

FDA response to 'Changing Landscape'

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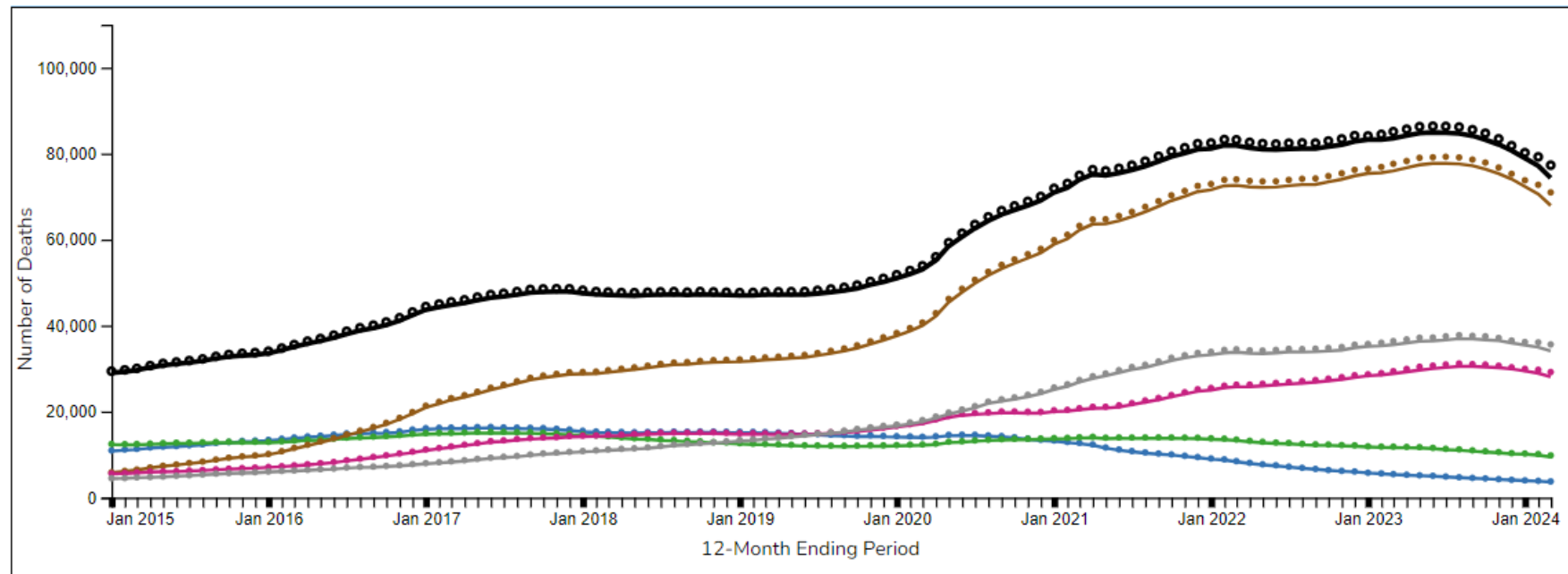
Disclaimer and conflict of interest statement



- 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

Drug Overdose Deaths in the United States

12 Month - ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class



Legend for Drug or Drug Class

Cocaine (T40.5)
Heroin (T40.1)
Natural & semi-synthetic opioids (T40.2)
Opioids (T40.0-T40.4,T40.6)
Psychostimulants with abuse potential (T43.6)

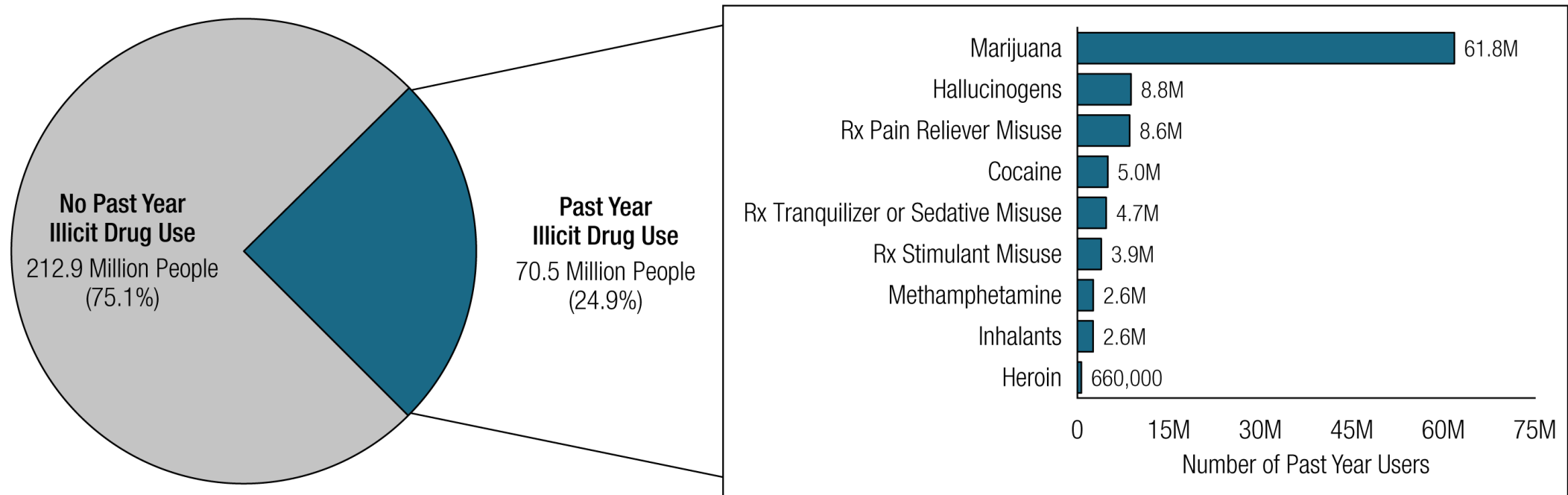
Synthetic opioids, excl. methadone (T40.4)

