Documents for the Record

Subcommittee on Health Hearing
Policies to Protect Our Communities from Illicit Drug Threats
March 26, 2026

Majority:

1. March 26, 2026, statement from Rep. McDowell.
2. March 24, 2026, letter to Chairman Guthrie from Gary Andres, Assistant Secretary for Legislation, U.S. Department on Health and Human Services.
3. Letter to Chairman Guthrie from Michael D. Miller, Section Chief, Congressional Affairs Section, Drug Enforcement Administration.
4. March 26, 2026, statement from the Alliance for Safe Online Pharmacies.
5. March 26, 2026, letter to Chairman Griffith and Ranking Member DeGette from Rep. Higgans.
6. January 1, 2023, article from Drug and Alcohol Dependence, Volume 242, entitled "Methadone-involved overdose deaths in the United States before and during the COVID-19 pandemic" submitted by Rep. Houchin.

Minority:

1. March 26, 2026, statement from Rep. Stansbury.
2. March 24, 2026, statement from ACR Health (NY) et al.
3. March 25, 2026, letter to Rep. Houchin from the American Society of Addiction Medicine et al.
4. February 13, 2023, letter to Assistant Secretary Delphin-Rittmon and Dr. Baillieu from William F. Haning, III, MD, DLFAPA, DFASAM, President, American Society of Addiction Medicine.
5. July 1, 2025, statement from the American Psychiatric Association.
6. March 31, 2025, letter to Majority Leader Thune, Speaker Johnson, Chairman Crapo and Chairman Guthrie from Brian Hurley, MD, MBA, FAPA, DFASAM, President, American Society of Addiction Medicine.
7. 2025, report entitled "2025 AMA Report on Substance Use and Treatment: Progress, Policy and Future Directions" by the American Medical Association submitted by Rep. Auchincloss.
8. May 13, 2025, article by the American Society of Addiction Medicine
9. February 9, 2023, letter to Substance Abuse and Mental Health Services Administration from Deborah S. Finnell, PhD, CARN-AP, FAAN, President, Association for Multidisciplinary Education and Research in Substance use and Addiction, on behalf of the 2022-2023 AMERSA Board of Directors.
10. March 26, 2026, statement from the Advocates for Opioid Addiction Treatment.
11. March 26, 2026, statement from the American Psychiatric Association.
12. August 16, 2025, statement from Edward W. Boyer, MD, PhD.

13. Letter to Members of the Sub-Committee on Health; House Energy and Commerce Committee from Richard G Frank, Leonard D Schaefer Chair in Economic Studies and Director of the Center on Health Policy, The Brookings Institution.
14. March 26, 2026, statement submitted by Rep. Lieu (CA-36).
15. Letter of Support for Tyler's Law (H.R. 2004) from Gretchin Murray et al.
16. March 26, 2026, statement submitted by Teresa Miller, JD, National Director of Health Initiatives, Legal Action Center.
17. May 26, 2026, letter to Chairman Griffith, Vice Chair Harshbarger, Ranking Member DeGette and Members of the Subcommittee on Health from Kristen E. Smith
18. Summary of FY 2026 Legislative Proposals from U.S. Food and Drug Administration submitted by Rep. Carter (LA).
19. September 4, 2025, letter to Chairman Cassidy, Ranking Member Sanders, Chairman Guthrie and Ranking Member Pallone from Shabbir Safdar et al. submitted by Carter (LA).
20. February 23, 2026, letter to Chairman Cassidy, Chairman Guthrie, Ranking Member Sanders, and Ranking Member Pallone from Alaska Longline Fishermen's Association et al. submitted by Carter (LA)
21. March 20, 2026, letter to Ranking Member DeGette from the Behavioral Health Group
22. Letter to Chairman Griffith from Consumer Choice Center et al.
23. March 26, 2026, statement from Juli Shamash.
24. February 14, 2023, letter to Assistant Secretary Delphine-Rittmon from Ellen M. Weber. J.D., Sr. Vice President for Health Initiatives, Legal Action Center.
25. March 26, 2026, memorandum from Haiden Huskamp, Harvard Medical School.
26. January 29, 2025, letter to Chairman Graham, Chairman Arrington, Ranking Member Merkley, and Ranking Member Boyle from the Mental Health Liaison Group.
27. April 30, 2025, letter to Chair Guthrie, Ranking Member Dr. Joyce, and members of the House Energy and Commerce Committee from Victor Dickson, President & CEO, Safer Foundation.
28. February 21, 2023, article by the National Association of State Alcohol and Drug Abuse Disorders.
29. March 25, 2026, letter to Committee Chairman Guthrie, Subcommittee Chairman Griffith, and Members of the Committee from Gretchen Burns Bergman, Lead Organizer, Moms United to End the War on Drugs.
30. March 26, 2026, letter to Honorable Chair and Members of the House Energy and Commerce Health Subcommittee from Brooke Sanders, MS, Director of Network Relations & Strategic Expansion, Students for Sensible Drug Policy.
31. March 17, 2026, statement from American Association on Health and Disability et al.
32. May 9, 2025, letter to Chairman Guthrie and Ranking Member Pallone from Andrew J. Ginther et al.
33. March 25, 2026, letter to Members of the E&C health subcommittee, US House of Representatives from Edward W Boyer MD PhD.

Committee on Energy & Commerce
Health Subcommittee Legislative Hearing
"Policies to Protect Our Communities from Illicit Drug Threats"

March 26, 2026
Congressman Addison McDowell

Chairman Griffith, Ranking Member DeGette, and Members of the Energy and Commerce Health Subcommittee:

Thank you for holding this legislative hearing and for your leadership in tackling the constant drug threats facing our communities. The opioid crisis is one of the most serious issues we face as a country. Drug overdoses, led primarily by fentanyl, kill nearly fifty thousand Americans every year. Unfortunately, my family and I know this tragedy all too well, having lost my brother Luke to a fentanyl overdose.

If the work I accomplish during my time representing the Sixth Congressional District of North Carolina saves even one life, it will all be worth it. Together, we have the opportunity to do much more; we have the opportunity to make a lasting impact and save thousands of lives by protecting our communities from illicit drug threats.

President Trump's decisive action stopped the unchecked flow of fentanyl across our southern border, and the House of Representatives overwhelmingly passed the HALT Fentanyl Act, which has given law enforcement the authority to seize fentanyl analogues. By building off these successes, we can prevent even more families from ever having to receive the next-of-kin knock on their front door.

Despite many examples of successful fentanyl interdictions in recent years, cartels continue to find ways to funnel this poison into our communities through the importation of illicit pill press machines.

Pill press machines, also known as tableting and encapsulating machines, are pharmaceutical tools being misused by drug traffickers to compress fentanyl into pills that are produced to look like legitimate prescription medication. Currently, these machines and unlisted chemical products are required to be self-registered with the Drug Enforcement Administration, along with any record of transaction.

Transnational criminal organizations bypass federal regulations by smuggling precursor chemicals and pill press machines through U.S. ports and customs, under misleading labeling, such as, “furniture parts” or “machine spare parts.” These parts are then reassembled as unregistered pill presses and used to mass produce counterfeit pills, mixed with the ingredients that create synthetic substances.

Loopholes like this make it difficult to track and prevent the illicit use of these products, which is why I introduced the Preventing Rogue Equipment for Synthetic Substances (PRESS) Act. The PRESS Act will equip law enforcement with the tools to prosecute foreign entities outside of the United States under its extraterritorial jurisdiction. It does this by criminalizing the intentional importation of unlisted precursor chemicals and related equipment, including tableting machines, encapsulating machines, press punches, die systems, and gelatin capsules, that will be used to manufacture controlled substances.

This bill will vastly strengthen the ability of federal law enforcement to fight the fentanyl epidemic that has left American families and communities in ruins for decades. I thank you for your time and attention to this issue, and I look forward to continuing to work with you to advance this critical legislation during the 119th Congress.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 202

MAR 2 4 2026

The Honorable Brett Guthrie
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Chairman Guthrie:

I write to inform you of the views of the Department of Health and Human Services (HHS) on H.R. 1266, a bill titled the "Combatting Illicit Xylazine Act".

We believe legislatively scheduling xylazine into Schedule III is appropriate to institute clear, meaningful controls given the dangers posed by xylazine as an adulterant in the illicit drug market. We also support exempting certain ultimate users from the registration requirement and providing a grace period for implementation to ensure continued availability for legitimate veterinary use.

We have provided technical assistance in several areas of this legislation to improve clarity and ease implementation.

On January 29, 2026, the President signed Executive Order 14379 which created the White House Great American Recovery Initiative aimed at bolstering the national response to combat the disease of addiction. This initiative will focus on the importance of prevention, early intervention, treatment, and recovery from substance use disorder. An important part of preventing illicit drug use is curbing supply and reducing availability by strengthening penalties for drug traffickers, including those involved with illicit xylazine.

The bill addresses the increasing prevalence of xylazine appearing mixed with illicit drugs, which presents a major public health challenge. HHS is supportive of this legislation as written as we believe that legislative scheduling of xylazine under the Controlled Substances Act is appropriate given the risks to individuals exposed to this chemical. We also agree with the framework to ensure the availability for legitimate veterinary use.

Xylazine is a sedative that is FDA-approved for use in animals, but it is not approved for use in humans in whom it may cause serious and life-threatening side effects. Veterinarians legitimately use drug products containing xylazine to sedate large animals, but it has increasingly been identified as a contaminant found in combination with opioids such as illicit fentanyl and with other illicit products that contain stimulants such as methamphetamine and cocaine. People who use illicit drugs may not be aware of the presence of xylazine. While xylazine is not an opioid, it is dangerous because it can depress breathing, blood pressure, heart rate and body temperature to critical levels. Additionally, people who inject drugs containing xylazine can develop severe skin wounds and patches of dead and rotting tissue

that easily become infected and, if left untreated, may lead to amputation. These wounds can develop in areas of the body away from the injection site and may become life-threatening. The agency previously communicated to health care providers[1] about the risks to patients exposed to xylazine in illicit drugs.

The Office of Management and Budget has advised that, from the standpoint of the Administration's program, there is no objection to the submission of this letter. We have also consulted with the U.S. Department of Justice to ensure coordination. I am sending an identical letter to the Ranking Member of the House Committee on Energy and Commerce.

Sincerely,

Gary Andres
Assistant Secretary for Legislation

[1] https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-risks-patients-exposed-xylazine-illicit-drugs

Department of Justice
Drug Enforcement Administration

Office of Congressional and Public Affairs *Springfield, VA 22152*

The Honorable Brett Guthrie
Chairman
House Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20510

Dear Chairman Guthrie:

Xylazine, an animal tranquilizer, is an essential sedative relied upon by veterinarians, farmers, and ranchers, with no cost-effective alternative available. Unfortunately, xylazine has become a significant public health threat due to its ongoing presence in the illicit drug supply. According to a recent report issued by the CDC[1], xylazine was involved in 6,096 drug poisoning deaths in 2023, making it the fourth most common substance in drug poisoning fatalities. Xylazine's combination with fentanyl has amplified the deadliest drug crisis in U.S. history with DEA labs showing xylazine present in over 25% of fentanyl powder exhibits and over 8% of pill exhibits in 2025. With this information in mind, The Drug Enforcement Administration (DEA) strongly supports the *Combatting Illicit Xylazine Act* (H.R. 1266) as written.

The *Combatting Illicit Xylazine Act* provides the tools necessary to address this ongoing threat while, importantly, safeguarding its essential use in veterinary medicine. This legislation will ensure continued critical access of xylazine to veterinarians, farmers, ranchers, and wildlife personnel. By scheduling xylazine as a Schedule III substance under the Controlled Substances Act (CSA), xylazine would become part of the closed system of distribution, enabling DEA to track its movement through the supply chain via ARCOS reporting. This tracking allows DEA to identify and address potential points of diversion in the legitimate supply chain. This is essential because DEA labs have identified specific markers from repurposed veterinary preparations of xylazine that was mixed with fentanyl in both counterfeit pills and powder samples. Additionally, this legislation would empower federal law enforcement to target online marketplaces and criminal networks trafficking the substance.

Due to its unique usage, administrative scheduling is not a viable solution to this urgent crisis. Through administrative scheduling, DEA is unable to carve out a definition of "ultimate user," which only permits a person to possess a controlled substance for an animal owned by themself or by a member of their household; this is often not the case for veterinarians, ranchers, farmers and wildlife personnel. Thus, a legislative solution is necessary to ensure that veterinarians, farmers, ranchers, and wildlife personnel can continue to use xylazine for its legitimate purpose. Further, since xylazine is a non-narcotic, administrative scheduling does not allow DEA to include it in ARCOS reporting. As previously mentioned, ARCOS reporting is critical to track xylazine and identify potential points of diversion in the legitimate supply chain.

[1] Garnett MF, Cisewski JA, Ahmad FB. Drugs most frequently involved in drug overdose deaths: United States, 2017–2023. Natl Vital Stat Rep. 2026 Mar;75(1):1–13. DOI: https:// dx.doi.org/10.15620/cdc/174640.

DEA appreciates your consideration of H.R. 1266, the *Combatting Illicit Xylazine Act.* This legislation is a balanced and necessary approach to combat the xylazine crisis, save lives, and protect communities while ensuring veterinarians and other professionals can continue to use xylazine for its intended purpose.

We hope you find this information useful.

Sincerely,

Michael D. Miller

Michael D. Miller
Section Chief
Congressional Affairs Section
Drug Enforcement Administration

c.c. Ranking Member Frank Pallone

March 26, 2026

The Honorable Brett Guthrie
Chair, House Energy & Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member, House Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Morgan Griffith
Chair, Subcommittee on Health
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Diana DeGette
Ranking Member Subcommittee on Health
U.S. House of Representatives
Washington, D.C. 20515

Re: Statement for the Congressional Record – Alliance for Safe Online Pharmacies (ASOP Global)

House Committee on Energy & Commerce, Subcommittee on Health Hearing: "Policies to Protect Our Communities from Illicit Drug Threats"

Dear Chairman Guthrie, Ranking Member Pallone, Chairman Griffith and Ranking Member DeGette:

The Alliance for Safe Online Pharmacies (ASOP Global) is pleased to submit a statement for the Congressional Record for the Health Subcommittee Hearing: "Policies to Protect Our Communities from Illicit Drug Threats." ASOP Global is a nonprofit 501(c)(4) organization that seeks to protect patient safety globally and ensure access to safe, legitimate online pharmacies in accordance with applicable laws. ASOP Global is active in the United States, Canada, Latin America, Europe, and Asia.

ASOP Global appreciates the House Energy and Commerce Committee's continued attention to the threats posed by illicit drugs, which continue to undermine US public health and national security. While today's hearing focuses on these dangers broadly, it is essential to highlight that the online space is a key, and often overlooked, channel through which illicit substances are sold and distributed to unsuspecting consumers.

Today, patients are increasingly turning to online pharmacies, telemedicine platforms, and direct-to-consumer healthcare services – options that can be essential when used safely and legally. But consumers also are enticed to buy medicines and supplements from social media posts, online marketplace offers, and stand-alone websites, often without understanding the risks. Since 2020, the ASOP Global Foundation has conducted national survey examining consumer perceptions and behaviors surrounding online pharmacies. The most recent survey, conducted in 2025, found that 38% of U.S. adults have purchased prescription medicines online, even though 66% consider using medicines purchased online risky—a 22% increase from 2023.

Most consumers purchasing drugs online are not seeking medications containing illicit substances, such as fentanyl, nitazenes, or xylazine – they're ordering medications they believe to be safe and trusted. That trust is often misplaced. While 87% of U.S. adults acknowledge the serious health risks of counterfeit or substandard online medicines, 65% falsely believe all websites offering online Rx/health services are reviewed/approved by FDA

or state regulators, and 51% assume that only safe, verified sellers appear on the first page of search results.[1] The consequences are real: 27% of those who have purchased prescription medicines online report having personally received substandard/counterfeit medicine or being harmed by a medicine they bought online.[2]

For these reasons, ASOP Global would like to commend the committee for working to advance legislation that directly addresses the issue of illicit drug threats in the U.S.

With regard to H.R. 2715, the Destruction of Hazardous Imports Act, ASOP Global supports the principle of giving greater destruction authority to FDA. According to our survey, 76% of those who have purchased prescription medicines online say they trust only medicines intended for the U.S. market, yet 59% of online purchasers report buying medicines they believed were shipped from or intended for sale outside the U.S.; and 91% knew/suspected this before purchase.[3] Bad actors exploit weaknesses in shipping declarations and regulatory loopholes, confident that many shipments will go undetected. Current procedures often require holding and adjudicating dangerous products rather than swiftly destroying them – inadvertently allowing rogue manufacturers to "port shop" and reship the same products back into the U.S. Streamlining the seizure and destruction of unapproved or adulterated medicines must be a priority. We recommend that any legislation addressing administrative destruction of these illegal medications be aligned with FDA's policy recommendation, given its advantages for implementing the policy once enacted. We stand ready to engage with the Committee and stakeholders to help achieve that alignment.

Should you or your staff have any questions related to illicit drug threats in the U.S., please view ASOP Global as a resource. We look forward to working with you to advance public health and patient safety. **Please visit ASOP Global's website for additional information on our work to help protect patients from illegal online drug sales.**

Sincerely,

Leigh Verbois
Chair of ASOP Global Board

[1] https://asopfoundation.pharmacy/wp-content/uploads/2025/11/ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf
[2] https://asopfoundation.pharmacy/wp-content/uploads/2025/11/ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf
[3] https://asopfoundation.pharmacy/wp-content/uploads/2025/11/ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf

CLAY HIGGINS
3RD DISTRICT, LOUISIANA

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COMMITTEE ON ARMED SERVICES
SEAPOWER AND PROJECTION FORCES
READINESS

Congress of the United States
House of Representatives
Washington, DC 20515

March 26, 2026

The Honorable Morgan Griffith
Chairman
Subcommittee on Health
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Health
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Chairman Griffith and Ranking Member DeGette,

I appreciate the inclusion of H.R. 2715, the *Destruction of Hazardous Imports Act*, in the upcoming Subcommittee on Health legislative hearing titled "Policies to Protect Our Communities From Illicit Drug Threats."

My bill, H.R. 2715, would ensure that contaminated imports, ranging from radioactive seafood to illegal Chinese vapes, do not reach American consumers and cause harm. Specifically, the bill grants the Food and Drug Administration (FDA) additional authority to destroy articles that fail initial inspection, thereby preventing importers from attempting to re-import or "port-shop" their products.

Under current law, the FDA has the authority to destroy any imported medical devices and medications that pose a health risk to the public. However, this authority does not extend to imported food or other products that fail to meet U.S. health and safety standards. In January, the FDA released its FY 2026 Legislative Proposals, which included a request for authority to require importers to destroy any FDA-regulated product refused entry into the U.S. that presents a significant public health concern.

I strongly encourage the swift and thoughtful passage of this legislation through the Subcommittee and stand ready to assist in any way necessary to help advance this measure. I look forward to continuing to work with you to protect American consumers and public health.

Respectfully,

Clay Higgins
Member of Congress

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Drug and Alcohol Dependence

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Methadone-involved overdose deaths in the United States before and during the COVID-19 pandemic

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ABSTRACT

Background: Few studies have characterized methadone-involved overdose deaths in the US since 2014 despite changing patterns of opioid use, the onset of the COVID-19 pandemic, and changes to take-home dose guidance in opioid treatment programs (OTPs) in March 2020.

