

Patient-Focused Drug Development Meeting on Chronic Pain

July 9, 2018

FDA will be live streaming the meeting, which is open to the public at: <https://collaboration.fda.gov/pfdd070918>. The recording, meeting slides, meeting transcript and summary report will be made publicly available after the meeting.

Wi-Fi Network: FDA-Public Password: publicaccess

 Follow along on Twitter using #ChronicPainPFDD and #PFDD.

Welcome

Meghana Chalasani

Office of Strategic Programs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

July 9, 2018

Agenda

- Opening Remarks
- Setting the context
 - Overview of Chronic Pain
 - Overview of Discussion Format
- Discussion Topic 1
- Lunch
- Discussion Topic 2 (with a short break)
- Open Public Comment
- Closing Remarks

Opening Remarks

Theresa Mullin, PhD

Associate Director for Strategic Initiatives

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U.S. Food and Drug Administration

July 9, 2018

An Overview of Chronic Pain

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July 9, 2018

Outline

- Definition and epidemiology
- Types of chronic pain
- Impacts of chronic pain
- Evaluation and assessment
- Treatment
- Patient-focused drug development
- Conclusions

Definition

International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”

- **Acute pain:**
 - Self-limited and lasts less than a few weeks
 - Postoperative
 - Acute musculoskeletal injury
- **Chronic pain:**
 - Pain persisting for longer than 1 month beyond resolution of the underlying insult
 - Pain persisting beyond 3 months
 - Chronic low back pain

Epidemiology

- Chronic pain affects approximately 100 million U.S. adults
- Pain contributes greatly to national rates of morbidity, mortality, and disability
- Pain is one of the most frequent reasons for physician visits
- Annual economic cost associated with chronic pain is estimated to be \$560-635 billion

Types of chronic pain

- Nociceptive - tissue injury
 - Visceral - such as chronic pancreatitis
 - Non-visceral - such as musculoskeletal pain
- Neuropathic - nervous system injury or dysfunction
 - Peripheral -such as diabetic peripheral neuropathy
 - Central - such as post-spinal cord injury pain
- Mixed nociceptive/neuropathic

Pain is complex and may or may not be related to a specific disease or injury

Our focus today is on chronic pain in general, of any type, etiology, characteristic, or severity

Pain characteristics

- Some pain-related characteristics:
 - **Quality:** aching, throbbing, tingling, burning, or stabbing
 - **Location:** localized, diffuse, or radiating
 - **Temporal aspects:** duration, onset, constant vs. intermittent
 - **Severity:** mild, moderate, or severe
 - **Triggers:** factors that exacerbate the pain

Potential impacts of chronic pain

- Physical signs and symptoms
 - Weakness, poor sleep
- Emotional stress
 - Anxiety, depression, isolation
- Difficulty maintaining employment or attending school
- Withdrawal from family or social interactions
- Limitations in activities of daily living (ADLs)
- Deterioration in quality of life

Evaluation and assessment

- Pain is a uniquely individual and subjective experience
- Tests and imaging can provide information about underlying etiologies or comorbidities, but these tests are not direct assessment of the pain
 - Physical and neurological examination, x-ray, MRI, CT scan, electrodiagnostic studies (EMG/NCS)
- **Patient input is the key factor in the evaluation and understanding of pain**

Treatment options

- **Pharmacologic treatment**

- Over-the-counter medications – such as acetaminophen and ibuprofen
- Prescription drugs – such as prescription NSAIDs, muscle relaxants, opioids, antidepressants, anticonvulsants, topical agents

- **Non-pharmacologic treatment**

- Physical therapy, occupational therapy, exercise, chiropractic manipulation, massage
- Cognitive behavioral therapy, stress management
- Complementary and alternative medicine
 - Acupuncture, herbal therapy, hypnosis, tai chi, biofeedback
- Vocational rehabilitation, disability management
- Medical procedures
 - Nerve blocks, pain pumps, spinal cord stimulators, surgery

Treatment approaches

- There are multiple options and considerations when determining the optimal treatment
- Treatment may focus on certain options or utilize a **multidisciplinary** treatment that provides an integrated management plan
- Health care providers and patients work together to develop a treatment plan and set goals in each individual case

Treatment goals and barriers

- **Goals of treatment:**
 - Decrease or control the pain
 - Improve physical function
 - Improve social and emotional well-being
 - Improve quality of life

- **Potential barriers to treatment:**
 - Access or availability
 - Cost / insurance coverage
 - Time / duration of therapy
 - Side effects of medication

Patient-focused drug development

- **There is an unmet medical need experienced by patients with chronic pain**
- Patients are experts in providing the information about the impact of pain on their lives and available treatments
- Collecting information from patients' experiences provides an opportunity for the FDA to enhance regulatory decision-making

Conclusions

- FDA is aware of the unmet medical needs experienced by patients who have chronic pain
- Patient-focused drug development is a unique opportunity for the FDA to hear from patients, caregivers, and family members about the impacts of chronic pain
- Thank you for participating in today's meeting on chronic pain and sharing your comments with us

Overview of Discussion Format

Meghana Chalasani

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Center for Drug Evaluation and Research

U.S. Food and Drug Administration

July 9, 2018

Discussion Overview

Topic 1: Symptoms and daily impacts of chronic pain that matter most to patients

- How would you describe your chronic pain?
- What are the most significant symptoms that you experience resulting from your condition?
- 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 chronic pain?
- How has your chronic pain changed over time?

Topic 2: Current Approaches to Treatment of Chronic Pain

- What are you currently doing to help treat your chronic pain?
- How well does your current treatment regimen manage your chronic pain?
- What are the most significant downsides to your current treatments, and how do they affect your daily life?
- What challenges or barriers to accessing or using medical treatments for chronic pain have you or do you encounter?
- What specific things would you look for in an ideal treatment for your chronic pain?