---- Reported Value

○ Predicted Value

Overview of 2023 NSDUH data

Past Year Illicit Drug Use: Among People Aged 12 or Older; 2023

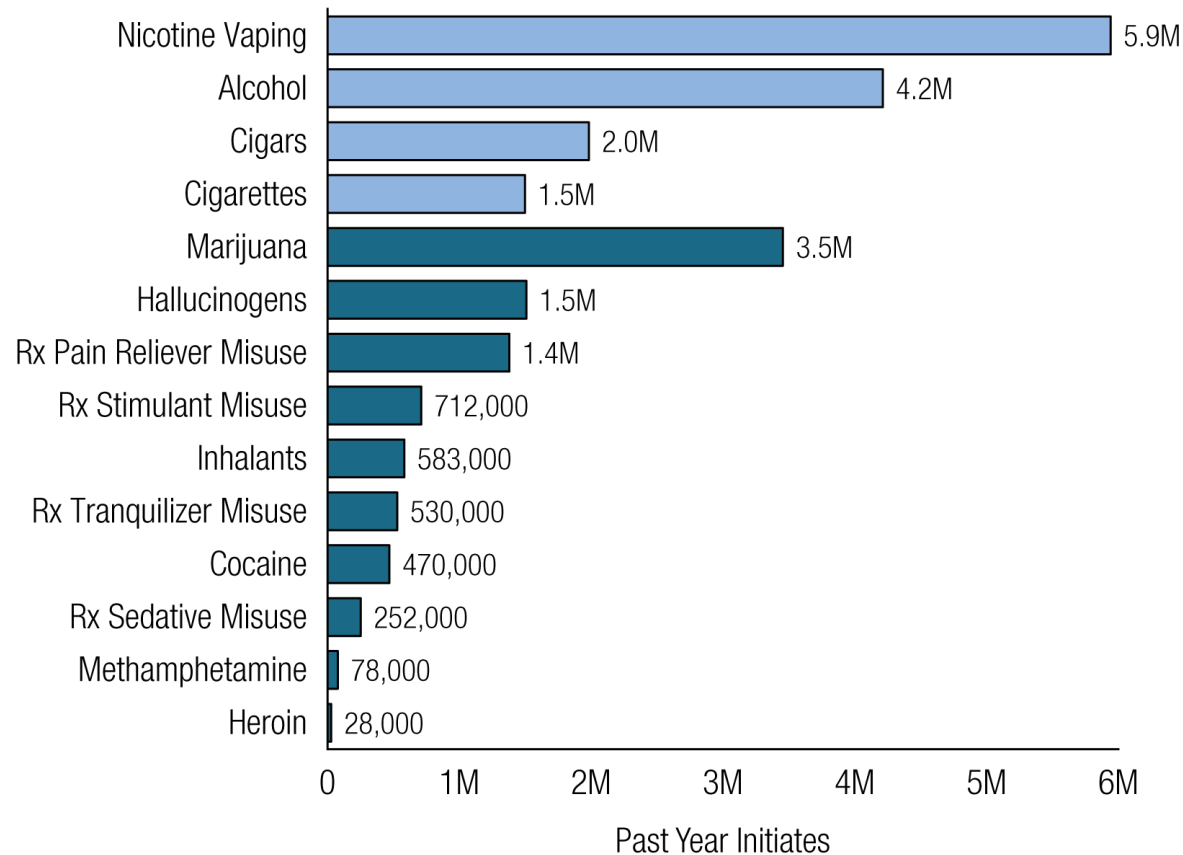


Rx = prescription.

Note: The estimated numbers of past year users of different illicit drugs are not mutually exclusive because people could have used more than one type of illicit drug in the past year.

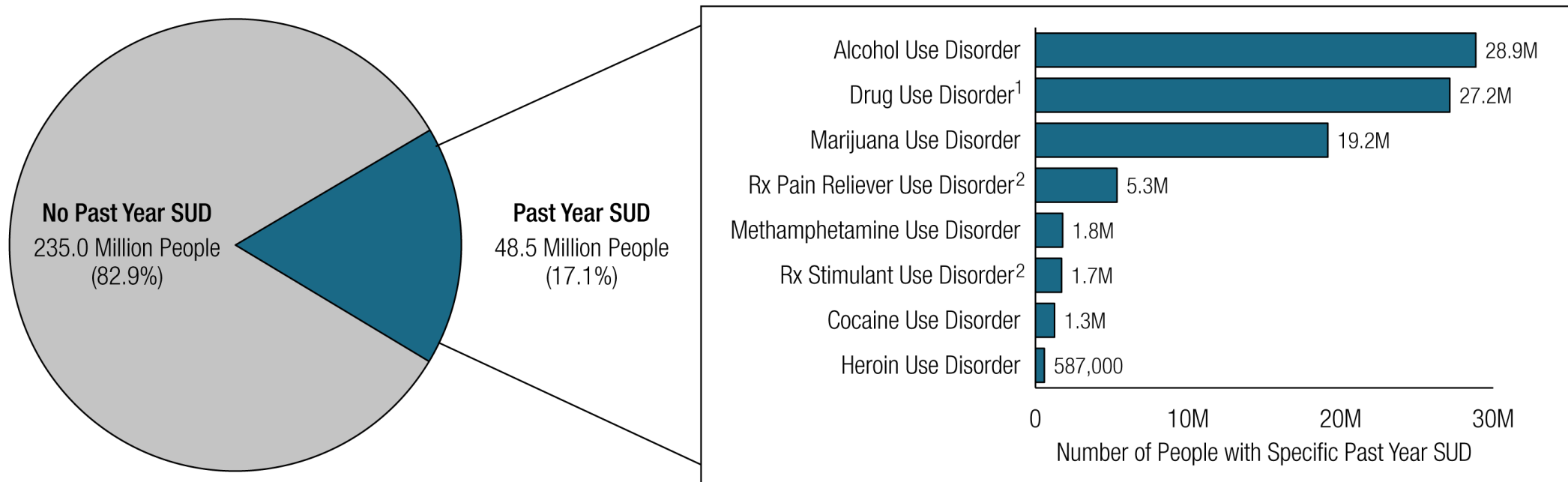
Overview of 2023 NSDUH data

Past Year Initiates of Substances: Among People Aged 12 or Older, 2023



Overview of 2023 NSDUH data

Past Year Substance Use Disorder (SUD): Among People Aged 12 or Older; 2023



Rx = prescription.

Note: The estimated numbers of people with SUDs are not mutually exclusive because people could have use disorders for more than one substance.

¹ Includes data from all past year users of marijuana, cocaine, heroin, hallucinogens, inhalants, methamphetamine, and prescription psychotherapeutic drugs (i.e., pain relievers, tranquilizers, stimulants, or sedatives).

² Includes data from all past year users of the specific prescription drug.

FDA Overdose Prevention Framework

1

- Support **primary prevention** by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing

