

## Developing Novel Therapies for Stimulant Use Disorder

Washington Marriott at Metro Center  
775 12th St NW • Washington, DC 20005  
December 16, 2019

### Agenda

Under a cooperative agreement between Duke-Margolis Center for Health Policy and the U.S. Food and Drug Administration, this public workshop will bring together experts and key stakeholders from federal agencies, academia, and professional organizations. Panelists will discuss the current public health and regulatory landscape of stimulant use disorder. This workshop will lay the groundwork for understanding this complex issue and promote the exchange of innovative ideas to advance the development of novel therapies for stimulant use disorder.

#### Meeting Objectives:

- Examine the complexities of stimulant use disorder with a focus cocaine and amphetamine-like substances (including methamphetamine).
- Explore emerging trends in problematic use of illicit and prescription stimulants.
- Identify drug development paradigms for novel treatments for stimulant use disorder.
- Discuss future directions and strategies for patient engagement in drug development.

#### 9:00 a.m. Welcome and Overview

##### Speakers:

- **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy
- **Douglas Throckmorton**, U.S. Food and Drug Administration

#### 9:10 a.m. Opening Keynote

**Speaker: Adm. Brett Giroir**, U.S. Department of Health and Human Services

#### 9:25 a.m. Session I: Overview of Stimulant Use Disorder and Emerging Trends

*Objective:* Define patient population demographics of cocaine and amphetamine-like problematic users. Discuss stimulant use disorder trajectories and key contributing factors. Define subtypes of stimulant use disorder and key symptoms, including withdrawal syndrome and craving. Differentiate between: binge vs. intermittent use, single vs. polysubstance use, and prescription vs. illicit use. Understand the differences and interactions between stimulant and opioid use disorder. Discuss the stigma associated with stimulant use disorder and the impact on patients prescribed stimulants.

**Moderator: Adam Kroetsch**, Duke-Robert J. Margolis, MD, Center for Health Policy

##### Presenters:

- **Wilson Compton**, National Institute on Drug Abuse
- **Daniel Ciccarone**, University of California, San Francisco

##### Panelists:

- **Janetta Iwanicki**, RADARS/Rocky Mountain Poison and Drug Safety
- **Amelia Arria**, University of Maryland, School of Public Health
- **Jody Green**, Inflexxion, Inc.

*Questions for Discussion:*

- How do we define stimulant use disorder, describe developmental trajectories, and distinguish between the various sub-types of stimulant use disorder?
- What are the trends in stimulant use disorder and how do they differ from other substance use disorder trends?
- What are some of the main drivers for the increases in the use of stimulants?

**10:45 a.m. Break**

**11:00 a.m. Session II: Medication Development – Challenges, Lessons Learned, and the Current Development Pipeline**

*Objective:* Discuss the challenges encountered while evaluating medication efficacy in cocaine and methamphetamine use disorders, lessons learned, evolving clinical trial designs, and the current pipeline of small molecules and biologics in preclinical and clinical development.

**Moderator: Adam Kroetsch, Duke-Robert J. Margolis, MD, Center for Health Policy**

**Presenters:**

- **David McCann**, National Institute on Drug Abuse

**Panelists:**

- **F. Gerard Moeller**, Virginia Commonwealth University
- **Frances Levin**, Columbia University
- **Thomas Kosten**, Baylor College of Medicine

*Questions for Discussion:*

- What practices can increase enrollment of appropriate patients?
- What pre-randomization procedures can be adopted to decrease the likelihood of medication non-adherence?
- What post-randomization procedures can be adopted to improve adherence?

**12:15 p.m. Lunch**

**1:15 p.m. Session III: Assessing Clinical Endpoints and Methods for Data Collection**

*Objective:* Identify meaningful outcomes that could be used in endpoints to establish safety and efficacy. Examine methods for data collection related to stimulant use disorder.

**Moderator: Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy**

**Presenter:**

- **Kathleen Carroll**, Yale School of Medicine

**Panelists:**

- **Philip Rutherford**, Faces and Voices of Recovery
- **Kenzie Preston**, National Institute on Drug Abuse Intramural Research Program
- **Celia Winchell**, U.S. Food and Drug Administration

*Questions for Discussion:*

- What are the outcomes that reflect patient priorities?
- What endpoints do clinicians think are relevant?
- How are data related to stimulant use disorder collected in routine clinical care?

**2:30 p.m. Break**

**2:45 p.m. Session IV: Current Treatment Paradigms**

*Objective:* Explore non-pharmacological and alternative therapies for stimulant use disorder to support remission, including psychosocial interventions. Discuss challenges to patients accessing evidence-based treatment and to managing comorbidities.

**Moderator:** Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

**Presenters:**

- **Kelly Clark**, American Society of Addiction Medicine

**Panelists:**

- **Larissa Mooney**, University of California, Los Angeles
- **Joshua Barocas**, Boston University School of Medicine
- **Caleb Banta-Green**, University of Washington Alcohol and Drug Abuse Institute
- **Daniel Raymond**, Harm Reduction Coalition

*Questions for Discussion:*

- What treatment gaps do patients who receive psychosocial intervention experience?
- What barriers to accessing evidence-based treatment do patients with stimulant use disorder face?

**3:45 p.m. Session V: Future Directions**

*Objective:* Discuss strategies to promote the development of new therapies for stimulant use disorder including increased patient engagement.

**Moderator:** Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

**Panelists:**

- **Kurt Rasmussen**, National Institute on Drug Abuse
- **Kathleen Carroll**, Yale School of Medicine
- **Kelly Clark**, American Society of Addiction Medicine
- **Philip Rutherford**, Faces and Voices of Recovery
- **Marta Sokolowska**, U.S. Food and Drug Administration

*Questions for Discussion:*

- How can researchers, sponsors, and FDA support the development of new treatments for stimulant use disorder?
- In addition to the current pipeline of projects, what other types of therapeutic agents merit evaluation?

**4:30 p.m. Closing Remarks and Adjournment**

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