



FDA Patient-Focused Drug Development Meeting for Nonhealing Chronic Wounds

Tuesday, August 25, 2026

FDA will be streaming a live webcast of the meeting with the presentation slides, which is open to the public. The webcast recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting.



Welcome

Robyn Bent, RN, MS

Director, Patient-Focused Drug Development Program

Office of the Center Director

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

Housekeeping Items

- **Lunch:** Pre-orders are available until **10:30 AM**. It is recommended that you place your order before then. You are also welcome to select and purchase lunch during the designated lunch break.
- **Water Station:** A water station will be available throughout the day, including during lunch and the afternoon break.
- **Restrooms:** The restrooms are located past the IT desk on your **right** as you exit the Great Room.
- **Reserved Rooms:** Three conference rooms are reserved for your use today. **Room 1404** is available for storing personal belongings. **Rooms 1406 and 1408** are available if you need a moment to step away for any reason. Please look for posted signage to help you find these rooms.

Agenda

- Opening Remarks
- Overview of FDA's Patient-Focused Drug Development Initiative
- Clinical Overview of Nonhealing Chronic Wounds
- Overview of Discussion Format
- Discussion Topic 1: Health Effects and Daily Impacts
 - Lunch Break (60 minutes)
- Discussion Topic 2: Current Approaches to Treatment
 - Break (10 minutes)
- Discussion Topic 3: Patient Perspectives on Clinical Trials
- Closing Remarks

Opening Remarks

Michelle Tarver, MD, PhD

Center Director

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Overview of FDA's Patient-Focused Drug Development Program

Ethan Gabbour, MS

Public Health Analyst, Patient-Focused Drug Development Program

Office of the Center Director

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

FDA's Role in Medical Product Evaluation and Development

FDA's mission is to **protect and promote public health** by evaluating the **safety and effectiveness of new drugs**

While FDA plays a critical oversight role in drug development, it is just one part of the process. **FDA does not develop drugs nor conduct clinical trials.**

FDA provides **regulatory oversight** during medical product development, makes decisions regarding **marketing approval for new drugs, biologics, and devices**, and provides **guidance** on clinical, scientific and regulatory matters.

What is Patient-Focused Drug Development (PFDD)?



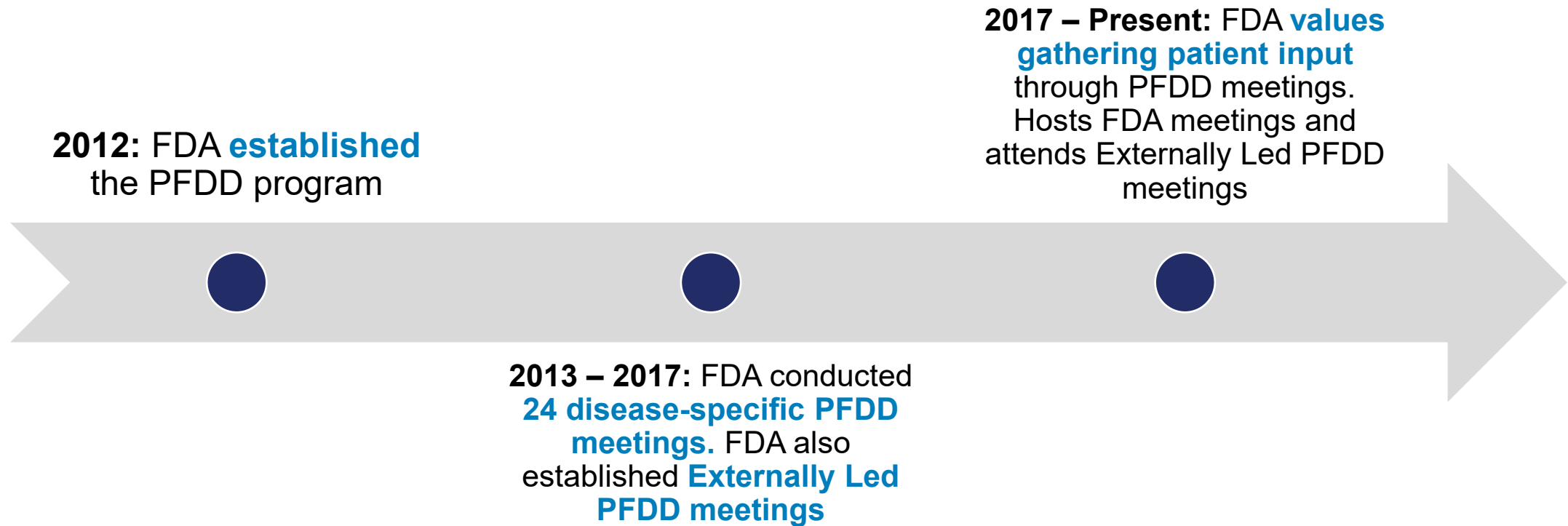
¹<https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary>

