



Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest

Hybrid Public Meeting

Thursday, June 27, 2024, from 9 am – 4 pm Eastern Time

1333 New Hampshire Avenue NW; Rooftop Meeting Room

Washington, DC, 20036

Meeting Description: The Reagan-Udall Foundation for the FDA, in collaboration with the FDA, is hosting a hybrid public meeting on “**Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest.**” Ketamine is a Schedule III controlled substance that is FDA-approved for induction and maintenance of general anesthesia. Although ketamine is not approved for the treatment of conditions such as depression or chronic pain, there has been increased interest in the use of ketamine for these types of conditions.

This public meeting will explore topics such as the scope of ketamine use, including use of approved products and compounded products, for these emerging areas of therapeutic interest; potential safety concerns; and online promotion of and access to ketamine. Speakers will include clinicians, academic researchers, patients and patient advocates, professional organizations, and federal partners.

Agenda

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| 9 am | Opening Remarks
Speakers: <ul style="list-style-type: none">• Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA• Marta Sokolowska, PhD, U.S. Food and Drug Administration |
| 9:10 am | Session 1: Overview of the Changing Ketamine Landscape
Presentation: <ul style="list-style-type: none">• Gerard Sanacora, MD, PhD, Yale University |
| 9:30 am | Session 2: Scope of Ketamine Use in Clinical Practice
Presentations: <ul style="list-style-type: none">• Steven P. Cohen, MD, Northwestern University Feinberg School of Medicine, Uniformed Services University School of Medicine• Eric Hermes, MD, Veterans Health Administration
Panel Discussion: <ul style="list-style-type: none">• Mikhail Kogan, MD, George Washington University Center for Integrative Medicine |

- Brittany O'Brien, PhD, Baylor College of Medicine
- Jessica Poole, DNAP, CRNA, Pennsylvania Association of Nurse Anesthetists
- Sandhya Prashad, MD American Society of Ketamine Physicians, Psychotherapists, and Practitioners

11 am Break

11:10 am Session 3: Identifying Safety Concerns and Potential Risks Associated with the Use of Ketamine Products

Presentations:

- Joseph Palamar, PhD, MPH, New York University Langone Health
- Megan Ehret, PharmD, MS, BCPP, University of Maryland Baltimore School of Pharmacy

Panel Discussion:

- Francesca Cunningham, PharmD, U.S. Department of Veterans Affairs
- Mark Rogge, PhD, University of Florida College of Pharmacy
- Eric Schwenk, MD, Thomas Jefferson University

12:05 pm Lunch

1:15 pm Session 4: Policy and Regulatory Challenges for the Medical Use of Ketamine

Presentations:

- Seth Mailhot, JD, Husch Blackwell
- A.J. Day, PharmD, RPh, National Community Pharmacists Association

Panel Discussion:

- Gail Bormel, RPh, JD, U.S. Food and Drug Administration
- Lisa Harding, MD, Yale University
- Lisa Robin, Federation of State Medical Boards
- Jenni Wai, RPh, MBA, Ohio Board of Pharmacy

2:15 pm Session 5: Online Promotion and Access to Ketamine

Presentations:

- Michael DiStefano, PhD, MBE, Colorado University Anschutz, Skaggs School of Pharmacy and Pharmaceutical Sciences
- Boris Heifets, MD, PhD, Stanford University School of Medicine

Panel Discussion:

- Ilisa Bernstein, PharmD, JD, Bernstein Rx Solutions
- Richard Quaresima, Federal Trade Commission

3 pm Break

3:10 pm Session 6: Potential Future Use of Ketamine

Panel Discussion:

- Eric Hermes, MD, Veterans Health Administration
- Caroline Huang, PhD, U.S. Food and Drug Administration
- Michelle Kim Leff, MD, MBA, Substance Abuse and Mental Health Services Administration
- Lisa Robin, Federation of State Medical Boards
- Gerard Sanacora, MD, PhD, Yale University

4 pm Adjourn

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