes that they're looking for. I don't need to go over that in a clinical trial.

And one last point I will make. It sure would be nice to have a clinical trial clearinghouse for wound care.

It is done with pancreatic cancer through PanCAN, and I will say that our oncologist has developed a network of navigators, nationwide navigators, who help patients navigate clinical trial -- the clinical trial maze.

I think that would be very helpful for wound care as well. Thank you.

MS. BENT: Thanks so much, both Janet and Richard. That was really helpful and really gave us some very concrete things that could be done to make clinical trial participation just more realistic for people. And I think we'll definitely take some of that back.

And so now we are going to hear from Corlis, who is also joining us virtually.

MS. WATKINS-NASS: Hello. My name is Corlis Watkins-Nass, and I am the co-founder and president of All Things PG, a nonprofit organization dedicated to supporting individuals affected by pyoderma gangrenosum.

I am also the administrator of All Things Pyoderma, a Facebook based patients' community -- support community.

I have personally lived with PG for eight years. I had chronic wounds for four of those years. So I understand firsthand that this disease

affects far more than the skin. It -- it impacts every aspect of a person's life, socially, economically, physically, mentally, and spiritually.

I am -- I am incredibly grateful to say that on August 8th I celebrated eight years in remission with no flares.

That experience has given me not only a personal perspective, but also a deep understanding of how important effective treatments and clinical trials are to patients and their families.

When I think about participating in clinical trials, one of the first concerns that comes to mind is the financial burden of living with -- with chronic wounds.

Compensation for trial participation is important, because patients may have to take time away from work, travel significant distances, arrange transportation, and potentially make childcare or other arrangements. These expenses can add up quickly.

For patients managing open wounds,

there is another layer of preparation. Before traveling, we have to make sure we have an adequate supply of wound care materials available, not only for the duration of the trip, but also in case an unexpected issue or emergency occurs.

These are practical realities that can determine whether a patient is able to participate in a clinical trial at all.

Another significant concern is the lack of rescue medication, particularly for patients with chronic wounds. For many, the medications they are currently taking may be working. They may finally see their wounds heal, their pain decrease, and their quality of life improve.

Asking them to discontinue a treatment that is working in order to participate in a trial can be an extremely difficult decision. One day without a medication that is controlling the wound can potentially result in weeks or even months of setbacks.

Having a rescue medication available

during a clinical trial could make a significant difference. It could give patients greater confidence that if their wound worsens, there is an established option to intervene.

More importantly, it would also allow patients to make a truly informed decision about participation, knowing there is a safety net if the investigational treatment or placebo does not adequately control their wound.

The logistics of a clinical trial are also extremely important. Patients want to know how long the trial will last, how frequently they will need to travel, how many in-person visits will be required, and what happens if they experience worsening of the wound while participating?

For some living with a chronic wound, frequent travel can be physically exhausting. Extreme fatigue is something many patients experience on a daily basis.

If virtual appointments could be offered when medication is not being administered or

when an in-person examination is not medically necessary, I believe more patients would be willing and able to participate.

Reducing unnecessary travel could also make clinical trials more accessible to patients who are already physically, emotionally, and financially exhausted.

Ultimately, I believe patients with chronic wounds would want better treatment options. We want to participate in research. We want to help advance science and make sure future patients do not have to experience what we have experienced.

But in order to participate, patients need to feel that the clinical trial recognizes the realities of living with chronic wounds.

Financial support, reasonable travel requirements, rescue medication, flexibility in trial visits, and clear communication about what happens if the wound worsens are not luxuries.

For many patients, they are the difference between being able to participate and

having to say no.

Thank you for this opportunity to speak to you.

MS. BENT: Thank you, Corlis. The concept -- that was really helpful and really, really informative. So thank you for taking your time with us.

We are now going to turn to Chaquira for -- to hear from your experiences and thoughts. Please go ahead.

MS. ANDRADE: Hello, everyone. My name is Chaquira Andrade; I'm currently a hidradenitis suppurativa patient, and I've been a patient for the last 16 years. I would like to be able to speak about my experience as an HS warrior going through clinical trials.

Clinical trials, one of the top difficult things that can be experienced, as other patients mentioned, was the -- the frequency of having these visits, being able to figure out what you're going to do with your transportation, and making sure

that you understand the balance of work and also your personal life.

Living with HS, you deal with a lot of different underlying problems that may be able to make these appointments limited to you, but also can be an experience that you have where it can be life changing, just like mine.

So, for example, something that can make it easier is definitely a flexible schedule. Being able to either have virtual visits, being able to have transportation assistance.

And, also, I would like to highlight -- as a social worker for the Department of Homeless Services in New York City, I would like to even discuss the social determinants of somebody's life.

And being able to analyze them for everything that's going in their life, based on their housing, their transportation, their means of dieting, how are they -- whether they're participating in government assistance.

To be able to make sure that you're

just not focusing on how to better somebody's quality of life, but you're able to give them the tools and the resources that's needed to maintain this quality of life.

Another logistic that I know that it's very important to be able to understand is patients being able to participate in research and managing those everyday life to life, whether it's a physical aspect, emotional aspect, or even a mental capacity that could play a role in you living with a chronic skin condition.

So such as going to wound care, being able to have those unnecessary burdens such as transportation or trying to figure out how you're going to be able to better your health taken off of your shoulder can be able to be a great deal for patients.

Another improvement that can be done is the importance of being able to understand that while living with this condition, there is something more than just the physical side of it.