2

- Encourage **harm reduction** through innovation and education

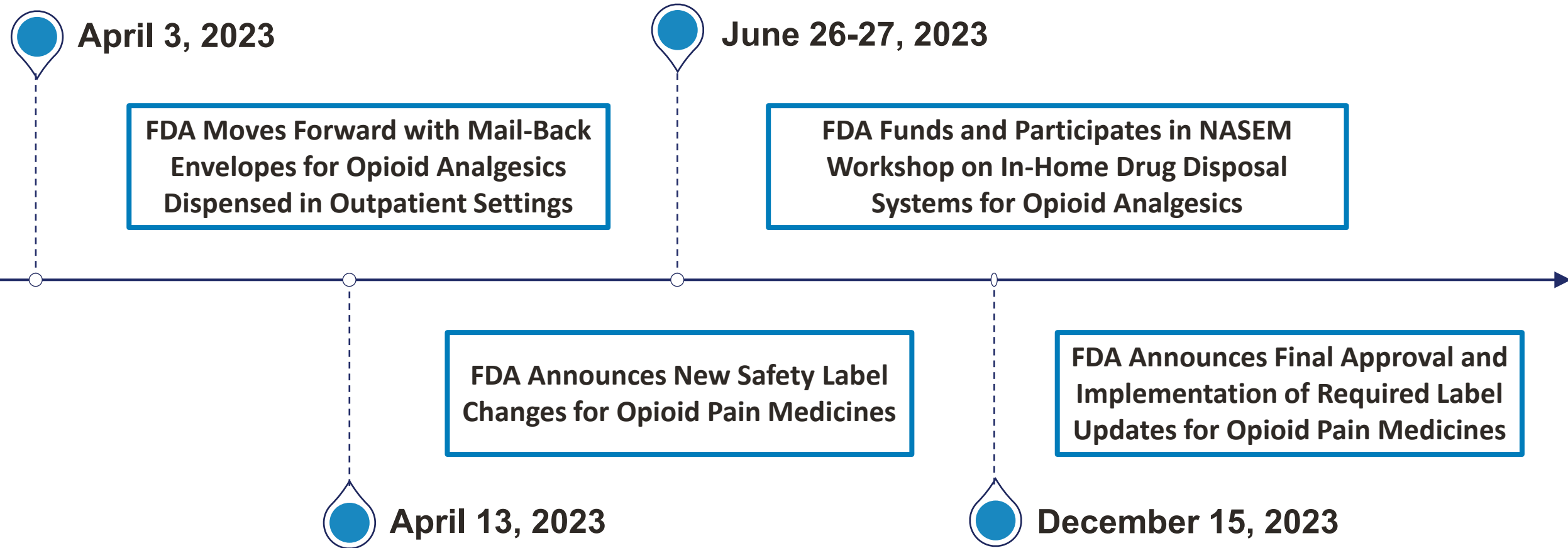
3

- Advance development of evidence-based **substance use disorder treatments**

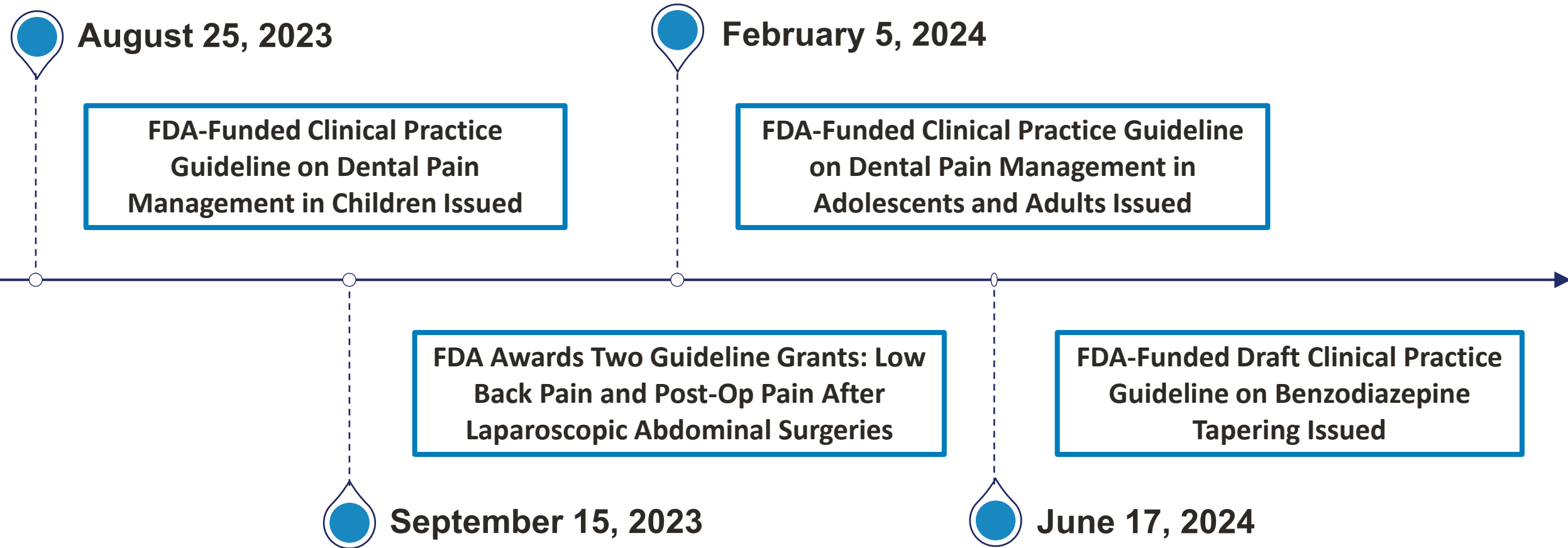
4

- Protect the public from **unapproved, diverted or counterfeit** drugs presenting overdose risks

FDA Actions: Primary Prevention – Opioids



FDA Actions: Primary Prevention – Guidelines



FDA Actions: Primary Prevention – Stimulants



Untreated ADHD among adults is associated with significant harms
Multiple treatment options for people with ADHD