Methods: Data on monthly overdose deaths in the US from January 1, 2007 to March 31, 2021 were obtained through CDC WONDER. Interrupted time series models were used to assess for changes in series levels starting in April 2020. Analyses were stratified by involvement of synthetic opioids in overdose deaths.

Results: An increase in methadone-involved overdoses of 105.4 deaths per month (95 % CI: 73.8–137.0) occurred starting in April 2020 compared with prior trends ($p < 0.001$). Trends in methadone-involved overdose deaths showed a step increase starting in April 2020 both with (54.2 deaths per month; 95 % CI: 39.4–68.9) and without (51.7 deaths per month; 95 % CI: 23.4–78.0) synthetic opioid involvement ($p < 0.001$ for both). Among overdose deaths without synthetic opioids, the increase in methadone-involved overdose deaths accounted for 26.5 % of the increase between the 12-month periods before and after March 2020. The relative percentage increase in methadone-involved overdose deaths, both with and without synthetic opioid co-involvement, was highest among Hispanic and non-Hispanic Black individuals.

Conclusions: Methadone-involved overdose deaths, both with and without other synthetic opioid co-involvement, increased during the 12-month period after March 2020, compared with prior trends. These results provide a cautionary addition to previous findings of no or limited methadone-related harms after the US regulatory changes during the COVID-19 pandemic.

1. Introduction

Methadone treatment reduces mortality among patients with opioid use disorder (OUD), yet methadone can also contribute to overdoses (Schuckit, 2016). In the US, methadone-involved overdoses have been most closely linked with the prescription of methadone for analgesia. During 2002–2014, the quantity of methadone prescribed as an analgesic was strongly associated with reports of diverted methadone and with methadone-involved overdose deaths (Jones, 2016). Following interventions to reduce methadone prescribing for analgesia, methadone-involved overdose deaths declined even as increasing numbers of individuals received methadone as treatment for opioid use disorder (Jones, 2016).

Few studies have described methadone-involved overdose deaths in the US since 2014, despite substantial changes in patterns of opioid use and the increased involvement of high-potency synthetic opioids in overdose deaths (Jones et al., 2018). Most significantly, patterns of methadone-involved overdose deaths since the onset of the COVID-19 pandemic have had limited characterization, despite large increases in total opioid-involved overdose deaths, particularly among racial and ethnic minority groups, and the increased eligibility for take-home doses through opioid treatment programs (OTPs) starting in March 2020 (Brothers et al., 2021; Amram et al., 2021; Jones et al., 2022).

Using death certificate data from the National Vital Statistics System, this study characterized methadone-involved overdose deaths throughout the US from January 1, 2007 to March 31, 2021, with a focus on the periods before and after the COVID-19 pandemic started in March 2020. Changes in methadone-involved overdose deaths were compared

Abbreviations: OUD, opioid use disorder.

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with changes in total overdose deaths without methadone. Given the substantial increase in synthetic opioid involved overdose deaths since 2019, analyses were stratified by involvement of synthetic opioids in overdose deaths (Hedegaard et al., 2021).

2. Methods

Overdose deaths among U.S. residents in the 50 states and the District of Columbia were identified through CDC WONDER on a monthly basis between January 2007 and March 2021 (National Center for Health Statistics). Overdose deaths prior to January 1, 2021 reflect final confirmed counts, while overdose deaths between January 1, 2021 and March 31, 2021 reflect provisional counts (National Center for Health Statistics). Overdose deaths were analyzed starting in 2007 given the release of methadone-related warnings from the Food and Drug Administration in 2006 and previous reports documenting decreasing methadone-related deaths beginning in 2007 (Jones, 2016).

Overdose deaths were identified based on ICD-10 codes of X40–44 (unintentional poisoning), X60–64 (intentional self-poisoning), X85 (homicide), and Y10–14 (undetermined intent) as underlying cause of death (Centers for Disease Control and Prevention, 2018). Methadone-involved overdose deaths were identified when ICD-10 code T40.3 was a contributing cause of death. Other involved substances were identified by ICD-10 codes listed as a contributing cause of death. Non-methadone opioids were identified based on codes T40.0 (opium), T40.1 (heroin), T40.2 (natural and semi-synthetic opioids [NSS]), T40.4 (synthetic opioids), and T40.6 (other and unspecified opioids). (Though methadone is also a synthetic opioid, the term 'synthetic opioid' in this manuscript will be reserved for the involvement of non-methadone synthetic opioids designated by ICD-10 code T40.4). Non-opioid involved substances were identified from codes T40.5 (cocaine), T42.4 (benzodiazepines), T43.6 (other psychostimulants), and T51.0 and T51.9 (ethanol and unspecified alcohols) (Jones et al., 2018; Kleinman and Weiss, 2022). Demographic information about the decedents was obtained through aggregated mortality reports from CDC WONDER that were stratified by demographic variable.

The demographics of decedents, co-involved substances, and trends in overdose deaths were descriptively analyzed. Monthly overdose trends were analyzed using seasonal autoregressive integrated moving average (ARIMA) modelling, with an interrupted time-series framework, to assess for changes in the level of the series starting after March 2020. Seasonal ARIMA models account for historical trends, lagged effects, seasonality, and autocorrelation between months of overdose trends (Schaffer et al., 2021). In a first step, seasonal ARIMA models were using fitted to trends in methadone-involved overdose deaths occurring from January 2007 to February 2020, using an automated procedure (Hyndman and Khandakar, 2008). We used augmented Dickey-Fuller tests to confirm stationarity after differencing and Box-Pierce tests to test for independence of residuals. We then modelled a seasonal ARIMA function using the same parameters as the model from January 2007 to February 2020, but with the addition of a step effect for months from April 2020 to March 2021. March 2020 was not included in the step effect given that OTP regulatory changes occurred part-way through the month (Substance Abuse and Mental Health Services Administration, 2020). The step effect represents the change in the level of monthly methadone-involved overdose deaths occurring starting in April 2020 compared with the expected values based on the prior trends.

For year-over-year analyses, we used chi-squared tests to compare the proportional changes in methadone-involved overdose deaths between the 12 months before and after March 2020 with the proportional changes in total overdose deaths without methadone. Given the substantial increase in synthetic opioid involved overdose deaths during the COVID-19 pandemic, analyses were stratified by involvement of synthetic opioids in overdose deaths.

To compare counts of methadone-involved overdose deaths within a demographic group between the 12-month periods before and after March 2020, we used z-tests under a normal approximation to a presumed Poisson distribution as recommended by Centers for Disease Control guidance for annual death counts > 100 (Xu et al., 2021). All statistical tests were conducted post-hoc and should be considered exploratory.

The Centre for Addiction and Mental Health Research Ethics Board determined that this study was exempt from review, in accordance with the Tri-Council Policy Statement on Research Ethics 2. The report follows the Strengthening the Reporting of Observational Studies in Epidemiology guidelines. Data was analyzed between January 7, 2022 and August 5, 2022 using R, version 4.1.1 (R Foundation for Statistical Computing).

3. Results

3.1. Time-series analyses

A total 55,225 methadone-involved overdose deaths occurred in the United States between January 1, 2007 and March 31, 2021 (Fig. 1a). Monthly methadone-involved overdose deaths decreased from January 2007 to February 2020. A step effect of an additional 105.4 (95 % CI: 73.8–137.0) monthly methadone-involved overdose deaths starting after March 2020 ($p < 0.001$ for step effect). Monthly overdose deaths co-involving methadone and synthetic opioids increased by 54.2 deaths per month (95 % CI: 39.4–68.9) starting in April 2020 compared with the expected values based on prior trends ($p < 0.001$) (Fig. 1b). Monthly overdose deaths involving methadone without synthetic opioids increased 51.7 deaths per month (95 % CI: 23.4 – 78.0) starting in April 2020 compared with the expected values based on prior trends ($p < 0.001$) (Fig. 1c).

3.2. Year-over-year analyses

Methadone-involved overdose deaths increased by 1067 (39.1 %) between the 12-month periods before and after March 2020, while total overdose deaths without methadone involvement increased by 23,611 (33.7 %) (χ^2 2.38 for proportional increases, df 1, p 0.12) (Table 2). Methadone-involved overdose deaths increased by 195 (70.4 %) among Hispanic individuals, by 209 (57.1 %) among non-Hispanic Black individuals, and by 627 (31.4 %) among non-Hispanic White individuals (Table 2). Total overdose deaths without methadone increased by 23,611 (33.7 %), with increases of 3482 (46.1 %) among Hispanic individuals, 5271 (49.4 %), non-Hispanic Black individuals, and 13,610 (27.6 %,) non-Hispanic White individuals.

3.2.1. Synthetic opioid co-involvement

Overdose deaths co-involving methadone and synthetic opioids increased by 714 (71.4 %) during the 12-month period after March 2020 compared with the 12 months prior to March 2020 (Table 2). In comparison, total overdose deaths involving synthetic opioids and without methadone increased by 22,631 (60.5 %). There was no significant difference in proportional increases (χ^2 2.61, df 1, p 0.11). The number of methadone-involved overdose deaths co-involving synthetic opioids increased by 116 (101.8 %) among Hispanic individuals, 160 (75.8 %) among non-Hispanic Black individuals and 404 (62.1 %) among non-Hispanic White individuals. In comparison, total overdose deaths with synthetic opioid involvement and without involving methadone increased by 3087 (77.2 %), 4673 (74.2 %), and 13,796 (52.9 %) among Hispanic, non-Hispanic Black and non-Hispanic White individuals, respectively.

3.2.2. Without synthetic opioid co-involvement

Overdose deaths involving methadone without synthetic opioids increased by 353 (20.4 %) between the 12-month periods before and after March 2020 (Table 2). The increase in total overdose deaths without synthetic opioids and without methadone over the same period

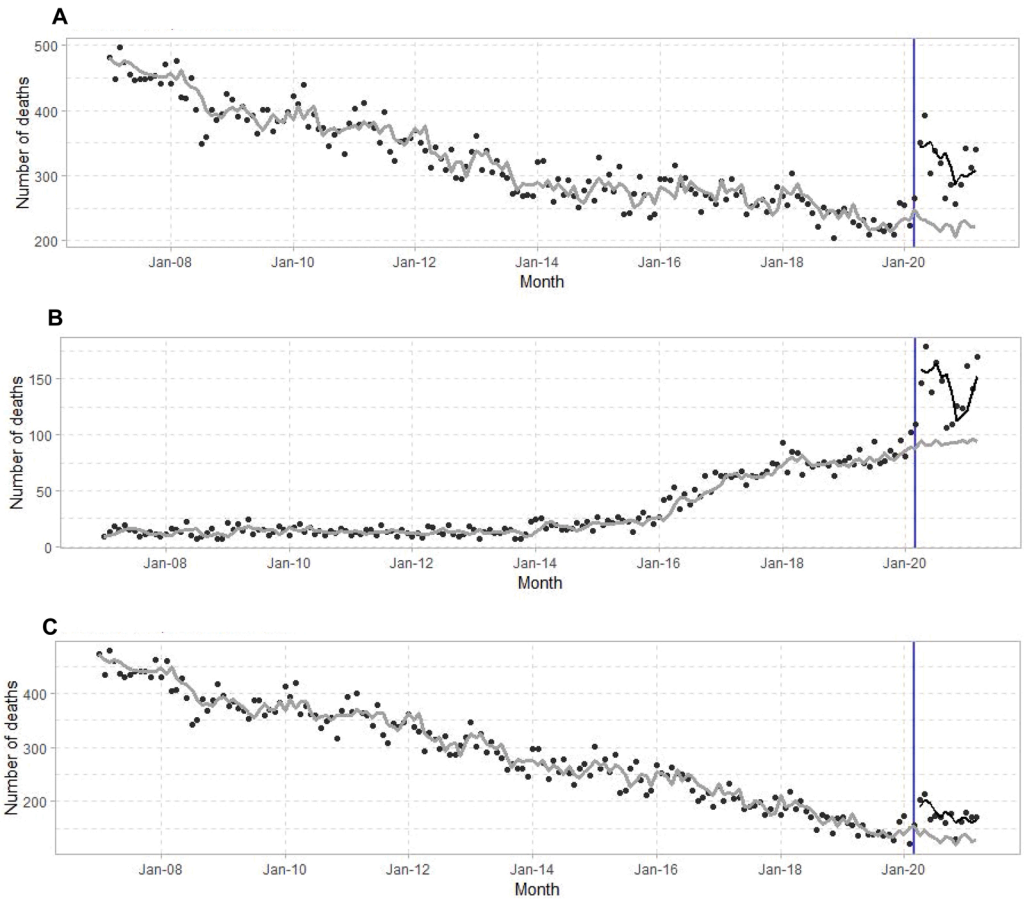

Fig. 1. Time-series of monthly methadone-involved overdose deaths from January 2007 to March 2021. March 2020 is identified with the vertical line. Seasonal ARIMA models were used to generate estimates of monthly overdose deaths based on trends prior to March 2020 (grey line) and with a step effect occurring after March 2020 (black line). (A) All overdose deaths involving methadone. (B) Overdose deaths involving methadone with synthetic opioids (T40.4). (C) Overdose deaths involving methadone without synthetic opioids.

was 980 (3.0 %). The proportional increase was significantly higher among overdose deaths involving methadone without synthetic opioids (χ^2 21.7, df 1, $p < 0.001$). The increase in methadone-involved overdose deaths without synthetic opioids represented 26.5 % of the total increase in overdose deaths without synthetic opioids between the two 12-month periods.

Methadone-involved overdose deaths without synthetic opioids increased by 79 (48.5 %) among Hispanic individuals, 49 (31.6 %) among non-Hispanic Black individuals and 223 (16.5 %) among non-Hispanic White individuals. These contrast with increases of 395 (11.1 %), 598 (13.7 %) in total overdose deaths without synthetic opioid and without methadone involvement among Hispanic and non-Hispanic Black individuals, respectively, and a decrease of 186 (0.8 %) among non-Hispanic White individuals.

3.2.3. *Co-involved substances*

In the 12-months prior to March 2020, (52.6 %) of methadone-involved overdoses involved another opioid (synthetic opioids: 1000 [36.7 %]; heroin: 510 [18.7 %], NSS: 470 [17.2 %]), 758 (27.8 %) involved benzodiazepines, 432 (15.8 %) involved cocaine, 372 (13.6 %) involved other psychostimulants, and 270 (9.9 %) involved ethanol or unspecified alcohols (Table 1). 638 deaths (23.4 %) did not co-involve additional opioids, benzodiazepines, cocaine, other psychostimulants or ethanol/unspecified alcohols.

In the 12 months after March 2020, 2191 (57.7 %) methadone-involved overdoses involved another opioid (other synthetic opioids: 1714 [45.2 %]; heroin: 612 [16.1 %], NSS: 646 [17.0 %]), 981 (25.8 %) involved benzodiazepines, 606 (16.0 %) involved cocaine, 613 (16.2 %) involved other psychostimulants, and 613 (10.5 %) involved ethanol or unspecified alcohols (Table 1). 750 deaths (19.8 %) did not involve additional opioids, benzodiazepines, cocaine, other psychostimulants, ethanol or unspecified alcohols.

4. Discussion

Methadone-involved overdose deaths among U.S. residents increased in the 12-months after March 2020 compared with prior trends. Methadone-involved overdose deaths increased above previous trends both with and without co-involvement of synthetic opioids. In analyses with and without involvement of synthetic opioids, there was an initial spike in methadone-involved overdose deaths during March – May 2020, after which these deaths stabilized but remained elevated above their prior trends. In year-over-year analyses comparing the 12 months before and after March 2020, methadone-involved overdose deaths without synthetic opioids had a significantly larger proportional increase than total overdoses without synthetic opioids or methadone. Among overdose deaths without synthetic opioids, the increase in methadone-involved overdose deaths accounted for 26.5 % of the total increase between the two 12-month periods. The proportional increase in methadone-involved overdose deaths that co-involved synthetic was not significantly higher than overdose deaths involving synthetic opioids without methadone. The increases in methadone-involved overdose deaths occurred despite a 24 % reduction in the number of patients receiving methadone in the US between 2019 and 2020 (from 408,550 in 2019 to 311,531 in 2020) (Substance Abuse and Mental Health Services Administration, 2021).

The number of individuals with methadone-involved overdose deaths increased in each demographic group, with the most prominent percentage increases among Hispanic and non-Hispanic Black individuals (both with and without co-involvement of synthetic opioids). It is unknown whether these overdose deaths occurred among individuals receiving methadone from OTPs or from other sources.

Table 1
Methadone-involved overdose deaths during March 2019 – February 2020 and April 2020 – March 2021.

	March 2019 – February 2020			April 2020 – March 2021[a]		
	All overdose deaths	All overdose deaths without methadone	Overdose deaths involving methadone	All overdose deaths	All overdose deaths without methadone	Overdose deaths involving methadone
All	72,809 (100 %)	70,081 (100 %)	2728 (100 %)	97,487 (100 %)	93,692 (100 %)	3795 (100 %)
Sex						
Female	23,314 (32 %)	22,158 (31.6 %)	1156 (42.4 %)	29,788 (30.6 %)	28,255 (30.2 %)	1533 (40.4 %)
Male	49,495 (68 %)	47,923 (68.4 %)	1572 (57.6 %)	67,699 (69.4 %)	65,437 (69.8 %)	2262 (59.6 %)
Race/ethnicity						
Hispanic	7822 (10.7 %)	7545 (10.8 %)	277 (10.2 %)	11,499 (11.8 %)	11,027 (11.8 %)	472 (12.4 %)
Non-Hispanic Black	11,036 (15.2 %)	10,670 (15.2 %)	366 (13.4 %)	16,516 (16.9 %)	15,941 (17 %)	575 (15.2 %)
Non-Hispanic White	51,338 (70.5 %)	49,339 (70.4 %)	1999 (73.3 %)	65,575 (67.3 %)	62,949 (67.2 %)	2626 (69.2 %)
Other[b]	2613 (3.6 %)	2527 (3.6 %)	86 (3.2 %)	3890 (4.0 %)	3768 (4.0 %)	122 (3.2 %)
Age						
0–19	1086 (1.5 %)	1056 (1.5 %)	30 (1.1 %)	1902 (2.0 %)	1854 (2.0 %)	48 (1.3 %)
20–29	11,783 (16.2 %)	11,526 (16.4 %)	257 (9.4 %)	16,279 (16.7 %)	15,928 (17 %)	351 (9.2 %)
30–39	18,779 (25.8 %)	18,091 (25.8 %)	688 (25.2 %)	25,826 (26.5 %)	24,913 (26.6 %)	913 (24.1 %)
40–49	15,523 (21.3 %)	14,936 (21.3 %)	587 (21.5 %)	20,999 (21.5 %)	20,130 (21.5 %)	869 (22.9 %)
50–59	15,654 (21.5 %)	14,959 (21.3 %)	695 (25.5 %)	19,951 (20.5 %)	19,043 (20.3 %)	908 (23.9 %)
60–69	7984 (11 %)	7572 (10.8 %)	412 (15.1 %)	10,362 (10.6 %)	9734 (10.4 %)	628 (16.5 %)
70+	1990 (2.7 %)	1932 (2.8 %)	58 (2.1 %)	2154 (2.2 %)	2077 (2.2 %)	77 (2.0 %)
Co-involved substances						
Synthetic opioids[c]	38,435 (52.8 %)	37,435 (53.4 %)	1000 (36.7 %)	61,780 (63.4 %)	60,066 (64.1 %)	1714 (45.2 %)
Heroin	13,916 (19.1 %)	13,406 (19.1 %)	510 (18.7 %)	12,450 (12.8 %)	11,838 (12.6 %)	612 (16.1 %)
NSS	12,044 (16.5 %)	11,574 (16.5 %)	470 (17.2 %)	13,772 (14.1 %)	13,126 (14 %)	646 (17.0 %)
Benzodiazepines	9927 (13.6 %)	9169 (13.1 %)	758 (27.8 %)	12,700 (13 %)	11,719 (12.5 %)	981 (25.8 %)
Cocaine	16,613 (22.8 %)	16,181 (23.1 %)	432 (15.8 %)	20,273 (20.8 %)	19,667 (21 %)	606 (16.0 %)
Psychostimulants[d]	16,925 (23.2 %)	16,553 (23.6 %)	372 (13.6 %)	26,512 (27.2 %)	25,899 (27.6 %)	613 (16.2 %)
Alcohols[e]	10,318 (14.2 %)	10,048 (14.3 %)	270 (9.9 %)	14,123 (14.5 %)	13,725 (14.6 %)	398 (10.5 %)

[a] Counts from January – March 2021 reflect provisional figures.
[b] Includes non-Hispanic individuals of other races (including multiple races) and individuals for whom Hispanic ethnicity status is not stated.
[c] ICD-10 code T40.4: synthetic opioids excluding methadone.
[d] ICD-10 code T43.6: psychostimulants other than cocaine.
[e] ICD-10 codes T51.0 and T51.9: ethanol and unspecified alcohols.