We all often deal with severe pain, drainage, odor, and there are multiple things that can be able to play a factor in our mobility.

So exercising, walking, socializing, or even wearing comfortable clothes, or being in a setting where you can be able to have that, can be dramatic to the quality of life of an HS patient.

Also, considering measuring these outcomes, another additional thing to be able to understand about wound healing is the quality of life and the frustration and the functions that go into it every single day.

So, for example, besides the pain being impactful, we deal with mobility issues, sleep, dressing changes, and the ability to participate in daily activities.

Lastly, I would like to speak about the research and the understanding and the biggest lesson of being part of a clinical trial. Patients are able to shine a light on their voices and enhance their quality of life with successful treatment.

Clinical trials is an outcome that is very important, because research also is considered, whether the treatment helps a person live that better quality of life, or whether it's managing and healing their wounds.

Me being able to participate in clinical trials for the last five years, from '20 to '25 -- from 2020 to 2025, and being able to gain my quality of life back, also with a treatment drug, has been the greatest blessing of my life.

But most importantly, I don't want to forget to mention my community that gave me the support I needed to be able to have the opportunity to thrive.

And thank you so much to the FDA for giving me this opportunity, as an hidradenitis suppurativa warrior, to be able to amplify the voices of my community.

MS. BENT: Thank you so much, Chaquira.

And so our last panelist today is Laura. We're going to turn to Laura, and then we're

going to turn back to our panelists for a few clarifying questions.

So please go ahead, Laura.

MS. PARNELL: Thank you. I appreciate it so much, Robyn. And thank you for organizing the chronic wound listening session.

I'm Laura Parnell. Most -- many of you will know me from my work in the Wound Healing Foundation, but my most important work has been being there for my daddy and my mama as they dealt with my dad's diabetic foot ulcers.

There's -- there's a real lack of education and understanding and practicing of the chronic wound care clinicians, and it's a real burden for the wound patients. And almost every single patient all day today has -- has led back to that.

What I'm going to talk about now is in the rural areas, this becomes an even bigger burden for rural wound patients.

In rural areas, it's not unusual to travel more than six hours, or even go out of the

country, in order to receive good wound care by experienced wound clinicians who can think outside the box and realize that this is not going specifically the way it should be.

Additionally, the lack of cell phone service and internet access can be a real limitation to your treatment options as well.

Until we got the Starlink, we had to drive 30 minutes into town to use the computers at the library in order to access the internet to search for potential answers or look for new clinicians. And, believe me, we went through a lot of clinicians before we found some that could actually listen.

When you're dealing with a wound, a chronic wound of any kind -- but in my dad's case, it was a diabetic foot ulcer -- combating wound infection such as MRSA in a rural area was fraught with a lot of difficulties.

We had to try to find a hospital that had capabilities and had the antibiotics it needed. And for us, that ended up being about two and a half

or three hours away.

Also, side effects, such as C. difficile that came after the MRSA antibiotics, having deep vein thrombosis and pulmonary emboli because of too tight casting, these things all became nightmares and were life threatening.

And you add the -- the additional trying to figure out what was wrong and go to find the hospital, it was not a situation you want to have anybody to have to go through or repeat.

I'll reemphasize what several patients have said that not all caregivers and not all clinicians are created equal. Your wound care will not necessarily be adequate between clinicians. This seems to be even more so in the rural areas.

How a clinical trial is broached with a wound patient and their families impacts their willingness to consider participating in a clinical trial. Considering the potential adverse effects can alarm patients.

But really the possibility of being in

the placebo-only group, which can delay the treatment. It can delay healing. It could possibly increase further deterioration, no improvement. What about the risk of infection? What's the protocol if it becomes infected?

Things of that -- those things have to be seriously considered by the family and the patient, because each of these little wins are so hard won, and it does not take very long at all to flip back into a bad setback.

Several people have mentioned about the logistics, and, again, speaking from the rural perspective, the logistics of coming and going from a clinical trial can be a huge issue for rural patients.

You're asking them to travel, which is not always easy. You're asking them to schedule yet another visit, which can disrupt their week. Try to fit it around all the other doctor's appointments. Everything takes longer to do.

It requires more effort and often there's more pain whenever you're going somewhere or

doing something new. All of these things have to be taken in consideration as part of that willingness to participate in the study.

Travel compensation is needed, especially if you're driving four to six hours away. But if it's that far, I'd encourage sponsors to consider compensation for a hotel too, since it can take all day or two partial days just to get there, to go to the appointment, and then get back home again.

This -- this can be done and it has been done. My dad's been in a couple of different clinical trials, and it's doable. But you have to have the right staff and the right mindset, and the patient has to decide that it is the option for them.

Patients like my daddy and my mama want to feel valued, and their opinions valued. They don't want to just be another body in a clinical trial.

When this is done well, the wound patients that become study subjects can enjoy or even look forward to participating in follow-up evals. They form bonds with the study staff and the

investigators.

These are things that even now, even after Daddy's been out of the study for a couple of years, they still go back and bring Christmas presents to the study staff. These person-to-person bonds are important, as -- as important as anything else.

In remote studies, these person-to-person bonds can be lacking and -- because it -- it forms over time. How easy or how well a coordinator or a doctor can connect with others over the internet or over the phone is an important consideration for remote evaluations.

And just, lastly, I'll wrap up and say that in addition to improvement of wound measurements and wound characteristics, a reduction in pain and improved mobility are excellent secondary measurements.

To my family, the healing durability -- that is, to not break down and become a wound again -- is a better characteristic to measure than faster healing.

