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CENTER for DRUG EVALUATION & RESEARCH

Controlled Substances Program Newsletter



U.S. FOOD & DRUG
ADMINISTRATION

A Message from Marta

Dear Colleagues and Friends,

I'm grateful for this opportunity to personally welcome you to the Spring season and the first issue of the Center for Drug Evaluation & Research's (CDER) Controlled Substances Program Newsletter.

We're excited to highlight our continued work in overdose prevention and to share the latest news about our activities in the controlled substances space. In future issues, we anticipate covering topics and events that will benefit our communities, address the concerns and needs of our stakeholders, and present opportunities to engage with FDA. For instance, today we've announced registration is open for our upcoming public meeting on understanding ketamine use for emerging areas of therapeutic interest, which will be held in collaboration with the Reagan-Udall Foundation for the FDA.

As you know, the overdose crisis is an evolving public health issue. But I want to assure you that though this crisis continues to evolve, we are steadfast in our commitment to using every tool we can to prevent overdoses and reduce overdose-related deaths.

I trust you'll find this newsletter to be informative and I hope we can continue to work together to address this crisis. Most importantly, we hope you'll accept our sincere invitation to join the conversation.



Marta Sokolowska, PhD

Deputy Center Director for Substance Use and Behavioral Health

What We've Been Up to Lately

- FDA announced an [extension on the shelf-life](#) of Narcan 4 milligram (mg) naloxone hydrochloride nasal spray products from 3-years to 4-years. This is the second action FDA has taken to extend Narcan's shelf-life and is the most recent step we've taken to prevent overdoses and reduce overdose-related deaths by expanding access to naloxone and other overdose reversal agents.
- FDA partnered with the Reagan-Udall Foundation for the FDA to hold a workshop, [Advancing Psychedelic Clinical Study Design](#), to bring together researchers, regulated industry, and other key stakeholders to discuss scientific issues that arise while working with psychedelics in clinical trials and drug development. Transcripts, speaker profiles and additional materials from the workshop are available through the [Reagan-Udall website](#).
- A new, FDA grant-funded [clinical practice guideline detailing dental pain management strategies for adolescents and adults](#) was issued by experts from the American Dental Association, University of Pittsburgh, and University of Pennsylvania. The development of this guideline—recommended in an FDA-commissioned report by the National Academies of Science, Engineering, and Medicine—compounds our ongoing collaborative efforts to reduce the risk of opioid addiction, overdose, and diversion.

Join the Conversation

[Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest](#)

(June 27, 2024)

Registration is open for this hybrid public meeting, held in collaboration with the Reagan-Udall Foundation for the FDA, which will explore the use of ketamine for emerging areas of therapeutic interest. Topics will include: the scope of use of ketamine for these areas of therapeutic interest, potential safety concerns, and online promotion of and access to ketamine. Presenters will include clinicians, academic researchers, patients and patient advocates, professional organizations, and federal partners.

[Register Now](#)

[FDA's Fifth Online Controlled Substances Summit](#) (July 25 - 26, 2024)

Registration is open for this year's summit, which aims to identify innovative solutions to reduce the illegal availability of controlled substances online. This summit will include a public workshop featuring remarks by FDA Commissioner Robert Califf and discussions with social media, internet, technology and controlled substances experts.

[Register Now](#)

Don't Forget!

[May is Mental Health Awareness Month](#)

[National Fentanyl Awareness Day - May 7, 2024](#)

About Our Work

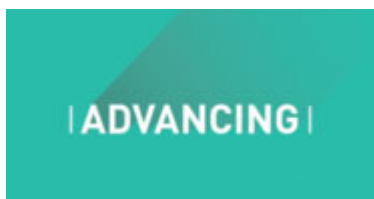
CDER's Controlled Substances Program is charged with executing activities under FDA's Overdose Prevention Framework, which consists of four overarching priorities that align with the U.S. Department of Health & Human Services' Overdose Prevention Strategy to address the public health emergency as it continues to evolve.



Supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing



Encouraging harm reduction through innovation and education



Advancing development of evidence-based treatments for substance use disorders



Protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks

Resources

[FDA Overdose Prevention Framework](#)

[HHS Overdose Prevention Strategy](#)

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