Previous analyses have highlighted numerous ways in which structural racism has been embedded within OTPs, and follow-up studies are needed to determine whether changes in OTP treatment provision during COVID-19 were implemented in a way that disproportionately harmed Hispanic and non-Hispanic Black individuals (Peterkin et al., 2021).

Previous studies have also assessed whether there were changes in methadone-associated harms associated with the onset of the COVID-19 pandemic and OTP regulatory changes in the US (Amram et al., 2021; Jones et al., 2022; Welsh et al., 2022). On March 16, 2020, the Substance Abuse and Mental Health Services Administration released guidance allowing states to request blanket exceptions to federal regulations limiting take-home methadone doses. These exceptions allowed up to 28 days of take-home doses for stable patients and 14 days of take home doses for less stable patients, who an OTP believed could handle take-home doses (Substance Abuse and Mental Health Services Administration, 2020). Previous regulations limited take-home doses to once per week over the first 90 days of treatment and 2 take-home doses over the subsequent 90 days (in addition to a single take-home dose for days in which the clinic was closed) (Substance Abuse and Mental Health Services Administration, 2015).

A nationwide study performed an interrupted time-series analysis (ITSA) to model methadone-involved overdoses before and after March 2020 (Jones et al., 2022). The study found, that as a proportion of overall ITSA-estimated overdose deaths, ITSA-estimated methadone-involved overdose deaths remained similar before and after March 2020 (Jones et al., 2022). The study also identified an increase in methadone-involved overdose deaths in March 2020 and attributed the increase to the increase in fentanyl driven deaths rather than OTP changes. However, the previous analysis did not stratify overdose deaths by synthetic opioid involvement, and in emphasizing the proportion of total overdose deaths involving methadone, obscured large relative percentage increases in methadone-involved overdose deaths.

Our analysis clarifies that methadone-involved overdose deaths without synthetic opioid co-involvement increased more rapidly than total overdose deaths without synthetic opioids, and that overdose

Table 2
Differences in total overdose deaths, total overdose deaths without methadone, and methadone-involved overdose deaths between the 12-month periods before and after March 2020.

	Total overdose deaths	Total overdose deaths without methadone	Methadone-involved overdose deaths	p-value
All	24,678 (33.9 %)	23,611 (33.7 %)	1067 (39.1 %)	< 0.001
Gender				
Female	6474 (27.8 %)	6097 (27.5 %)	377 (32.6 %)	< 0.001
Male	18,204 (36.8 %)	17,514 (36.5 %)	690 (43.9 %)	< 0.001
Race/ethnicity				
Hispanic	3677 (47 %)	3482 (46.1 %)	195 (70.4 %)	< 0.001
Non-Hispanic Black	5480 (49.7 %)	5271 (49.4 %)	209 (57.1 %)	< 0.001
Non-Hispanic White	14,237 (27.7 %)	13,610 (27.6 %)	627 (31.4 %)	< 0.001
Other	1277 (48.9 %)	1241 (49.1 %)	36 (41.9 %)	0.015
With synthetic opioid involvement	23,345 (60.7 %)	22,631 (60.5 %)	714 (71.4 %)	< 0.001
Sex				
Female	6193 (58.2 %)	5971 (58.1 %)	222 (60.7 %)	< 0.001
Male	17,152 (61.7 %)	16,660 (61.4 %)	492 (77.6 %)	< 0.001
Race/ethnicity				
Hispanic	3203 (77.9 %)	3087 (77.2 %)	116 (101.8 %)	< 0.001
Non-Hispanic Black	4833 (74.2 %)	4673 (74.2 %)	160 (75.8 %)	< 0.001
Non-Hispanic White	14,200 (53.1 %)	13,796 (52.9 %)	404 (62.1 %)	< 0.001
Other	1109 (104.9 %)	–	–	–
Without synthetic opioid involvement	1333 (3.9 %)	980 (3 %)	353 (20.4 %)	< 0.001
Sex				
Female	281 (2.2 %)	126 (1.1 %)	155 (19.6 %)	< 0.001
Male	1052 (4.8 %)	854 (4.1 %)	198 (21.1 %)	< 0.001
Race/ethnicity				
Hispanic	474 (12.8 %)	395 (11.1 %)	79 (48.5 %)	< 0.001
Non-Hispanic Black	647 (14.3 %)	598 (13.7 %)	49 (31.6 %)	0.01
Non-Hispanic White	37 (0.2 %)	-186 (−0.8 %)	223 (16.5 %)	< 0.001
Other	168 (10.8 %)	–	–	–

Relative percentage increases from the 12 months before March 2020 to the 12 months after March 2020 are shown in parentheses. P-values compare counts of methadone-involved overdose deaths between the two 12-month periods. P-values are calculated using z-tests. Omitted data could not be displayed due to data suppression rules.

deaths involving methadone and synthetic opioids increased at least as rapidly as total overdose deaths involving synthetic opioids. The lower base rate of synthetic opioid involvement among methadone-involved overdose deaths than among total overdose deaths accounts for the difference in results when stratifying. These results highlight the importance of stratification along synthetic opioid involvement during the period under study.

Findings from international jurisdictions provide conflicting results about an association between increased methadone take-home doses and adverse events. In England, guidance recommended that individuals prescribed opioid agonist treatments during the COVID-19 pandemic, be provided with two weeks of carries during March – May 2020. A time-series ecological study from England found that methadone-involved overdose deaths increased both among recipients (22 %) and non-recipients of prescribed opioid agonist treatments (74 %). Unsupervised dosing of methadone for OUD in the late 1990s and early 2000s was associated with high overdose rates in England and Scotland, and the rate of methadone-involved overdoses per quantity of methadone dispensed decreased after supervised dosing was instituted (Strang et al., 2010). In Ontario, Canada, where methadone can be prescribed from office-based settings and dispensed at pharmacies, a retrospective propensity-matched cohort study using administrative data found that individuals whose methadone dispensing was changed from daily to receiving 5 – 6 take home doses per week had lower rates of treatment discontinuation, opioid overdose and than matched individuals continuing daily dispensing (Kleinman et al., 2022; Gomes et al., 2022). However, residual confounding remains possible, particularly since Ontario's guidance at the time recommended that an assessment of suitability for take-home doses be based on social stability and a patient's ability to safely manage take-home doses, markers of clinical stability that may not be reflected in administrative data (Lam et al., 2022).

The results in this study make several important contributions to the understanding of methadone-involved overdose deaths. First, the study uses a nationwide, population-level data set and provides the most comprehensive assessment of methadone-involved overdose deaths during the year before and during the COVID-19 pandemic in the US. Second, the stratified analysis used in this study highlights the increases in methadone-involved overdose deaths both with and without synthetic opioid co-involvement. Third, this study highlights the disproportionate increased incidence of methadone-involved overdoses without synthetic opioids among Hispanic and non-Hispanic Black communities. Fourth, this study highlights the degree to which other substances are co-involved in methadone-involved overdose deaths, regardless of whether synthetic opioids were involved.

This study has several important limitations. First, when multiple substances are involved in an overdose death, death certificate data do not indicate the relative contributions of each involved substance to the overdose death. This can result in the misidentification of methadone as a contributing substance to overdose deaths that were largely caused by other substances, such as synthetic opioids. Second, this study is observational and does not allow for a causal attribution of the increase in methadone-involved overdose deaths to any specific factor. Third, the provisional data included for January – March, 2021 may be subject to revision as further information becomes available, though minimal revisions are expected (Jones et al., 2022). Fourth, this study cannot distinguish whether individuals who die from methadone-involved overdoses receive methadone through OTPs, as prescriptions for pain, or through other sources, including diverted methadone. Fifth, ICD-10 codes for alcohol likely underestimate alcohol involvement in overdose deaths. Finally, all statistical tests were conducted post-hoc and should be considered exploratory.

The current study found an increase in methadone-involved overdose deaths temporally associated with this period despite a decrease in the number of individuals receiving methadone. Numerous societal changes occurred concurrently, and the absolute increases in methadone-involved overdose deaths found in this report are small compared with the total increase in overdose deaths in the US since the beginning of the pandemic. Additionally, monthly methadone-involved overdose deaths remained lower than in the late 2000s when methadone was more frequently prescribed for analgesia. Prospective controlled studies would be necessary to fully understand whether and to what degree OTP regulatory changes contributed to these increases. The impact of any OTP changes among Hispanic and non-Hispanic Black individuals should be specifically considered, especially in light of the disproportionate increases in methadone-involved overdose deaths in

these groups. In determining whether OTP regulatory changes should be extended, any potential association between the changes and an increase in methadone-involved overdose deaths would have to be balanced with the benefits of increasing access to take-home doses, including enhancing patient autonomy, destigmatizing methadone treatment, and the numerous ways that patients identify take-home doses as improving their lives (Frank et al., 2021; Kleinman et al., 2022; Treloar et al., 2007).

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Contributor statement

The study was conceived by RAK. RAK drafted the manuscript. MS critically revised the manuscript and assisted with the statistical analysis. Both authors approved the final copy.

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STATEMENT FOR THE RECORD TO THE HOUSE ENERGY & COMMERCE COMMITTEE

In support of H.R. 5880, the Fight Illicit Pill Presses Act

Congresswoman Melanie Stansbury (NM-01)

March 26, 2026

Thank you Chairman, Ranking Member, and Members of the Committee for convening this legislative hearing and for your attention to the urgent and ongoing fentanyl crisis. I appreciate the opportunity to submit this statement for the record in support of H.R. 5880, the Fight Illicit Pill Presses Act, of which I am proud to be a co-leader.

The Fentanyl Crisis is New Mexico

The devastating impact of the fentanyl and opioid epidemic is deeply personal for me. Like millions of Americans, this crisis has touched my own life with the loss of several friends and family members. Across New Mexico, families and communities are grappling with the tragic consequences of illicit fentanyl, which continues to drive overdose deaths and devastate communities in both urban and rural areas.

In New Mexico, we have been particularly devastated by the fentanyl crisis, experiencing some of the highest overdose death rates in the country. Nearly 1,000 lives are lost each year statewide, and my hometown of Albuquerque continues to see some of the highest overdose rates in the state. These are not just statistics—they represent real people: families torn apart, communities strained, and lives tragically cut short.

H.R. 5880 will help address this crisis in New Mexico by targeting the production of counterfeit fentanyl pills that are increasingly prevalent across the state. By stopping these pills before they are manufactured and distributed, this legislation will reduce supply, prevent overdoses, and save lives in communities from Albuquerque to rural and tribal areas.

About the Fight Illicit Pill Presses Act (H.R. 5880)

Illicit pill presses are a central driver of today's fentanyl crisis. These machines enable criminal organizations to mass-produce counterfeit pills that are often indistinguishable from legitimate prescription drugs, yet frequently contain lethal doses of fentanyl.

The Office of National Drug Control Policy (ONDCP) has identified the need to deny illicit synthetic drug producers access to pill presses, die molds, encapsulating machines, and other equipment used to manufacture counterfeit pills. H.R. 5880 directly responds to this need by targeting the production side of the illicit drug supply chain.

By targeting these machines and the components needed to operate them, H.R. 5880 takes a proactive, upstream approach to combating the opioid epidemic. Specifically, this legislation will:

- Help stop fentanyl by preventing the large-scale production of counterfeit fentanyl-laced pills before they ever reach the street.
- Provide law enforcement with critical tools to identify and disrupt illicit pill production networks.
- Disrupt illegal drug trafficking networks by creating traceability and accountability for pill press equipment, making it significantly harder for traffickers to operate undetected.
- Save lives by reducing the availability of counterfeit pills that unsuspecting individuals may consume, often with fatal consequences

Additionally, H.R. 5880 establishes meaningful enforcement mechanisms by imposing penalties on those who fail to comply with serialization, recordkeeping, reporting, and registry requirements. Drug traffickers and suppliers are constantly adapting their methods, and our policies must keep pace. By regulating pill presses and related equipment, this legislation aims to stop the production of counterfeit fentanyl-laced pills at its source—before they reach our communities and claim more lives.

Our Work to Combat the Fentanyl Crisis

H.R. 5880 is a key component of our office's broader strategy to combat the fentanyl crisis in New Mexicans and support our communities at home.

In addition to co-leading H.R. 5880, I have introduced the Stop the Opioid Pill Presser and Fentanyl Act (STOPP Act) and cosponsored the Combating Online Fentanyl Trafficking Act, along with numerous bills and amendments to expand funding for addiction recovery, health care, and the wraparound services needed to address this crisis.

Through Community Project Funding, I have also secured millions of dollars to support our communities in combating drug-related crime and helping individuals on the path to recovery. These investments include funding for new addiction recovery centers in Albuquerque, a behavioral health clinic in the International District, the Albuquerque Sobering Center, expanded Healthcare for the Homeless services, and a new recovery center in Sandoval County.

I've also secured millions of dollars to support first responders and emergency operations centers in Albuquerque, Valencia County, the East Mountains, Fort Sumner, and Sandia Pueblo—communities on the front lines of saving lives every day. In addition, I have delivered funding to equip the New Mexico State Police, Albuquerque Police Department, and the Bernalillo, Sandoval, and Valencia County Sheriff's Offices with the tools and technology needed to strengthen drug interdiction efforts.

At the same time, I've secured significant investments in transitional housing and recovery programs across my district to help individuals and families overcome addiction and rebuild their lives.

Every day, we are working hand-in-hand with impacted families, public health leaders, law enforcement, nonprofits, faith-based organizations, and local and Tribal governments to confront this crisis. Addressing the

fentanyl epidemic requires a comprehensive approach—one that meets this moment by tackling the challenge from every angle: from prevention and enforcement to treatment and recovery.

By targeting the equipment used to manufacture counterfeit pills, H.R. 5880 closes a critical gap in our response. This legislation is a focused, commonsense, bipartisan solution that strengthens our enforcement framework and addresses a vulnerability traffickers have exploited for far too long.

I look forward to working with the Committee and my colleagues to advance this legislation and strengthen our nation's response to the fentanyl crisis.

Thank you for your consideration.

March 24, 2026

Hon. Chuck Grassley
Chair
Senate Judiciary Committee

Hon. Dick Durbin
Ranking Member
Senate Judiciary Committee

Hon. Jim Jordan
Chair
House Judiciary Committee

Hon. Jamie Raskin
Ranking Member
House Judiciary Committee

Hon. Brett Guthrie
Chair
House Energy & Commerce

Hon. Frank Pallone
Ranking Member
House Energy & Commerce

Re: Combating Illicit Xylazine Act (H.R. 1266/S. 545), Nitazene Control Act (H.R. 5415 /S. 3076), and STOP Nitazenes Act (H.R. 7970)

Dear Chair Grassley, Ranking Member Durbin, Chair Jordan, Ranking Member Raskin, Chair Guthrie, Ranking Member Pallone, and Honorable Members of the U.S. Congress:

We, the undersigned national organizations, urge you to oppose the Combating Illicit Xylazine Act (H.R. 1266/S. 545), Nitazene Control Act (H.R. 5415 /S. 3076), and STOP Nitazenes Act (H.R. 7970). These bills criminalize the unauthorized use and distribution of xylazine, nitazenes, and nitazene analogues. However, the bills will not meaningfully prevent or reduce overdose deaths or address problematic drug use. Instead, we implore Congress to invest in health-based strategies and interventions that heal people and save lives.

Xylazine is a non-opioid sedative used as a veterinary tranquilizer.[1] In humans, xylazine can slow down brain functioning and breathing, reduce heart rate and blood pressure, and cause soft tissue wounds that can become infected.[2] Nitazenes are a group of synthetic opioids that first significantly emerged in the drug supply in 2019.[3] Nitazenes are used for their similarity with other synthetic opioids and can

[1] CDC. (2024). *What You Should Know About Xylazine.* ://www.cdc.gov/overdose-prevention/about/what-you-should-know-about-xylazine.html.
[2] Ibid.
[3] Schwarz, E. S., Dicker, F., Lothet, E., Spungen, H., & Levine, M. (2025). Nitazenes: An Old Drug Class Causing New Problems. *Missouri medicine, 122*(4), 329–333. https://pmc.ncbi.nlm.nih.gov/articles/PMC12331301.

cause respiratory depression and arrest. Both substances became more common in the drug supply after the federal crackdown on fentanyl.

People who use drugs are not seeking out these substances; rather, drug criminalization has led to a chaotic and dangerous drug supply that people are trying to survive.[4] This means that criminalizing xylazine, nitazenes, and nitazene analogues will impact many people who do not know they possess the substances. Further, these substances are typically found in combination with other illicit drugs. Xylazine, for instance, is predominantly found in conjunction with fentanyl, for which criminal penalties already exist.[5] In fact, 99.5% of xylazine-involved deaths in 2021 also involved illicitly manufactured fentanyl or fentanyl analogues, substances that are already criminalized.[6] Similarly, nitazenes are often found in combination with other illicit substances, like fentanyl, cocaine, or methamphetamine. In the era of synthetic drugs, what people need are health and evidence-based solutions that help people understand the supply, deal with the harms of drug use, and put them on a path to recovery, not the failed policies of criminalization.

Recent overdose death declines were primarily due to health interventions.

After decades of climbing overdose deaths, recent years have finally brought a reduction. In 2024, drug fatalities fell by 27%, and in 2025 they declined by another 21%.[7] Some emerging evidence does indicate that China's increased regulation of precursors played a role by reducing the supply of fentanyl.[8] However, history tells us that such wins are likely temporary, as they incentivize the introduction and proliferation of new, often more potent drugs, such as nitazenes.[9] As a result, most experts agree that the recent decline in overdose deaths is not attributable to harsher sentencing, but to the expansion of health-based interventions—like increased access to medications for opioid use disorder, naloxone distribution, expanded drug checking, and prevention programs.[10] Meanwhile, decades of punitive drug

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[4] Los Angeles County Department of Public Health. (June 2023). *Xylazine in Illicit Drugs: Increased Overdose Risks in Los Angeles County.* PDF. Los Angeles County, California. http://publichealth.lacounty.gov/sapc/docs/public/overdose-prevention/XylazineLACounty.pdf; Cohen, A., Vakharia, S. P., Netherland, J., & Frederique, K. (2022). How the war on drugs impacts social determinants of health beyond the criminal legal system. *Annals of medicine, 54*(1), 2024–2038. https://doi.org/10.1080/07853890.2022.2100926.