This is, obviously, a complicated dynamic. And, certainly, healing faster has some benefits, such as lower colonization and infection risks, but so does durability. And this allows the body to remodel and strengthen the wound scar and not break down over and over again.

I want to thank everybody for their time today and letting me share our family's wound experiences with you. And I'd be more than happy to take any questions you might have.

Thank you very much for this opportunity.

MS. BENT: Thank you so much, Laura. That rural dimension of the experience, the six hour drives, the internet access or lack of internet access until you had -- able to access Starlink, and other things are really -- just kind of put things in perspective for those of us who are living in the metropolitan Washington, D.C., area. So really appreciate that.

And so thank you to all of our Topic 3

panelists: Adrienne, Janet and Richard, Corlis, Laura, Chaquira. Your perspectives were really -- will really directly inform how we think about clinical designs for -- or clinical trial designs for nonhealing chronic wounds.

I would like now to turn to our panelists, our FDA panelists, our -- and WCCC panelists, and our newly arrived NIH panelists, and just see if you have any clarifying questions.

I think, Sarah, did we want to start or -- okay. We're going to start with Dr. Mejia. Then I know Dr. Driver has a question.

And I know, Sarah, you have a question.

So we'll just work the way down. And for our panelists, if you -- who are online, if you would like to answer the question, any of the questions, clarifying questions, please feel free to just turn on your camera and we'll come to you one at a time.

And if anyone in the room who is a patient or caregiver would like to respond to some of

the questions, please raise your hand and we will have one of our mic runners bring it on over to you.

So please go ahead, Dr. Mejia.

DR. MEJIA: Sure. Thanks.

So this question is first directed towards Corlis, but if anybody else wants add clarification, that would be great.

So most of the clinical trials we see involve standard of care in the control arm to ensure that participants are still getting high quality care even if they don't get the investigational product.

Can you explain or tell us a little bit more about your concerns around not receiving treatment or needing rescue medication?

MS. WATKINS-NASS: So I can speak from the perspective of having lived with pyoderma gangrenosum.

What I am receiving from many of the folks that are in the support group is they are so scared because the medications that they are currently on seem to be working, and so when they are being

asked to participate in a clinical trial and everything is taken away from them, that in itself is more than enough for them to say no.

But what they are telling me is -- is if there is a rescue drug that's available, just in case they happen to start flaring, then they would be more willing to be able to actually participate in a trial.

MS. BENT: Okay. Thank you.

All right. Was there anyone else who wanted to speak to that a little? All right. So I see -- so let me go to Adrienne, then Laura, then Chaquira. And go ahead.

MS. SHAPIRO: So one of -- one of the things we found that's been really helpful for this is that in -- as part of your clinical trial design, you have a -- a process for interacting with the -- the care provider of that person.

So that you've already worked out how things are going to -- how you're going to communicate and -- and I -- I guess, increase the comfort level of

not feeling like your care is -- is going to -- to drop out.

The other thing is we found that in the actual design of the trial, that it's really important that you have a person that's there from the very beginning of the design, who is either a patient or caregiver, but someone who has lived with the disease.

So you can make sure that in the whole design, from the very beginning, you're capturing all the things you need in order to -- to ensure a more effective and -- and successful trial.

MS. BENT: Thank you.

Let me think. I think I said Laura next; right?

MS. PARNELL: So I would just mention that, at least for diabetic foot ulcers, whenever we discussed it as a family, it was not something that we wanted to do as far as standard of care, because you can actually lose some progress.

For some people -- 20 percent of people will improve on standard of care, but we just did not

feel that the risk was worth the benefit.

Studies that my dad has participated in, it was for ophthalmology. It was actually one of those things, the standard of care was a already approved treatment versus a treatment that was more of an advancement potentially.

So for us, it was just a -- going back to the standard of care was just a no go starter.

MS. BENT: Great. Thank you.

And Chaquira?

MS. ANDRADE: Yes. Hi. I would just like to mention being able to live with HS, sometimes it can be a very invisible disease.

And sometimes we don't have the actual, you know, caretakers or caregivers surrounded by a warrior, just for the fact that this is something we try to hide for a long period of time, especially the fact that it comes with so much embarrassment, so much of the unknown.

So I just wanted to make sure that I just shared my experience on how I was actually one of

those patients that didn't have anyone. And I leaned on my medical team and leaned on my dermatologist to be able to help me.

And understand that, going back to the -- the social determinants of life, there can be things that can be put into place for me to be able to be understood and have that support system.

Along with being able to speak about, like, the step therapy act where you have to try all these medication drugs to be able to get the one that your doctor knows is right.

So just being able to have someone on the back end that can be able to understand your journey and know what you have encountered, and what may work, and what's available to you can also be able to help your quality of life, and comfort somebody to be able to participate in clinical trials. Because it gave me so much hope.

MS. FRANK: I -- if I could -- if I could add, also, that, you know, when Rich was in a clinical trial, he was -- the first one was watch and

wait or immunotherapy. And the watch and wait is when he developed problems based on CT scans and -- and blood testing.

Trial number two compared two different standards of care in combination with the clinical trial drug. And so there was a way to really layer this, so that both cohorts could be evaluated on the clinical trial drug with a given standard of care. It's just there were two different standards of care.

Okay. And then the second thing is that I -- I agree with everyone who said it's important to have a support person.

And in our case it was an oncologist who was kind of keeping watch over things. He happened to know all the clinical trials, and he was in contact with the clinical trial team.