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.¹

Value of FDA's PFDD Meetings

- Patients are uniquely positioned to inform FDA understanding of the clinical context for drug review and regulatory decision making
- Prior to PFDD, available mechanisms for obtaining patient input were limited to discussions related to specific applications under review, such as Advisory Committee meetings and only a few patient representatives
- PFDD meetings provide a more systematic way to obtain patients' perspectives on severity of a condition, and its impact on daily life, and their assessments of available treatment options

PFDD Meetings Provide an Opportunity for Key Stakeholders to Hear the Patient's Voice

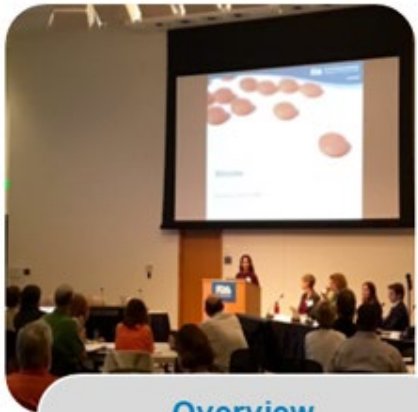


FDA-led PFDD Meetings in a Wide Range of Disease Areas Providing Insights



2013	2014	2015	2016	2017
Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis	Sickle Cell Disease	Breast Cancer	Psoriasis	Sarcopenia
HIV	Fibromyalgia	Chagas Disease	Neuropathic pain associated with peripheral neuropathy	Autism
Lung Cancer	Pulmonary Arterial Hypertension	Functional Gastrointestinal Disorders	Patients who have received an organ transplant	Alopecia Areata
Narcolepsy	Inborn Errors of Metabolism	Parkinson's Disease and Huntington's Disease		Hereditary Angioedema
	Hemophilia A, B, and other Heritable Bleeding Disorders	Alpha-1 Antitrypsin Deficiency		
	Idiopathic Pulmonary Fibrosis	Non-Tuberculous Mycobacterial Lung Infections		
	Female Sexual Dysfunction			
2018	2020	2021	2023	2026
Opioid Use Disorder	Stimulant Use Disorder	Vitiligo	Long COVID	Nonhealing Chronic Wounds
Chronic Severe Pain	Systemic Sclerosis			

PFDD Meetings Follow a Town Hall Style Discussion Format



Overview

- Clinical Background and Current Available Treatments



Symptoms and Daily Impacts

- Panel of patients and caregivers
- Facilitated group discussion



Current Treatment Options

- Panel of patients and caregivers
- Facilitated group discussion



Clinical Trials*

- Panel of patients and caregivers
- Facilitated group discussion

Each PFDD Meeting is Tailored to the Needs of the Specific Disease Area

- FDA encourages patient advocates, researchers, drug developers, healthcare providers and other government officials to attend PFDD meetings
- However, our focus is on hearing directly from patients and their caregivers, so we ask that others remain silent in listening mode during the discussions since the meetings are a **platform to hear directly from patients, caregivers and patient representatives.**
- After the PFDD meeting, a **Voice of the Patient report** summarizes the input shared by patients and caregivers.

Thank you!



WOUND CARE
Collaborative
Community

Beyond the Surface: Navigating Your Path to Advanced Wound Healing

Dr Vickie R Driver DPM MS FACFAS

FDA PFDD session, August 2026

Guided by Clinical Excellence and WCCC Standards

Thank You

- Thank you to the FDA for organizing this meeting and creating space for this conversation.
- Thank you to the patients living with chronic wounds for sharing your experience so openly.
- Thank you to the caregivers whose daily support makes healing possible.
- Gratitude for My Team: They work hard day in and day out to find better solutions for improving care.
- Because of you, we can hear your voice directly — and let it guide better diagnostics and treatments.