Discussion Format

We will kick off our discussion with comments from a panel of individuals with chronic pain

- The purpose is to set context for a broader discussion with the audience
- Panel commenters reflect a range of experiences with chronic pain
- Some panelists are affiliated with advocacy or support organizations

We will then broaden the dialogue to include individuals and family members in the audience

- The purpose is to build on the experiences shared by the panel
- We will ask questions and invite you to raise your hand to respond
- When speaking, you may remain anonymous or state your first name

Discussion Format, continued

You'll have a chance to answer “polling” questions

- Their purpose is to aid our discussion
- In-person participants, use the “clickers” to respond
- Web participants, answer the questions through the webcast
- Individuals or family members only, please

Web participants can add comments through the webcast

- Although they may not all be read or summarized today, your comments will be incorporated into our summary report
- We'll occasionally go to the phones to give you another opportunity to contribute

Send us your comments!

You can send us comments through the “public docket”

- The docket will be open until September 10, 2018
- Comments will be incorporated into our summary report
- Anyone is welcome to comment
- You can submit as anonymous

Visit:

<https://www.regulations.gov/document?D=FDA-2018-N-1621-0001>

Or Search “Patient Focused Drug Development Chronic Pain” on www.regulations.gov

And **Click Comment Now!**

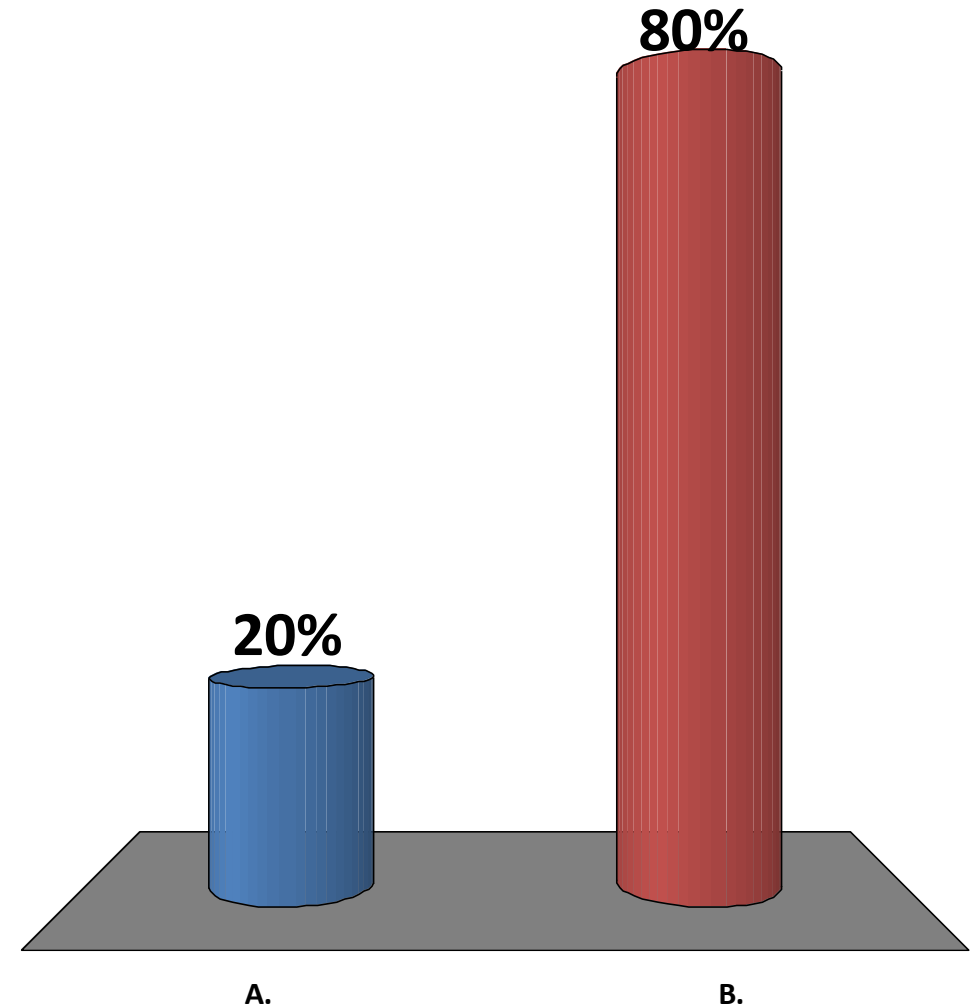
The screenshot shows the 'regulations.gov' website interface. The main heading is 'Patient-Focused Drug Development on Chronic Pain; Public Meeting; Request for Comments'. Below the heading, there is a 'Comment Now!' button. A red arrow points from the text 'And Click Comment Now!' to this button. The page also displays document information, including the ID 'FDA-2018-N-1621-0001', the date posted 'May 15, 2018', and the federal register number '2018-10284'. At the bottom right, a box indicates '851 Comments Received'.

Discussion Ground Rules

- We encourage all individuals and family members to contribute to the dialogue
- FDA is here to listen
- Discussion will focus on chronic pain health effects, daily impacts and management approaches
 - Open Public Comment Period is available to comment on other topics
- The views expressed today are personal opinions
- Respect for one another is paramount
- Complete an evaluation form to let us know how the meeting went today

Where do you live?

