



Understanding Fatal Overdoses to Inform Product Development and Public Health Interventions to Manage Overdose

March 8 from 1-4:45 pm ET & March 9 from 1-4:45 pm ET
Virtual Public Meeting

Agenda

Meeting Description:

The U.S. Food and Drug Administration (FDA), in partnership with the Reagan-Udall Foundation for the FDA, will hold a two-day virtual public meeting titled "Understanding Fatal Overdoses to Inform Drug Development and Public Health Interventions to Manage Overdose." Drug overdose persists as a major public health issue in the United States, with an estimated 108,000 fatal overdoses occurring in the 12-month period ending in May 2022. Synthetic opioids, such as fentanyl and its analogs, were the primary driver of the increase in overdose deaths. Other controlled substances, including benzodiazepines and stimulants (particularly methamphetamine), are also being used in combination with opioids. To support efforts to develop products and approaches to treat overdose and prevent fatalities, stakeholders will explore the evolving context surrounding fatal overdoses. Participants will discuss epidemiological trends, drug supply changes, public health interventions to manage overdose, and drug development opportunities.

Meeting Goals:

- Understand the current landscape of fatal overdoses in the U.S., including changes in patterns of drug use, trends in the illicit drug supply, and real-world experience of overdose
- Understand the gaps and opportunities for product development, as well as optimization of treatment of opioid-involved overdose with existing opioid overdose management products
- Discuss other (non-pharmacological) public health interventions/approaches to better manage overdose, especially in the pre-hospital setting or by laypersons

Day 1

1 pm

Welcome

Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA

1:05 pm

Opening Remarks from FDA

Robert M. Califf, MD, Commissioner, U.S. Food and Drug Administration

1:15 pm

Session 1: The Current Landscape of Drug Use and Overdose in the U.S.

Presentations:

- Christopher M. Jones, PharmD, DrPH, MPH, Centers for Disease Control and Prevention
- Angela Huskey, PharmD, Millennium Health
- Eric D. Wish, PhD, University of Maryland

All times are listed in Eastern Time.

2:15 pm Session 2: Pharmacology of Opioids and Overdose Management Products

Presentations:

- Albert Dahan, MD, PhD, Leiden University Medical Center
- David Strauss, MD, PhD, U.S. Food and Drug Administration

Reactor Panel:

- Bruce Goldberger, PhD, University of Florida College of Medicine
- Alexander A. Vinks, PharmD, PhD, Cincinnati Children's Hospital Medical Center

3:20 pm Break

3:30 pm Session 3: Real-World Experiences with Managing Opioid Overdose

Presentations:

- Erin Winstanley, PhD, West Virginia University School of Medicine
- Alice Bell, LCSW, Prevention Point Pittsburgh

Reactor Panel:

- Sessi K. Blanchard, Community Access
- Justin Strickland, PhD, Johns Hopkins University
- Zachary Dezman, MD, MS, U.S. Food and Drug Administration

4:45 pm Adjourn Day 1

Day 2

1 pm Welcome and Recap of Day 1

Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA

1:05 pm Session 4: Novel Approaches to Preventing Overdose Deaths

Presentation:

- Mary Sylla, JD, MPH, National Harm Reduction Coalition

Reactor Panel:

- Mark Lysyshyn, MD, MPH, Vancouver Coastal Health
- Jermaine Jones, PhD, Columbia University Irving Medical Center
- Emanuel Sferios, MA, DanceSafe
- CAPT Jennifer Fan, PharmD, JD, Substance Abuse and Mental Health Services Administration

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2:05 pm Session 5: Regulatory Considerations for Developing Opioid Overdose Management Products

Presentation:

- Srikanth C. Nallani, PhD, U.S. Food and Drug Administration

2:25 pm Session 6: Considerations for Opioid Overdose Management Product Development

Presentations:

- Carin King Malley, MD, University of Pittsburgh Medical Center
- Iván Montoya, MD, MPH, National Institute on Drug Abuse

Reactor Panel:

- Jesse Pines, MD, US Acute Care Solutions
- Phillip Fiuty, The Mountain Center
- Nabarun Dasgupta, PhD, University of North Carolina
- Jessica Paulsen, U.S. Food and Drug Administration
- Srikanth C. Nallani, PhD, U.S. Food and Drug Administration

3:40 pm Session 7: Future Directions

Panelists:

- Marta Sokolowska, PhD, U.S. Food and Drug Administration
- Nora Volkow, MD, National Institute on Drug Abuse
- Yngvild K. Olsen, MD, MPH, Substance Abuse and Mental Health Services Administration
- Phillip Fiuty, The Mountain Center
- Jermaine Jones, PhD, Columbia University Irving Medical Center

4:45 pm Adjourn Day 2

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