[5] Kariisa, M., O'Donnell, J., Kumar, S., Mattson, CL., Goldberger, BA. (2023). Illicitly Manufactured Fentanyl–Involved Overdose Deaths with Detected Xylazine — United States, January 2019–June 2022. MMWR. *Morbidity and Mortality Weekly Report, 72*(26). https://doi.org/10.15585/mmwr.mm7226a4.

[6] Ibid.

[7] Stobbe, Mike. (Jan. 19, 2026). "U.S. overdose deaths fell through most of 2025, federal data reveal," *Los Angeles Times.* https://www.latimes.com/science/story/2026-01-19/us-overdose-deaths-fell-2025.

[8] Vangelov, Kasey, et al. (2026). "Did the illicit fentanyl trade experience a supply shock?" *Science*, 391: 6781. https://www.science.org/doi/10.1126/science.aea6130.

[9] McKenna, Stacey. (Feb. 11, 2025). *An Ever-Changing, Increasingly Toxic Drug Supply Makes Harm Reduction Essential.* R Street Institute Policy Study No. 315. https://www.rstreet.org/research/an-ever-changing-increasingly-toxic-drug-supply-makes-harm-reduction-essential.

[10] CDC. (2025). *CDC Reports Nearly 24% Decline in U.S. Drug Overdose Deaths.* https://www.cdc.gov/media/releases/2025/2025-cdc-reports-decline-in-us-drug-overdose-deaths.html.

policies have contributed to increasing drug potency, leading to record overdose deaths. For example, after the federal classwide scheduling of fentanyl-related substances in 2018, overdose deaths surged, rising from 67,367 in 2018 to 107,941 in 2022.[11] Additionally, new substances like xylazine and nitazenes were introduced into the drug supply.

Criminalization endangers lives and undermines demand reduction efforts.

Criminal penalties not only fail to deter drug use, they also disproportionately target sellers at the lowest levels of the supply chain, who are often struggling with a substance use disorder.[12] Threats of prosecution and the associated risks of job loss, housing insecurity, or child custody loss deter individuals from seeking treatment, taking actions to reduce their own overdose risk, or calling 911 if they witness an overdose.[13]

Furthermore, incarceration provides inadequate access to gold standard treatment and severs needed support systems, setting people back and exacerbating cycles of harm.[14] Consequently, in the first two weeks after leaving prison, individuals are 27 times more likely to die of opioid overdose than the general population.[15]

Criminalization perpetuates racial and economic injustice.

Drug enforcement practices and their associated harms play out differently according to people's race and class. Black Americans–despite using illicit drugs at rates similar to white Americans–comprise a disproportionate share of those arrested and sentenced for drug offenses.[16] Moreover, Black, Latino, and Native Americans face steep barriers to finding help with limited access to education, tools, supplies, and medications that can aid a person's recovery.[17] In addition, poor individuals and

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[11] Drug Policy Alliance. *Reduce Harms of Fentanyl.* https://drugpolicy.org/issue/reduce-harms-of-fentanyl.
[12] U.S. Sentencing Commission. (2011). *2011 Report to the Congress: Mandatory Minimum Penalties in the Federal Criminal Justice System,* Chapter 8. https://www.ussc.gov/research/congressional-reports/2011-report-congress-mandatory-minimum-penalties-federal-criminal-justice-system.
[13] McKenna, Stacey. (Sept. 29, 2025). "Why Laws that Equate Drug Distribution to Murder are Counterproductive," R Street Institute Analysis. https://www.rstreet.org/commentary/why-laws-that-equate-drug-distribution-to-murder-are-counterproductive.
[14] SAMHSA. (2019). *Substance Abuse and mental Health Data Archive, National Survey on Drug Use and Health, 2019.* https://datatools.samhsa.gov/#/survey/NSDUH-2019-%20DS0001?column=UDPYILL&control=TXYRPRIIL&filter=NOBOOKY2%21%3D0%26UDPYILAL%3D1&results_received=true&row=NOBOOKY2&run_chisq=false&weight=ANALWT_C; Wdira, Emily. (2024). *Addicted to punishment: jails and prisons punish drug use far more than they treat it.* Prison Policy Initiative. https://www.prisonpolicy.org/blog/2024/01/30/punishing-drug-use.
[15] Hartung, D.M., McCracken, C.M., Nguyen, T., Kempany, K., & Waddell, E.N. (2023. Fatal and nonfatal opioid overdose risk following release from prison: A retrospective cohort study using linked administrative data. *Journal of substance use and addiction treatment,* 147, 208971. https://doi.org/10.1016/j.josat.2023.208971.
[16] Neath, Scarlet, et al. (2024). *Redesigning Public Safety. Center for Policing Equity.* https://policingequity.org/wp-content/uploads2024/04/CPE-WhitePaper-SubstanceUse.pdf.
[17] Drug Policy Alliance. (2024). "The Impact of the Overdose Crisis on Black Communities in the United States." DPA Fact Sheet. https://drugpolicy.org/wp-content/uploads/2024/06/DPA-ImpactOnBlackCommunitiesFactSheet-

communities are often policed more closely than wealthier ones, increasing the likelihood of arrest for drug-related activities.[18]

Criminal records create lifelong barriers to employment, housing, and economic mobility. Formerly incarcerated individuals are 10 times more likely to experience homelessness than the general public. Misdemeanor convictions reduce annual earnings by 16%, and incarceration slashes income by more than 50%.[19] These penalties make recovery, stability, and reintegration nearly impossible for many.

Invest in health policies to address the harms of drug use.

Addiction is a chronic, complex health condition that can involve multiple recovery attempts.[20] Yet, the Trump administration and this Congress have already made considerable cuts to addiction treatment, overdose response, research, and public health surveillance funding.[21] It is precisely the moment to assess the scope of these reductions and the gaps they may create or exacerbate. If government is to be more limited, it must also be more effective. We therefore urge you to ensure that remaining funds are directed to frontline organizations delivering evidence-based treatment and care coordination. This is not the time to close off pathways to treatment and recovery.

Congress can help promote pathways to recovery, further stem overdose deaths, and minimize the public health consequences of drug use by:

- **Reducing barriers to Medications for Opioid Use Disorder (MOUD)**: Medications like methadone and buprenorphine are gold standard treatments that save lives, promote stability,

InDesign-Interactive.pdf; Drug Policy Alliance. (2024). "The Impact of the Overdose Crisis on LatinX Communities in the United States." DPA Fact Sheet. https://drugpolicy.org/wp-content/uploads/2024/08/DPA-ImpactOnLatinxCommunitiesFactSheet-InDesign-Interactive.pdf; Drug Policy Alliance. (2024). "The Impact of the Overdose Crisis on Native American Communities in the United States," DPA Fact Sheet. https://drugpolicy.org/wp-content/uploads/2024/08/DPA-ImpactOnNativeCommunitiesFactSheet-InDesign-Interactive.pdf.

[18] Garriott, William. (2011). *Policing Methamphetamine: Narcopolitics in Rural America.* NYU Press. https://nyupress.org/9780814732403/policing-methamphetamine; Campbell, Walter, et al. (2022). "The behavior of police: class, race, and discretion in drug enforcement." *Police Practice and Research,* 23: 3. https://www.tandfonline.com/doi/abs/10.1080/15614263.2021.2022482.

[19] Brennan Center for Justice. (2020). *Conviction, Imprisonment, and Lost Earnings: How Involvement with the Criminal Justice System Deepens Inequality*. hinttps://www.brennancenter.org/sites/default/files/2020-09/EconomicImpactReport_pdf.pdf

[20] Kelly, J.F., et al. (2019). "How many recovery attempts does it take to successfully resolve an alcohol or drug problem? Estimates and correlates from a national study of recovering U.S. adults," *Alcoholism: Clinical and Experimental Research*, 43: 7. https://pubmed.ncbi.nlm.nih.gov/31090945; Cloud, W. and Granfield, R. (2009). "Conceptualizing recovery capital: expansion of a theoretical construct," *Substance Use and Misuse*, 43. https://pubmed.ncbi.nlm.nih.gov/19016174.

[21] Drug Policy Alliance. (2025). *Tracker: Federal Cuts to Overdose Prevention & Addiction Treatment.* https://drugpolicy.org/resource/federal-cuts-threaten-overdose-prevention/

and cut illicit drug use.[22] However, they are overregulated and over-surveilled, deterring health providers and institutions (including jails and prisons) from offering them.[23]

- **Supporting health services**: Life-saving health services—for example, naloxone distribution, case management, and mental health services—reduce drug use, connect individuals to treatment, and slash the public health impact of substance use (e.g., reducing transmission of communicable disease).[24] Overregulating and defunding these services prevents communities from tailoring interventions to keep their populations as safe and healthy as possible.[25]
- **Facilitating research and public health surveillance**: To better promote treatment and save lives, research must understand the shifting U.S. illicit drug supply. Scheduling, especially classwide scheduling, can hinder the development of novel medications for treatment or overdose reversal, and make it more difficult to collect and disseminate information about the state and dangers of the ever-changing drug supply. We must invest in and reduce barriers to such research, especially solutions that are proven to work, like community drug checking and forensic and toxicology review.

Congress is at a crucial point in history–at a time when overdose numbers have finally begun to decline from their peak, and in the midst of historic cuts to our country's health infrastructure, we must prioritize an approach to drug policy that is proven to reduce demand while saving lives.[26] For any questions about this letter, please contact Maritza Perez Medina at mperez@drugpolicy.org and Stacey McKenna at smckenna@rstreet.org.

Sincerely,

ACR Health (NY)
AIDS United
American Civil Liberties Union
A New PATH (Parents for Addiction Treatment & Healing) (CA)
Blacks in Law Enforcement
Broken No More
Challenges Inc SC (SC)
Doctors for Drug Policy Reform
Dream.org

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[22] Committee on Medication-Assisted Treatment for Opioid Use Disorder et al. (2019). Medications for Opioid Use Disorder Save Lives, ed. Alan I. Leshner and Michelle Mancher. *National Academies Press,* 25310, https://doi.org/10.17226/25310.

[23] McKenna, Stacey. (Nov. 7, 2023). *How Red Tape Limits Access to Medications for Opioid Use Disorder,* R Street Institute Explainer. https://www.rstreet.org/research/how-red-tape-limits-access-to-medications-for-opioid-use-disorder.

[24] Pridgen, Bailey E., et al. (2025). "U.S. substance use harm reduction efforts: a review of the current state of policy, policy barriers, and recommendations." *Harm Reduction Journal*, 22: 101. https://pmc.ncbi.nlm.nih.gov/articles/PMC12147315/.

[25] Ibid.

[26] CDC. (2025). *CDC Reports Nearly 24% Decline in U.S. Drug Overdose Deaths.* https://www.cdc.gov/media/releases/2025/2025-cdc-reports-decline-in-us-drug-overdose-deaths.html; Drug Policy Alliance. (2025). *Tracker: Federal Cuts to Overdose Prevention & Addiction Treatment.* https://drugpolicy.org/resource/federal-cuts-threaten-overdose-prevention.

Drug Policy Alliance
Due Process Institute
End It For Good
Fair and Just Prosecution
Faith in Harm Reduction
Federal Public and Community Defenders
Florida Access Network (FL)
Florida Harm Reduction Collective (FL)
Harm Reduction Action Center (CO)
Impact MN (MN)
Housing Works, Inc. (NY)
JustLeadershipUSA
Law Enforcement Action Partnership
MATSA Org.
Mom United to End the War on Drugs
More Than Our Crimes
NASTAD
National Association of Criminal Defense Lawyers
National Association of Social Workers
National Harm Reduction Coalition
National Health Care for the Homeless Council
National Homelessness Law Center
New York State Harm Reduction Association (NYSHRA) (NY)
NEXT Distro
PA Harm Reduction Network (PA)
Prison Policy Initiative
Queer Recovery + Harm Reduction (NY)
R Street Institute
Reframe Health and Justice
Southern Tier AIDS Program (NY)
St. Ann's Corner of Harm Reduction (NY)
StoptheDrugWar.org
Students for Sensible Drug Policy (SSDP)
The Network for Public Health Law
The Courage Center (SC)
The Porchlight Collective SAP (IL)
The Sentencing Project
Transcanwork (CA)
Truth Pharm, Inc.
Underground Recovery Jax (FL)
Vera Institute of Justice
Vilomah Foundation
VOCAL-KY (KY)
VOCAL-NY (NY)
VOCAL-TX (TX)
Washington Office on Latin America
Whose Corner Is It Anyway (MA)
Wren Action Group
Yaya Por Vida (FL)

Young People in Recovery YPR

cc:
Members of the Senate Judiciary Committee
Members of the House Judiciary Committee
Members of the House Energy & Commerce Committee

March 25, 2026

The Honorable Erin Houchin
U.S. House of Representatives
Washington, DC 20515

Dear Representative Houchin:

The undersigned national organizations, representing thousands of physicians, pharmacists, and other healthcare professionals on the frontlines of our country's addiction and overdose crisis, thank you for supporting policies that prevent and treat opioid use disorder (OUD) and promote safer communities. We share these laudable goals with you. **Accordingly, we would welcome the opportunity to collaborate with you on critical revisions to H.R. 5629 that would promote safety, integrated care, affordability, patient choice, and provider diversification.**

H.R. 5629's Reversal of the 2024 HHS Final Rule Would Increase Overdoses and Reduce Access to Evidence-Based OUD Care, Especially in Rural Areas

H.R. 5629 would largely nullify the 2024 Final Rule of the Department of Health and Human Services (HHS), titled *"Medications for the Treatment of Opioid Use Disorder."* If enacted as currently drafted, the bill would result in more opioid overdoses, because fewer people would get methadone treatment for OUD, with no improvement in safety for our communities. It would mean federal methadone policy taking a giant leap backwards at the very moment when **American families *need more, not less*, access to evidence based- addiction treatments.** At the same time, several studies evaluating the 2024 HHS Final Rule's key flexibilities – some originally introduced during the first Trump Administration - have found no evidence that they increased methadone-involved overdose mortality at a population level.[1,2,3,4]

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[1] Harris RA. Methadone Take-Home Policies and Associated Mortality: Permitting versus Non-Permitting States. *Substance Use: Research and Treatment*. 2024;18. doi:https://doi.org/10.1177/29768357241272379

[2] Harris RA, Long JA, Bao Y, Kranzler HR, Perrone J, Mandell DS. Methadone-involved overdose deaths in urban and rural communities before and after the public health emergency flexibilities for methadone take-home doses. Drug Alcohol Depend Rep. 2025 Apr 24;15:100339. doi: 10.1016/j.dadr.2025.100339. PMID: 40458079; PMCID: PMC12127620.

[3] Jones CM, Compton WM, Han B, Baldwin G, Volkow ND. Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs. JAMA Psychiatry. 2022 Sep 1;79(9):932-934. doi: 10.1001/jamapsychiatry.2022.1776. PMID: 35830198; PMCID: PMC9280608.

[4] Roy V, Buonora MJ, Murray-Krezan C, Fabio A, Joudrey PJ. U.S. states opting out of expanded methadone take-home policies and associated mortality. J Subst Use Addict Treat. 2025 Dec;179:209800. doi: 10.1016/j.josat.2025.209800. Epub 2025 Sep 6. PMID: 40921251; PMCID: PMC12861035.

Additionally, the **2024 HHS Final Rule provides a key regulatory foundation for the White House's Great American Recovery Initiative[5] and Rural Health Transformation Program**.[6] The rule's telehealth and care delivery- flexibilities help address geographic gaps in OUD treatment and support patient-centered care. **Congress *should preserve, not reverse* these flexibilities** if it wants a more effective provider landscape, especially in rural America.

It's also important to understand the historical context in which H.R. 5629 sits. Methadone treatment for OUD represents a unique exception in American medicine. More than half a century ago, Congress directed the HHS Secretary to regulate the practice of medicine involving methadone for OUD,[7] a function traditionally left to the States. Until the introduction of H.R. 5629, Congress recognized that it lacked the medical expertise necessary to directly regulate the practice of medicine involving methadone treatment. If H.R. 5629 were enacted as-is, then federal lawmakers would be dictating medical practice by reinstating an outdated federal rule that improperly restricts the use of professional clinical judgment, including with respect to methadone's use and dosing. **We stand ready to work with you to revise H.R. 5629 so that it fulfills an appropriate and lifesaving purpose: empowering States to serve their unique populations with safe and effective treatment models that include methadone as one evidence-based option for OUD treatment, as more fully described below.**

Indiana Has Been a Congressional Leader in Promoting Integrated Models of Care that Can Offer Methadone for OUD and Competition

When Indiana Governor Mike Braun served in the U.S. Senate, he helped lead S. 644 - the *Modernizing Opioid Treatment Access Act (MOTAA)*.[8] **MOTAA was bipartisan legislation that passed the Senate HELP Committee in December 2023 and was endorsed by more than 100 organizations, including the Indiana State Medical Association and the Kentucky Medical Association.[9]** It was designed to enable access to methadone treatment for OUD in a way that keeps communities safe: through the expertise and guidance of addiction specialist physicians and community pharmacists. **By aligning H.R. 5629 with MOTAA's principles *and* revising it to permit *supervised* dosing options at those pharmacies, we can usher in modern, more accessible, more patient-centered approaches to accessing methadone for OUD in Indiana and across America.**

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[5] Addressing Addiction through the Great American Recovery Initiative. The White House. Published January 29, 2026. https://www.whitehouse.gov/presidential-actions/2026/01/addressing-addiction-through-the-great-american-recovery-initiative/

[6] Rural Health Transformation (RHT) Program | CMS. Cms.gov. Published 2025. https://www.cms.gov/priorities/rural-health-transformation-rht-program/overview

[7] 21 U.S.C. § 823(h)

[8] Text - S.644 - 118th Congress (2023-2024): Modernizing Opioid Treatment Access Act. Congress.gov. Published 2023. https://www.congress.gov/bill/118th-congress/senate-bill/644/text

[9] MOTAA Endorsement Letter, dated May 16, 2023. https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/letters-and-comments/motaa/08.13.24_motaa-stakeholder-endorsement.pdf?sfvrsn=f66eb4b6_1

Federal Barriers Are Stifling Legitimate Medical Access to Methadone for OUD

Such revisions to H.R. 5629 are critical. Unnecessary federal barriers continue to stifle medical treatment for OUD with methadone in the United States. As described in the American Society of Addiction Medicine (ASAM)'s 2025 public policy statement on methadone:[10]

- Methadone is a lifesaving treatment for OUD, **decreasing the risk of all-cause mortality and opioid-related overdose by 50% among people with OUD**.[11]

- People who use high potency synthetic opioids, like fentanyl, its analogues, the nitazenes, and orphines, **may be retained in treatment longer with methadone treatment**, as compared to other FDA-approved medications for OUD.[12]

- One census documented fewer than **500,000** Americans receiving methadone treatment for OUD in 2021,[13] despite **7.6 million** people in the U.S. estimated to have OUD in 2019.[14]

- An insufficient number of federally certified opioid treatment programs (OTPs) nationally contributes to long travel times for many patients;[15] **patients are 29% more likely to miss a dose if they live more than 10 miles from the nearest OTP, as compared to within 5 miles from the OTP.**[16] In-person dosing visits at OTPs can be particularly inconvenient for patients with childcare or employment responsibilities.[17]

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[10] Reducing Federal Bureaucratic Barriers to Methadone for Opioid Use Disorder and Empowering State Innovation. Default. Published July 22, 2025. https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2025/07/22/reducing-federal-bureaucratic-barriers-to-methadone-for-opioid-use-disorder-and-empowering-state-innovation

[11] Santo T, Jr., Clark B, Hickman M, et al. Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-analysis. *JAMA Psychiatry*. 2021;78(9):979-993. doi:10.1001/jamapsychiatry.2021.0976

[12] Nosyk B, Min JE, Homayra F, et al. Buprenorphine/Naloxone vs Methadone for the Treatment of Opioid Use Disorder. *JAMA*. 2024;332(21):1822-1831. doi:10.1001/jama.2024.16954

[13] National Association of State Alcohol and Drug Abuse Directors. *Technical Brief: Census of Opioid Treatment Programs*. 2022. Accessed March 28, 2025. https://nasadad.org/wp-content/uploads/2022/12/OTP-Patient-Census-Technical-Brief-Final-for-Release.pdf

[14] Krawczyk N, Rivera BD, Jent V, Keyes KM, Jones CM, Cerdá M. Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019". *Int J Drug Policy*. Jul 19 2022:103786. doi:10.1016/j.drugpo.2022.103786

[15] Amiri S, Hirchak K, McDonell MG, Denney JT, Buchwald D, Amram O. Access to medication-assisted treatment in the United States: Comparison of travel time to opioid treatment programs and office-based buprenorphine treatment. *Drug Alcohol Depend*. Jul 1 2021;224:108727. doi:10.1016/j.drugalcdep.2021.108727

[16] Amiri S, Lutz R, Socías ME, McDonell MG, Roll JM, Amram O. Increased distance was associated with lower daily attendance to an opioid treatment program in Spokane County Washington. *J Subst Abuse Treat*. Oct 2018;93:26-30. doi:10.1016/j.jsat.2018.07.006

[17] Hutchison M, Russell BS, Leander A, et al. Trends and Barriers of Medication Treatment for Opioid Use Disorders: A Systematic Review and Meta-Analysis. *Journal of Drug Issues*. 2023;55(2):193-214. doi:10.1177/00220426231204841

- **Waiting in line for methadone at OTPs can increase a patient's risk for returning substance use disorder symptoms** when they see peers with whom they previously used substances.[18]
- **Approximately 80% of counties** have no OTP, and half of those counties without an OTP are rural.[19]
- Methadone has been inappropriately singled out as **the *only* medication in U.S. healthcare governed by detailed federal regulations governing the practice of medicine**.