And I think that by doing that, he could guide us in separate visits and whatever else he chose to do outside of the clinical trial to guide us and say, "Yeah, I think this is a good path. Yeah, I'm going to talk to the clinical trial team about

this."

And he even gave us some additional information about resistance to the clinical trial drug based on his journeys to talk to other researchers.

So I think that piece of having a support person, not only somebody who is outside the trial who is supporting you and monitoring things, but also that -- Rich alluded to the clinical trial nurse who is there for logistics and questions and coordination and guidance.

That is so important. Because I think I communicate with the clinical trial nurse once a week, and she does check in on us. So I think that's so important for making the patients really, really feel comfortable in the clinical trial.

MS. BENT: Great. Thank you very much.

All right. Sarah, did you have a question you wanted to ask?

MS. ROSENBERG: I -- I do. Thank you.

So I've heard a lot about quality of

life, but there's a lot that goes into that, and we've heard from a lot of different experiences with underlying diseases that quality of life can look very different for each person.

So I'd like to get a little more nitty gritty about it. As a measurement scientist, it's very hard to measure quality of life. But I was just curious as to what specific signs or symptoms most affect your quality of life?

So for example, if you have pain, is it pain reduction during dressing changes that is meaningful? And I was just hoping one of the patients could actually just elaborate a little bit more about what that looks like to them.

MS. SHAPIRO: Well, I know from our -- in the sickle cell community, if the wound is causing lots of pain, then that will have you -- will many times throw you into crisis.

So then you have the VOC happening at the same time that you're -- you're having an eruption from your ulcer. So, absolutely, calming that down

and keeping it under control would make a big difference.

MS. BENT: Thank you.

Chaquira, did you have something you wanted to say?

MS. ANDRADE: Yeah. I was just going to say specifically for an HS patient dealing with wound care, you say that you can't measure the quality of life or you don't know how it may look if, you know -- for -- for us specifically dealing with the skin and dealing with drainage and the odor, I feel like you can see the improvements within what we're able to do in the improvement.

So, for example, mobility. If somebody was not able to lift their arms up all the way or extend it to a certain point, if you're measuring how far and how better they're going with their mobility to be able to extend their arm.

Or if the drainage is -- is -- used to fill up a whole bandage and now it's just a dot or two. The odor, if -- if she's using a specific body

wash or -- or a product that is available for an HS patient and she's seeing better results and -- and less odor.

So it's those kind of things that we would like to measure, and we would like other people to understand. With those measurements we could be able to understand if we are improving a condition or if it's getting worse.

And especially with the nodule count, I remember participating in clinical trials and being able to know that my treatment drug was working for me because my diagram of my body figure, my lesions, and my nodules, and my boils, and the flares that was occurring was decreasing and was actually healing.

And that's how I was able to understand that my quality of life was being improved. Especially that we deal with surgeries and think that we need wound care to be such a factor of and be measured to the best ability to see the improvements.

MS. BENT: Thank you.

And then we'll go to Corlis, and then

over to Dr. Driver for the next question.

Corlis, go ahead.

MS. WATKINS-NASS: All right. As a person living and have lived with PG, the pain perspective is -- is -- it's most important.

What we know about PG is the pain is oftentimes unbearable, especially if you are in the midst of having an infection, it literally feels like your body is on fire.

Oftentimes when I know -- I knew that I had an infection by the level of pain that I was in at that particular time. There was always pain but there were different levels of it.

And when it got to the point where I could no longer take the pain -- because I -- you know, having the disease, you already have a high tolerance for a pain level.

But when I got to the point where I could no longer take the pain, I knew at that particular point that that was time for me to get myself to the hospital because I had an infection.

And once that infection was able to be able to gotten under control, then we were able to start the healing process again.

So that and also the smell. It is quite embarrassing when you are out. I was still trying to teach at the time, and just the odor that goes along with you wherever you go, it's -- it's embarrassing and it just makes you want to retreat and not go out to see anyone.

And you just want to stay at home because, you know, just having that was just so embarrassing. So those two things are of utmost importance for those of us with PG.

MS. BENT: Thanks so much. And I can only imagine trying to teach in the best of times, let alone with dealing with nonhealing wounds. So thank you for sharing that.

So I'm going to turn to Dr. Driver who -- because I think you had a question.

And then I know Dr. Jones has a question as well. So let me come to you.

DR. DRIVER: Yeah. So my question is -- so we know, because we've been studying, the percent of patients that are actually allowed in clinical trials to be very low. Some people say 10 percent. It's actually more like 2 or 3 percent.

So I'd like to know from the patients and caregivers, in your experience, what has excluded you from clinical trials?

Because we are moving, actually, fairly quickly on redesigning clinical trials to include more patients that are representative of everyday patients seen in our clinics.

MS. SHAPIRO: So I can say that in the last 10 years -- 'cause it was 10 years ago, I had my first clinical trial where I was an advisor -- that trials that have put in support for the patients, the -- the psych social support and the financial part, those really are an incentive to know that you're going to have that -- not have that burden; right?

Because the other thing is when -- how

can I put it? Okay. The doctors are the other thing that happens; right? So many times you don't know about the trial, and your doctor has to decide whether or not you are, like, trial worthy; right?

And not understanding that you may miss doctor's appointments because you're not well. There's -- there's -- one doc said to me, "Well, they didn't keep their appointments."

And I'm like, "Well, you're having them come, and they have to pay $22 for parking, and gas for coming for 45 miles." And, initially, the doctor didn't think -- well, that's no big deal; right?

