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.

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 Clinical Use, Epidemiology, and Abuse Liability  
Objectives:  
• Understand clinical perspectives on treatment goals for benzodiazepine therapy  
• Discuss epidemiologic data on patterns of use and non-medical* use of benzodiazepines, including use with other substances (i.e., polysubstance use) and associated harms  
• 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.

Presentations  
Q&A

2:45 pm  Break

* 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]
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

4:30 pm  Closing Remarks

Mark McClellan, Duke-Margolis Center for Health Policy
Welcome and Summary of Day 1
Mark McClellan, Duke-Margolis Center for Health Policy

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
Panel Discussion

Break

Session 4: Balancing the Benefits and Risks of Benzodiazepines
Objectives:
- Discuss takeaways from information shared and gathered over the course of the workshop, including gaps in data and understanding

Panel Discussion

Closing Remarks
Mark McClellan, Duke-Margolis Center for Health Policy

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