

Public Meeting on Patient-Focused Drug Development for Chronic Pain

July 9, 2018

- 10:00 – 10:05 am **Welcome**
Meghana Chalasani
Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA
- 10:05 – 10:10 am **Opening Remarks**
Theresa Mullin, PhD
Associate Director for Strategic Initiatives, CDER, FDA
- 10:10 – 10:25 am **Background on Chronic Pain and Treatment Options**
Sepideh Haghpanah, MD
Division of Anesthesia, Analgesia and Addiction Products (DAAAP), CDER, FDA
- 10:25 – 10:35 am **Overview of Discussion Format**
Meghana Chalasani
OSP, CDER, FDA
- 10:35 – 11:05 am **Topic 1 Panel: Symptoms and Daily Impacts of Chronic Pain**
Topic 1: Symptoms and daily impacts that matter most to patients. A panel of patients and patient representatives will provide comments to start the discussion.
- 11:05 – 12:00 pm **Large-Group Facilitated Discussion on Topic 1**
Patients and patient representatives in the audience are invited to add to the dialogue.
- 12:00 – 1:00 pm **Lunch**
- 1:00 – 1:05 pm **Afternoon Welcome**
Meghana Chalasani
OSP, CDER, FDA
- 1:05 – 1:35 pm **Topic 2 Panel: Patients' Perspectives on Treatments for Chronic Pain**
Topic 2: Patient perspectives on current approaches to chronic pain. A panel of patients and patient representatives will provide comments to start the discussion.
- 1:35 – 2:30 pm **Large-Group Facilitated Discussion: Topic 2**
Patients or patient representatives in the audience are invited to add to the dialogue.
- 2:30 – 2:45 pm **Break**
- 2:45 – 3:20 pm **Large-Group Facilitated Discussion: Topic 2 Continued**
- 3:20 – 3:50 pm **Open Public Comment**
- 3:50 – 4:00 pm **Closing Remarks**
Sharon Hertz, MD
Director, DAAAP, CDER, FDA

Discussion Questions

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

1. How would you describe your chronic pain? (Characteristics could include location, radiation, intensity, duration, constancy or intermittency, triggers etc.)
2. What are the most significant symptoms that you experience resulting from your condition? (Examples may include restricted range of motion, muscle spasms, changes in sensation, etc.)
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? (Examples of activities may include work or school activities, sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
4. How has your chronic pain changed over time? (Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities)

Topic 2: Patients' perspectives on current approaches to treatment of chronic pain

1. What are you currently doing to help treat your chronic pain? (Examples may include prescription medicines, over-the-counter products, and non-drug therapies)
 - a) How has your treatment regimen changed over time, and why? (Examples may include change in your condition, change in dose, or treatment side effects)
 - b) What factors do you take into account when making decisions about selecting a course of treatment?
2. How well does your current treatment regimen manage your chronic pain? (Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities)
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?

Docket Information: We encourage you to submit your written comments to the docket by September 10, 2018: <https://www.regulations.gov/document?D=FDA-2018-N-1621-0001> or go to www.regulations.gov and search for: **chronic pain patient-focused drug development**.