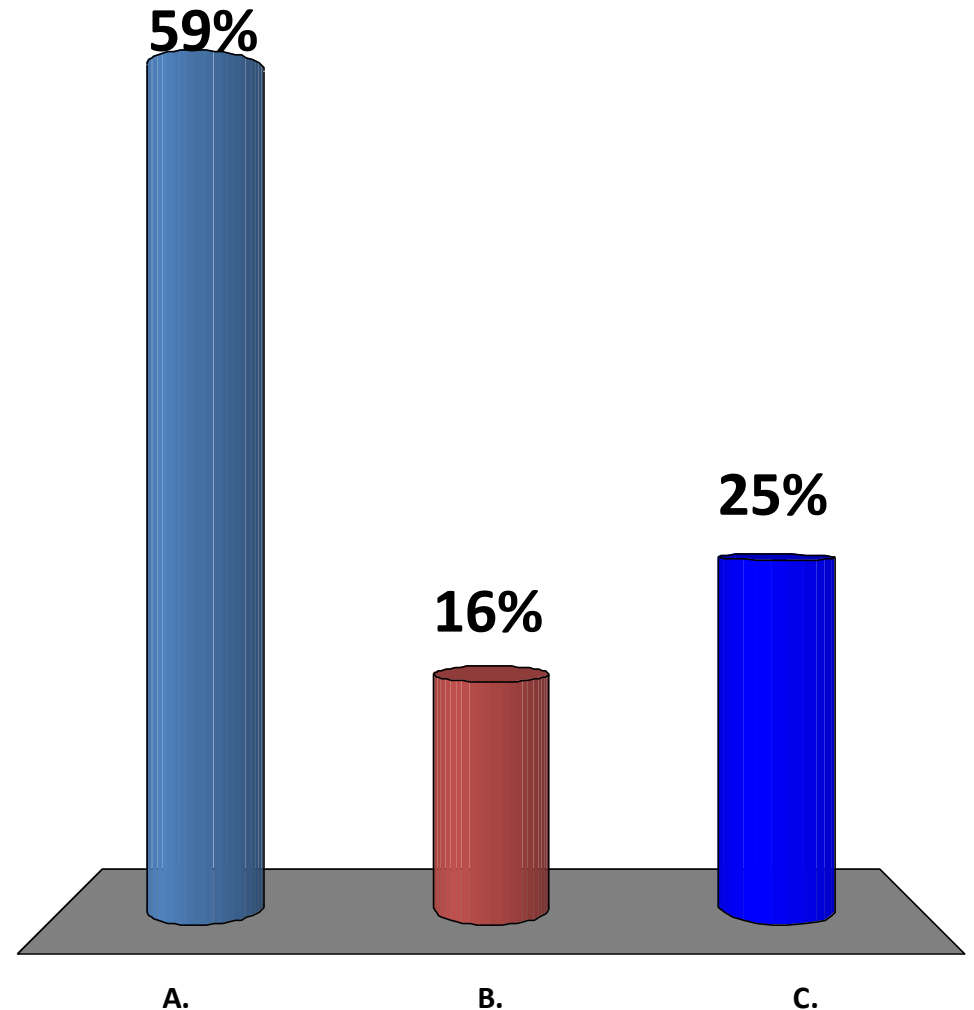
- A. Within Washington, D.C. metropolitan area (including the Virginia and Maryland suburbs)
- B. Outside of the Washington, D.C. metropolitan area



Participation in the polling questions was voluntary. The results were only used as a discussion aid during the meeting and should not be considered scientific data.

Which statement best describes you?

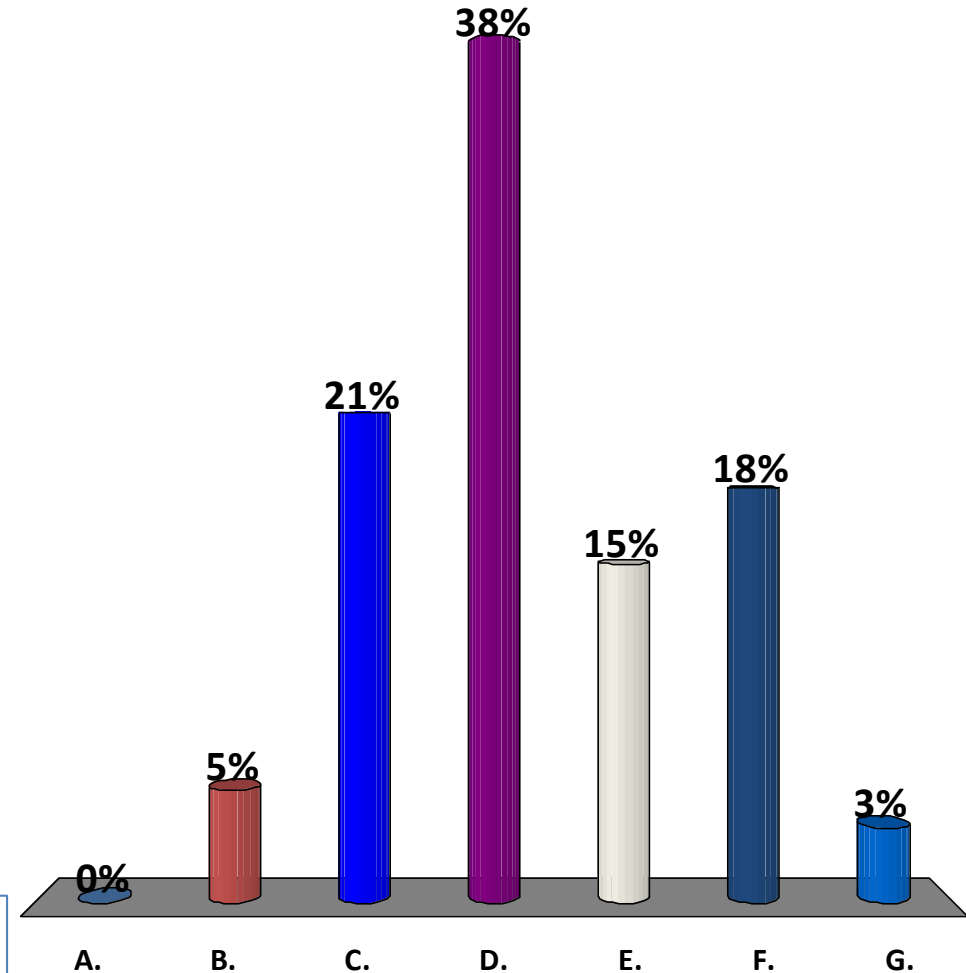
- A. An individual who experiences chronic pain
- B. A family member or caregiver of an individual(s) who experiences chronic pain
- C. An advocate for individuals who experience chronic pain



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What is your/your loved one's age?

