



Overdose Prevention Framework

FDA Priorities

In 2021, a record number of Americans – more than 107,000 – died from drug overdoses.¹ The individual and societal costs resulting from this public health crisis, including but not limited to death, are enormous.² The drug overdose crisis is multifaceted and has evolved beyond prescription opioids. In recent years illicit opioids, largely driven by fentanyl and its analogues, have become key contributors to the overdose crisis. Other controlled substances, including benzodiazepines and stimulants (particularly methamphetamine), are also being used in combination with opioids. While FDA’s previous strategies have largely focused on opioid use and overdoses, the evolving nature of this crisis calls for a new approach.

In October 2021, the U.S. Department of Health and Human Services announced an Overdose Prevention Strategy, which supports the National Drug Control Strategy. The Office of the Assistant Secretary for Planning and Evaluation led the broad interagency effort to develop

the HHS Strategy with support from FDA and other HHS agencies. HHS’ Strategy reflects the evolving nature of the overdose crisis and features four priority areas: primary prevention; harm reduction; evidence-based treatment; and recovery support. The HHS Strategy is also guided by four cross-cutting principles: equity; data and evidence; coordination, collaboration, and integration; and stigma reduction.

Deriving from the HHS Strategy, FDA has identified specific Overdose Prevention Priorities to provide a framework and focus for FDA’s actions to address the crisis and sustain long-term recovery outcomes. FDA’s priorities build upon existing initiatives and incorporate a greater focus on the evolving crisis. Priority areas one through three in the HHS Strategy correspond with FDA’s priorities one through three. FDA’s fourth priority reflects our critical role to regulate drug supply safety. The FDA Framework is guided by the same four cross-cutting principles as the HHS Strategy.

FDA’s four priorities are:

1. **Supporting primary prevention** by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing;
2. **Encouraging harm reduction** through innovation and education;
3. **Advancing development of evidence-based treatments** for substance use disorders; and
4. **Protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.**

¹ [Provisional Drug Overdose Death Counts](#)

² [The High Price of the Opioid Crisis, 2021](#)

Supporting Primary Prevention

To eliminate unnecessary initial exposure and inappropriate prolonged prescribing of substances with abuse potential, FDA is:

- Promoting appropriate prescribing of medications with abuse potential, including opioids, stimulants, and benzodiazepines
- Exploring the need for potential new authorities for opioid approval standards
- Supporting development of alternative, non-addictive therapies and technologies
- Evaluating innovative packaging and disposal solutions of medications with abuse potential

 USG Partners: HHS, CDC, CMS, NIH, SAMHSA

Encouraging Harm Reduction

To reduce morbidity and mortality associated with overdoses, FDA is:

- Expanding availability and access to overdose reversal products, including naloxone, by supporting accelerated review of products and exploring over-the-counter access
- Supporting development of novel overdose reversal products
- Supporting development and authorization of fentanyl test strips to test human specimens at the point of care

 USG Partners: HHS, CDC, CMS, IHS, NIH, SAMHSA

Advancing Evidence-Based Treatments

To expand therapy options, availability, and access, FDA is:

- Expanding availability and access to evidence-based treatments for substance use disorders
- Facilitating development of treatments for substance use disorders, with focus on stimulant use disorder
- Facilitating opportunities to incorporate stakeholder engagement into treatment development

 USG Partners: HHS, CDC, CMS, DEA, IHS, NIH, SAMHSA, VA

Protecting the Public from Unapproved, Diverted, or Counterfeit Drugs Presenting Overdose Risks

To enhance the security of the U.S. drug supply chain, FDA is:

- Preventing and reducing counterfeit and illegal online sales
- Instituting enhanced targeting and screening methods at International Mail Facilities, Express Couriers, and Ports of Entry
- Taking compliance and enforcement actions against unapproved, diverted, or counterfeit drug products

 USG Partners: CBP, DEA, DOJ, FBI, HSI, and USPIS

Acronyms

CBP - U.S. Customs and Border Protection

CDC - Centers for Disease Control and Prevention

CMS - Centers for Medicare & Medicaid Services

DEA - Drug Enforcement Administration

DOJ - U.S. Department of Justice

FBI - Federal Bureau of Investigation

FDA - Food and Drug Administration

HHS - U.S. Department of Health and Human Services

HSI - U.S. Department of Homeland Security Investigations

IHS - Indian Health Service

NIH - National Institutes of Health

USPIS - U.S. Postal Inspection Service

SAMHSA - Substance Abuse and Mental Health Services Administration

VA - U.S. Department of Veterans Affairs