So having those sorts of things in place. And I think we're -- you know, again, these kind of conversations are driving us towards that.

MS. BENT: Thanks, Adrienne. Is there anyone -- any of our panelists online who want to speak to what -- kind of what barriers have you encountered as far as not being able to be eligible for clinical trials?

I'll also turn to the people in the

room and see if there's anyone who had wanted to participate in a clinical trial but had been not eligible, and who wanted to share that information.

I'm not seeing anyone, so I'm going to appeal to our online community.

MS. WATKINS-NASS: Yes.

MS. BENT: Oh, wait, suddenly I see three people. Excellent. All right. Let me go Laura, Chaquira, Corlis. I'm not sure what order you went in, so I apologize if that's not the correct order.

MS. WATKINS-NASS: That's okay.

MS. PARNELL: I was actually last, but I'll be really brief.

For us, it was the weekly -- needing to come in weekly. And that just was not realistic for us in -- in where we were, particularly given that we were going to have to drive, you know, five hours just one way and then five hours back. On a weekly basis, that just didn't work.

MS. BENT: Great. So it was more of a

logistics issue then that kept you from being eligible in, like -- from your -- because of your life, and not as much of a -- like, a lab value or a concomitant medication or anything like that?

MS. PARNELL: It -- It was both the in-person evaluation as well as the lab draws.

MS. BENT: Great.

MS. PARNELL: Because the nearest lab is, like, two hours away. So we just couldn't comply with their protocol.

MS. BENT: Yeah. That feels like a significant burden. So no, thank you.

All right. Chaquira?

MS. ANDRADE: For me, I could be able to just speak on how when you're living with hidradenitis suppurativa, a lot of, like, the outcome to be able to remove the tunneling and the flare is surgery.

And I did find that while on clinical trials I was exempt from, like, having deroofings, any surgeries, or in-site steroid injections.

So just those limitations -- you know, my doctor had to plan accordingly before me going on clinical trials to be able to get my mobility and be able to have these procedures scheduled in a matter of time for me to still be able to have the opportunity to go into clinical trials.

So also just highlighting when you know that there's a different option for your warrior to be able to take during the matter if you're still trying to find her the hope of the treatment drug. So that was one of my limitations and barriers that I faced.

So I'm just grateful that I had the time and my body had the strength to be able to allow me to have those surgeries and then participate in clinical trials, because I couldn't do two things at the same time that I knew was going to be effective to me being able to have my quality of life.

MS. BENT: Thank you. I think that was really good information. We really appreciate it.

Corlis?

MS. WATKINS-NASS: One of the things

that we are concerned about is the lack of awareness of the trials themselves.

The dermatologists not knowing that the trials are out there to be able to let their patients know that there are the trials, that they hopefully will be able to get into them.

So if we had a way of communicating that information, you know, that would be most helpful. If there was a -- a website -- and I know there -- there are.

But most of the patients don't know exactly where to go to see what trial that they would be able to participate in. So just lack of awareness.

MS. BENT: Thank you. And I know Janet mentioned that earlier as well, so that is a recurring theme as well.

Janet, please go ahead.

MS. FRANK: Yeah. Yeah. I just wanted to say I think that if you go to the websites and look at the clinical trials -- because we did in the hunt for a clinical trial that would help Rich -- it's

really hard to understand. They're not user friendly.

And I think that's why it's really important for this idea of navigators or a -- a physician or nurse who has expertise in this area to guide -- guide us.

And -- and let me just say one other thing. You know one of the issues that has come up repeatedly is that if there's a complication -- and comorbidities plays a huge part in clinical trials; right?

Because some clinical trials will allow you in with certain comorbidities and others will not. Some will allow you to continue in the clinical trial, even though you have developed new comorbidities, because you entered the clinical trial without them.

And so one of the issues that has come up repeatedly is we have to talk -- if something comes up, we have to talk to the clinical trial team to see if medication X is under the protocols.

And that necessitates a call to the sponsor by the clinical trial team. And that can

delay treatment some. Because sometimes it takes a day or so to get a response from the sponsor.

So there are all kinds of logistics that -- you know, when I've heard multiple people say, you know, that they -- they are reluctant because they have made progress with their wound care.

And we've had two. Fortunately, we -- we've had good coordination between the clinical trial team and the wound care specialist. So we're working in tandem.

But it's a balance, and I think getting that -- finding that balance, whereby you can still participate in a clinical trial team while also dealing with other comorbidities or other issues, wound care or whatever, is so important for patients.

And I just want to say that it is -- it is something that has come up repeatedly.

MS. BENT: Thanks so much, Janet.

So I'm going to make an appeal -- because we've heard from a variety of our panelists about their thoughts. We realize that we don't

have -- we have some from Laura.

But if there's anyone who is listening to the meeting who has thoughts on this, particularly if you have a diabetic foot ulcer or something like that, if you wouldn't mind sharing -- like, calling in to share your perspectives on what would be meaningful improvement, especially from a quality of life standpoint, that would be really helpful.

The number 1-800-527-1401. That would be -- we would be appreciative to kind of hear your perspectives as well, because we're noticing that there are slightly different things that matter to people with different conditions, and just want to kind of cast a wide net to get a broader understanding.

While we're waiting on -- while we're waiting to hear from others, I would like to turn to Dr. Jones.

I think you had a question that you wanted to ask.

And then we will move to polling

questions. Very exciting.