A Revised H.R. 5629 Can End Silos of Care, Promote Affordability, Patient Choice, and Provider Diversification, and Undercut International Drug Cartels

Allowing safe access to methadone treatment for OUD in non-OTP medical settings and modernizing oversight through States can (1) increase integrated models of care and patient choice, (2) strengthen rural providers and pharmacies,[20] (3) enhance patient safety through prescription drug monitoring systems,[21] and (4) reduce reliance on an increasingly consolidated OTP-only system[22,23] that hinders the ability of patients on methadone to move across the full continuum of care.[24] In contrast, continuing to maintain an OTP-only approach needlessly forces too many Americans to travel long distances for a single medication for a single indication[25] – even as they access their other medications at a nearby pharmacy. **When policies make legitimate medical access to methadone treatment for OUD harder, more Americans with OUD who need methadone are pushed right back to a 24/7, on-demand, illicit drug market dominated by ruthless international drug cartels – making none of us safer**.

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[18] Hoffman KA, Foot C, Levander XA, et al. Treatment retention, return to use, and recovery support following COVID-19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis. *J Subst Abuse Treat*. May 8 2022:108801. doi:10.1016/j.jsat.2022.108801

[19] Duff JH, Carter JA. *Location of Medication-Assisted Treatment for Opioid Addiction : In Brief Location of Medication-Assisted Treatment for Opioid Addiction : In Brief*. 2019.

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Collaborative Revisions Are Needed to Make H.R. 5629 Great

The undersigned organizations would welcome the opportunity to collaborate with you on essential revisions to H.R. 5629. Specifically, these revisions could include:

- positioning States, not a federal agency in Washington, DC, as the primary regulators of the practice of medicine involving methadone for OUD dispensed from pharmacies;
- permitting addiction specialist physicians who specially register with the Drug Enforcement Administration to prescribe methadone for OUD that can be dispensed at community pharmacy locations providing *supervised* and safe access options closer to patients' homes;
- incorporating federal safety and diversion-control measures for models of care providing methadone for OUD through pharmacies;
- preserving States' authorities to issue more restrictive regulations than current federal regulations governing OTP take-homes and telehealth flexibilities; and
- encouraging federal activities that increase the participation of primary care physicians, particularly those practicing in rural and other underserved areas, in subspecialty training in addiction medicine – with the goal of expanding integrated care models that combine the onsite delivery of primary care, specialty addiction treatment, and recovery support services across the country.

Conclusion

Indiana has demonstrated national leadership through Governor Braun's work on MOTAA when he served in the U.S. Senate. Your bill now gives the U.S. House of Representatives an opportunity to pick up where he left off. **Together, let's pave more roads to recovery and make the White House's Great American Recovery Initiative truly great.**

Thank you for your consideration. We stand ready to support your office in such a groundbreaking endeavor. **If you wish to discuss further, then please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@ASAM.org.**

Sincerely,

American Society of Addiction Medicine (ASAM)

American Academy of Family Physicians (AAFP)

American Association of Psychiatric Pharmacists (AAPP)

American College of Academic Addiction Medicine (ACAAM)

American College of Emergency Physicians (ACEP)

American Psychological Association Services

American Society of Health-System Pharmacists (ASHP)

Association for Multidisciplinary Education and Research in Substance use and Addiction (AMERSA)

International Nurses Society on Addictions – USA

International Nurses Society on Addictions - Global

cc: Members of the U.S. House Committee on Energy and Commerce

February 13, 2023

Substance Abuse and Mental Health Services Administration (SAMHSA)
Department of Health and Human Services
Attention: SAMHSA – Center for Substance Abuse Treatment
5600 Fishers Lane, Room 13-E-30
Rockville, MD 20857

Re: Comments on Notice of Proposed Rulemaking regarding Medications for the Treatment of Opioid Use Disorder (RIN 0930-AA39)

Dear Assistant Secretary Delphin-Rittmon and Dr. Baillieu:

On behalf of the American Society of Addiction Medicine ("ASAM"), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction and co-occurring conditions, thank you for the opportunity to provide comments on proposed modifications to 42 C.F.R. Part 8 ("Part 8") in SAMHSA's notice of proposed rulemaking (87 Federal Reg. 77330) (the "NPRM"). ASAM advocates to reduce barriers to appropriate access to medications for opioid use disorder (MOUD) and optimize the quality of addiction care, including at opioid treatment programs (OTPs). Treatment with MOUD reduces illegal opioid use, the risk of overdose, symptoms of opioid use disorder (OUD), and risk of transmission of infectious disease. Treatment with MOUD also increases the chances a patient stays in treatment, which itself also reduces the risk of overdose, risk of transmission of infectious disease, and criminal legal involvement, and increases the chances of employment.[1] Therefore, ASAM strongly supports policy changes that facilitate effective treatment with MOUD, through patient-provider relationships that are an integrated core

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component of general healthcare and chronic disease management.[2]

The deadly role of fentanyl driving the rise of and disparities in overdoses and deaths in the United States demands urgency in policy responses, including expanding access to prevention, harm reduction, and addiction treatment services. The federal government's national drug control strategy aims to achieve universal access to MOUD throughout all health settings by 2025, including in federal prisons, and increase access by 50 percent in state prisons and local jails.[3] **Aligned with recent actions taken to achieve these goals, including the removal of the DATA 2000-waiver program in the Consolidated Appropriations Act, 2023 (the "CAA 2023"), ASAM urges SAMHSA to eliminate all references related to the former DATA 2000-waiver program; consider limiting the scope of its final rule to the dispensing of methadone for OUD (i.e., not "MOUD") as controlled medications in schedule III, IV, or V were explicitly carved out of Section 303(h) of the Controlled Substances Act under the CAA 2023; and adjust all cross-references, where appropriate, to account for all federal legislation passed in December 2022, prior to finalizing the rule.**

In this letter, ASAM also offers additional comments to the NPRM for SAMHSA's consideration, as further described below. These additional comments address areas where SAMHSA seeks comment and respond to the NPRM's stated objectives. If adopted, these comments will further encourage an approach to OUD within a chronic disease model of care and better align treatment with methadone for OUD with the practice of medicine by addiction specialist physicians.[4]

Executive Summary of Key Recommendations

With respect to SAMHSA's proposed continuation and enhancement of regulatory flexibilities beyond the COVID-19 public health emergency ("COVID PHE"), ASAM recommends in the first section that SAMHSA finalize proposals to remove time in treatment and abstinence requirements from unsupervised use criteria; allow for clinical consideration of unsupervised use of methadone when a patient enters treatment; allow for patient evaluations with audio-visual or audio-only telehealth for Schedule III addiction medications; and allow for patient evaluations with audio-visual telehealth for Schedule II addiction medications. ASAM further recommends that SAMHSA:

- Clarify that the unsupervised use criteria in § 8.12(i)(2) do not apply to buprenorphine and buprenorphine products;
- Permit patients in methadone treatment from 31 days of treatment to access up to a 30-day supply of methadone for unsupervised use, in lieu of 28 days;
- Modify § 8.12 so that it only applies to "unsupervised use" and "supply/doses of methadone for unsupervised use," considering the existence of technologies that allow for remote, supervised dosing; and
- Strike the proposal that would allow for audio-only devices for patient evaluations for treatment with Schedule II medications.

To expand access to and improve the quality of OTP treatment, in section three, ASAM recommends that SAMHSA finalize the proposals that provide that patient refusal of counseling shall not preclude them from receiving MOUD; allow for split dosing of methadone for pregnant patients; eliminate the one-year history of addiction prior to OTP admission; and allow for clinical consideration in initial dosing adjustments of methadone. ASAM additionally recommends that SAMHSA:

- Require initial physical health assessments to include universal or opt-out screening for hepatitis C virus;
- Clarify that additional laboratory testing and an administrative exception are not needed if the OTP practitioner has judged split dosing is clinically appropriate;
- Ensure that patients be informed that they have the right to refuse pregnancy testing and that the exercise of such right will not jeopardize their receipt of specialized services;
- Modify § 8.12(h)(3)(i) to ensure more availability of methadone formulation innovations (e.g., diskettes and tablets);
- Require OTPs to conduct patient surveys to assess patients' experiences; and
- Adjust the interim treatment period from 180 to 360 days and expand its use beyond public or nonprofit, private OTPs.

In section four, ASAM offers that the NPRM, as proposed, fails to provide access to MOUD for all individuals in confined settings who have a right to medically necessary care. Therefore, ASAM recommends that SAMHSA finalize the definition of long-term care facilities, with modifications to include local jails, and state and federal prisons, and further modify the proposals to expand the reach of these facilities. ASAM further recommends that SAMHSA finalize proposals to allow non-OTP practitioners and certain, other providers to provide various services, including allowing non-OTP practitioners to conduct the required initial medical examination of a patient.

To promote patient-practitioner relationships in an integrated system of collaborative care, ASAM recommends in section five that SAMHSA finalize the proposals to expand the definition of qualifying OTP practitioners, with modifications to account for the enactment of the CAA 2023. Importantly, ASAM strongly recommends that SAMHSA require OTP medical directors to have a minimum amount of experience in addiction treatment to ensure benefits and minimize harms to patients at OTPs. Further, ASAM recommends that SAMHSA:

- Clarify that a program remains eligible for OTP certification if it dispenses methadone in the treatment of OUD using **practitioners for prescribing, and appropriately licensed community pharmacists for administering or dispensing directly (but not prescribing), methadone from the stock of one or more community pharmacies that (i) will comply with standards established by the Attorney General respecting security of methadone stock and the maintenance of records on methadone and/or (ii) will obtain any necessary exceptions from the Attorney General.**

I. Continuing and Enhancing Regulatory Flexibility Beyond the COVID-19 PHE for Unsupervised Use of MOUD and Telehealth

Criteria for Unsupervised Use of MOUD (§ 8.12(i))

The NPRM recognizes that SAMHSA's regulations for OTPs have remained unchanged for over twenty years and that the COVID PHE has provided a growing body of research that demonstrates that certain regulatory flexibilities have facilitated greater access to methadone treatment for OUD. Part 8's current regulatory restrictions on unsupervised use of MOUD are a structural barrier to care as they require some patients to visit OTPs daily or nearly daily, disrupt employment[5] and other daily activities, and disproportionately impact individuals without access to transportation or with childcare responsibilities.

The NPRM notes that the flexibilities left patients feeling more respected as responsible individuals and references reports that there was no significant change in rates of diversion. In addition, the NPRM references a study showing increases in methadone-involved deaths during the COVID-19 pandemic were largely attributable to the increase in fentanyl-driven deaths.[6] **ASAM applauds the proposed revisions to the extent they remove from the unsupervised use criteria the required consideration of the length of time an individual has been in treatment, as well as absence of substance use, demonstrated by toxicology tests.[7] Similarly, ASAM supports SAMHSA's proposed revisions that would allow for unsupervised use of methadone when a patient enters treatment, based on the clinical judgment of the treating practitioner, and the requirement that patients be educated on safe transport and storage of medication.**

However, state regulators may easily misconstrue SAMHSA's proposed language to foreclose the clinical judgment of addiction specialist physicians and other practitioners well-trained in addiction medicine to calibrate when unsupervised use of buprenorphine should continue. Most buprenorphine is prescribed in office-based settings to patients who fill prescriptions at regular pharmacies in the U.S.,[8] and concerns over increased access to buprenorphine have been found to be largely unfounded.[9] Further, as noted above, the CAA 2023 has eliminated the x-waiver program and associated patient limits. **To align buprenorphine treatment in OTPs with buprenorphine treatment in other medical settings, ASAM recommends that the final rule make it clear that the unsupervised use criteria in § 8.12(i)(2) do not apply to buprenorphine and buprenorphine products; such clarification would be consistent with the existing exemption of buprenorphine and buprenorphine products from the dispensing restrictions in §8.12(i)(3)(i) through (iii).**

Schedule for Unsupervised Use of Methadone (§ 8.12(i)(3)(i) – (iii))

SAMHSA seeks comment on the proposed schedule for unsupervised use doses of methadone, which is, during the first 14 days of treatment, 7 days; from 31 days of treatment, 14 days, and from 31 days of treatment, 28 days, if clinical rationale is documented and consistent with good faith efforts to ensure patients are not receiving services at another OTP. ASAM submits that most states permit appropriately licensed practitioners to prescribe, dispense, and administer 30

days of Schedule II-controlled medications.[10] Thus, a reasonably foreseeable alternative[11] to the NPRM to improve patient engagement and retention in evidence-based treatment services would give patients of an OTP the opportunity to receive a supply of methadone for unsupervised use more like patients taking Schedule II medications do in other medical settings. **To that end, ASAM recommends that the final rule permit patients in methadone treatment from 31 days of treatment to access up to a 30-day supply of methadone for unsupervised use, in lieu of 28 days.** This recommended change would better align methadone treatment for OUD with the use of other prescription medications in a chronic disease model of care.

In addition, today, there are newer technologies that would allow for "take home" supply/use that is supervised. In other words, the terms "take home" and "unsupervised" are not necessarily synonymous. Furthermore, "unsupervised use" is the terminology used in applicable statute (21 U.S.C. 823(h)). SAMHSA, however, inconsistently uses the modifiers "take home" and "unsupervised" to describe the terms "use," "doses," and "supply," throughout the proposed §8.12. **Therefore, ASAM strongly recommends that SAMHSA explicitly acknowledge the existence of such technologies in the final rule; take their potential use into account when finalizing the final rule's language, and make global changes so that § 8.12 only applies to "unsupervised use" and "supply/doses of methadone for unsupervised use."**

Telehealth for Initiating Methadone and Buprenorphine Treatment (§ 8.2 (Definition of "Telehealth or telemedicine), § 8.12(f)(2)(B)(v))

The NPRM reviews evidence that telehealth is an important tool to integrate care, extends the reach of specialty providers, and results in patients receiving buprenorphine having a high level of satisfaction with telehealth services. ASAM concurs with SAMHSA that the evidence underlying the initiation of buprenorphine using telehealth translates, to some degree, to the treatment of OUD with methadone. Accordingly, ASAM largely supports permitting the use of telehealth to conduct the required two-part initial examination of a patient, including the screening and full examination, with appropriate guardrails as outlined in the proposal, and the inclusion of the proposed definition of telehealth in the NPRM.

Specifically, ASAM applauds SAMHSA's proposal to the extent it allows for audio-visual telehealth in evaluating patients for treatment with Schedule II addiction medications like methadone. However, ASAM does not support the proposal to the extent it would allow for audio-only devices for evaluating patients for treatment with Schedule II medications, even if the patient is in the presence of certain licensed practitioners, especially considering those practitioners can obtain access to audio-visual technologies.[12] If SAMHSA finalizes its audio-only proposal with respect to Schedule II medications, then, at a minimum, ASAM recommends that SAMHSA clarify what is exactly meant by "in the presence of a licensed practitioner who can *prescribe (including dispense) (emphasis added)* controlled medications," in § 8.12(f)(2)(B)(v)(A). For example, under the Controlled Substances Act, the term "dispensing" includes "prescribing." These terms can also mean different things under State law. **ASAM does support audio-only telehealth for patient evaluations for Schedule III addiction medications like buprenorphine.**[13]

II. Updating Certification and Expanding Medication Units (§ 8.2 (Definition of Conditional certification and Medication unit), § 8.11(a)(3)-(6), § 8.11(h)(2))

ASAM supports the proposed changes facilitating information sharing and updating the OTP certification process to reflect better practice, including the new proposed category creating a one-year temporary, conditional certification for an OTP that has sought certification renewal and received a temporary one-year accreditation, to address areas of non-conformance that are not immediate, high-risk health and/or safety concerns. As proposed, an OTP with such certification must obtain a standard three-year accreditation within one year. **ASAM also applauds the proposal to add one licensed physician with "experience treating OUD with MOUD," which would be added to accreditation body applicant's staff.**

ASAM notes that the proposed rule defines "Medication units" as "an entity that is established as part of, but geographically separate from, an OTP from which appropriate, licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit." **ASAM applauds that proposed definition, as well as the proposal to add that medication units can offer "any services that are provided in an OTP,"** "assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space."

III. Expanding Access to and Improving the Quality of OTP Services

Integrating Harm Reduction and Recovery Support Services (§ 8.2 (Definition of Harm reduction, Recovery support services), § 8.12(f)(4)(i), § 8.12(f)(5)(i))

The NPRM recognizes that definitions and paradigms of care for OUD have evolved over the past twenty years to become more multimodal and patient-centered, and successful treatment interventions are individualized and incorporate harm reduction and recovery support services. Accordingly, ASAM supports SAMHSA's proposed definitions and integration of harm reduction and recovery support services into the proposed rule, including the incorporation of such services into the required patient care plan, counseling and psychoeducational services of OTPs, and in the definition of "comprehensive treatment." **ASAM specifically applauds the proposed provision that provides that "Patient refusal of counseling shall not preclude them from receiving MOUD,"** as requiring that these services be accepted by all patients, especially early in care, can present a barrier to accessing OTP services for some patients.[14]

ASAM recommends that the definition of harm reduction be modified to reflect that the proposed regulatory definition specifies types of harm reduction interventions, rather than reflecting the philosophy of harm reduction. Thus, in § 8.2, the definition would be modified as follows, **"Harm reduction services include, but are not limited to,** practical, evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted

infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services."