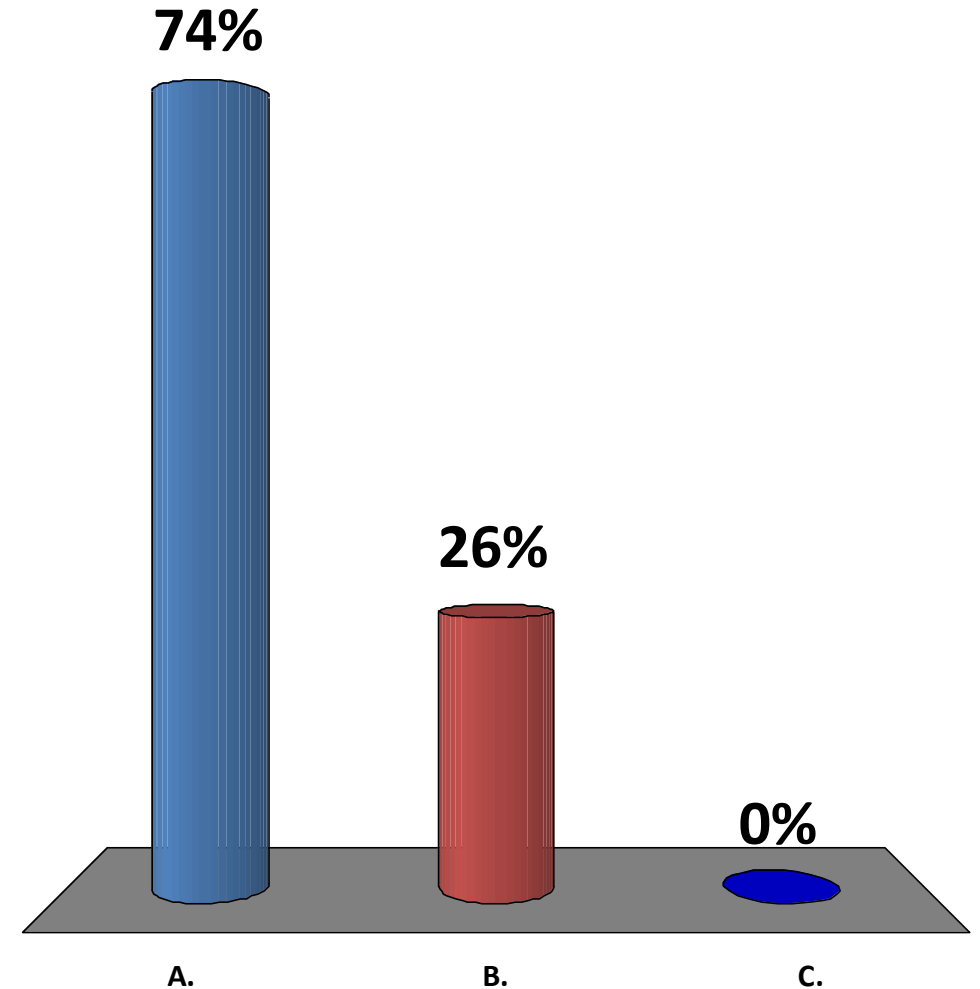
- A. Younger than 18
- B. 18-29
- C. 30-39
- D. 40-49
- E. 50-59
- F. 60 – 69
- G. 70 or greater



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Do you/your loved one identify as:

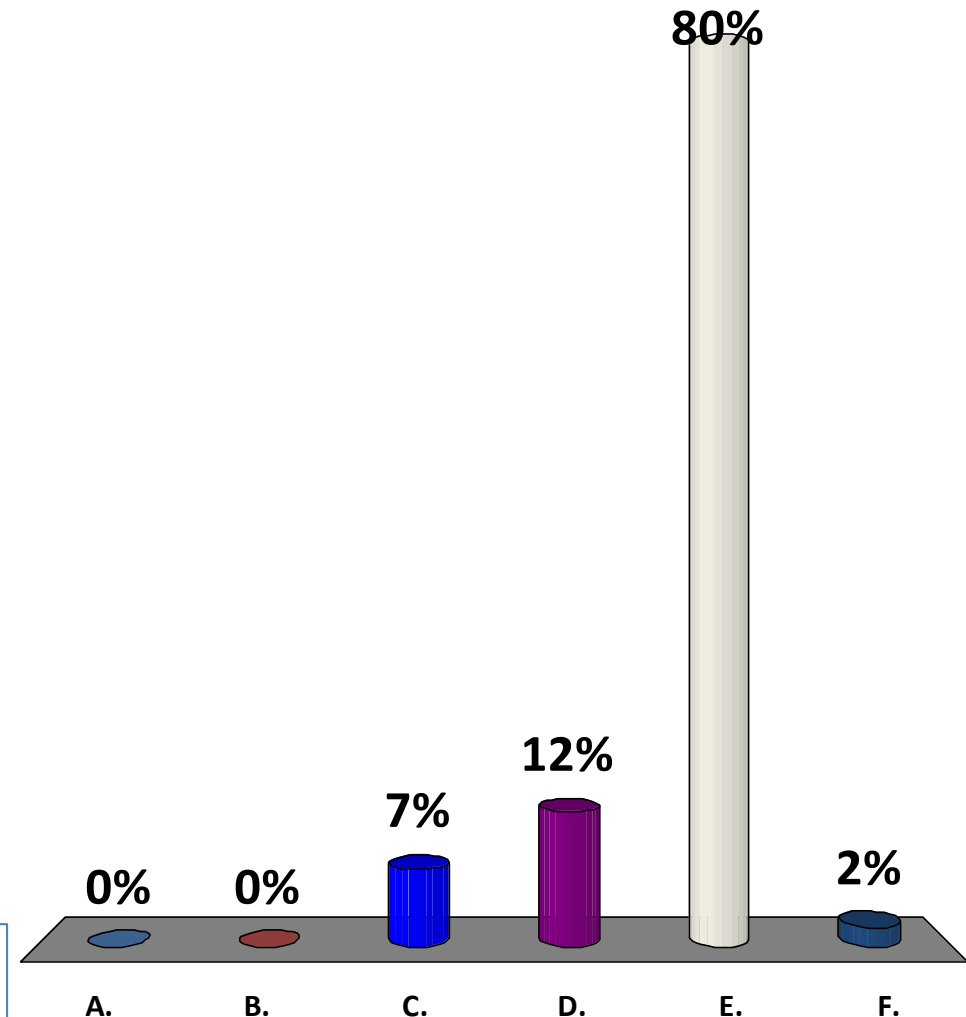
- A. Female
- B. Male
- C. Other



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How long have you/your loved one experienced chronic pain?