Why This Is Personal: I lost both of my parents early to diabetes, and two of my sisters live with the disease today — each has faced major non-healing ulcers on multiple parts of their bodies.

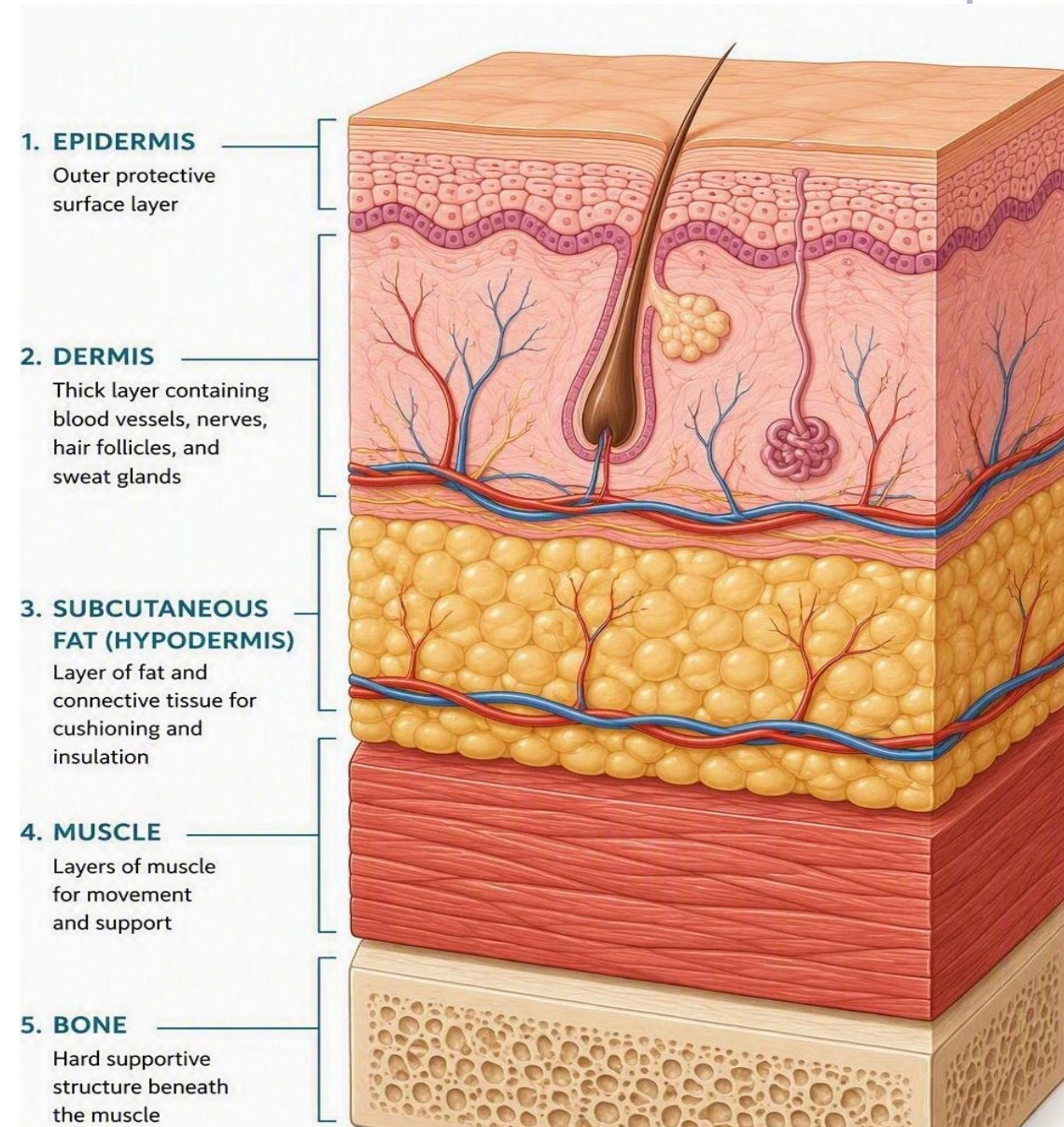


Why Some Wounds Are Slow to Heal

- What is a chronic wound? Any wound that has not healed much after 4 weeks.
- Poor blood flow: Not enough blood means the skin does not get the oxygen it needs.
- Infection: Germs in the wound make it harder for the skin to heal.
- Pressure: Staying in one position too long puts steady pressure on the skin.
- Other health issues: Diabetes, immune conditions, and blood flow problems slow healing.
- Good to know: Chronic wounds can happen to people of any age.