DR. JONES: Okay. Well, thank you. And I want to -- I really want to thank all the participants for sharing their stories, and I'd also like to thank the FDA for sponsoring this in this format of listening. I've listened and hope we can really include that in the research we do at NIH.

So I have a question about the duration of clinical trials. We've gotten a lot of good feedback about what people like and don't like about trials.

So this is about how you weigh the duration, how long a trial will last. I mean there's a time commitment, which would be a negative.

On the other side, a longer trial, you might really then understand the full course of the disease, the quality of life, and for diabetic foot ulcers, you know, the durability of healing.

But there's a kind of balance there. So I'd like to hear from our participants on this question. Thank you.

MS. BENT: And as a spoiler, we will also ask that as a polling question after, but I think the details -- that would give us just a very blunt tool.

I think hearing from you all about your thoughts about trial duration and being able to dig deeper into kind of your rationale for what you're thinking would be very helpful.

So do we have anyone who would like to talk to us?

All right. Go ahead, Janet.

MS. FRANK: Okay. So what I would say is -- and I know that in wound care it's different than in cancer; right? In cancer you can have CT scans, you can have blood measurements, and whatnot.

But as long as there is some sort of feedback to the patient as to what is improving or what is changing, I think that's so important.

And I mean, you know, feedback every single visit. That is helpful for a patient to know that -- that their participation in the clinical trial

is making headway. Okay? I think the -- the hardest thing is to not know.

And I think as -- as clinical trial patients, we want to know -- I know my husband wants to know -- how am I doing compared to last week, last month? Is there progress? Is there change, positive change? Is there negative change? And that really makes a difference for a patient.

MS. BENT: Great. Thank you. And I think to your point, it feels like one of the main things that we're hearing today is the importance of communication in so many different realms. And so I think that's really -- that's -- we hear you.

Laura, did you have something? You disappeared from my screen, but --

MS. PARNELL: No, I just wanted to mention that whenever we were looking at duration, as long as the -- the visits, the evaluations and things of that nature weren't excessive in our mind, so maybe, like, a once a month visit.

But we would be happy to sign up for

two years, a once a month visit, as opposed to weekly for six weeks. It -- it just fits into our lives better that way.

So, you know, it's not always about get as much information as you can in six weeks. Sometimes that -- that longer course is the better way of going about for patients. And certainly you would get -- you capture different data, but sometimes we want to see more of what's going on.

With wounds, you know, sometimes a month can be a whole lifetime in the span of a wound, at least to the patients. So that doesn't work for everybody, but from a rural perspective, it would.

The other thing I would mention is the communication that Janet had mentioned. Whenever you hear, "Hey, you know, your -- this is looking a lot better. You've improved this much. These things -- you know, everything's looking really good. There's no infection."

Those are the types of things that not only make you feel good, the fact that you're doing

that, but it gives you that hope that normalcy is on the horizon. You haven't gotten there yet.

It's almost like trying to chase a -- a pot of gold at the end of the rainbow. It -- the rainbow just keeps moving, but eventually you can capture that pot of gold. And, fortunately, for my dad, he was able to get both of his DFUs healed.

But I would say duration, you know, setting a -- an expectation of X amount of weeks isn't always necessarily an endpoint that -- that patients would agree with.

MS. BENT: Thanks so much. And that feedback that you mentioned, and Janet mentioned, and Jae mentioned earlier with them saying that they celebrate everything, celebrate every success, is really, I think, so important.

So let's see. Maybe it's time for us -- and I know we've exhausted everybody, but we're going to go to polling questions and see how many people are still hanging with us.

We've got just about 20 minutes left,

so we'll go through the polling questions. Please be ready for them, and we will -- there's three of them, just to give you some context. And then we will turn to some of our callers on the phone.

So let's start with polling question number 1, which is: "Would you join a study testing a treatment that improved symptoms; for example, improves odor, reduces itchiness, or increases movement, but did not always close the wounds?"

And the answers options are: "yes, no, or not sure." I will remind you that there is a bit of delay, but, hopefully, more than one person will respond. Woo hoo.

All right. Right now we've got a "yes," "no," and "not sure." And I can appreciate the "not sure." There needs to be a few more details, perhaps, before you could really make a significant commitment to something like that.

All right. But it does look like there's openness from at least a good number of people to something that is really working on those symptoms.

And so that is really helpful information.

All right. All right. Let's move on to the next question: "How long" -- and I kind of lied about there being a clinical trial duration polling question. Apologies. I'm about to be outed by myself.

"How long would you be willing to wait to see results from a wound treatment before you would consider it not working?"

Would that be: "2 to 4 weeks, 6 to 8 weeks, 10 to 12 weeks, 16 to 20 weeks, or 'it depends on the wound type and severity?'"

All right. So right now we're seeing a majority of the people saying six to eight weeks as a time to give it a chance to work.

All right. And let's now move to our final polling question before we go to our callers on the phone: "What is the biggest barrier to joining a clinical trial for wound care?"

And please select one answer, understanding that all of these probably apply, but

what is the most significant: "transportation to the trial site, eligibility criteria, mistrust, time constraints, lack of information, fear of side effects, fear of receiving inactive treatment, other barriers not noted -- not mentioned."

All right. So what we're seeing is the concern over receiving an inactive treatment is really what people are saying. It seems to be the largest barrier or concern.

We're also seeing fear of side effects as our second -- oh wait, no, eligibility criteria. Sorry, the letters are very small. Eligibility criteria being the most significant, followed by fear of inactive treatment, and then fear of side effects.