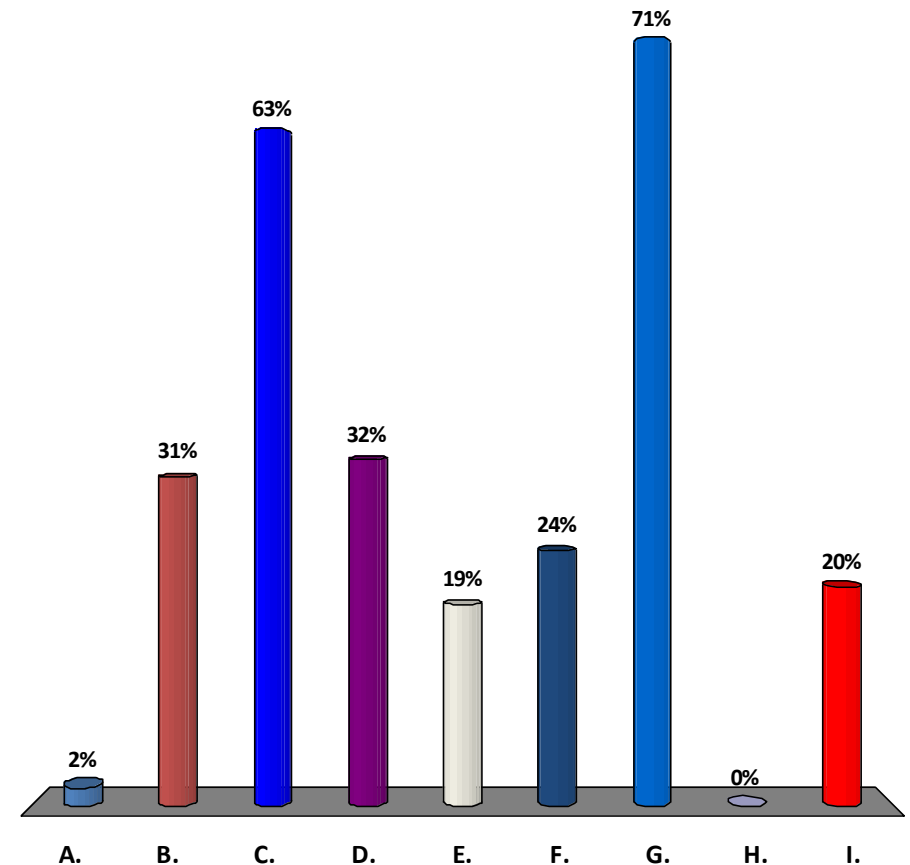
- A. Less than 1 year
- B. 1 years to 2 years
- C. 2 years to 5 years
- D. 5 years to 10 years
- E. More than 10 years
- F. I'm not sure



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What type of chronic pain do you/your loved one experience? Check all that apply.

- A. Cancer Pain
- B. Post-surgical or post-traumatic pain
- C. Neuropathic (nerve) pain
- D. Headache
- E. Orofacial (mouth, jaws, face) pain
- F. Visceral (organ) pain
- G. Musculoskeletal pain (such as arthritis)
- H. I don't know
- I. Other



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Discussion Topic 1

Symptoms and daily impacts of chronic pain that matter most to patients

Meghana Chalasani

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Center for Drug Evaluation and Research

U.S. Food and Drug Administration

July 9, 2018



Topic 1 Discussion Questions

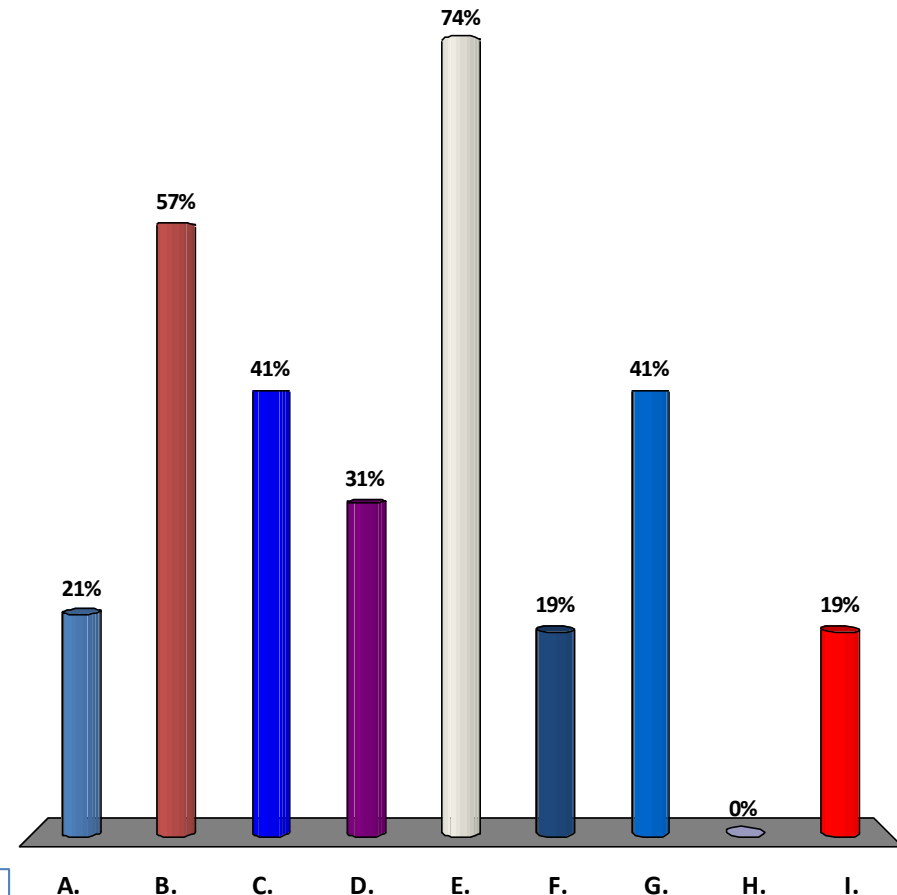
1. How would you describe your chronic pain?
2. What are the most significant symptoms that you experience resulting from your condition?
3. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your chronic pain?
4. How has your chronic pain changed over time?

