

CDER Perspective on Opioids and Overdose Prevention

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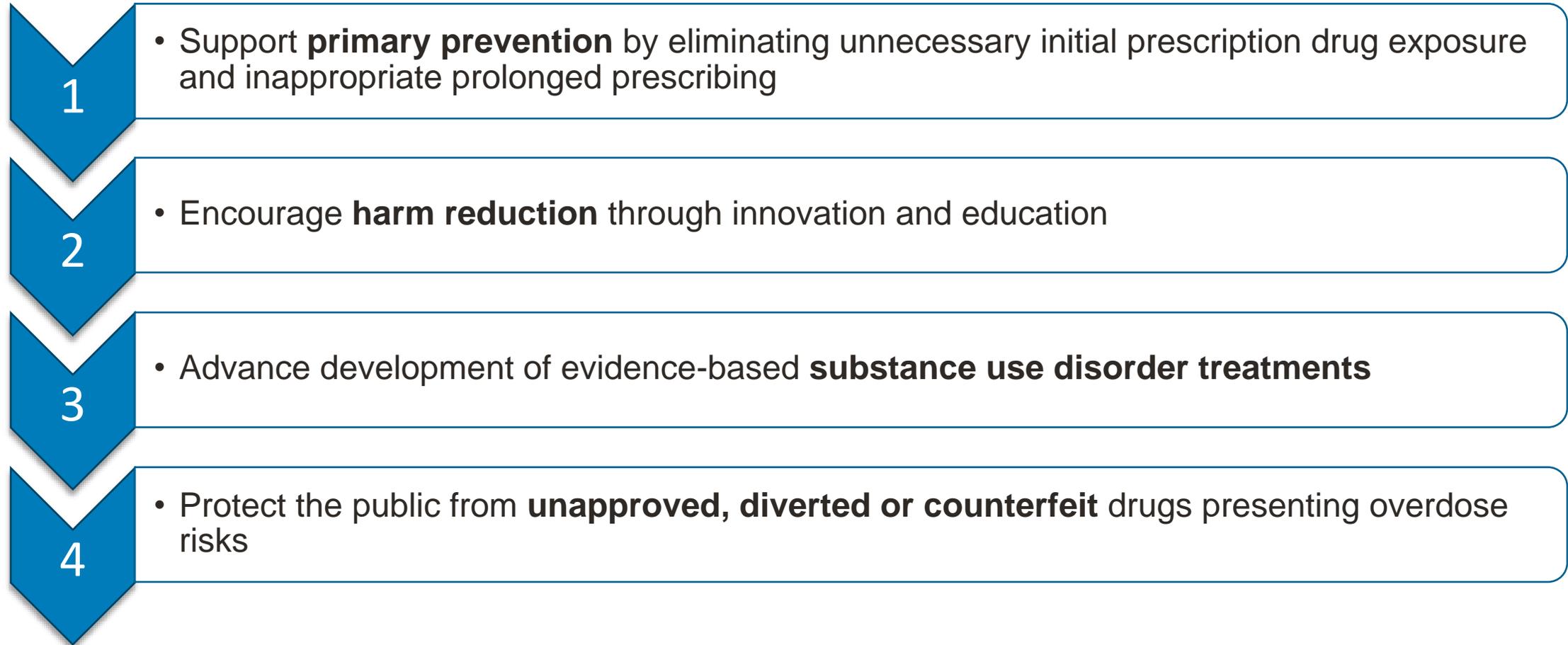
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Disclaimer and Conflict of Interest Statement

- This presentation reflects the views of the author and should not be construed to represent FDA's views or policies
- I have no conflicts of interest to disclose



FDA Actions: Primary Prevention

April 3, 2023

FDA Moves Forward with Mail-Back Envelopes for Opioid Analgesics Dispensed in Outpatient Settings

June 26-27, 2023

FDA Funds and Participates in NASEM Workshop on In-Home Drug Disposal Systems for Opioid Analgesics

April 13, 2023

FDA Announces New Safety Label Changes for Opioid Pain Medicines

December 15, 2023

FDA Announces Final Approval and Implementation of Required Label Updates for Opioid Pain Medicines