The NPRM also provides that OTPs must provide specific counseling on HIV, hepatitis C virus (HCV), and other sexually transmitted infections (STIs), and linkage to treatment, for patients with positive OTP test results. A patient's admission to an OTP is an opportunity to maximize the benefit to public health, and incidence and prevalence of HCV infection have increased significantly because of increasing rates of injection drug use.[15] Universal or opt-out screening policies that test everyone allow individuals to choose whether to participate rather than self-disclose as a member of a risk-based group, and have been shown to result in earlier detection, reduced stigma, and increase the number of screened individuals.[16] **Accordingly, ASAM requests that SAMHSA include in OTP's initial physical health assessment required services,** "Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, **and universal or opt-out screening for hepatitis C virus (HCV)**," in § 8.12(f)(4)(i).

Including Housing, Shared Decision Making, and Split Dosing in OTP's Required Services (§ 8.2 (Definition of Split dosing), § 8.12(f)(3), § 8.12(f)(4))

ASAM's public policy statement on advancing racial justice in health care through addiction medicine recommends "healthcare settings should consider and address the social determinants of health—including housing, education, transportation, employment, and racism itself."[17] Accordingly, ASAM applauds SAMHSA's proposal to include "housing" as a key area to be addressed as part of treatment by OTP medical practitioners and the OTP multi-disciplinary team, as well as the proposal to include "shared decision making" in patient care plans, to improve care.

ASAM applauds the NPRM's proposals that provide a definition and the opportunity for split dosing of methadone for pregnant patients;[18] however, ASAM recommends that SAMHSA clarify that additional laboratory testing demonstrating a patient is a "rapid metabolizer" and the submission of administrative exception documentation are not required for the provision of split dosing to a patient. ASAM also applauds the proposal to require OTPs to provide reproductive health services for pregnant and postpartum patients.[19] It is important to recognize, however, that that the decision in *Dobbs v. Jackson Women's Health Organization* to overturn *Roe v. Wade* bears a disproportionate impact on pregnant people who use substances and that requiring documentation of pregnancy confirmation in one's medical record could cause fear among certain patients. **Therefore, ASAM recommends that SAMHSA make it clear in the final rule that patients be informed that they have the right to refuse pregnancy testing and that the exercise of such right will not jeopardize their receipt of specialized services.**

Revising Patient Admission Criteria and Individualizing Initial Dosing (§ 8.12(e)(4), § 8.12(f)(1), § 8.12(g)(1), and § 8.12(h)(3)(i))

The NPRM proposes amending certain elements of current regulations considering quickly changing trends in illegal substance supply and use, including the proliferation of fentanyl, methamphetamine, xylazine, and other substances, which impact treatment. **ASAM applauds the elimination of the one-year requirement for OUD before admission to an OTP when the patient "meets diagnostic criteria for moderate or severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose."** ASAM also supports the proposed rule's elimination of the requirement for two documented unsuccessful attempts at treatment within one year for individuals under 18 to be admitted to an OTP, as well as the requirement for their parents' consent to treatment in the absence of a requirement of state law.

ASAM applauds the proposal allowing for the use of clinical judgment in initial dosing adjustments above 40mg of methadone for patients if such a decision is documented in the patient's record. ASAM recommends further modification to accommodate OTPs that already utilize methadone formulated in diskettes or tablets,[20] and to allow for more OTPs to adapt to formulation innovations and for practitioners to individualize medication formulations for patients, by amending language in § 8.12(h)(3)(i) as follows: "Methadone shall be administered or dispensed only in oral form ~~and shall be formulated in such a way as to reduce its potential for parenteral misuse~~." **Further, ASAM recommends that SAMHSA clarify language in §8.12(h)(3)(ii) as follows:** "Should ~~this~~ **the initial 30 mg dose or total daily 40 mg dose be determined** not **to** be sufficient to suppress symptoms of withdrawal~~,~~ **by** the OTP practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, **they** must document in the patient's record a specific rationale indicating ~~that 40 milligrams did not adequately suppress opioid withdrawal symptoms, and~~ that a higher dose was clinically indicated and thus provided to the patient." ASAM also supports the proposed changes that tapering be provided to patients with informed consent and "at a mutually agreed-upon rate that minimizes taper-related risks," in § 8.12(e)(4).

ASAM submits that patient experience surveys[21] can inform policymakers' efforts to help build meaningful patient-provider relationships, establish effective and constructive communication, and develop care that is grounded in empathy and compassion.[22] **Therefore, ASAM further recommends that OTPs be required to conduct patient surveys to assess patients' experiences**. Furthermore, not all OTPs utilized, and not all states applied for, SAMHSA's blanket exemptions during the COVID-19 pandemic to provide methadone for unsupervised use and ease patients' access to treatment. **Thus, ASAM requests that the finalized rule include the following language**: "The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients, **and the program sponsor must ensure that patients are surveyed annually to assess their experiences with the OTP's required services, and the OTP's provision of methadone for unsupervised use**," in § 8.12(f)(1), and "OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care **and survey and evaluate patient experiences with the OTP's required services, and the OTP's provision of methadone for unsupervised use**," with the parallel reporting and confidentiality requirements, in § 8.12(g)(1). SAMHSA should ensure appropriate funding for, and develop a methodology and framework for, the OTP patient experience surveys and draw on the expertise

of the Centers for Medicare and Medicaid Services' (CMS) Outpatient and Ambulatory Survey (OAS) Consumer Assessment of Healthcare Providers and Systems (CAHPS) family of surveys for such development.[23]

Optimizing Interim Treatment with Methadone (§ 8.2 (Definition of Interim treatment), § 8.11(f)(1), § 8.11(f)(2)(iv), § 8.12(j)(1), § 8.12(j)(4))

Interim treatment with methadone has been found in randomized controlled trials to reduce illegal opioid use, criminal activity, and arrests, as well as increase engagement in comprehensive services, compared to wait list control groups,[24] yet interim treatment is still relatively uncommon in clinical practice.[25] **ASAM applauds the proposals to update the definition of interim treatment, remove the prohibition on unsupervised use for patients in interim treatment, and permit interim treatment for patients "if comprehensive services are not readily available," rather than "cannot be placed in a public or nonprofit private program."** ASAM further supports the newly proposed requirements for OTP practitioners treating patients in interim treatment with respect to patient transfers, documented plans for patient's treatment continuation, and the provision of crisis and ancillary services.

SAMHSA's specific request for comment on its proposed revision of the interim treatment period from 120 to 180 days indicates that the agency is contemplating a change to this period.[26] The NPRM's stated objective is to accommodate OTPs and states in addressing addiction care workforce shortages that are not easily resolved in 120 days and add an opportunity to the care continuum. The NPRM offers a one-year period for conditional certification and temporary accreditation for OTPs, to provide them an opportunity to resolve low-risk non-conformance issues. ASAM submits that addiction care workforce shortages are neither easily resolved, nor are OTPs opened, accredited, or certified, in 180 days. In fact, OTPs have expanded much more slowly than the growth of the prevalence of OUD and most U.S. counties have no OTPs.[27]

Reasonably foreseeable alternatives[28] to the NPRM would further extend the interim treatment period to align it with the conditional certification and temporary accreditation period for OTPs, and not continue to limit interim treatment to public or non-profit, private OTPs. **As such, ASAM recommends that SAMHSA adjust the interim treatment period from 180 to 360 days, to maximize the net public health and safety benefit of the final rule**, in § 8.2, § 8.11(f)(2)(iv), § 8.12(j)(1), and § 8.12(j)(4), respectively. **In addition, ASAM recommends SAMHSA remove the phrase "public or nonprofit, private"** from § 8.11(f)(1) and § 8.12(j)(1). Further, ASAM recommends to avoid redundancy, that SAMHSA remove the following language from § 8.12(j)(1), "Interim treatment shall be provided in a manner consistent with all applicable Federal and State laws~~, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11)~~.

IV. Increasing Access to MOUD for Individuals in Confined Settings Who Have a Right to Medically Necessary Care (§ 8.2 (Definition of Long-term care facility); § 8.11(h)(3))

There is a growing recognition that the OTP certification process is a regulatory barrier for some institutions to implement methadone treatment for OUD for individuals who reside in confined settings and must be on premises to receive medically necessary care. The NPRM further acknowledges the heightened costs of overdoses and deaths in the absence of treatment with MOUD, which, if criminal legal costs are included, rise to savings of $25,000 to $105,000 in lifetime costs per person, compared with no treatment.[29]

The nearly two million individuals who are incarcerated in the U.S. have high rates of chronic diseases, including substance use disorder (SUD), yet only an estimated 12 percent of jails and prisons offer treatment with any MOUD.[30] Plaintiffs who are incarcerated have been granted injunctive relief by federal courts from inflexible policies that deny them access to medically necessary treatment, including methadone and buprenorphine for OUD, given likely violations of the Americans with Disabilities Act (ADA) and/or the Eighth Amendment to the U.S. Constitution's prohibition of cruel and unusual punishment,[31] yet a lack of access to methadone and buprenorphine treatment for OUD continues to be a challenge in many jails and prisons.[32]

Large numbers of disproportionately racially and ethnically marginalized individuals confined in jails and prisons are at high risk for overdose and death and have the right to medically necessary care.[33] The risk for overdose and death is particularly high for individuals when returning from incarceration,[34] and, in jails, is likely shortly after incarceration begins.[35] Alongside the federal government's goal to expand access to treatment with MOUD in jails and prisons, the Drug Enforcement Administration (DEA) has made recent regulatory changes that aim to expand MOUD in jails and prisons, through OTP mobile medication units,[36] but the expansion of said treatment is especially slow with methadone—in part due to SAMHSA's regulations. Further, jails and prisons frequently have substantial experience handling and preventing the diversion of controlled medications,[37] and salient to their budgets is that methadone is more cost effective as a generic medication than buprenorphine.

The NPRM proposes to define long-term care facilities by listing a range of facility types that can forgo the OTP certification requirement to provide treatment with MOUD for a patient who requires it and is admitted for a primary medical condition other than OUD. The NPRM fails to list local jails and state and federal prisons or specifically seek comment on the inclusion of certain institutions in the proposed definition of "long-term care facilities" that provide "rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living." **Thus, to correct this procedural harmless error,[38] ASAM recommends that SAMHSA finalize that definition in § 8.2 as follows, "those facilities that provide rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include: extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; ~~and~~ chronic care hospitals, local jails, and state and federal prisons."** In addition, the final rule should make it clear

that if such facilities are registered with the DEA as a "hospital/clinic," then they do not need to obtain separate registration under 21 U.S.C. 823(h) to treat OUD with methadone for people admitted to a hospital or long-term care facility (including a jail or prison) for the treatment of medical conditions other than OUD.

Further, the NPRM states that SAMHSA intends to depart from the prescriptive model of care in its current regulations and revise them to align with the chronic disease model of care. However, the proposed rule fails to recognize that a patient with OUD can be admitted to a hospital or long-term care facility (including a jail or prison) for reasons other than the treatment of a medical condition secondary to OUD (e.g., incarceration for an alleged or committed crime). **Therefore, to correct the procedural harmless error,[39] ASAM recommends that the final rule also recognize that a patient with OUD can be admitted to a hospital or long-term care facility (including a jail or prison) for reasons other than the treatment of a medical condition secondary to OUD (e.g., incarceration for an alleged or committed crime) and that the Department of Health and Human Services (HHS) Secretary has the statutory authority to determine if an applicant is qualified to engage in methadone treatment of OUD as the primary medical condition and certify it as an OTP, even if the applicant does not meet all the requirements of § 8.12, subject to applicable DEA regulations regarding the security of such medications and related maintenance of records (or DEA-granted exceptions thereto).**

V. Promoting Patient-Practitioner Relationships in a System of Integrated, Collaborative Care

Ensuring Appropriate Training in Addiction Care at OTPs (§ 8.2 (Definition of Practitioner), § 8.12(b)(2), § 8.12(d))

Laws and regulations for MOUD have dramatically changed in the last twenty years, including the recent enactment of the CAA 2023, which expands the range of practitioners who can dispense (including prescribe) buprenorphine treatment for OUD. **ASAM applauds the NPRM's proposed expansion of the definition of a qualifying OTP practitioner, while recommending, below, codification of additional qualifications for OTP medical directors and reiterating the need to eliminate all references related to the former DATA 2000 waiver program.** ASAM also supports the proposed addition that all OTP healthcare providers maintain licensure and/or certification requirements of their respective professions.

ASAM concurs that it is likely that methadone-involved deaths during the COVID-19 pandemic were largely attributable to the increase in fentanyl-driven deaths.[40] Although ASAM notes (and raises questions[41] about) studies of methadone-involved deaths before and after the COVID-19 pandemic published subsequent to the NPRM, which point to a potential role of regulatory changes in the increase in methadone-involved deaths, ASAM agrees that proposed regulatory changes, as modified herein, should be finalized, albeit with continued monitoring for unintended consequences, in the absence of direct evidence of risk. **A reasonably foreseeable alternative[42] to the NPRM would consider sufficient training needed to oversee the provision of addiction care if a final rule were to expand who qualifies as an OTP practitioner, as proposed. Thus,**

ASAM requests that SAMHSA require such sufficient training in addiction treatment in regulation, rather than in SAMHSA's 2015 Federal Guidelines for Opioid Treatment Programs.[43] **Thus, at a minimum, ASAM recommends that SAMHSA finalize § 8.12(b)(2) to read as follows:** "The medical director shall assume responsibility for administering all medical and behavioral services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations. **The medical director must have completed an accredited residency training program and have at least 1 year of experience in addiction medicine or addiction psychiatry. Board certification in his or her primary medical specialty and in addiction psychiatry or addiction medicine is strongly preferred."**

Integrating Non-OTP Providers to Create Patient-Centered Treatment (§ 8.12(f)((2))

Patients with SUD often encounter a siloed health care system that can impede access to care, requiring efforts to integrate services across the care continuum for effective treatment. As part of past pilot projects, some hospitals have accomplished a patient's OTP admission by having the OTP physician review the patient's physical examination performed by an addiction medicine consult physician seeing the patient in the hospital.[44] Therefore, **ASAM applauds the proposals in this section to allow non-OTP practitioners and other providers, with documented agreements with OTPs, to provide various services, including allowing non-OTP practitioners to conduct the required initial medical examination of a patient**, comprised of two parts: the screening examination and the full history and examination, with the proposed guardrails outlined in the NPRM. Further, ASAM recommends that SAMHSA, to facilitate timely patient transitions between other settings and OTPs, further clarify in § 8.12(f)((2)(B)(ii) that, "Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. **The intent is for patient transitions from other settings to OTPs to be timely and for treatment with MOUD to be continuous**."

Dispensing Methadone at Community Pharmacies (§ 8.11(a)(1) and § 8.12(h)(1))

The NPRM specifies that "OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, or by an agent of such practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law." **As the NPRM explicitly states, "to accommodate variations among states," the NPRM proposes to eliminate the requirement in the current § 8.12(h)(1) that the agent be a "pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs."** ASAM submits that states allow for most controlled medications, including methadone for pain, to be dispensed at pharmacies from pharmacy stock.

To better achieve SAMHSA's objectives to so accommodate states, promote patients' recovery behaviors like sustained employment, and support patients who live long distances from OTPs, **a reasonably foreseeable alternative**[45] **to the NPRM's proposals would be to permit a pharmacist**

to dispense methadone for OUD to patients from community pharmacy stock if certain standards were met.[46] Therefore, ASAM recommends SAMHSA finalize § 8.11 (a)(1) to read as follows, which includes language that would help avoid an overinclusive final rule:[47]

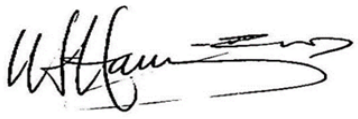
"An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(~~g~~h) of the Controlled Substances Act (21 U.S.C. 823(~~g~~h)) to dispense methadone ~~MOUD~~ in the treatment of OUD, **which, for the avoidance of doubt, may include a program that dispenses methadone in the treatment of OUD using practitioners for prescribing, and appropriately licensed community pharmacists for administering or dispensing directly (but not prescribing), methadone from the stock of one or more community pharmacies that (i) will comply with standards established by the Attorney General respecting security of methadone stock and the maintenance of records on methadone and/or (ii) will obtain any necessary exceptions from the Attorney General.** An OTP must be determined to be qualified under section 303(~~g~~h)~~(1)~~ of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(~~g~~h)~~(1)~~, to be registered by the Attorney General to dispense methadone ~~MOUD~~ to individuals for treatment of OUD."

VI. Global Changes to Language in the Proposed Rule

The NPRM proposes to use language in the final rule that reflects modern medical terminology and person-first language. **ASAM applauds the proposed terminology changes from "medication-assisted treatment" to "medications for opioid use disorder"; from "maintenance" to "continuous medication treatment," and from "detoxification" to "withdrawal management."** However, the NPRM also proposes global changes to language regarding from whom necessary approvals of various items are required. **ASAM strongly recommends that SAMHSA reviews these proposed changes and ensures that the final rule is consistent with references that designate from whom various approvals must be obtained and explains the rationale for such changes**.

In conclusion, ASAM is grateful for SAMHSA's thoughtful NPRM. The NPRM presents an unprecedented vision for expanding access to MOUD and improving the quality of addiction care, especially care that is provided by OTPs. ASAM will continue to advocate for cautious policy changes that facilitate effective treatment with MOUD and reduce structural barriers to care for individuals made vulnerable by inequities created by personal, institutional, and systemic mechanisms. If you have any questions or concerns, then please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@asam.org or at 301-547-4111.

Sincerely,



William F. Haning, III, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine

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[6] Jones, et al., find that methadone-involved overdose deaths remained similar before and after March 2020, and that an increase in methadone-involved overdose deaths in March 2020 was largely attributable to the increase in fentanyl driven deaths, rather than regulatory changes to OTP practices. See Jones, Christopher M., Wilson M. Compton, Beth Han, Grant Baldwin, and Nora D. Volkow. "Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs." JAMA Psychiatry 79, no. 9 (September 1, 2022): 932–34. https://doi.org/10.1001/jamapsychiatry.2022.1776.
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[11] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a final rule was a logical outgrowth where the final rule was within a range of foreseeable alternatives by the public. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.
[12] American Society of Addiction Medicine, (ASAM). "Optimizing Telehealth Access to Addiction Care." October 2, 2022. https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2022/10/12/public-policy-statement-on-optimizing-telehealth-access-to-addiction-care.
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[24] See ASAM, "Regulation of the Treatment of Opioid Use Disorder with Methadone."
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[26] Courts will uphold a final rule if the NPRM expressly asks for comment on a particular issue and the agency modifies its final rule based on comments – this is the simplest expression of the logical outgrowth doctrine. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.
[27] See ASAM, "Regulation of the Treatment of Opioid Use Disorder with Methadone."
[28] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a final rule was a logical outgrowth where the final rule was within a range of foreseeable alternatives by the public. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.
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[37] Rising, Josh, Sara Whaley, and Brendan Saloner. "How the Drug Enforcement Administration Can Improve Access to Methadone in Correctional Facilities and Save Lives," May 31, 2022. https://americanhealth.jhu.edu/sites/default/files/2022-07/JHU-026%20Methadone%20White%20Paper-r2.pdf.
[38] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. In some cases, a court will affirm an agency's final rule, even when the final rule is not a logical outgrowth if the result of the final rule is a harmless error. Harmless error stems from the judicial review

provision in section 706 of the Administrative Procedures Act (5 U.S.C. § 3 706). A party claiming error on the part of an agency must state a prejudicial harm has flown from the error for a harmless error to have occurred. A harmless error is not substantive or does not affect parties' "substantial rights." See Lifton, Henry. (2017). "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92. 2(943). https://scholarship.law.nd.edu/ndlr/vol92/iss2/9. See also: Jurrens, Cannon. (2021). "The Not-so Harmless Error Rule: Applying 706 of the APA in A More Effective Matter." Administrative Law Review Accord. 6:4 (289-314). https://administrativelawreview.org/wp-content/uploads/sites/2/2021/11/Accord_6.4_Jurrens_Final.pdf.