Topic 1 Panelists

- Amy
- Katie
- Tien
- Debbie

How do your chronic pain symptoms typically manifest? **Check all that apply.**

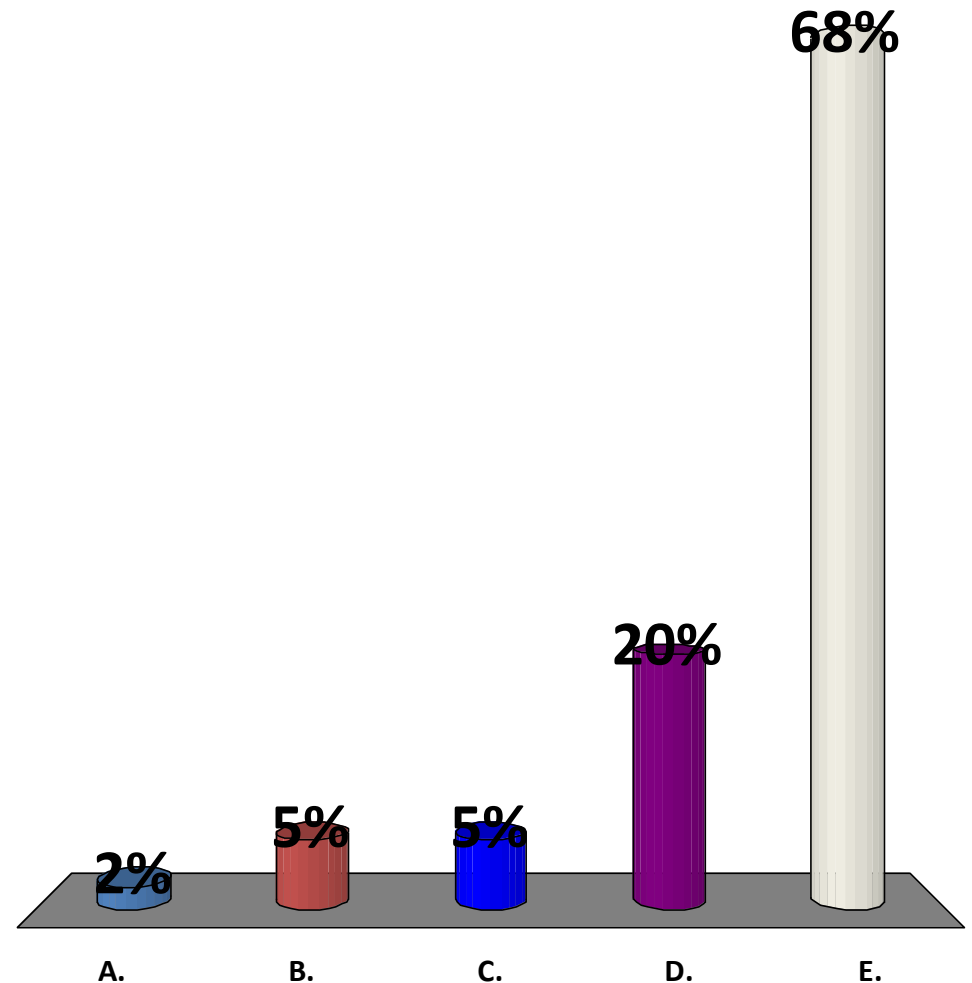
- A. I have periods without pain
- B. My pain appears suddenly
- C. My pain appears subtly
- D. My pain is intermittent
- E. I always have pain and the intensity changes over time
- F. I always have pain and the intensity doesn't change over time
- G. My pain worsens over time
- H. I don't know
- I. My pain manifests in another way



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Over the course of a typical day, how much time do you spend in pain?

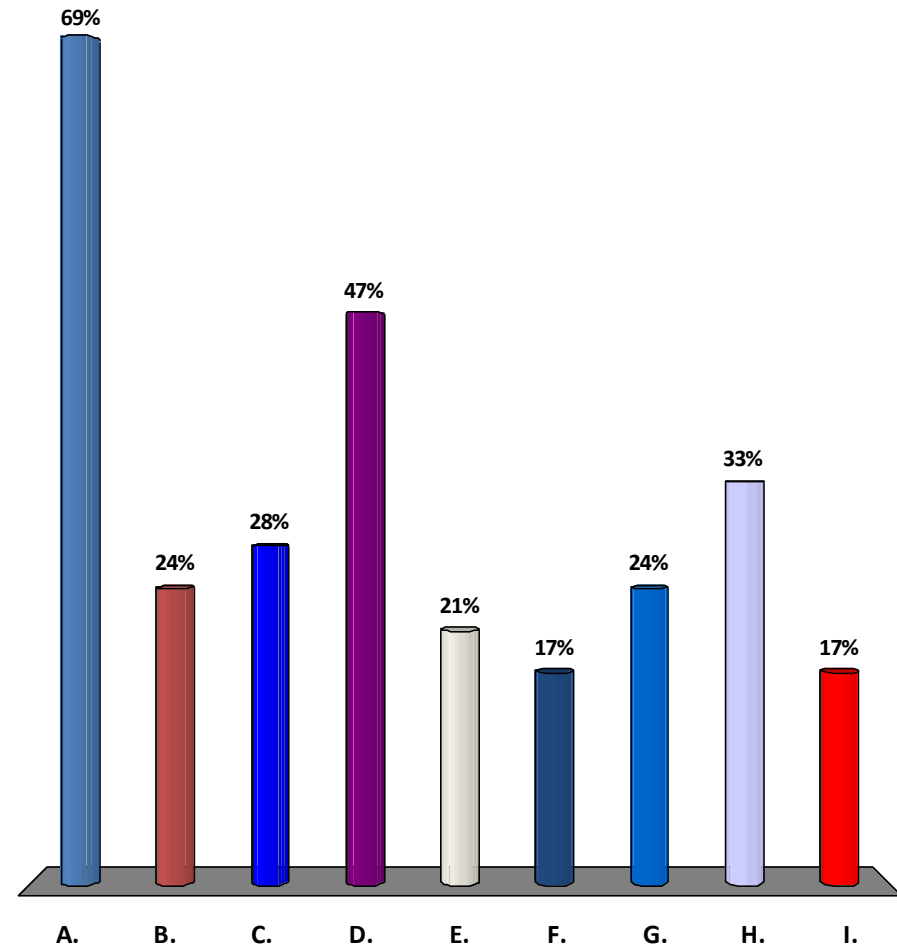
- A. Several minutes
- B. Less than 4 hours
- C. Between 4 to 12 hours
- D. More than 12 but less than 24 hours
- E. All day (24 hours)



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What are the most bothersome impacts of your chronic pain on your daily life? **Please choose up to three impacts.**

- A. Ability to participate in or perform activities (such as work, participation in sports or social activities, driving, make or keep plans for activities, etc.)
- B. Ability to fall asleep or stay asleep
- C. Ability to concentrate or stay focused
- D. Ability to care for self, family, and others
- E. Impacts on relationships
- F. Stigma or embarrassment
- G. Social discrimination
- H. Emotional impacts (such as mood, fear, hopelessness, etc.)
- I. Other impacts not mentioned



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Send us your comments!