So thank you, everyone. This was really helpful and it helps us to -- kind of, again, it's to help with our discussion. It's not a scientific survey, but it does give us an idea of what people are thinking; and we do really appreciate that.

And so with, that I'd like to turn to our callers. We have two callers on the line, and so

we'll take -- I'm going to ask you -- I know you've been waiting for a while. I'm going to ask you to be brief so that we are able to end on time and we can get both of you in.

And then we'll turn to Ethan for the comments online, and then we will go to closing remarks. So with that, I'd like to go to our caller on line one.

UNIDENTIFIED SPEAKER: Hi.

MS. BENT: Hello. Please go ahead.

UNIDENTIFIED SPEAKER: Oh, am I supposed -- am I supposed to respond to a particular prompt or --

MS. BENT: So if you have thoughts on anything that we've been talking about, please feel free to answer questions, especially around what would be a meaningful improvement to you related to your wound.

But if there's anything that you would like us to specifically hear from you, an aspect of your experience living with a wound or caring for

someone with a wound, please feel free to share that as well.

UNIDENTIFIED SPEAKER: Thank you for the clarification. I will make it brief.

I am speaking on behalf of both my mother who is 79 with lupus and comorbidities, my aunt who is 91 recently placed on hospice care in a nursing home.

My mother's wounds come from what has turned into acute kidney disease. They include excessive scratching to the point of breaking skin throughout the body, and legs were weeping uncontrollably.

It took some time to get it controlled. It took three specialists. If there was something that could have helped her, she -- she would have absolutely done a clinical trial.

What she would need to know would be would she be able to maintain her lupus medication, her heart medication, her blood pressure medication, et cetera? Because she's not able to go off of

those -- those pills.

And what would the time frame look like? Because she has macular degeneration, so she -- she depends on my husband and me for transport, and to be there with her, and her eyes.

Then going to my aunt who is 91. Right now, they're not really looking to heal her, per se. She has a wound that does not heal. She has Factor V Leiden, and it has left her in bed immobile.

And because of hospice's guidelines -- she's in Arizona -- she's not able to try to achieve healing, rather comfort. And she is able to pull herself off of hospice if she chooses, but she'll lose certain aspects of her care.

So she can't move because of that wound, the debriding is a terrible process for her, and she would like to be able to move but she cannot do anything until that wound is healed.

And we would like to see some improvements for my aunt in that end as well, just to help her live out the rest of her life without the

pain that she's experiencing, to be able to at least go through physical therapy for comfort.

And I -- I think that's -- that pretty much covers. Thank you.

MS. BENT: No, thank you. I think the -- this is a perspective that we hadn't heard before, and it is really helpful to hear that. So thank you for taking the time to speak with us.

All right. We are going to go to our last online caller, Mark.

MARK: Hi. Thanks for taking my comments today. So as someone living with pemphigoid, I would consider participating in a clinical trial if I believe that the treatment could actually improve my daily life, not just my disease score.

So I think what would motivate me most would be the possibility of healing my wounds faster, preventing new blisters, reducing the pain and itching, and spending less time every day on wound care.

I would really want to understand how

the treatment works, how it is given, and the potential side effects, and how quickly it might -- I might expect to see some benefit.

I would say that the logistics of a trial would also matter enormously. You know, the frequency of the visits, how long they last, distance to travel. Because, you know, having to travel when my skin is painful or I have difficulty walking can really make participation very difficult.

So flexible scheduling, remote visits when possible, maybe local testing, and assistance with travel would make participation much easier.

And I'd also want the study team to understand that pemphigoid can be very unpredictable, and that a flare or difficult wound should not automatically make it impossible for me to participate.

I would say one of my biggest concerns would be having to stop a treatment that is helping me, or go through a period of where my disease could get worse, just to participate in the trial.

And I think most importantly, I would want the clinical trial to measure what matters to me as a patient. Did my wounds actually heal? Did I have fewer new blisters? Did my pain and itching improve? Could I sleep better or walk more easily?

Be able to just take a shower or dress without fear putting clothes on, and spend less time changing dressings.

And I really would also like to know whether I could return to normal activities, like eating, working, socializing, and spending time with my family without constantly thinking about my skin as an issue.

So for me, successful treatment is not simply an improved disease score. It means healing, regaining my independence, and getting my life back. Thank you.

MS. BENT: Thank you. Thank you very much. And that is, I think, a theme that we have been hearing from a lot of people.

So now before we head into our closing

remarks, I'm going to turn to Ethan to hear the comments that you all have shared with us online, and thank you so much for that.

So please go ahead, Ethan.

MR. GABBOUR: Yes. Thank you. So we received a couple of comments that answer some of the questions the panel had posed.

One person reiterated that receiving standard of care does not ensure high quality care for the control arm. The fear of going backwards if you get into a control arm is a real concern.

And something that can impact participation is access to clinical trials and limited options, especially being in a rural area.

Additionally, allergies, like medication and food, can limit participation.

And specifically for someone with a diabetic foot ulcer, meaningful improvement is closing the wound for good and not opening it every single time. The patient noted they are willing to take risks in a trial if the therapy will help close the

wound for good.

And then another caregiver of somebody with a DFU said, "If the study allowed current or similar treatment of the wound while studying the symptom -- while studying the symptoms, especially for reduction in itch or pain, I'd be open to it."

Thank you.

MS. BENT: Yes, go ahead.

Can somebody run a mic -- oh, there we go. Ethan's going to run a microphone to Joyce.