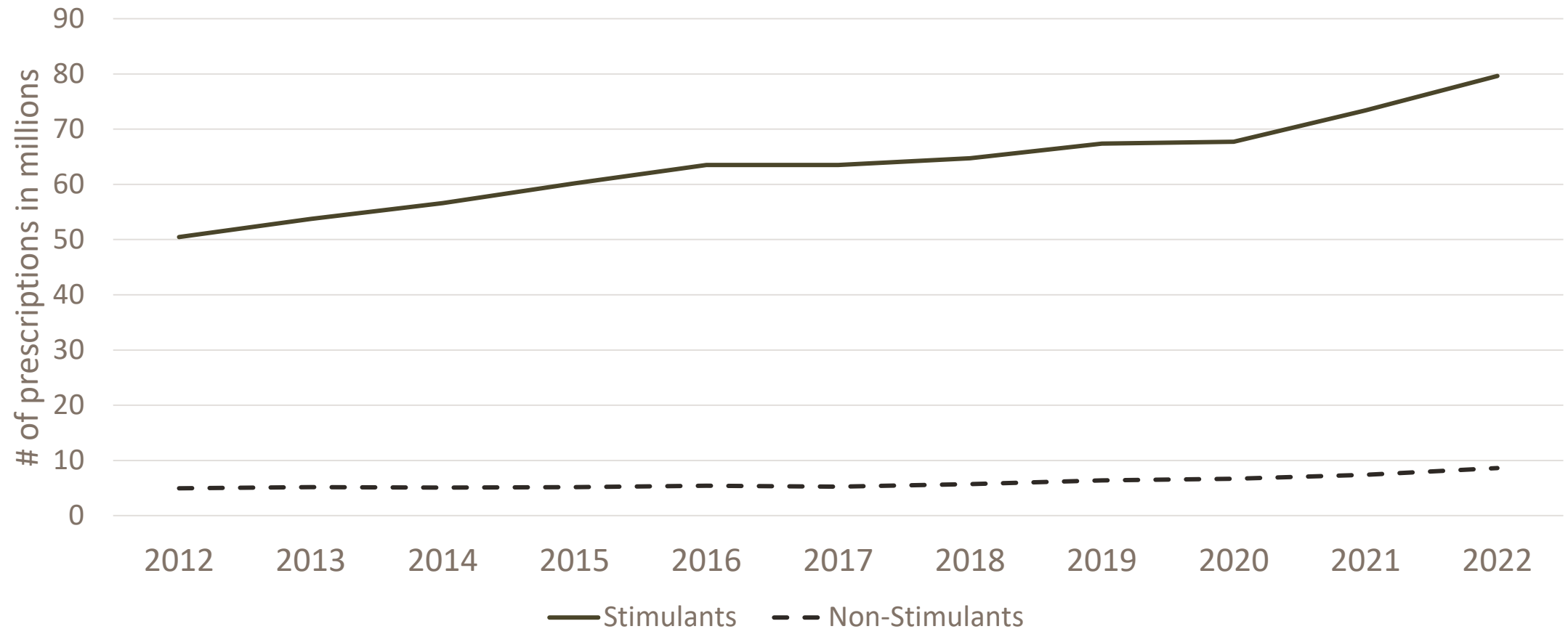
Pharmacological treatments

- Stimulant
- Non-stimulant

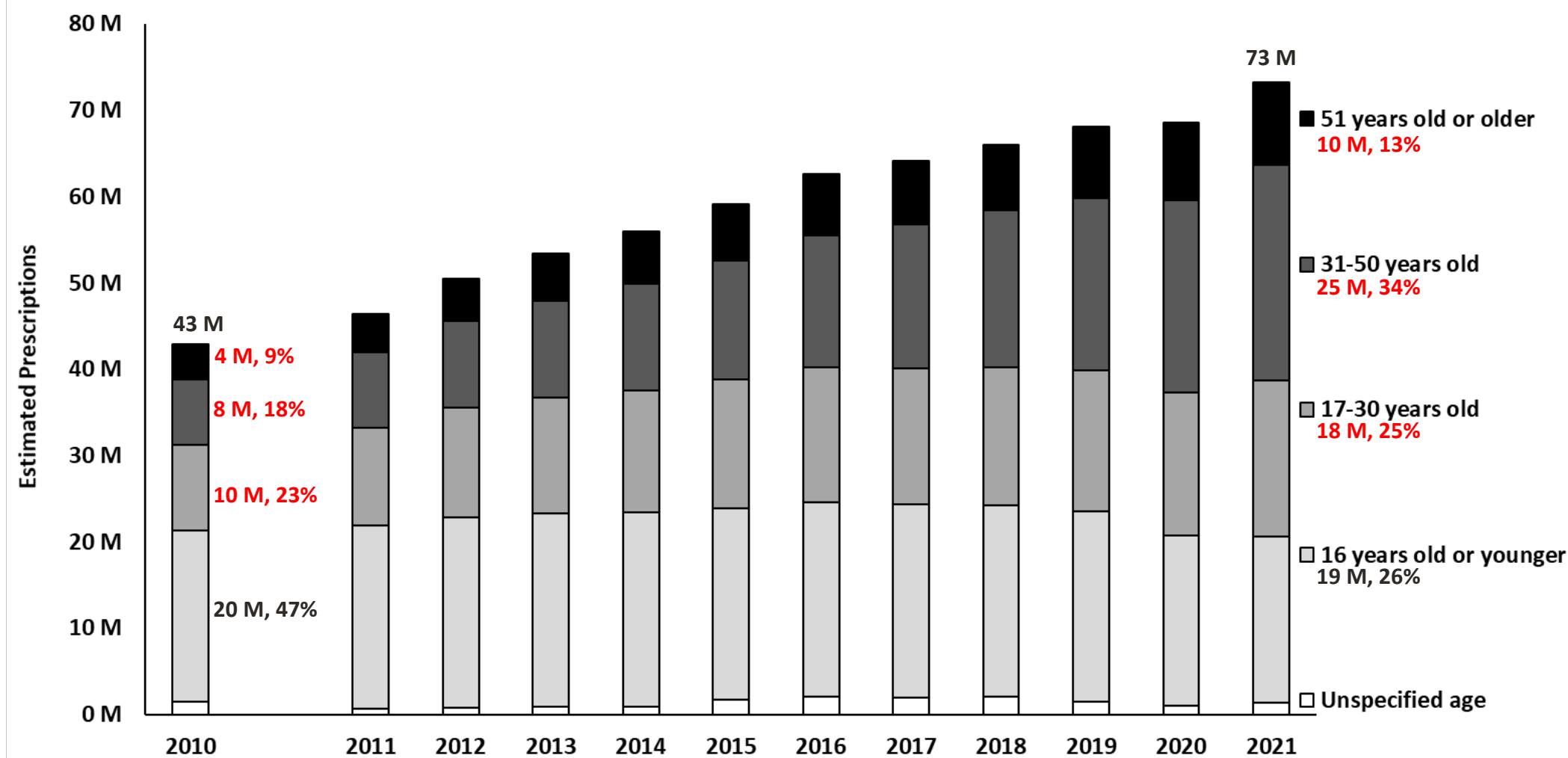
Non-pharmacological treatments

- Devices
- Behavioral therapies

Dispensed prescriptions for stimulant and non-stimulant ADHD treatment molecules from 2012 to 2022



Increases in stimulant use driven by prescriptions to adults



Estimated prescriptions for Schedule 2 (C-II) stimulants dispensed from U.S. outpatient pharmacies, by age group, annually 2010-2021. Source: Symphony Health Metys™. Study period 2010-2021, data extracted March 2022. M = millions. Outpatient pharmacies include retail and mail-order pharmacies. Data include all dosage formulations.

Perfect storm for potentially inappropriate prescribing?



“Scary easy. Sketchy as hell.”: How startups are pushing Adderall on TikTok

A telehealth company called Done wants Gen Z’s attention.

By Sara Morrison | sara@vox.com | Aug 29, 2022, 6:30am EDT

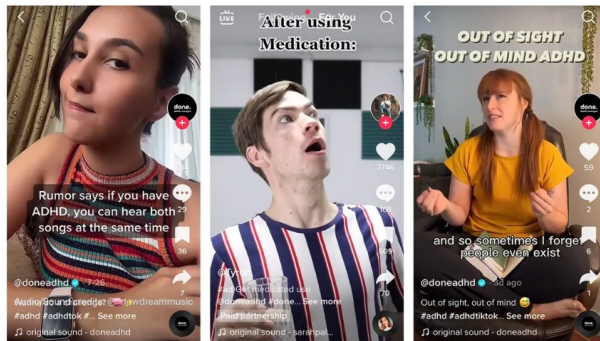


Adult ADHD Is the Wild West of Psychiatry

The Adderall shortage exposed a troubling gap in how doctors care for the disorder.

By Yasmin Tayag

The Atlantic



Screenshots via @doneadhd and @tyron_adhd

What’s Driving the Demand for ADHD Drugs Like Adderall

HEALTH • MENTAL HEALTH

TIME

THE WALL STREET JOURNAL.

Startup Cerebral Soared on Easy Adderall Prescriptions. That Was Its Undoing.

The online mental health company surged to a \$4.8 billion valuation after it started dispensing ADHD medication, but staffers grew concerned that it was pushing the drugs too aggressively

Perfect storm for potentially inappropriate prescribing?



PRESS RELEASE



Founder/CEO and Clinical President of Digital Health Company Arrested for \$100M Adderall Distribution and Health Care Fraud Scheme

“As alleged in the indictment, the defendants provided easy access to Adderall and other stimulants by exploiting telemedicine and spending millions on deceptive advertisements on social media. They generated over \$100 million in revenue by arranging for the prescription of over 40 million pills,” said Principal Deputy Assistant Attorney General Nicole M. Argentieri, head of the Justice Department’s Criminal Division. “These charges are the Justice Department’s first criminal drug distribution prosecutions related to telemedicine prescribing through a digital health company. As these charges make clear, corporate executives who put profit over the health and safety of patients — including by using technological innovation — will be held to account.”

The screenshot shows a mobile app interface for 'done.' with a sponsored post ID: 1648682062154011. The ad promotes 'Personalized ADHD care for just \$79/month from the comfort of home.' with a list of benefits: available appointments, affordability with or without insurance, and a 30-day money-back guarantee. The ad features an image of two white pills and a list of services: initial diagnosis, personalized treatment plan, online refills, and continuous care. At the bottom, it says 'done.' and 'MANAGE MY ADHD'. A footer banner offers a \$200 savings on an ADHD evaluation at donefirst.com, with a 'Learn More' button.



21 U.S. Code §355(d)

Extensive resources and progress made on ADHD in children and adolescents...

FROM THE AMERICAN ACADEMY OF PEDIATRICS | CLINICAL PRACTICE GUIDELINE |
OCTOBER 01 2019

Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents **FREE**

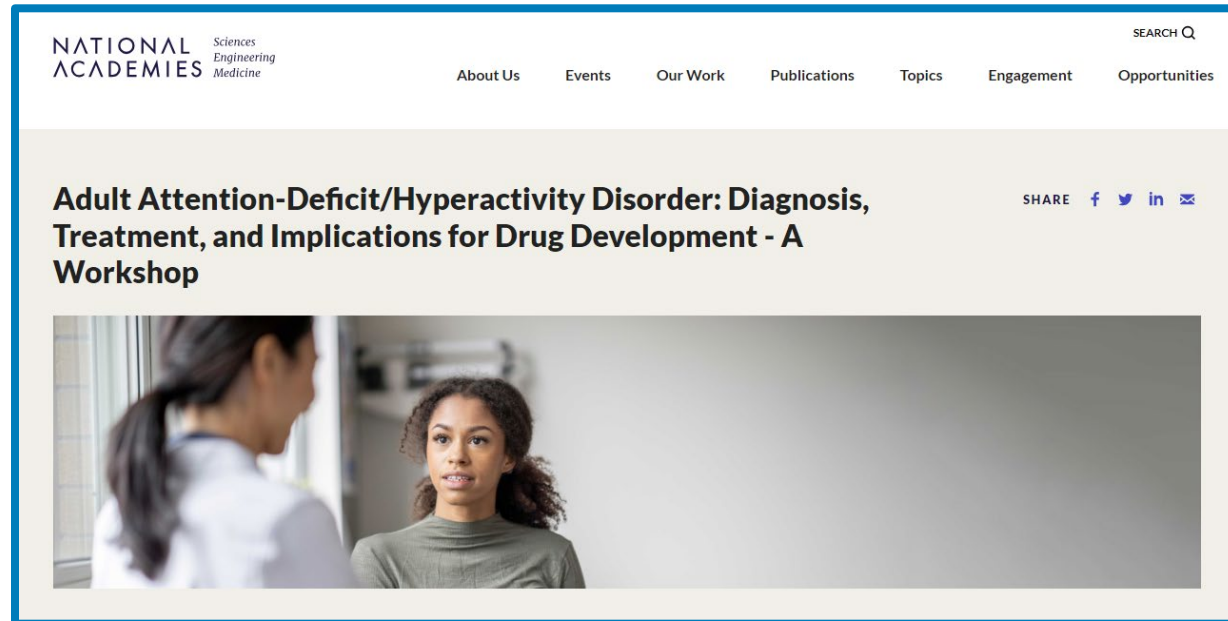
Mark L. Wolraich, MD, FAAP; Joseph F. Hagan, Jr, MD, FAAP; Carla Allan, PhD; Eugenia Chan, MD, MPH, FAAP;
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Christoph Ulrich Lehmann, MD, FAAP; Herschel Robert Lessin, MD, FAAP; Kymika Okechukwu, MPA;
Karen L. Pierce, MD, DFAACAP; Jonathan D. Winner, MD, FAAP; William Zurhellen, MD, FAAP;