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Visit:

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Or Search “Patient Focused Drug Development Chronic Pain” on www.regulations.gov

And **Click Comment Now!**

The screenshot shows the regulations.gov website interface. At the top, there is a navigation bar with links for Home, Help, Resources, and Contact. The main heading is "Patient-Focused Drug Development on Chronic Pain; Public Meeting; Request for Comments". Below this, there is a section for "Action" with the text "Notice of public meeting; request for comments." and a "Summary" section. A red arrow points from the text "And Click Comment Now!" to a "Comment Now!" button located in the top right corner of the page. The button is blue with white text. Below the button, there is a "Document Information" section with fields for "Date Posted" (May 15, 2018) and "Federal Register Number" (2018-10284). At the bottom right, there is a "Comments" section showing "851 Comments Received".



National Suicide Prevention Lifeline

1-800-273-8255

LUNCH

Discussion Topic 2

Current Approaches to Treatment of Chronic Pain

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U.S. Food and Drug Administration

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Topic 2 Discussion Questions

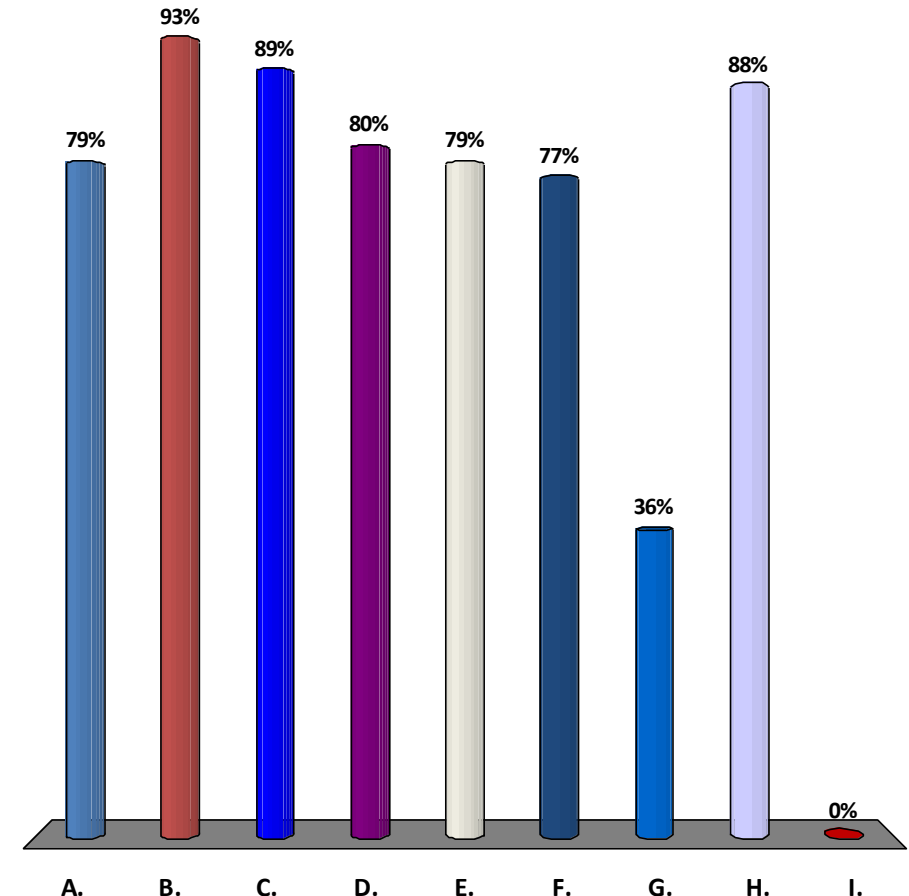
1. What are you currently doing to help treat your chronic pain?
2. How well does your current treatment regimen manage your chronic pain?
3. What are the most significant downsides to your current treatments, and how do they affect your daily life?
4. What challenges or barriers to accessing or using medical treatments for chronic pain have you or do you encounter?
5. What specific things would you look for in an ideal treatment for your chronic pain?

Topic 2 Panelists

- Lindsay
- Louis
- Rose
- Hilary

Have you ever used any of the following therapies to manage your chronic pain? **Check all that apply.**