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[41] Two recent studies highlight that there were increases in methadone-involved deaths in 2020 and raise questions about the role of the regulatory changes to OTP practices in the increase in methadone-involved deaths. However, both studies' authors identify significant limitations of their study in demonstrating direct causality. Kleinman, et al., highlights that there were increases in methadone-involved overdose deaths both with and without synthetic opioid co-involvement in the 12-month period after March 2020, compared with prior trends. Another study by Kaufman, et al., also identifies an increase in methadone overdoses in 2020 relative to 2019, while examining the methadone-involved unintentional overdose rate from 1999 to 2020. Kleinman, et al.'s study has several limitations, including that its model may be biased, because the study examines data from a significant time period from before the beginning of the pandemic (January 2007- March 2020), and a small time period from after the beginning of the pandemic (March 2020- March 2021). This is despite the availability of additional provisional overdose death data after March 2021, when methadone-involved deaths stabilized. Kaufman, et al. offer in their study that confounding policy changes could account for the increase in overdoses, including reduced urinalysis and the use of telehealth, or that methadone's long half-life could result in it being increasingly preferentially listed on death certificates, instead of more rapidly eliminated, or more obscure substances. The Kleinman, et al. and Kaufman et al. studies both also generate a statistic from SAMHSA's 2019 and 2020 National Survey on Substance Abuse Treatment Services (N-SSATS) Data on Substance Abuse Treatment Facilities, to indicate that the number of patients receiving methadone in the U.S. was reduced by 24% from 2019 to 2020, from 408,550 to 311,531. However, the N-SSATS surveys gathered data on March 29, 2019, and March 31, 2020, respectively, in other words, the 2020 N-SSATS survey census was taken on one day at the height of the beginning of the pandemic. Furthermore, a census of OTPs conducted by the National Substance Abuse and Drug and Alcohol Dependence (NASADAD) and American Association for the Treatment of Opioid Use Disorder (AATOD) between April and December 2021, found 476,763 patients treated with methadone at OTPs in 2021. See Kleinman, Robert A., and Marcos Sanches. "Methadone-Involved Overdose Deaths in the United States before and during the COVID-19 Pandemic." Drug and Alcohol Dependence 242 (January 1, 2023): 109703. https://doi.org/10.1016/j.drugalcdep.2022.109703. See also Kaufman, Daniel E., Amy L. Kennalley, Kenneth L. McCall, and Brian J. Piper. "Examination of Methadone Involved Overdoses during the COVID-19 Pandemic." Forensic Science International 344 (January 31, 2023): 111579. https://doi.org/10.1016/j.forsciint.2023.111579. See also National Association of State Alcohol and Drug Abuse Directors, and American Association for the Treatment of Opioid Dependence. "TECHNICAL BRIEF: CENSUS OF OPIOID TREATMENT PROGRAMS | NASADAD," December 5, 2022. https://nasadad.org/2022/12/technical-brief-census-of-opioid-treatment-programs/.

[42] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a final rule was a logical outgrowth where the final rule was within a range of foreseeable alternatives by the public. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.

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[44] See ASAM, "Regulation of the Treatment of Opioid Use Disorder with Methadone."

[45] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a final rule was a logical outgrowth where the final rule was within a range of foreseeable alternatives by the public. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.

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[47] The logical outgrowth doctrine in administrative law states that an agency's final rule should be a logical outgrowth of the proposed rule; logical outgrowth is a fact-specific inquiry and judicial interpretation of the proper fit between an agency's proposed and final rules. Courts will find a logical outgrowth failure when the final rule covers a broader scope than originally proposed. See Lifton, Henry. "Defining Fair Notice: Logical Outgrowth Doctrine Applied to the Waters of the United States." Notre Dame Law Review 92, no. 2 (March 1, 2017): 943.

AMERICAN PSYCHIATRIC ASSOCIATION

APA Statement on Passage of the Senate Version of H.R. 1

July 01, 2025

Washington, D.C., — The American Psychiatric Association (APA) is very disappointed by the U.S. Senate's passage of H.R. 1, which would significantly cut Medicaid funding. If the House passes this bill, knowing that Medicaid is the largest payer of mental health and substance use disorder services, it will have irreversible repercussions for patients and their families.

"This is a huge blow for access to health care in America," said APA President Theresa Miskimen Rivera, M.D. "In very real terms, this legislation will result in irreparable gaps in access to care for our country's most vulnerable, many of whom have mental health and substance use disorders, and they will suffer as a result."

"The country is already facing a mental health and substance use disorder crisis. We cannot afford to have patients lose access to vital Medicaid services," said APA CEO and Medical Director Marketa M. Wills, M.D., M.B.A. "We urge the House of Representatives to vote against this legislation. Despite this major setback, APA will continue to work for progress on behalf of psychiatrists and the patients they serve."

American Psychiatric Association

The American Psychiatric Association, founded in 1844, is the oldest medical association in the country. The APA is also the largest psychiatric association in the world with more than 39,200 physician members specializing in the diagnosis, treatment, prevention, and research of mental illnesses. APA's vision is to ensure access to quality psychiatric diagnosis and treatment. For more information, please visit www.psychiatry.org.

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Medical leadership for mind, brain and body.

March 31, 2025

The Honorable John Thune
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
Washington, 20515

The Honorable Mike Crapo
Chairman
Senate Finance Committee
U.S. Senate
Washington, DC 20510

The Honorable Brett Guthrie
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, 20515

Re: Medicaid Expansion: Our Secret Weapon Against the Drug Cartels

Dear Majority Leader Thune, Speaker Johnson, Chairman Crapo and Chairman Guthrie:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 8,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction, **I urge you to keep fighting the drug cartels by protecting Medicaid Expansion for Americans battling addiction - a treatable, chronic medical disease**.

In 2017, President Trump declared the opioid crisis a public health emergency. That public health emergency is still in effect today, having been recently renewed by Health and Human Services (HHS) Secretary Robert F. Kennedy Jr.[1] Eight years later, drug overdose deaths, fueled by illicit, high-potency synthetic drugs like fentanyl, continue to devastate our country. To save lives and create healthier communities, the 119th Congress and the White House have signaled eagerness in crushing the drug cartels and cutting off the flow of highly addictive and deadly illicit fentanyl into America. **Yet simultaneously, there are proposals floating in Congress that would undermine one of our most effective weapons against the drug cartels and the illicit synthetic drugs they traffic – Medicaid Expansion for Americans with substance use disorders (SUD) who earn up to 138% of the federal poverty level.**

Medicaid Expansion is a lifeline for many Americans on their path of recovery and simultaneously undermines the drug cartels' business model by decreasing demand for illicit drugs. It increases the likelihood of beneficiaries entering addiction treatment.[2] **In 2021, nearly one million Medicaid beneficiaries who received treatment for opioid use disorder were eligible for coverage due to Medicaid Expansion.**[3] Among the privately insured, however, patients' out-of-pocket costs can *reduce* addiction treatment initiation, retention, and adherence.[4,5]

Despite the vital role Medicaid Expansion plays in treating addiction and undercutting the influence of drug cartels, it has become a potential target in Congress' quest for cost savings. Specifically, some have portrayed Medicaid Expansion's funding formula as a bastardization of the program's original charge, which has been to serve those with disabilities, low-income children, and other populations in need. **However, ASAM urges you to view this funding formula to help Americans with SUD - who earn up to 138% of the federal poverty level - as a proper and wise use of Medicaid dollars, especially since some states are otherwise unlikely to provide the same Medicaid coverage for able-bodied, working-age adults with SUD.**

For example, according to Paragon Health Institute's own estimates, under its proposals to reduce Medicaid's federal reimbursement, "current non-expansion states would not expand their programs under our proposals" and "about a quarter of people living in current expansion states would live in a state that pulls back its expansion."[6] Yet, reducing federal support for Medicaid for this high-risk population could mean expanding the drug cartels' customer base, more uninsured hospitalizations,[7] weakening the nation, and making the nation less safe – adversely affecting thousands of families and communities,[8] including the original Medicaid population. It could also compromise the effectiveness of, and lead to increased inefficient spending in, our healthcare system.[9,10]

And the drug cartels stand ready to profit.

Work requirements have also been proposed as a cost-cutting measure but making healthcare coverage contingent on work could put Americans suffering from SUD in a horrible catch-22. Employment or community engagement would become prerequisites for Medicaid eligibility for many, but SUD treatment, including long-term remission monitoring, is fundamental to health and to the ability of Americans to maintain a job or to volunteer. **Evidence-based treatment and incentives for more employers to provide health insurance - with SUD and mental health benefits for all their employees - not more bureaucratic hurdles and paperwork,[11,12] are the solution.**

If Congress is serious about fighting the drug cartels, then it must not weaken one of the greatest tools we have to defund them. Any limitations on Medicaid Expansion for Americans with SUD threaten to undo the progress made in the fight against the overdose epidemic. Just weeks ago, the CDC reported an astounding, nearly 24% drop in overdose deaths.[13] If America continues this positive trend, then it would not be unrealistic to think that President Trump could end the opioid public health emergency before his term ends. **Thus, in lieu of attempts to fundamentally alter federal Medicaid financing for this population, impose work requirements on Medicaid beneficiaries with SUD, or reduce current ACA subsidies available to Americans with SUD,**

Congress should take steps to address improper payments and fraud, waste, and abuse found in Medicaid (and Medicare), *as those terms are traditionally understood*,[14] and consider other policies like (1) limiting employers' eligibility for additional tax cuts unless they provide lower-wage employees with health insurance equivalent to Medicaid Expansion benefits and (2) taking additional steps to prevent any manipulation of Medical Loss Ratios (MLR) by Medicaid Managed Care Organizations, including improved oversight of vertically integrated insurers.[15]

In short, please do not grow complacent and start to undermine Medicaid Expansion on the backs of Americans with SUD who earn lower wages. Medicaid Expansion for them is our nation's secret weapon against the drug cartels and for building stronger communities across America.

Thank you for considering our concerns. If you have any questions about this letter or wish to discuss this matter further, then please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@ASAM.org.

Sincerely,

Brian Hurley, MD, MBA, FAPA, DFASAM
President, American Society of Addiction Medicine

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AMA
AMERICAN MEDICAL ASSOCIATION

2025 AMA Report on Substance Use and Treatment: Progress, Policy and Future Directions

24-1474750:450:1/26

Letter from the CEO

Dear Colleagues,

The overdose epidemic touches all of us. If you've cared for patients in pain, supported someone with addiction, or treated those facing mental health challenges, you know this crisis's devastation. While opioid-related deaths dropped from more than 110,000 in 2023 to 75,000 last year, most are still driven by illicitly made fentanyl—and nearly 60 percent involve more than one dangerous substance. The drug supply is more toxic and unpredictable than ever.

We're also seeing harms rise even as more states legalize cannabis. Emergency visits for cannabinoid hyperemesis syndrome have climbed more than 400 percent since 2016, and more than 19 million people met criteria for cannabis use disorder in 2023. The evidence needs to guide us moving forward. Legal doesn't mean harmless or useful, and we can't ignore these trends.

For more than a decade, the AMA Substance Use and Pain Care Task Force has worked to support patients with pain and addiction. We've seen progress: buprenorphine prescriptions—key treatment for opioid use disorder—are up 83 percent, and nearly 2 million naloxone prescriptions are written each year.

But the data show big gaps to close.

> *Pain care:* Opioid prescriptions have dropped from 260.5 million in 2012 to 125.7 million in 2024. Yet patients still struggle to access non-opioid pain care because insurers often don't cover it or make it hard to get.
>
> *Treatment for opioid use disorder:* Buprenorphine and methadone save lives. Still, stigma, regulatory hurdles, and insurance restrictions keep too many people from getting the treatment they need. This year's report takes the deepest look yet at these barriers.
>
> *Naloxone:* Wider access to naloxone continues to save lives. We support OTC availability, emergency department distribution, and strong community programs that get naloxone into the hands of people who can use it.
>
> *Emerging threats:* Polysubstance use is rising, fueled by stimulants, xylazine, kratom, tianeptine, inhalants, and other dangerous combinations. Cannabis use disorder is increasing too, with real mental health and pregnancy-related risks. This report expands significantly on these trends because they demand urgent attention.

The bottom line: this epidemic is evolving faster than our systems are. Small steps aren't enough.

We need physicians, policymakers, payers, and communities working together to remove barriers, expand treatment, and respond quickly to new threats. Every patient deserves care without stigma and without delay.

We know what works. I hope you'll join us.

John Whyte, MD, MPH
CEO and Executive Vice President
American Medical Association

Executive summary

The American Medical Association continues its commitment to addressing the nation's overdose epidemic and improving care for patients with pain and substance use disorders (SUD). Despite progress in reducing opioid prescribing—down **52% since 2012**—patients still face barriers to evidence-based pain care. Despite widespread recognition that medications for opioid use disorder (MOUD) are the gold standard for treatment for opioid use disorder (OUD), health insurance company barriers and other restrictions continue to limit patient access to MOUD. Key challenges for patients with pain and those with OUD or other substance use disorder include restrictive state laws, payer policies, stigma and limited access to non-opioid alternatives.

Key highlights from the 2025 report

- **Pain care: Opioid prescriptions have decreased** from 260.5M in 2012 to 125.7M in 2024, yet access to non-opioid pain care remains inadequate. The AMA advocates for individualized patient care decisions, legislative and other reforms to preserve physician discretion, and increased access to multimodal, multispecialty therapies.
- **OUD treatment: MOUD, including buprenorphine and methadone, saves lives** but remain underutilized due to stigma, regulatory barriers and insurance restrictions. The AMA calls for eliminating prior authorization and expanding methadone access beyond OTP settings.
- **Naloxone: Increased naloxone availability prevents overdose deaths.** The AMA supports OTC access, emergency department distribution and community-based programs to ensure timely administration.
- **Emerging threats: Polysubstance use is rising**—involving stimulants, xylazine, kratom, tianeptine and inhalants. Cannabis use disorder prevalence is growing, with associated mental health and pregnancy risks. The AMA calls for increased surveillance, research and public policies to mitigate further harm.
- **Policy priorities:** Enforce mental health and SUD parity laws, **remove barriers to treatment for pain** and SUDs, and **strengthen overdose prevention efforts** targeting youth and vulnerable populations.

AMA advocacy actions

2025 continued to demonstrate the AMA's and physicians' efforts to improve outcomes and advocate for evidence-based policies to end the nation's overdose and death epidemic. Examples of AMA advocacy included:

- Partnered with key medical societies urging the U.S. Food and Drug Administration to clarify that higher doses of buprenorphine may be appropriate for patients with OUD.
- Joined physician-pharmacy coalition to urge DEA to clarify policies to reduce pharmacy and distributor reluctance in dispensing buprenorphine.
- Supported new state laws in Colorado, Illinois, Virginia and Washington on policy priorities, including pain care, mental health and substance use disorder parity, and access to naloxone.
- Collaborated on the Mental Health Parity Index to monitor insurer compliance.
- Advanced state and national initiatives to improve naloxone access and protect patients with pain.

In 2026, the AMA will continue efforts to build **collaborative efforts among physicians, policymakers, insurers and community organizations** to ensure equitable access to care, reduce stigma and save lives.

Introduction

The American Medical Association presents the 2025 report on the nation's overdose and death epidemic, a report that once again demonstrates how—despite multiple, positive signs of physicians' actions and advocacy—there remains a tremendous amount of work to do to protect patients with pain and increase access to evidence-based care for individuals with a substance use disorder (SUD).

The AMA is pleased that most states saw reductions in drug-related overdose deaths in 2024. It is a sobering fact, however, that there still are approximately 75,000 Americans dying each year—predominantly from potent, illegally made fentanyl (IMF). IMFs, however, are not the only concern.

Tens of thousands of Americans are now dying from causes related to the use of illicit stimulants, in particular, methamphetamine and cocaine. Misuse of other emerging toxic agents including xylazine, hemp-derived intoxicating cannabinoids, kratom, tianeptine and medetomidine add further complications. Often, these substances are used in combination. Individuals are also unknowingly being exposed to these substances through adulterated pills, powders and other forms. Cannabis use remains a high concern with increasing data and research highlighting public health and patient harms.

As in previous reports,[1] this AMA report provides trend data regarding the dispensing of opioid analgesics, buprenorphine and naloxone. These three data trends help provide policymakers with apples-to-apples views of key metrics surrounding the epidemic. For example, while prescriptions of opioid analgesics have decreased by 52% since 2012, policy proposals remain focused on further reductions and restrictions for opioid therapy—even when they harm patients with cancer, sickle cell disease or who are receiving hospice or palliative care.

In addition, while there has generally been a positive increase in policies to remove barriers for medications for opioid use disorder (MOUD), prescriptions for buprenorphine to treat opioid use disorder (OUD) have remained level since 2019. While the available data may not tell the whole story, the AMA continues to advocate to remove all barriers to MOUD. This includes advocating for health insurance companies to finally end all prior authorizations for MOUD, for state departments of insurance to enforce mental health and substance use disorder (SUD) parity laws, and for increasing access to methadone from office-based physician practices.

Our nation is losing tens of thousands of family members, friends and neighbors to unintentional overdose every year—more than 200 lives every day. I urge physicians, policymakers and all others to use this report to identify and commit to taking action in 2026.

