

Safe Use of Benzodiazepines: Clinical, Regulatory, and Public Health Perspectives

Public Meeting | July 12 & 13, 2021

In September 2020, the U.S. Food and Drug Administration announced a requirement that the [Boxed Warning](#) and other sections of benzodiazepine drug products' labeling be updated to provide a more comprehensive description of risks related to nonmedical use, addiction, physical dependence, and withdrawal reactions. Benzodiazepine nonmedical use is widespread, and individuals frequently co-use benzodiazepines with alcohol, prescription opioids, and illicit drugs. Associated harms of benzodiazepine nonmedical use are substantial but occur primarily when people use benzodiazepines in combination with other drugs.

This two-day public workshop will convene regulators, academic researchers, clinicians, patient advocates, and other stakeholders to share information underlying this action and gather input related to the safe use of benzodiazepines. Participants will discuss epidemiological and abuse liability data, patient and clinician perspectives and experiences, and gaps in data and understanding about the safe use of benzodiazepines.

Day 1 Agenda

- 1:00 pm** **Welcome and Overview**
- **Mark McClellan**, Duke-Margolis Center for Health Policy
- 1:10 pm** **FDA Opening Remarks**
- **Douglas Throckmorton**, U.S. Food and Drug Administration
- 1:25 pm** **Session 1: Benzodiazepine Abuse Liability, Epidemiology, and Clinical Considerations**
- Objectives:*
- Review available data and research on factors related to the abuse liability of benzodiazepines, including drug discrimination, self-administration, and clinical studies assessing reinforcing effects
 - Discuss epidemiologic data on use and non-medical^[1] use of benzodiazepines, including use with other substances and associated harms, and benzodiazepine dependence and withdrawal
 - Understand clinical perspectives on benzodiazepine use, including treatment goals for benzodiazepine therapy
- Presentations:*
- **Chad Reissig**, U.S. Food and Drug Administration
 - **Jana McAninch**, U.S. Food and Drug Administration
 - **Kurt Kroenke**, Indiana University School of Medicine
- Questions and Answers*

^[1] The World Health Organization defines non-medical use of drugs as “taking of prescription drugs, whether obtained by prescription or otherwise, other than in the manner or for the reasons or time period prescribed, or by a person for whom the drug was not prescribed.” ([link](#))

2:45 pm **Break**

3:00 pm **Session 2: Clinical, Pharmacologic, and Public Health Perspectives**

Objectives:

- Discuss the epidemiologic and abuse liability data, and identify remaining gaps in understanding of risks associated with use, misuse, and abuse of benzodiazepines
- Discuss whether there are differences among products within the class of benzodiazepines that may contribute to varying levels of risk for misuse or associated harms

Panel Discussion:

- **Janetta Iwanicki**, Rocky Mountain Poison & Drug Safety
- **Naama Levy-Cooperman**, Altreos Research Partners
- **Kerri Schoedel**, Altreos Research Partners
- **Wilson Compton**, National Institute on Drug Abuse
- **Carla Foster**, New York City Department of Health and Mental Hygiene
- **Kelly Clark**, Addiction Crisis Solutions

4:25 pm **Closing Remarks**

- **Mark McClellan**, Duke-Margolis Center for Health Policy

4:30 pm **Adjourn**

Day 2 Agenda

- 1:00 pm** **Welcome and Summary of Day 1**
- **Mark McClellan**, Duke-Margolis Center for Health Policy
- 1:10 pm** **Session 3: Health Professional and Patient Advocate Perspectives – Best Practices, Experiences, and Concerns**
- Objectives:*
- Understand clinician-identified best practices, gaps in education, and other issues related to benzodiazepine prescribing and tapering
 - Discuss experiences of health professionals, patients, and caregivers with benzodiazepine initiation, short-term and long-term use, and tapering
- Presentations:*
- **Steven Wright**, Alliance for Benzodiazepine Best Practices
 - **Barbara Farrell**, Bruyère Research Institute
 - **Sangeeta Tandon**, U.S. Food and Drug Administration
- Panel Discussion:*
- **Chinyere Ogbonna**, Kaiser Permanente
 - **Sumit Agarwal**, Brigham and Women’s Hospital
 - **Christy Huff**, Benzodiazepine Information Coalition
 - **Barbara Farrell**, Bruyère Research Institute
 - **Steven Wright**, Alliance for Benzodiazepine Best Practices
 - **Scott Winiecki**, U.S. Food and Drug Administration
- 2:45 pm** **Break**
- 3:00 pm** **Session 4: Balancing the Benefits and Risks of Benzodiazepines**
- Objective:*
- Discuss takeaways from information shared and gathered over the course of the workshop, including gaps in data and understanding
- Panel Discussion:*
- **Kurt Kroenke**, Indiana University School of Medicine
 - **Wilson Compton**, National Institute on Drug Abuse
 - **Chinyere Ogbonna**, Kaiser Permanente
 - **Christy Huff**, Benzodiazepine Information Coalition
 - **Marc Stone**, U.S. Food and Drug Administration
 - **Marta Sokolowska**, U.S. Food and Drug Administration
- 3:55 pm** **Closing Remarks**
- **Mark McClellan**, Duke-Margolis Center for Health Policy
- 4:00 pm** **Adjourn**