

Center for Drug Evaluation and Research (CDER)
Public Meeting on Patient-Focused Drug Development for Stimulant Use Disorder
Silver Spring Civic Building
1 Veterans Pl, Silver Spring, MD 20910
Tuesday, March 10, 2020

AGENDA

- 11:30 – 12:30 pm **Registration**
- 12:30 – 12:35 pm **Welcome**
Robyn Bent, RN, MS, CAPT, US Public Health Service
Office of the Center Director (OCD), Center for Drug Evaluation and Research (CDER), FDA
- 12:35 – 12:40 pm **Opening Remarks**
Marta Sokolowska, PhD
OCD, CDER, FDA
- 12:40 – 12:50 pm **Overview of FDA’s Patient-Focused Drug Development Initiative**
Theresa Mullin, PhD
OCD, CDER, FDA
- 12:50 – 1:00 pm **Background on Stimulant Use Disorder**
Maryam Afshar, MD
Division of Anesthesiology, Addiction Medicine, and Pain Medicine, CDER, FDA
- 1:00 – 1:10 pm **Overview of Discussion Format**
Robyn Bent, RN, MS, CAPT, US Public Health Service
OCD, CDER, FDA
- 1:10 – 1:20 pm **Topic 1: Health Effects and Daily Impacts**
Speakers will share their experiences with stimulant use, and the health effects and daily impacts of stimulant use disorder.
- 1:20 – 2:00 pm **Large-Group Facilitated Discussion on Topic 1**
Individuals with stimulant use disorder and impacted family members in the audience will be invited to add to the dialogue.
- 2:00 – 2:20 pm **Break**
- 2:20 – 2:30 pm **Topic 2: Current Approaches to Management**
Speakers will start off the discussion on treatment goals and decision factors considered when seeking a treatment for stimulant use disorder.
- 2:30 – 3:45 pm **Large-Group Facilitated Discussion on Topic 2**
Individuals with stimulant use disorder and impacted family members in the audience will be invited to add to the dialogue.
- 3:45 – 4:15 pm **Open Public Comment**
- 4:15 – 4:30 pm **Closing Remarks**
Marta Sokolowska, PhD
OCD, CDER, FDA

DISCUSSION QUESTIONS

Topic 1: Health Effects and Daily Impacts

1. How would you describe your journey with stimulant use disorder?
 - a. Which stimulant(s) did you start using first?
 - b. What stimulant(s) are you using now?
 - c. Did you use any other illicit or prescription drugs before you started using the stimulant that you are currently using?
 - d. How are you using stimulants? How has your stimulant(s) use changed over time? Are you using more frequently or at higher doses?
 - e. Do you use stimulants in combination with other drug(s)? If so, what other drugs do you use and why?
 - f. Have you used a stimulant(s) as treatment for opioid withdrawal and/or overdose?
2. Of all the ways that stimulant use disorder impacts your health and well-being, which effects have the most significant impact on your daily life and the daily life of your family and/or friends? *Examples may include physical and mental effects of using stimulants (effects on your body and thinking), effects of stimulant withdrawal, effects of cravings, impacts on your ability to function in personal or professional life, or emotional or social effects.*
 - a. What drives your use of stimulants?
 - b. Are there certain activities that you can only do if you take a stimulant? If so, what are those activities?
 - c. 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 stimulant use? *Examples of activities may include daily hygiene; meeting school, work, or family responsibilities; participation in social activities.*
 - d. How does your stimulant use affect daily life on your best days? On your worst days?
 - e. What worries you most about your condition?

Topic 2: Current Approaches to Management

1. Have you considered seeking treatment? Why or why not?
2. What are you currently doing to help manage your stimulant use?
 - a. How well have these management approaches worked for you?
 - b. How well have they helped address the effects of stimulant use that are most troubling to you?
 - c. What are the biggest problems you have faced in using these approaches? *Examples may include bothersome side effects, challenges or barriers to access, concern about stigma.*
3. What are the biggest factors that you consider when making decisions about seeking out or engaging in treatment for stimulant use disorder?
4. What specific things would you look for in an ideal treatment for stimulant use disorder?
5. If you had the opportunity to participate in a clinical study to test an experimental treatment for stimulant use disorder, what factors would you consider when deciding whether you would participate?

Docket Information: We encourage you to submit written comments to the docket by May 11, 2020:

<https://www.regulations.gov/document?D=FDA-2020-N-0259-0001> or go to <https://www.regulations.gov/> and search for: **patient-focused drug development stimulant use disorder**.