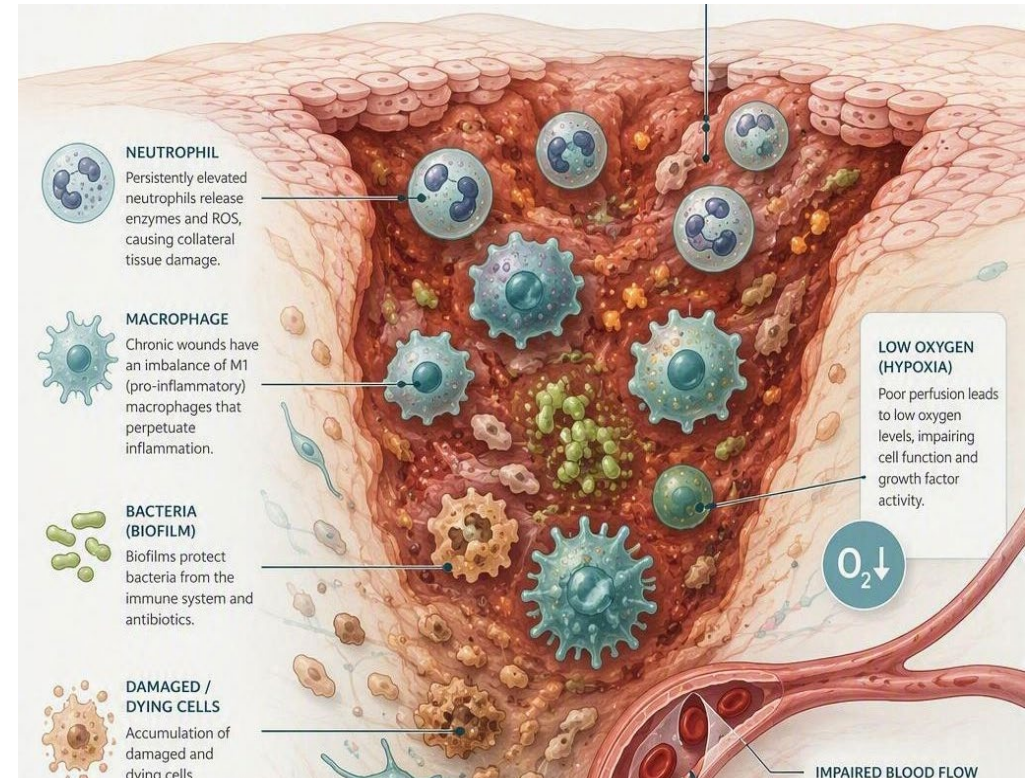
Location & Progression: The Hidden Depth

- Healing happens from the bottom up—wounds often change and deepen over time.
- Superficial Tissue Loss: Affects only the outer skin layer.
- Deeper Soft Tissue Damage: Moves into the underlying fat and muscle layers.
- Bone Exposure: Advanced progression risking deep-seated bone infections (osteomyelitis).



Pathology: What Happens at the Cellular Level?

- Stalled Healing: The wound gets stuck in a permanent, continuous inflammatory phase.
- Hypoxia (Lack of Oxygen): Restricting blood flow starves healthy skin cells.
- Necrosis (Tissue Death): Starved cells die, turning into yellow slough or black, hardened eschar.
- Cellular Stalling: Healthy rebuilding signals are completely overwhelmed by cellular waste.



