Mitigating Risks from Human Xylazine Exposure

Wednesday, October 4 from 9:15am – 5pm ET
Hybrid Public Meeting
In-Person: Marriott Marquis
901 Massachusetts Ave NW, Washington DC, 20001
Metro Stop: Mount Vernon Sq. 7th St. Convention Center

Meeting Description:
The Reagan-Udall Foundation for the FDA, in partnership with the U.S. Food and Drug Administration (FDA), is holding a hybrid public meeting entitled **"Mitigating Risks from Human Xylazine Exposure"**. This hybrid public meeting will explore real-world experiences and scientific evidence on emerging data trends for human xylazine exposure. This meeting also seeks to examine concrete strategies for drug development and clinical research that directly supports the mitigation and reduction of risks associated with human exposure to xylazine. Workshop presentations and discussions will include clinical and scientific experts, community and harm reduction organizations, academic researchers, and federal partners.

Xylazine is a non-opiate sedative, analgesic, and muscle relaxant only authorized in the United States for veterinary use, as approved by the FDA. It is not currently a controlled substance under the U.S. Controlled Substances Act, nor is it approved for human-use. However, human exposure of xylazine has emerged as a growing public health issue. Last year, the Drug Enforcement Administration reported that forensic laboratory identifications of xylazine have risen in all four U.S. Census regions between 2020 and 2021. Furthermore, due to its impact on the opioid crisis, fentanyl mixed (adulterated) with xylazine has also been declared an emerging threat by the White House's Office of National Drug Control Policy. Given this emerging threat, FDA believes a better understanding of the landscape of available tools and preventive strategies for reducing illicit use of xylazine is needed to advance the development and access to evidence-based treatment for human exposure.

Meeting Goals:
1. Understand the current landscape of xylazine and similar drug compounds in the United States, including changes in patterns of drug use, trends in the illicit drug supply, and real-world experience of overdose.
2. Identify specific areas of exploratory research that can be used to mitigate risks associated with human xylazine exposure.
3. Discuss existing data gaps and specific strategies for improving current surveillance systems.

9:15 am **Welcome**

Speaker: Susan C. Winckler, RPh, Esq, Chief Executive Officer, Reagan-Udall Foundation for the FDA

9:25 am **Opening Remarks: Public Health Strategy**

Speaker: David Holtgrave, PhD, Assistant Director, White House Office of National Drug Control Policy

9:40 am **Opening Remarks: Overview of Xylazine and Addressing Data/Research Gaps**

Speaker: Marta Sokolowska, PhD, Deputy Center Director for Substance Use and Behavioral Health, Center for Drug Evaluation and Research (CDER), FDA

9:55 am **Session 1: Current Landscape and Epidemiological Trends**

- CDR Jean Ko, PhD, Deputy Director of Scientific Programs, Division of Overdose Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention
- Amanda DiStefano, Intelligence Analyst II, Liberty Mid-Atlantic High Intensity Drug Trafficking Area
- Van Jackson, Drug Intelligence Officer, Liberty Mid-Atlantic High Intensity Drug Trafficking Area
- Traci Green, PhD, MSc, Professor and Director of Opioid Policy Research Collaborative, Brandeis University
- Erin Russell, MPH, Principal, Health Management Associates

11:05 am **Session 2: Pharmacological and Clinical Research Needs**

- Keith K. Burkhart, MD, Senior Advisor for Medical Toxicology, Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA
- Zoë McElligott, PhD, Associate Professor, Bowles Center for Alcohol Studies, University of North Carolina
- Gonçalo Gamboa da Costa, PhD, Senior Science Advisor, National Center for Toxicology Research, FDA
- Alex Krotulski, PhD, Associate Director-Toxicology/Chemistry, Center for Forensic Science and Research and Education

12:05 pm **Lunch**

In-person attendees are responsible for their own lunch. Please see handout/event staff for a list of nearby options.

1:10 pm **Session 3: Exploring Product Development Research Needs**

- Jeanmarie Perrone, MD, Director, Center for Addiction Medicine and Policy, Perelman School of Medicine, University of Pennsylvania
- CAPT Christopher Jones, PharmD, DrPH, Director, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration
- Nabarun Dasgupta, PhD, MPH, Co-Founder and Board Chair with Remedy Alliance/For the People

- Timothy Stenzel, MD, PhD, Director, Office of In Vitro Diagnostics, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, FDA
- Zachary Dezman, MD, MS, Division of Anesthesia, Addiction Medicine, and Pain Medicine, Office of Neuroscience, Office of New Drugs, CDER, FDA

2:20 pm Session 4: On the Ground Response to Xylazine

- Martin Lína Alcaraz, peer educator, SANOS Corporation, Puerto Rico
- Alice Bell, LCSW, Overdose Prevention Project Coordinator, Prevention Point Pittsburgh
- Malik Burnett, MD, MBA, MPH, Medical Director, Harm Reduction Services, Maryland Department of Health
- Luis Roman, PsyD, Clinical Psychologist, Intercambios, Puerto Rico
- Lewis Nelson, MD, MBA, Director, Division of Medical Toxicology and Addiction Medicine, Rutgers New Jersey Medical School
- Jennifer Tuerke, Executive Director, Voices of Hope Maryland

3:35 pm Session 5: Future Directions

- Rachel S. Wightman, MD, Associate Professor of Emergency Medicine and Epidemiology, Alpert Medical School, Brown University
- Jane Acri, PhD, Acting Deputy Director, Division of Therapeutics and Medical Consequences, National Institute on Drug Abuse, National Institutes of Health
- Elizabeth M. Oliva, PhD, VA National Opioid Overdose Education and Naloxone Distribution (OEND) Coordinator, VA Office of Mental Health and Suicide Prevention, Veterans Health Administration
- Laurie Konsella, MPA, Senior Public Health Advisor, Office of Regional Health Operations, Region 8, Office of the Assistant Secretary for Health, US Department of Health and Human Services

4:45 p.m. Closing Remarks

Speaker: Marta Sokolowska, PhD, FDA

5 p.m. Adjourn

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