MARCH 2024

SYSTEMATIC REVIEW AND META-ANALYSIS

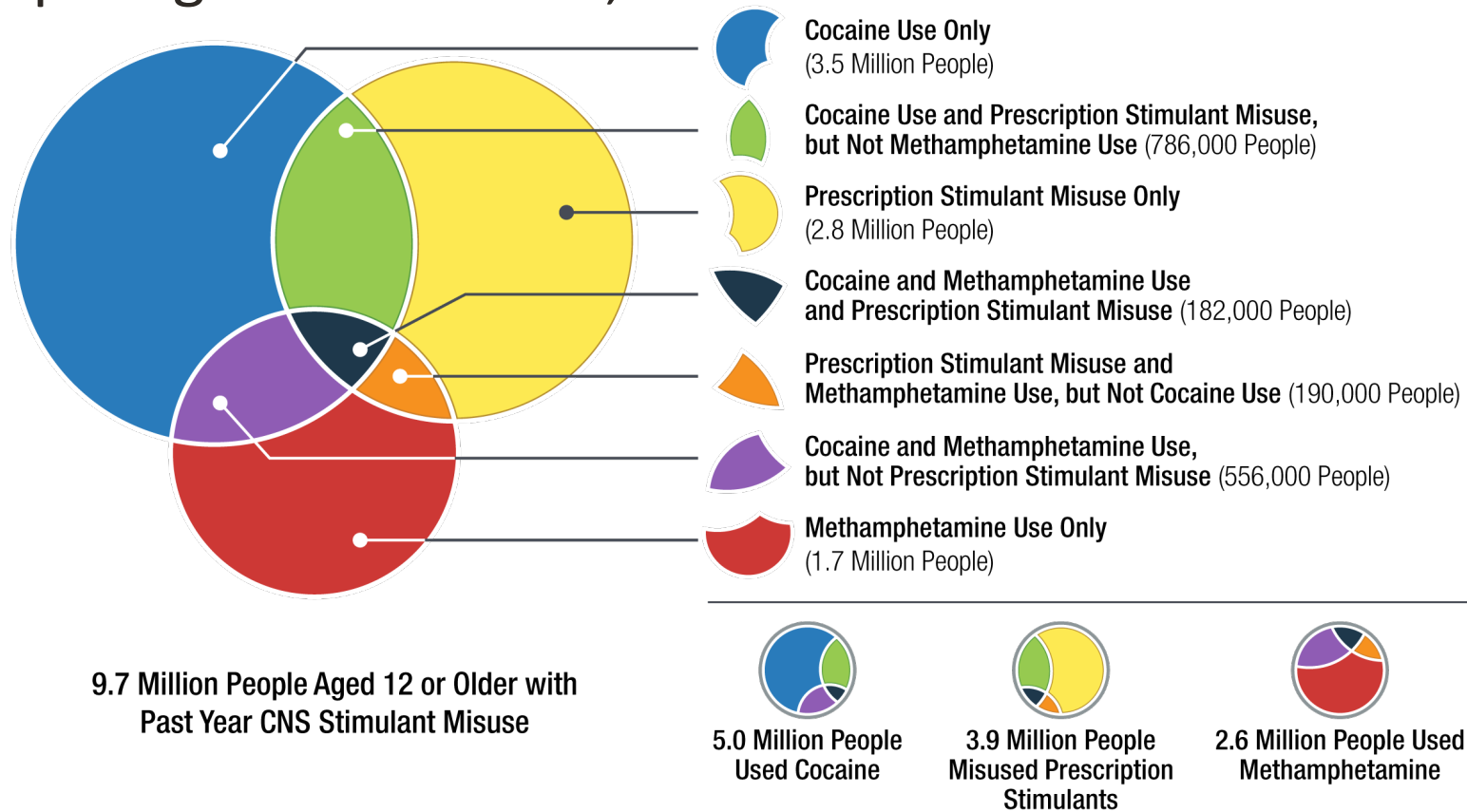
ADHD Diagnosis and Treatment in Children and Adolescents