Advanced Diagnostics & FDA-Approved Treatment

- Precision Diagnostics: Digital tissue imaging, perfusion mapping, and molecular bioburden tracking.
- Comprehensive Toolbox: Utilizing multiple FDA-approved advanced modalities.
- Advanced Dressings: Specialized bio-engineered coverings tailored to tissue type.
- Therapeutic Debridement: Aggressive removal of dead or infected tissue to restart healing.
- Advanced Therapies: Negative Pressure Wound Therapy (NPWT), growth factors, and cellular therapies.



Guided by the Experts: Clinical Standards

- WCCC Framework: Strictly aligned with the Wound Care Collaborative Community guidelines.
- Objective Metrics: Using standardized digital tracking tools to measure precise healing over time.
- Patient-Centered Endpoints: Focusing treatment plans on how you feel, function, and live day-to-day.
- Evidence-Based Focus: Incorporating protocols from recently published peer-reviewed medical papers.

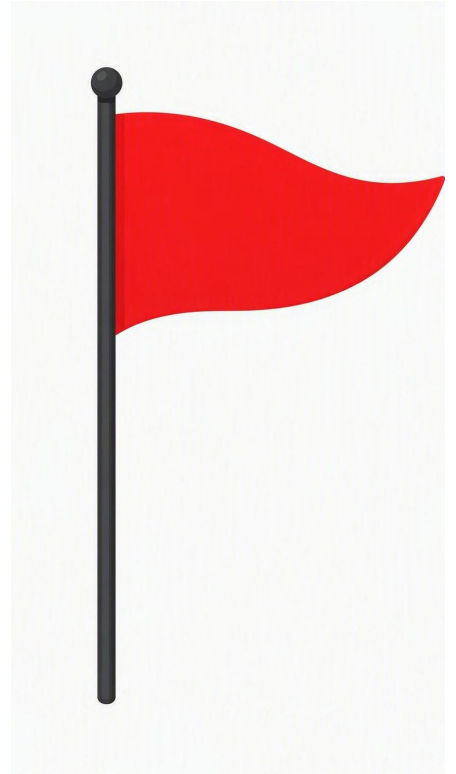
Home-Based Care & Your Quality of Life

- Quality of Life (QOL) Impact: Chronic wound disease causes physical pain, anxiety, and social isolation.
- The Real-World Challenge: Traditional care demands exhausting weekly clinic visits.
- Navigating Constraints: Accommodating patients who are employed, have transit issues, or care for others.
- Modern Solutions: Advanced home dressings and diagnostic tracking minimize clinic disruption while ensuring safety.



Clinical Red Flags

- **Essential Partnership: Daily at-home care prevents complications, limb loss, or systemic sepsis.**
- Contact Us Immediately If You Notice:
 1. Sudden, severe increase in localized pain or throbbing.
 2. A foul odor coming from the dressing or the wound bed.
 3. Rapidly spreading redness, warmth, or swelling in surrounding skin.
 4. A sudden heavy increase or uncontrolled fluid drainage from the wound.



Moving Forward Together: What Comes Next

- A Steady Journey: Healing complex wounds is a calculated, step-by-step process.
- We Understand the Burden: Living with a chronic wound is exhausting — the pain, the setbacks, and the toll on daily life are real.
- You Are Not Alone: Clinicians, researchers, the FDA, Medicare and Medicaid, and patients are working side by side on this challenge.
- Better Tools Ahead: That partnership is driving earlier, more precise diagnostics and more effective treatments.
- Shared Commitment: Every visit, every measurement, and every shared experience moves care forward.

Overview of Discussion Format

Robyn Bent, RN, MS

Director, Patient-Focused Drug Development

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Discussion Overview

Topic 1: Health Effects and Daily Impacts That Matter Most to Patients

- Health effects of chronic wound(s) that have the most significant impact on your daily life
- How your wound(s) has changed over time
- What worries you most about your wound(s)

Topic 2: Current Approaches to Treatment

- Your experience with treating your wound(s)
- What approaches you use to treat your wound(s)
- What you have found to be most effective in helping you treat your wound(s)
- What factors you would consider when considering or seeking treatment

Topic 3: Clinical Trials

- What your experience was like participating in a clinical trial for your wound(s)
- What factors would weigh into your decision to participate in a clinical trial
- What outcomes for wound(s) are most important to measure in a trial setting