FDA Actions: Harm Reduction

March 29, 2023

FDA Approves First Branded Over-the-Counter Naloxone Nasal Spray

July 18, 2023

FDA Approves First Generic Over-the-Counter Naloxone Nasal Spray

August 7, 2024

FDA Approves First Prescription Nalmefene Auto-Injector

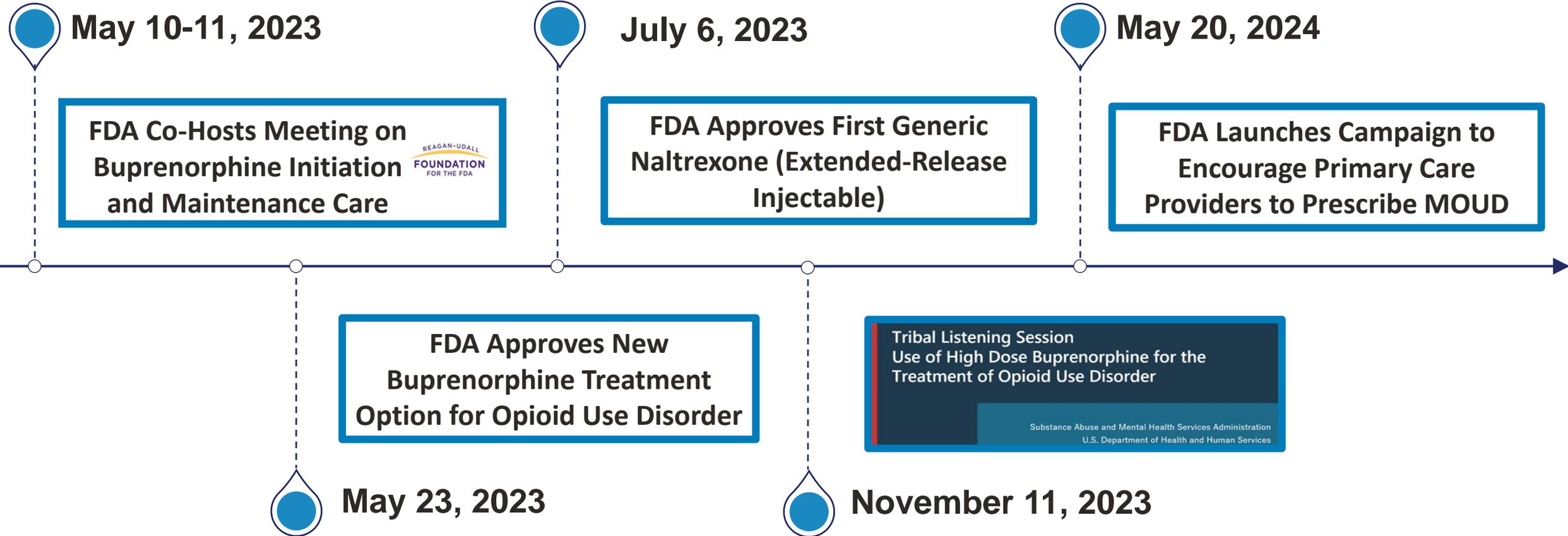
FDA Approves First Prescription Nalmefene Nasal Spray

May 22, 2023

FDA Announces Shelf-Life Extension of Narcan Nasal Spray Products from 3 years to 4 years

January 17, 2024

FDA Actions: Evidence-Based Treatment for SUD



FDA Actions: Protecting the Public

October 4, 2023

FDA Co-Hosts Public Meeting on Mitigating Risks from Human Xylazine Exposure

January 24, 2024

FDA Announces Open Period for Applications to Support Human Abuse Potential Study on Botanical Kratom

FDA Warns Consumers Not to Purchase or Use Neptune's Fix Tianeptine Products

November 21, 2023

FDA Co-Hosts Meeting to Address Availability of and Demand For Online Controlled Substances

July 25-26, 2024

- Supporting primary prevention by eliminating unnecessary prescription drug exposure.
- Working to broaden access to overdose reversal agents, including Rx and non-Rx naloxone.
 - More work needs to be done to understand optimal dosing for different populations with different needs and preferences.
- Expanding therapy options, availability of, and access to evidence-based treatments for substance use disorder.
- Developing surveillance, enforcement, and interdiction work targeting illegal, unapproved, counterfeit, and potentially dangerous products at our borders and through online sales.
- Monitoring new substances that can pose a threat to public health.