...but until recently, limited attention and progress on ADHD in adults

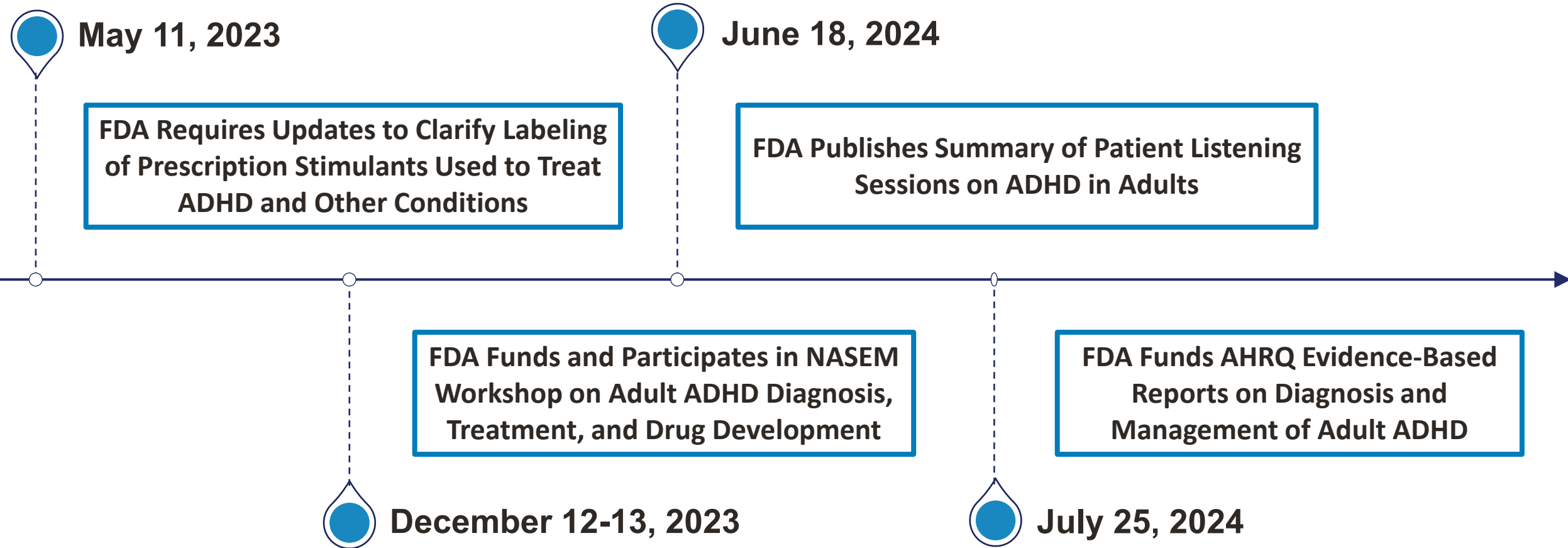


Overview of 2023 NSDUH data

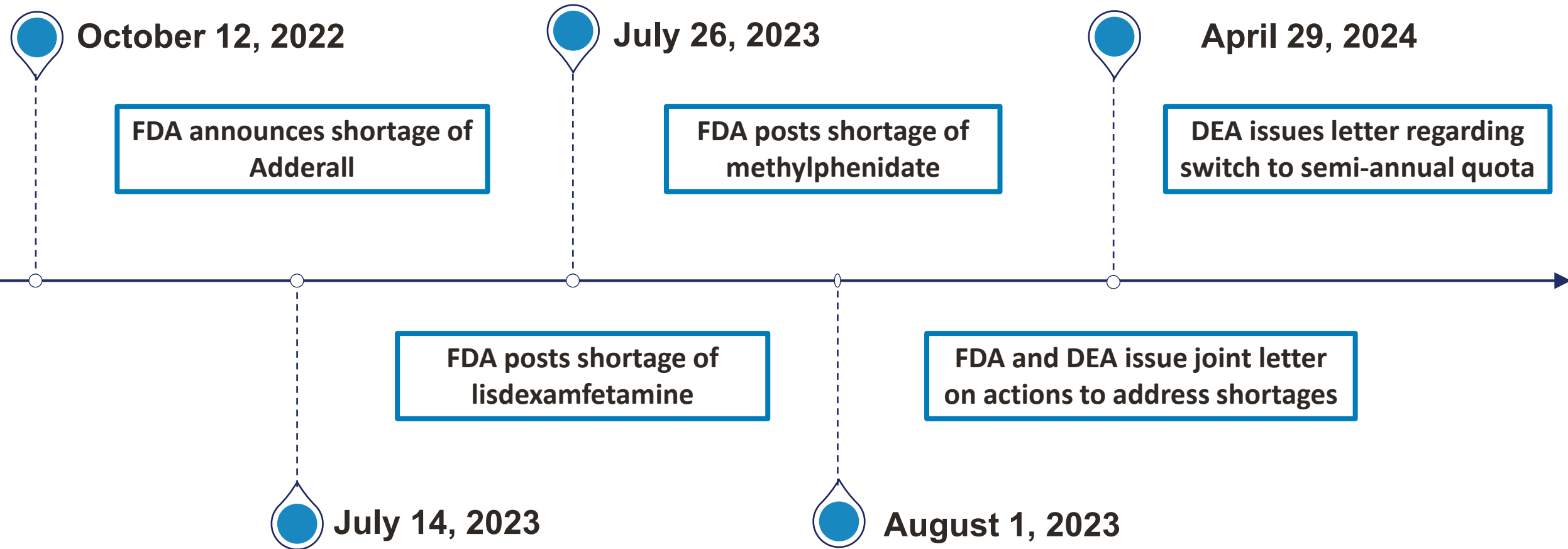
Past Year Central Nervous System (CNS) Stimulant Misuse: Among People Aged 12 or Older; 2023



FDA Actions: Primary Prevention – Stimulants



Federal actions: Stimulants shortages



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

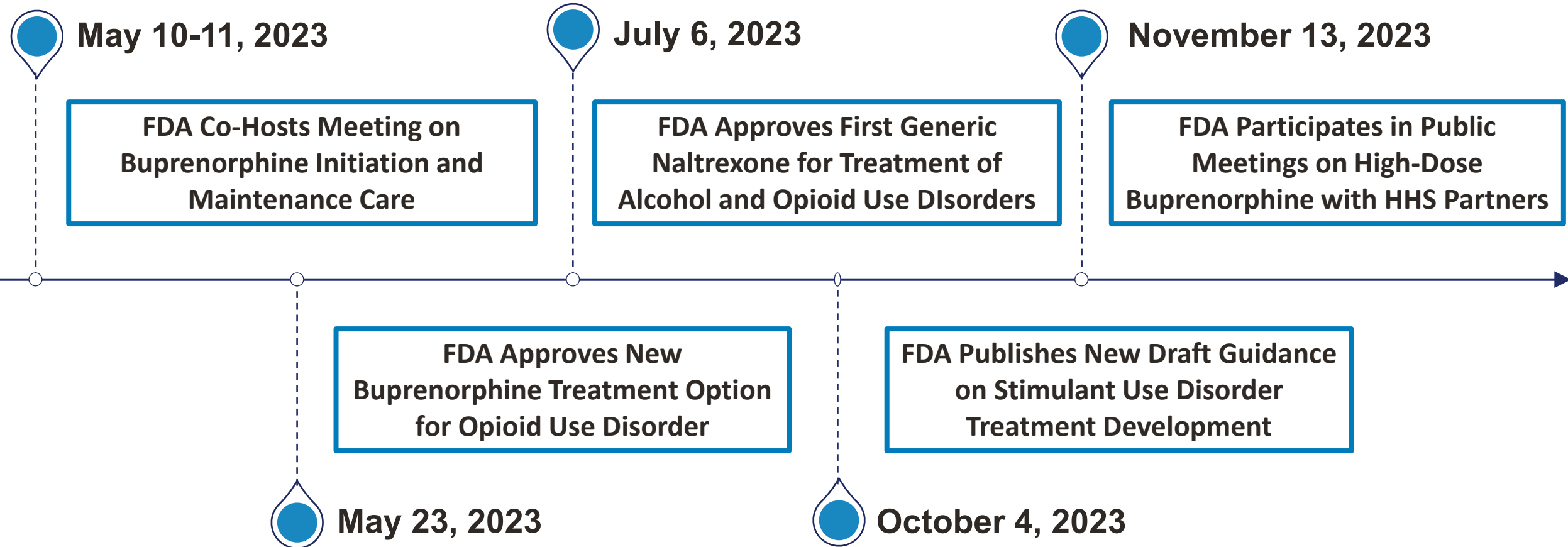
FDA Approves First Prescription Nalmefene Nasal Spray