Discussion Format, Continued

You will have a chance to answer polling questions

- Their purpose is to aid our discussion
- Participants can use the [mentimeter.com](https://www.mentimeter.com) link to answer polling questions
- Individuals or family members only, please

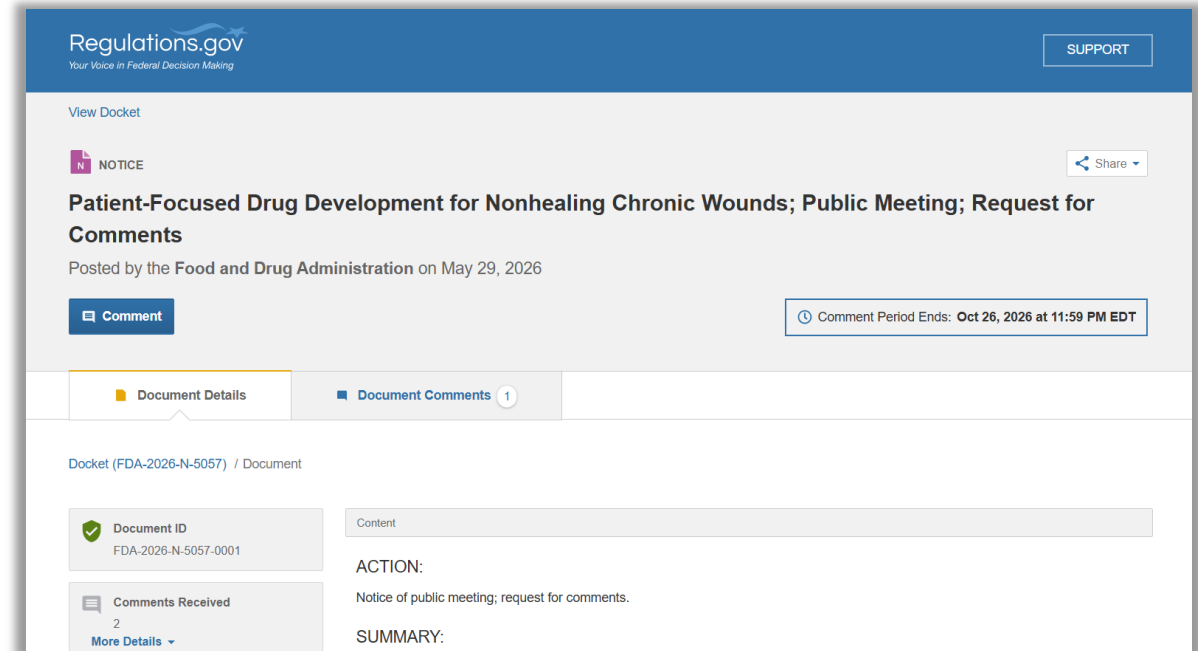
Participants can add comments through the webcast or by telephone

- Although they may not all be read or summarized today, your comments will be incorporated into our summary report

Send us your Comments!

You can send us your comments through the “public docket”

- The docket will be open until October 26, 2026
- Comments will be incorporated into our summary report
- Anyone is welcome to comment
- Visit the following link:
<https://www.regulations.gov/document/FDA-2026-N-5057-0001>
 - Or Search “patient-focused nonhealing chronic wounds” on www.regulations.gov
- And **Click “Comment”**



Discussion Ground Rules

- We encourage all individuals and family members to contribute to the dialogue
- FDA is here to listen
- Discussion will focus on the health effects, treatment, and clinical trials related to nonhealing chronic wounds
- The views expressed today are personal opinions
- Respect for one another is paramount

Where do you live? Please select one answer.

- a. Within the Washington, D.C. metropolitan area (including the Virginia and Maryland suburbs)
- b. Outside of the Washington, D.C. metropolitan area

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

Which statement best describes your experience with nonhealing chronic wounds? Please select one answer.

- a.** An individual who currently has or has had a nonhealing chronic wound
- b.** A family member or caregiver of an individual(s) who currently has or has had nonhealing chronic wounds

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

What is your/your loved one's age? Please select one answer.