MS. REX: First of all, I would like to thank y'all so much for inviting us. I've truly enjoyed it. And a lot of that just gave me an understanding of what my wounds are really about, too. And I just really enjoyed it.

And -- and one thing I want to say, it's so important to have an advocate. My daughter is my advocate. I'm sure y'all could tell that.

She spoke -- she -- I said I wanted to -- when -- when my doctors, my local doctors, said they had to amputate, they would not let me out of the

hospital for three weeks with no blood flow to my legs.

All along they were telling her she was delusional because I was so sick that I couldn't stand to travel anywhere. She was insistent. Then they said, "Well, we" -- she said, "I want -- my mother wants a second opinion, so we're going to do everything we can to get her a second opinion."

They said, "You've had second, third, and fourth." Because this was the doctors on the same team. She said, "The doctors on the same team is not a second opinion. A second opinion is outside of your team."

So -- so for some reason she -- she got in touch with Kym McNicholas -- I think that's her last name -- with the Global PAD Association. They worked hard and tried to help her get a second opinion. And we got another second opinion, but this doctor was just so amazing.

So now it's good to have a good cardiologist on -- a cardiologist on your team, a good

wound care doctor, and a good family doctor on your team. And I'm blessed to have all three.

And one thing, I had hyperbaric oxygen and I've had topical oxygen, but the topical oxygen is not paid by FDA for a person that's not in the VA. They told me the only way they could pay me if I was a veteran.

I'm not a veteran, so my cost was, like, about $4,000 a month that I had to pay out of my pocket for -- I think it was, like, four or five months we had to pay this. And I'm sure y'all know I -- all my credit cards are just to the top because I had to pay that.

But if FDA can find some kind of way to help with the topical oxygen for individuals that's not the veterans, that would be greatly appreciated.

So that's what I had to say. And, again, thank y'all so much.

MS. BENT: Thank you. Thank you so much.

And so now we're going to move into our

wrap up session. And so I just want to thank all of you who are here today, both virtually and in person.

To our panelists who have been with us throughout the day, you came here and you gave us something that no data set can: the truth about what it's life to live with this condition. Thank you.

To everyone who shared a comment today, in person or on the phone or through the webcast, your voice is in this room and it will be in our report.

If we did not get to your comment today, it is not lost. Please submit to the public docket, which remains open again through October 26, 2026. The link is on the screen, and we will send it to all registered participants following the meeting.

And before we move to closing remarks, I just want to take a moment to express my sincere gratitude to the team that made this meeting possible. Putting together a meeting like this one takes an enormous amount of work.

And I'm proud and tearful and grateful to the PFDD and Medical Product Review Centers' review

staff who have worked tirelessly on the details of this meeting, from panelist outreach to logistics.

To our Great Room and FDA studio staff who have managed the audio and video, thank you for your patience and for your technical expertise.

To our colleagues and the Patient Engagement Staff in the Office of the Commissioner who helped us out today, we couldn't have done it without you.

And I also want to extend a heartfelt thank you to the Wound Care Collaborative Community, the WCCC, for their partnership, their clinical expertise, and their dedication to making sure that patients with nonhealing chronic wounds have a seat at the table. As well as our colleague at NIH.

None of this happens without all of this. Thank you so much.

And I'm going to turn over to Dr. Mejia to give us our closing remarks.

DR. MEJIA: All right. I'll be brief.

But, again, thank you to all patients

and care partners for sharing your experiences and perspectives today. We want you to know that we're listening.

We heard from most of you, who shared your stories or participated in polling, that your wounds have never meaningfully improved or healed despite multiple therapeutic interventions.

We heard a pinhole-size lesion took away an entire year of one patient's life, and a mosquito bite led to a partial foot amputation for another patient. We heard impacts of a chronic wound are worse than stage 4 cancer.

We heard nonhealing chronic wounds directly and adversely affect marital and other family relationships. We heard these wounds damage lives. They lead to isolation, loss of independence, physical and emotional scarring. They make patients feel as if they're disappearing.

We heard that the response of wounds to treatment is often variable and unpredictable even in the same patient. And, therefore, care plans require

a combination of therapies and differing approaches, as well as multiple changes in the course of treatment.

We heard that wound healing means freedom. Freedom from pain, infection, and burdensome dressing changes. Freedom to wear shoes and comfortable, cute clothing. Freedom to engage at work, school, and in social situations.

And we were reminded that there's more to the clinical data that's collected and analyzed. There are people and their families suffering and struggling from the effects of chronic wounds.

These insights and feedback are extremely valuable. They directly support the development of new therapies to improve daily function and quality of life for individuals with chronic wounds.

It's clear that wounds impact every aspect of patients' and caregivers' lives, and that addressing chronic wounds needs a holistic approach and a comprehensive empathic effort.

Today's dialogue and ongoing conversations are important, not only to us here at FDA, but also for the pharmaceutical companies, researchers, and other medical device and product developers.

Thank you, again, to all the patients and care partners for helping advance the development of new therapies and approaches that will improve how you and others with chronic wounds feel and function each day.

And, as Robyn said, thank you to everyone who made today's discussion possible. Thank you.

(Whereupon, the meeting concluded at 4:30 p.m.)

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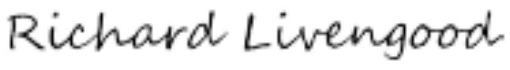

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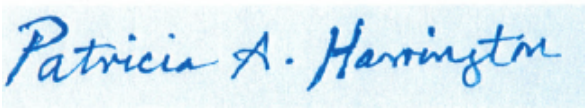

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