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 Substance Use Disorders



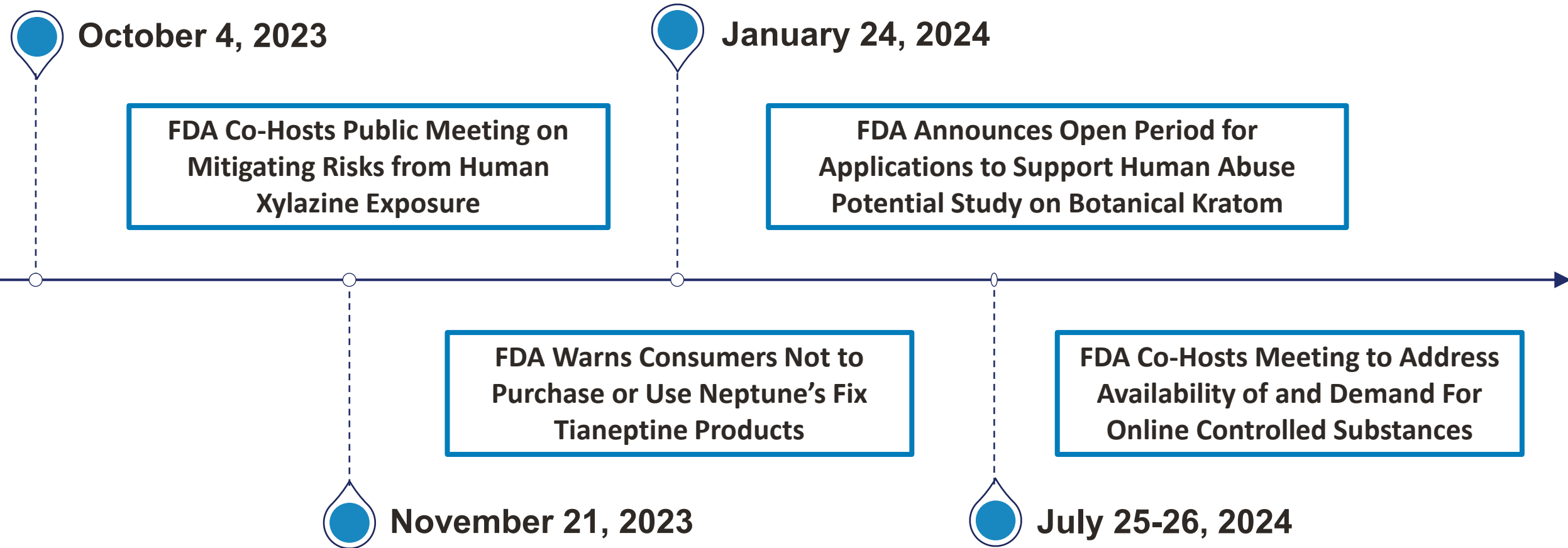
Spotlight: High-Dose Buprenorphine



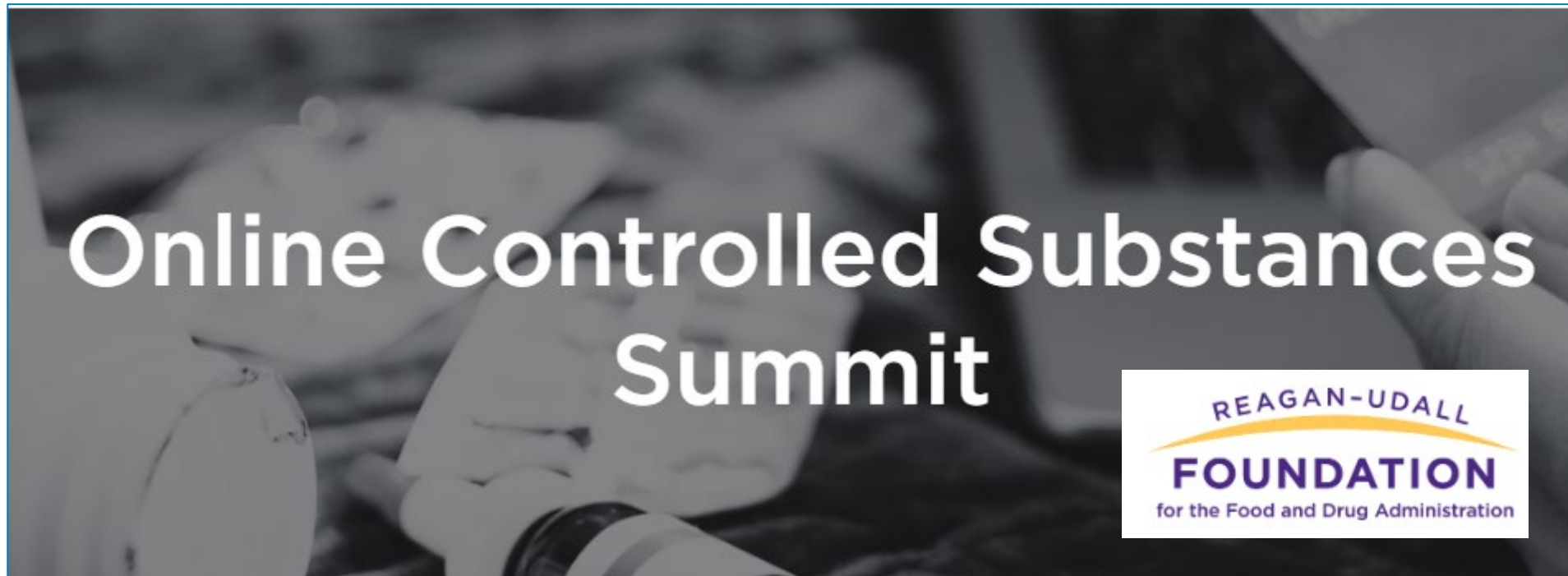
Tribal Listening Session Use of High Dose Buprenorphine for the Treatment of Opioid Use Disorder

Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

FDA Actions: Protecting the Public

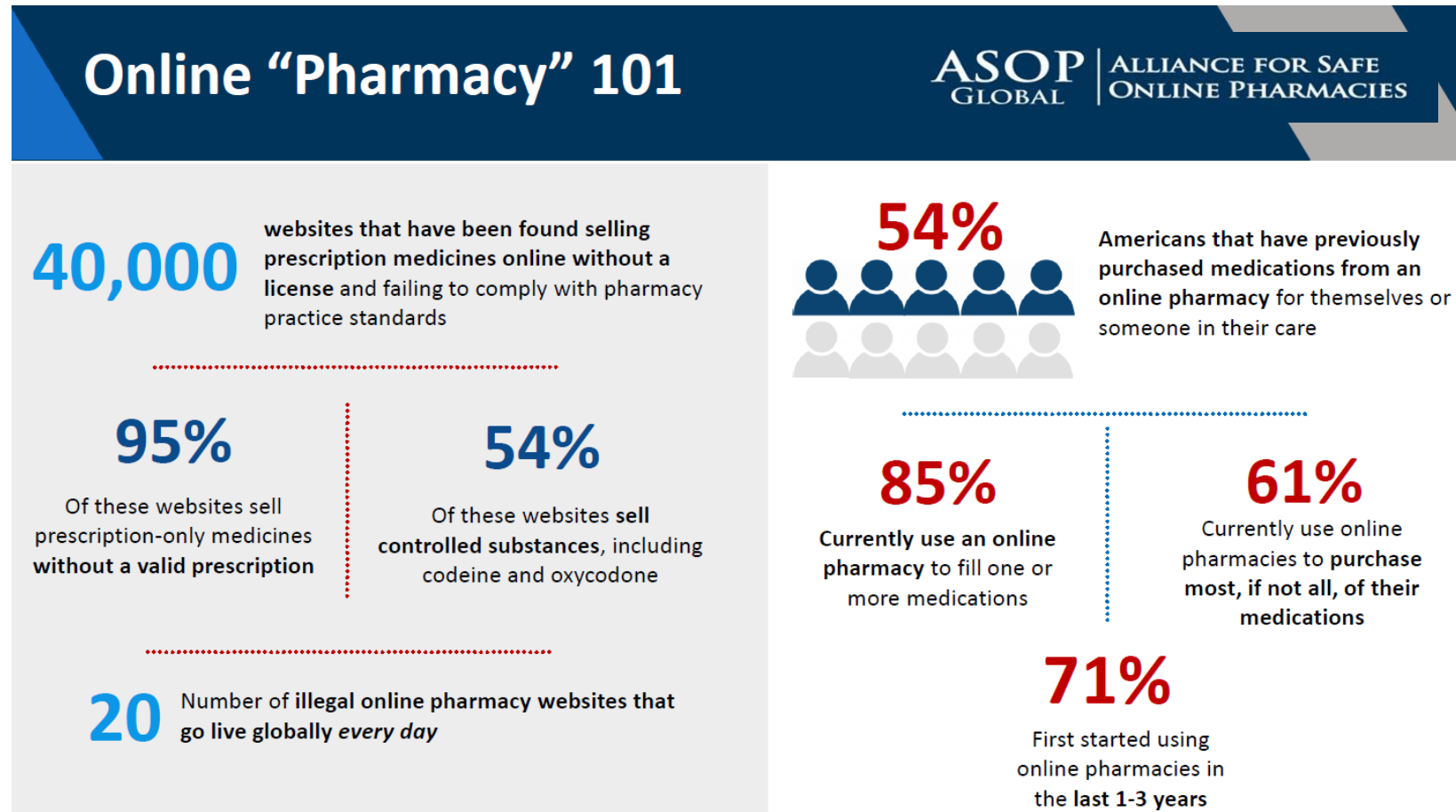


Spotlight: Protecting the Public



<https://reaganudall.org/news-and-events/events/online-controlled-substances-summit>

Online Controlled Substances Summit



Online Controlled Substances Summit

Many Americans Assume Online “Pharmacies” are Safe, Verified, and Regulated



- **54%** of Americans falsely believe **ALL WEBSITES** offering healthcare services/prescription medications to Americans **have been approved by the FDA or state regulators.**