- a. Less than 10 years old
- b. 10 – 18 years old
- c. 18 – 45 years old
- d. 45 – 65 years old
- e. 65 – 75 years old
- f. 75 – 85 years old
- g. 85+ years old

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Do you identify as (Please select one answer):

- a. Male
- b. Female
- c. Other
- d. Prefer not to say

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

Where is/was your/your loved one's chronic wound(s) located? Please select all that apply.

- a. Foot or toe
- b. Lower leg
- c. Upper leg
- d. Hip or buttocks
- e. Back
- f. Arm or hand
- g. Other location
- h. I'm not sure

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Discussion Topic 1

Health Effects and Daily Impacts of Nonhealing Chronic Wounds

Topic 1 Discussion Questions

1. What types of chronic wound/s do you have, and how long have you been living with it?
 - a) Has your wound ever improved for a time without fully closing? Please describe what that was like.
2. What are the top 1-3 ways your chronic wound affects your daily life the most? (*Examples may include pain, difficulty walking, avoiding social activities, unpleasant odor, etc.*).
 - a) If you have more than one wound, do they affect your daily life differently? How?
3. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your wound? (*Examples of activities may include walking, exercising, working, participating in social activities, personal hygiene, intimacy with a spouse or partner, etc.*).
4. When you think about your wound, what is a “good day” like for you? What is a “bad day” like?
5. In relation to your wound, how has your overall condition changed over time?
 - a) Do you feel your condition is well-managed today?
6. What concerns you most about living with your wound?

What types of chronic wound(s) do you/your loved one currently have or have had? Please select all that apply.

- a. Venous ulcer
- b. Arterial ulcer
- c. Pressure ulcer/bedsore
- d. Diabetic ulcer
- e. Other type of chronic wound

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How long are you typically affected by a wound episode – from the time it develops to meaningful improvement or closure? Please select one answer.

- a. Less than 3 months
- b. 3 – 6 months
- c. 6 – 12 months
- d. 12 – 18 months
- e. 18 – 24 months
- f. More than 2 years
- g. My wounds have never meaningfully improved or healed

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

What do you find to be the most bothersome impact(s) of nonhealing chronic wounds on your daily life? Please select up to three answers.

- a. Limits movement or walking
- b. Affects ability to work
- c. Interferes with sleep
- d. Restricts participation in social activities
- e. Impacts personal hygiene routines
- f. Affects intimate relationships
- g. Limits exercise or physical activities
- h. Mental health impacts
- i. Other impacts not mentioned
- j. None of the above

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Lunch Break

Please return at 1:15 PM ET.

Discussion Topic 2

Current Approaches to Treatment

Topic 2 Discussion Questions

1. What are you currently doing to help manage or treat your wound, if anything? (*Examples: wound dressings, prescription medications, removal of dead tissue, casts or cushions, diet and exercise*).
 - a) In your own words, what does “healing” mean to you? What would healing look or feel like?
2. How well has your current treatment helped address the effects of chronic wounds that are most troubling to you?
3. What are the biggest challenges or downsides you have experienced with your treatments? (*Examples may include bothersome side effects, pain during procedures, lack of effectiveness, etc.*).
4. Even if a treatment does not cure your wound completely, what improvements would be meaningful to you?
 - a) Are there risks, side effects, or treatment burdens that you would be willing to accept if it meant your wound could heal faster or stay healed longer?
 - b) What does “effective treatment” mean to you? (*Examples may include full closure, less drainage, less pain, fewer dressing changes, easier walking, and better sleep*). Would a treatment still be helpful to you if it did not fully close the wound but improved your daily life?

Have you/your loved one ever used any of the following to manage chronic wounds? Please select all that apply.

- a. Topical wound care products (such as wound dressings, gauze, and prescription topical medications like Becaplermin gel)
- b. Specialized wound therapies (such as negative pressure wound therapy, hyperbaric oxygen therapy)
- c. Compression therapy (such as stockings, wraps, bandages)
- d. Clinical or surgical procedures (such as debridement or removal of dead tissue)
- e. Supportive devices (such as shoes, casts, cushions)
- f. Diet and lifestyle modifications (such as nutritional supplements or elevation)
- g. Other approaches not mentioned
- h. I am not using any approaches to treat chronic wounds

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

What are the biggest challenges or barriers you face in managing you/your loved one's chronic wound? Please select up to three answers.