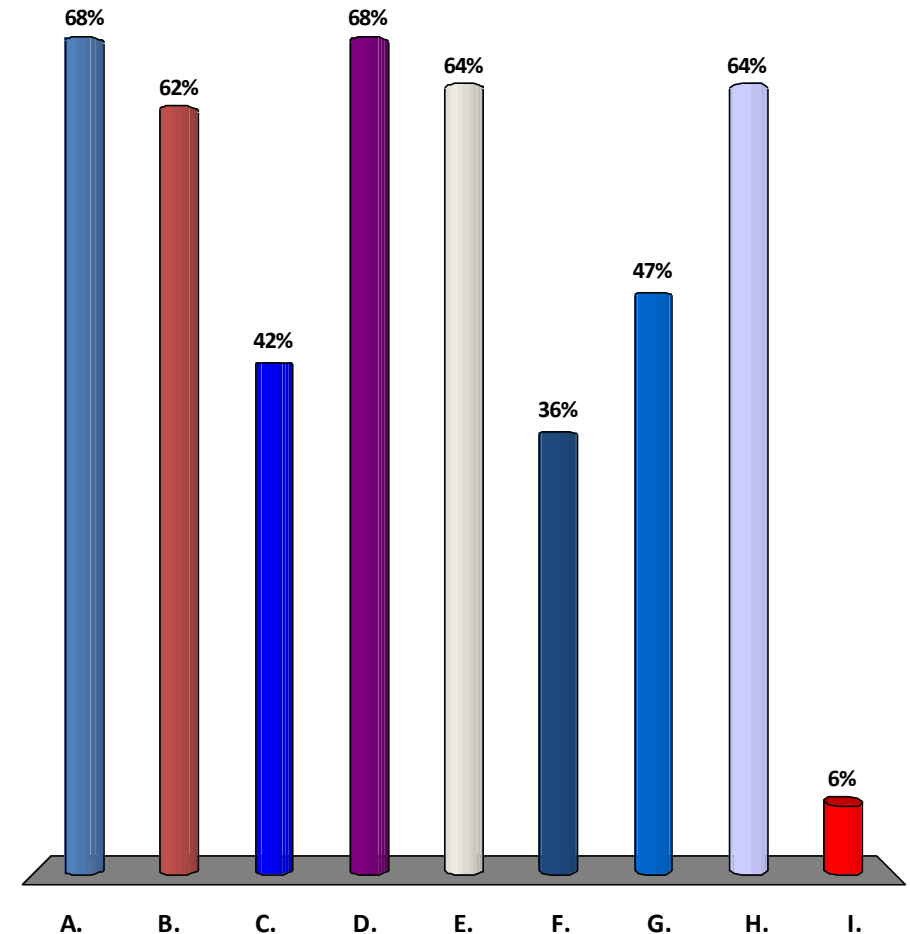
- A. Transdermal or topical patches (such as lidocaine)
- B. Acetaminophen, prescription nonsteroidal anti-inflammatory drugs (NSAIDs such as diclofenac), or over-the-counter products (such as ibuprofen and naproxen)
- C. Opioid medication
- D. Antidepressant drugs (such as Elavil (amitriptyline), Prozac (duloxetine), Effexor (venlafaxine))
- E. Non-invasive medical devices (such as transcutaneous electrical nerve stimulation or TENS)
- F. Anticonvulsant medications (such as neurontin (gabapentin) or lyrica (pregabalin))
- G. Implantable medical devices and/or surgical procedures (such as spinal cord stimulator implants, implantable infusion pumps, or surgical destruction of nerves)
- H. Other therapies (drugs or medical devices) not mentioned
- I. I'm not using any therapies (drugs or medical devices)



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Besides the therapies mentioned previously, what else are you doing to manage your chronic pain? **Check all that apply.**

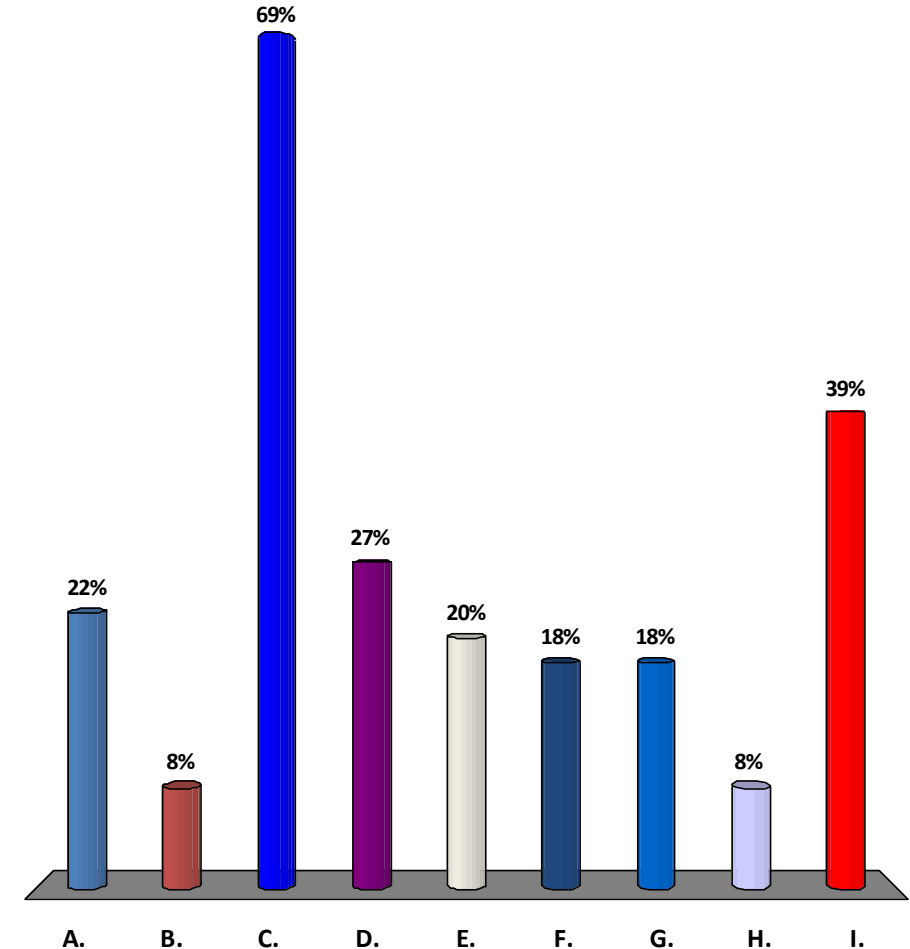
- A. Dietary and herbal supplements
- B. Diet modifications and behavioral changes (such as changes to alcohol and tobacco use)
- C. Cannabinoids (such as medical marijuana)
- D. Complementary or alternative therapies (such as acupuncture, massage, relaxation, meditation and biofeedback)
- E. Physical or occupational therapy
- F. Mobile applications
- G. Counseling or psychological treatment
- H. Other therapies not mentioned
- I. I am not doing or taking any therapies to treat my chronic pain



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For the therapies you use, what do you consider to be the most burdensome or concerning downsides? Please choose up to three answers.

- A. How the therapy is administered (such as a pill, injection, or invasive procedure)
- B. The frequency and length of treatment
- C. Difficulty in accessing treatment (for example, insurance or cost)
- D. The treatment only provides minimal benefit or is effective only for a short-term
- E. Bothersome short-term side effects of the treatment (such as nausea or fatigue)
- F. Concern about serious risks of the treatment
- G. Uncertainty about long-term effects of treatment
- H. The risk of developing drug abuse and addiction
- I. Other downsides not mentioned



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BREAK

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Open Public Comment

Shanon Woodward

Office of Strategic Programs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

July 9, 2018

Closing Remarks

Sharon Hertz, MD

Director

Division of Anesthesia, Analgesia, and Addiction Products

Center for Drug Evaluation and Research

July 9, 2018