- *68% of those with online pharmacy experience share this same misconception*



- **44%** of Americans falsely believe that **online pharmacies do not need a prescription** from a healthcare provider

- *53% of those with online pharmacy experience share this same misconception*

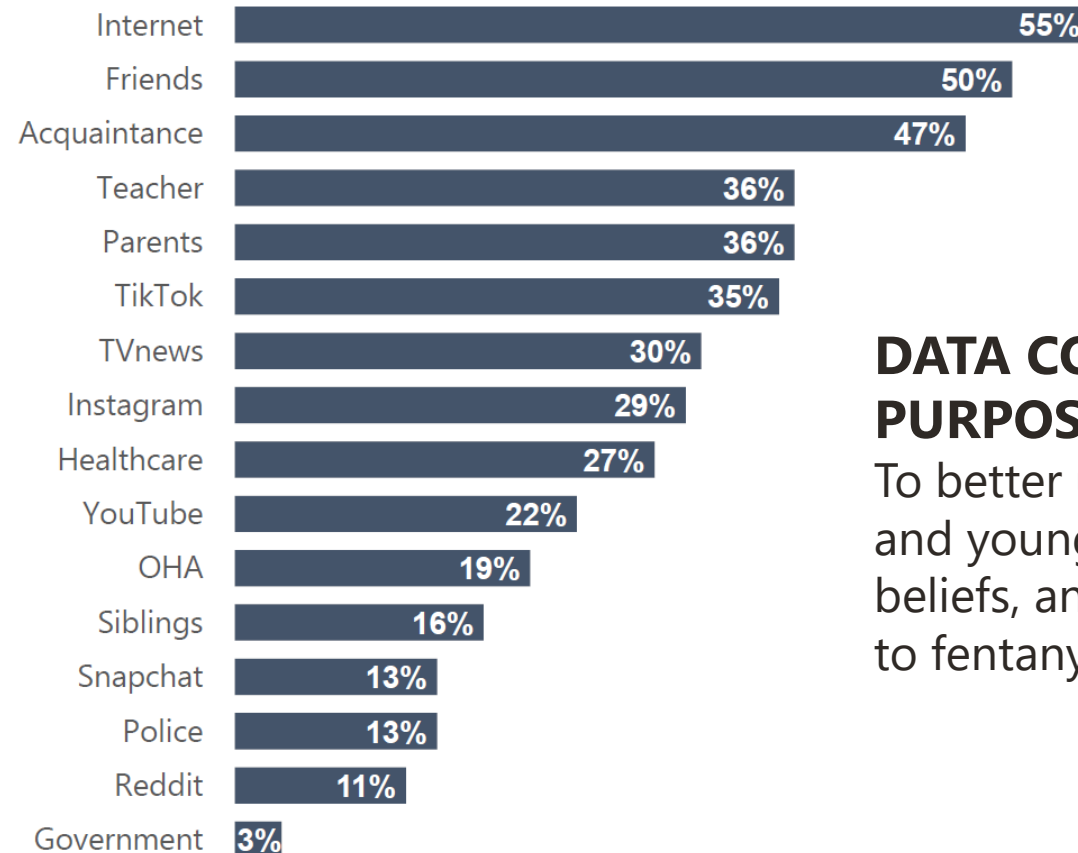


- **47%** of Americans falsely believe that **only safe, verified websites selling prescription medications appear on the first page of search engine results**

- *61% of those with online pharmacy experience share this same misconception*

ASOP | ALLIANCE FOR SAFE
GLOBAL | ONLINE PHARMACIES

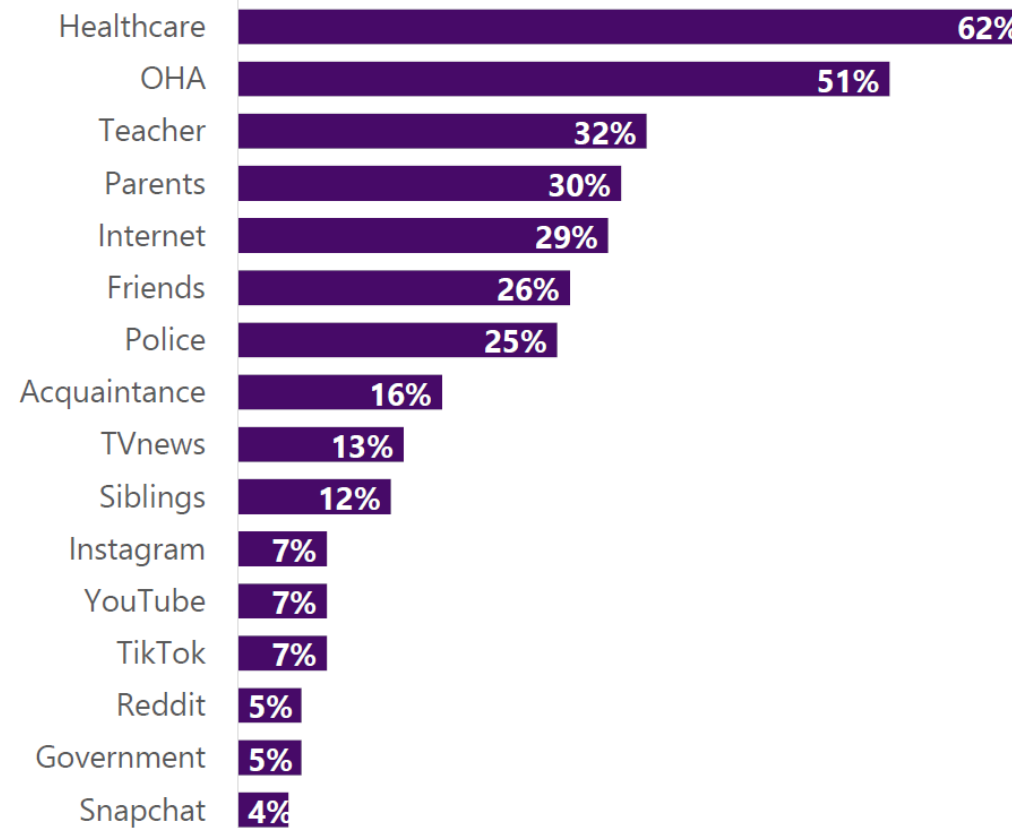
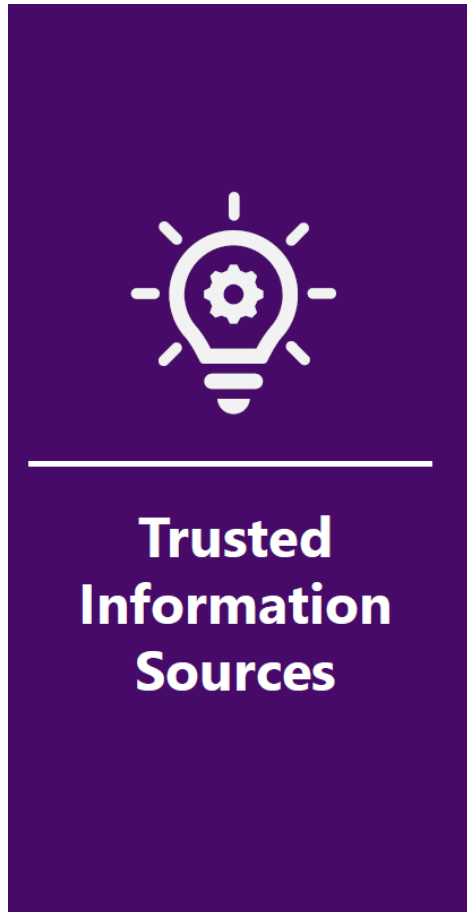
Online Controlled Substances Summit



DATA COLLECTION PURPOSE

To better understand youth and young adults' awareness, beliefs, and behaviors related to fentanyl and counterfeit

Online Controlled Substances Summit





Acknowledgements

- Caroline Huang and Hillary Dolinsky
- CDER team

Thank you