- a. Time or cost of maintenance
- b. Difficulty accessing specialized wound care
- c. Pain during treatment procedures
- d. Slow or no improvement despite treatment
- e. Side effects from treatments
- f. Difficulty following treatment instructions
- g. Lack of information about treatment options
- h. Other challenges not mentioned

Participation in the polling questions is voluntary. The results are used as a discussion aid only and should not be considered scientific data.

If you are considering a new treatment for chronic wounds, which of the following benefits would you consider to be the most meaningful?

Please select up to three answers.

- a. Complete wound healing
- b. Faster healing time
- c. Improved mobility
- d. Reduced risk of infection
- e. Less frequent dressing changes
- f. Improved quality of life
- g. Prevention of wound reoccurrence
- h. Other benefits not mentioned

Break

Please return at 3:00 PM ET.

Discussion Topic 3

Clinical Trials

Topic 3 Discussion Questions

1. If you considered participating or have participated in a clinical study for chronic wounds, please tell us about your experience.
 - a) Was there anything about the clinical trial that made it easier for you to participate or consider participating?
 - b) Was there anything about the clinical trial that made it more difficult for you to participate?
2. If you were deciding whether to join a clinical trial, how important would the following be to you?
 - a) The treatment being studied. *(Examples may include possible side effects and how the treatment is given- such as pills, injections, or devices).*
 - b) The trial logistics. *(Examples may include how long the study lasts, whether visits are in-person or remote, and how far you must travel).*
3. What results or improvements are most important for a clinical trial to measure? *(Examples may include reduced pain, fewer dressing changes, faster healing, and improved mobility).*

Would you join a study testing a treatment that improved symptoms (e.g., reducing itchiness, increased movement) but didn't always close wounds? Please select one.

- a. Yes
- b. No
- c. I'm not sure

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How long would you be willing to wait to see results from a wound treatment before you would consider it “not working?” Please select one.

- a. 2 – 4 weeks
- b. 6 – 8 weeks
- c. 10 – 12 weeks
- d. 16 – 20 weeks
- e. It depends on the wound type and severity

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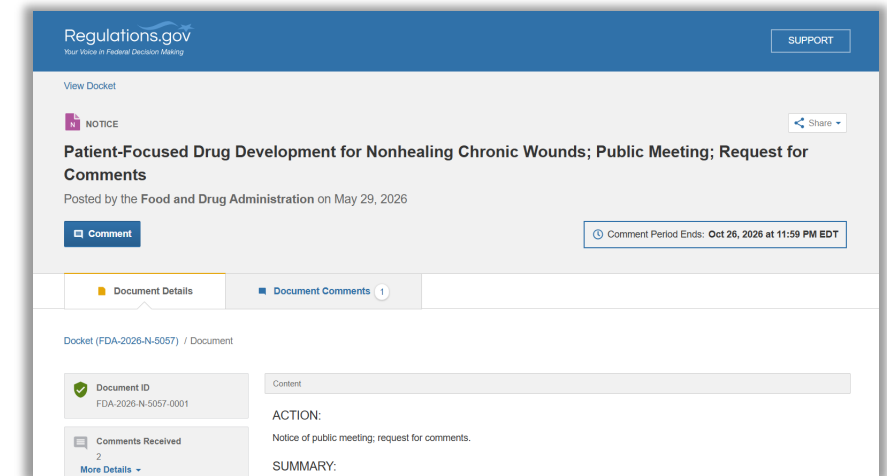
What is the biggest barrier to joining a clinical trial for wound care? Please select one.

- a. Transportation to trial site
- b. Eligibility criteria
- c. Mistrust
- d. Time constraints
- e. Lack of information
- f. Fear of side effects
- g. Fear of receiving placebo/inactive treatment
- h. Other barriers not mentioned

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 - Or Search “patient-focused nonhealing chronic wounds” on www.regulations.gov
- And **Click “Comment”**



Closing Remarks

Maryjoy Mejia, MD

Medical Officer, Division of Dermatology and Dentistry
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

The logo consists of the letters 'FDA' in a bold, blue, sans-serif font, positioned within a white square. The 'F' and 'D' are connected, and the 'A' is slightly separated.

FDA

**U.S. FOOD & DRUG
ADMINISTRATION**