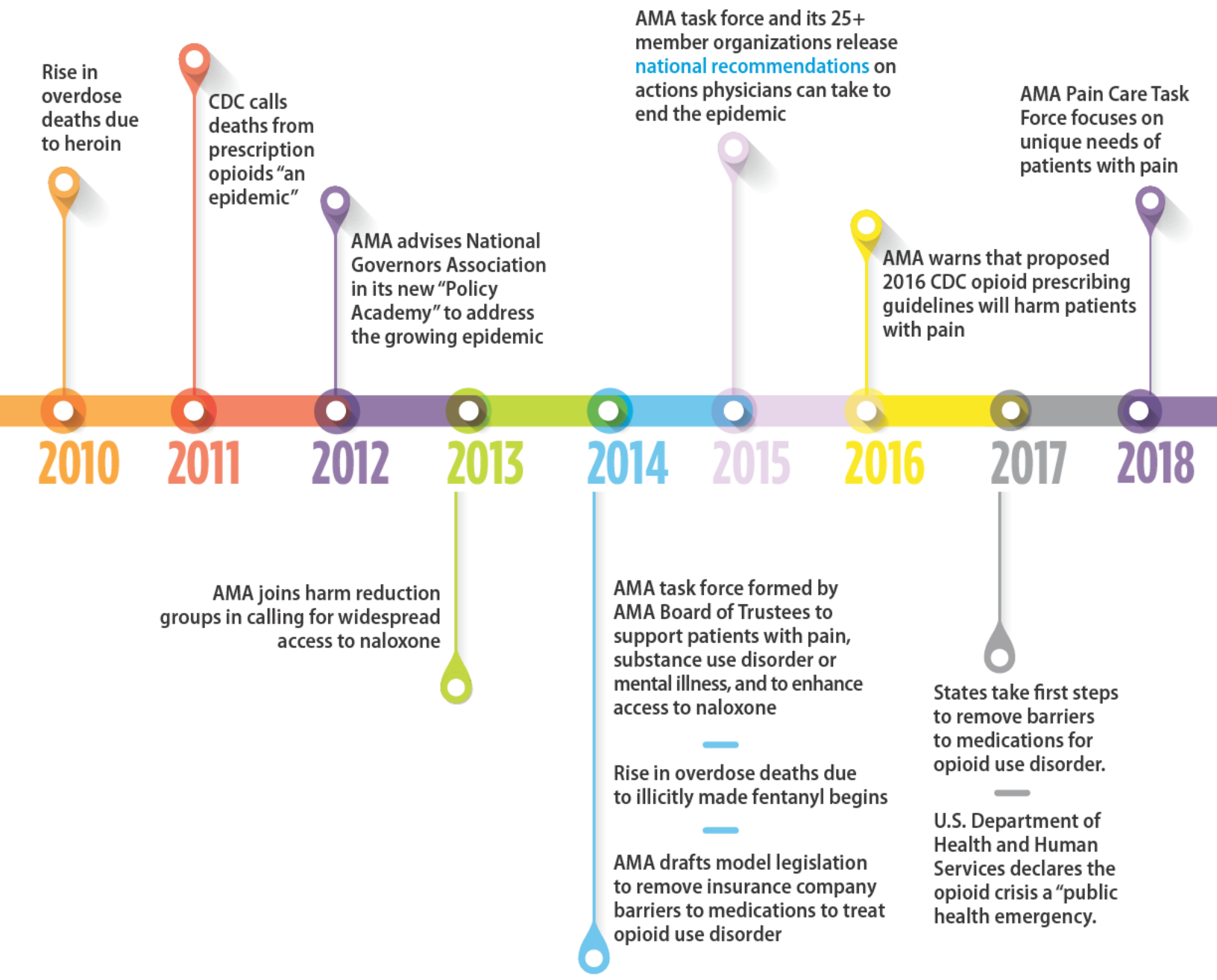
Bobby Mukkamala, MD
President, American Medical Association
Chair, AMA Substance Use and Pain Care Task Force

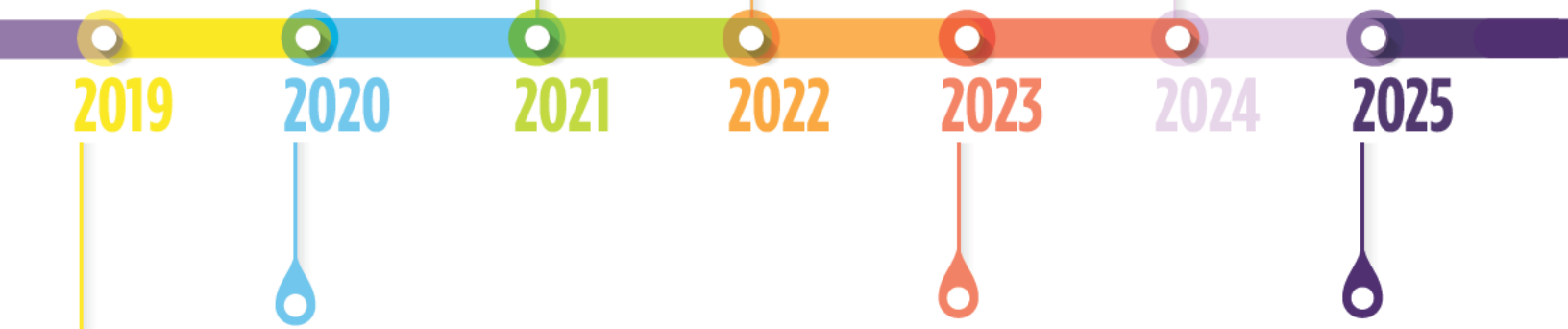
Thankfully, there continues to be broad support for widespread access to naloxone—one of the nation's public health successes to save lives from overdose. Here, too, however, the available data show that there are opportunities to further public policies to ensure naloxone is available at pharmacies, upon discharge from the emergency department, and in public settings as well as colleges, universities and other educational settings.

Finally, this report provides specific policy recommendations and a review of key advocacy issues from the past year. The AMA urges medical societies, policymakers and other key stakeholders to use the data and policy recommendations in this report to support their own advocacy efforts. This report includes examples of regulatory and legislative best practices to increase access to evidence-based treatment for SUD as well as for pain. Using the recommendations and data in this report can directly help improve outcomes and reduce drug-related mortality. To meet those goals, however, we must work together, measure our efforts and rely on the clinical evidence we have at our disposal.

Timeline

The nation's overdose and death epidemic continues to change—requiring continued physician advocacy for evidence-based policies for treatment of pain, substance use disorders and other primary and secondary prevention initiatives. This timeline presents key moments in the policy, clinical and epidemiological history of the epidemic.





2019

AMA Opioid Task Force and member organizations urge policymakers to take action to remove barriers to evidence-based care

Cocaine and methamphetamine kill more people than heroin or Rx opioids

2020

Deaths related to illicitly made fentanyl top 56,000

Evidence-Informed Pain Management: Principles of Pain Care from the AMA Pain Care Task Force released

2021

AMA task force renews call to remove all barriers to care, increase emphasis to reduce inequities due to racial, gender, ethnic and other biases

2022

Overdose deaths top 107,000

US DOL, HHS, IRS report details widespread mental health/substance use disorder parity violations by health insurance companies

CDC proposes to remove numeric thresholds from revised opioid prescribing guideline

2023

Xylazine and Nitazenes emerge as the latest adulterant complicating overdose response efforts

FDA approves over-the-counter naloxone

CDC says inflexible or rigid opioid dosage policies are "misapplication," "inappropriate" and "inconsistent" with its Opioid Prescribing Guideline

Opioid prescriptions decrease for 13th consecutive year

2024

HHS reports that CMS fails to ensure states comply with federal parity laws

Despite OTC status, naloxone availability, particularly in pharmacies, is inadequate

FSMB adopts updated pain-related strategies focused on individualized patient care

SAMHSA issues final rule for Opioid Treatment Programs (OTPs) expanding access to buprenorphine and methadone

2025

U.S. Department of Health and Human Services continues to renew the federal public health emergency for the opioid crisis

AMA recommendations to White House Office of National Drug Control Policy highlight complexity of epidemic [2]

FDA clarifies that buprenorphine doses are not subject to a maximum limit [3]

National snapshot of how the epidemic affects states

Utah counties received millions to battle the opioid epidemic. Many haven't spent a dime
–KUER

Fatal overdoses linked to 'zombie drug' Xylazine in Fargo-Moorhead area
–Valley News

Youth Emergency Visits for Cannabis Vomiting Disorder Spiked in Recent Years — Rates highest in states with recreational cannabis
–MedPage Today

North Dakota Senate tosses out kratom regulations in favor of study
–North Dakota Monitor

Pregnant Women Should Not Use Cannabis, New Medical Guidelines Say
–The New York Times

Free naloxone vending machine installed in Wyoming.
–ABC 13 News

Emergency department treatment with buprenorphine puts people struggling with opioid use disorder on path to long-term recovery
–Globe Newswire

Millions in Iowa's opioid settlement fund sit idle
–The Gazette

Amid opioid crisis, UCLA researchers find 14% more emergency physicians are prescribing buprenorphine than in 2017
–UCLA Magazine

MDHHS study finds harm reduction efforts make significant impacts on overdose deaths, hospitalizations, cases of hepatitis C
–MDHHS

Methamphetamine overtakes fentanyl as leading cause of drug-related deaths in Nevada
–NBC 3 News

Teens work to overcome addiction at one of America's largest recovery high schools
–ABC News

Oklahoma's harm reduction programs have helped hundreds with addiction. They're at risk of ending
–The Oklahoman

In Alaska, where overdose deaths are rising again, Narcan and community are a lifeline
–The Guardian

At least 1 in 6 pregnant Michigan women uses cannabis –MSU Today

Providers: Rollout of $1.5B opioid settlement a 'huge disaster' in Michigan –Bridge Michigan

Milwaukee is losing a generation of Black men to the opioid crisis –PBS Wisconsin

Wisconsin communities expand fentanyl prevention efforts into schools as overdose deaths surge. –News 8 Now

How Chicago succeeded in reducing drug overdose deaths –The Guardian

Indiana teens face higher rates of cocaine, meth, and heroin use, sparking concerns –WBIW

Nearly half of Ohio's opioid settlement money is untraceable, according to new database –WOSU Public Media

'Losing that is terrible.' Federal budget cuts lead to the shutdown of a UMMC opioid addition treatment project. –Starkville Daily News

Florida AG issues emergency rule banning kratom compound –Florida Phoenix

As Fentanyl Deaths Slow, Meth Comes for Maine –The New York Times

New kratom bill is back at R.I. State House. Is it improved? Reviews are mixed. –Rhode Island Current

RI seeing powerful veterinary sedatives in illicit drug supply. –WPRI.com

Kratom regulation bill clears Rhode Island House –Rhode Island Current

Street drugs are being cut with a potent sedative, but criminalizing it may worsen Philly's addiction crisis –Philly Voice

Report finds D.C.'s older Black men are most vulnerable to opioid overdoses –WAMU 88.5 Radio

SC lawmakers championed the passage of their fentanyl bill. Some prosecutors say it's useless –Post and Courier

Care for opioid-addicted mothers and infants is one way SC is spending opioid settlement dollars. –South Carolina Daily Gazette

Florida bill targets growing 'tranq' drug crisis with tougher penalties as its use surges –USA Today

Promoting optimal pain care

Patients with pain deserve the same level of care and compassion as patients with any other symptom(s) or medical condition. AMA advocacy in support of patients with pain is focused on ensuring individuals with pain have access to comprehensive, multi-disciplinary, multi-modal evidence-based treatment. The AMA places particular emphasis on supporting individualized patient care decisions as well as policies that do not arbitrarily restrict patients' access to care. This includes support for both pharmacologic and nonpharmacologic options that are based on the physician's best medical judgment and individualized patient characteristics.

51.7% ↓

decrease in opioid prescriptions
from 260.5M in 2012 to 125.7M in 2024

Prescriptions for opioid analgesics have decreased every year since 2012—from 260.5 million to 125.7 million in 2024. Total dosage strength, measured in morphine milligram equivalents, decreased by 65% from 2012 to 2024.

More work needs to be done to ensure patients with pain receive timely, affordable, high-quality care recommended by their physician. If opioid therapy is indicated, the AMA continues to recommend that physicians "start low and go slow"—continually ensuring that care management is based on ensuring the benefits outweigh the risks.

The AMA points out, however, that the combination of state laws restricting access to opioid analgesics, reduced opioid production quotas from the U.S. Drug Enforcement Administration, restrictive payer and pharmacy policies, and ongoing stigma of opioid therapy continues to negatively affect patients with pain, including those with cancer.[4] **The AMA also continues to observe that patients' access to nonopioid pain care options remains challenging due to high cost, limited insurance coverage and the need to balance access with daily activities such as child care, employment and related social determinants of health.**

Here are three key steps to help patients with pain:

- **Legislative advocacy** – Enact legislation based on updated U.S. Centers for Disease Control and Prevention (CDC) recommendations or Minnesota and Illinois statutes that preserve physician discretion rather than strict adherence to pre-determined morphine milligram equivalency dose or quantity limits.[5]
- **Regulatory advocacy** – Adopt the April 2024 Federation of State Medical Boards "Strategies for Prescribing Opioids for the Management of Pain."[6] The Federation of State Medical Boards (FSMB) strategies provide clear guidance to boards and physicians about the need for individualized patient care decisions while highlighting the importance of patient-physician shared decision-making when considering whether to initiate opioid medication, taper medication, or take measures to discontinue medication. The FSMB strategies also emphasize that evaluating the "success" of a treatment plan is multifaceted and could include functional improvement, improvement in quality of life, as well as reductions in a patient's pain.
- **Education** – Medical students, residents and practicing physicians can help ensure they have the latest clinical and research guidance regarding pain management, safe opioid prescribing and a broad array of pain medicine topics.[7] Education ranges from journal articles *JAMA*®, the JAMA Network™, materials developed by multiple specialties, information from the Providers Clinical Support System and educational modules developed by the AMA on the AMA Ed Hub™.

AMA advocacy efforts support updated FDA opioid label[8]

"The FDA's requirement on opioid labels appropriately focuses on physicians making individualized, informed decisions about opioid prescribing while supporting informed decision-making for patients. The new FDA label continues the approach laid out by CDC in its 2022 opioid prescribing guideline emphasizing the importance of individualized, shared decision-making between the patient and physician."

Bobby Mukkamala, MD
President, American Medical Association and Chair, Substance Use and Pain Care Task Force

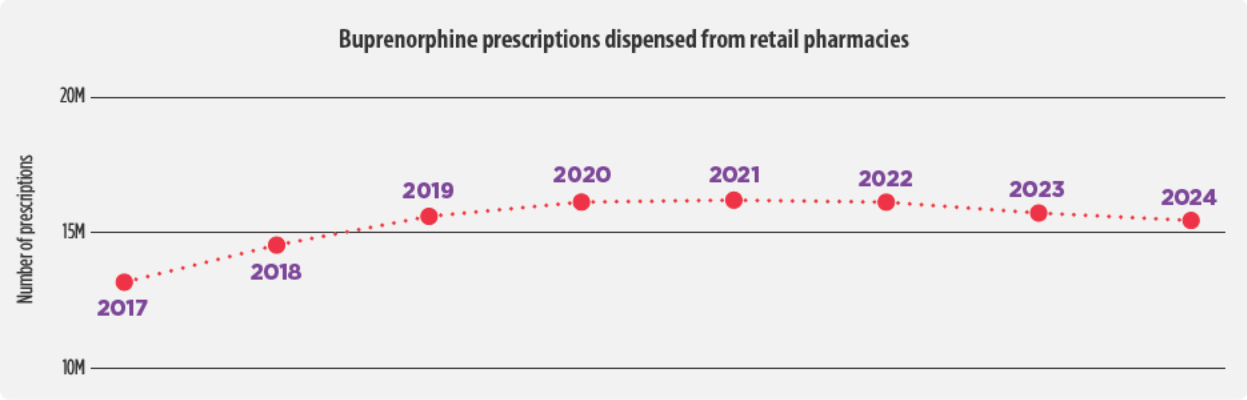
Treatment for opioid use disorder (OUD)

The medical evidence and clinical experience continue to clearly demonstrate the value of medications for opioid use disorder (MOUD) to improve outcomes and save lives. The benefits of MOUD include reduced overdose deaths, reduced cravings, improved maternal and infant outcomes, increased treatment retention, reduced criminal activity and reduced costs to society.[9] Buprenorphine—whether alone or in combination with naloxone—along with methadone continue to be the main types of MOUD benefiting patients with an OUD.

Increasing access to buprenorphine and methadone, however, has always been difficult. People who benefit from MOUD have been falsely and unfairly stigmatized as "trading one addiction for another," as though MOUD is any different than treatment for any other chronic illness such as heart disease or diabetes. Access to buprenorphine—until just a few years ago—was restricted for more than 20 years to only physicians who took extra training and subjected themselves to increased scrutiny by the DEA through the X-waiver program.[10] The stigma surrounding methadone is equally pervasive despite 50 years of efficacy showing methadone successfully treats OUD.[11] Stigma, along with significant policy restrictions, are chief reasons why less than 20% of people who need SUD treatment receive it.[12]

There have been three main trends in buprenorphine prescribing since 2012:

2012–2017: Increases in dispensing as physicians' training and recognition increased (1.4M prescriptions in 2012 to 13.2M prescriptions in 2017)



2018–2022: Continued growth in dispensing, including growth during the COVID-19 years due to increased federal flexibility and increases in telehealth prescribing (14.5M prescriptions in 2018 to 16.0M in 2022)

2023–2024: Slight decrease in total buprenorphine prescriptions dispensed (15.7M in 2023 to 15.4M in 2024) It is not entirely clear why prescriptions dispensed for buprenorphine have decreased—a point that needs greater review. Potential reasons vary and may include:

- More individuals are receiving prescriptions for a greater number of days
- Increased use of long-acting, injectable formulations
- Health insurance company restrictions, such as prior authorization, continue to frustrate and lead to prescription abandonment
- Pharmacy and distributors' fears of buprenorphine being targeted by the DEA as a suspicious drug of concern has led to limited stocking of buprenorphine in the pharmacy
- State laws that place increased scrutiny on physicians who prescribe buprenorphine

Policy recommendations to increase access to MOUD

1. Prohibit prior authorization for MOUD, including for buprenorphine prescriptions greater than 24mg daily.[13] D.C. Medicaid[14] and the State of Illinois[15] have accomplished this.
2. Support actions at the state and federal levels[16] to increase access to methadone, including policy changes that allow office-based addiction medicine and addiction psychiatrists to prescribe methadone outside of an OTP setting so that patients can access their medication from a community pharmacy.
3. Ensure that all individuals entering a jail or prison have access to MOUD; can continue treatment throughout their sentence; and are linked to community-based treatment upon release.[17]
4. Protect families and individuals who are pregnant or breastfeeding by removing penalties that automatically report a positive toxicology test to child welfare authorities.[18]
5. Change policies or practices by pharmacies and/or distributors that restrict access to buprenorphine out of fear of suspicious order reporting (SOR) requirements from the DEA.[19]
6. Enforce state and federal mental health and substance use disorder (SUD) parity laws so that health insurance companies are held accountable for policies and practices that illegally delay and deny care for mental illness and substance use disorders.

Snapshot of AMA advocacy in 2025

- Joined multiple medical societies and other advocates urging—and succeeding—in having SAMHSA clarify that higher doses of buprenorphine are suitable, when warranted, to treat certain cases of SUD. As explained[20] by the American Society of Addiction Medicine, "The label update follows the Food and Drug Administration's (FDA) December 2024 recommendation[21] that transmucosal buprenorphine product labels be updated to address misperceptions of a daily maximum dose of 16 or 24mg. Instead, practitioners should take a patient-centered approach and adjust dosages based on the patient's therapeutic needs and responses. For some patients, doses higher than 24mg may be appropriate." The AMA urges all payers to update their own policies to remove restrictions on buprenorphine that are tied to daily dosage limits.
- Recommended that the DEA clarify or rescind its application of the SOR requirements to buprenorphine for OUD treatment, to reduce pharmacy and distributor reluctance and expand access to life-saving care.[22]
- Continued to support H.R. 2483, the SUPPORT for Patients and Communities Reauthorization Act of 2025.[23]
- Continued to support S. 665, the Fatal Overdose Reduction Act. The establishment of the Health Engagement Hub Demonstration Program, as this bill proposes, aligns with the AMA's ongoing commitment to increase access to treatment for opioid use disorder and other SUDs.[24]
- Joined medical societies in Colorado, Virginia and Washington to strengthen mental health and SUD parity laws.[25] The AMA also developed multiple resources that medical societies can use to enact

additional provisions in law or rule to require health plans to use medical guidance—rather than financial considerations—for determining medical necessity and the generally accepted standard of care.[26]

- Collaborated with The Kennedy Forum and Third Horizon to launch a pilot of the Mental Health Parity Index (MHPI), a free, open-access visual interactive mapping tool that allows physicians, patients, policymakers and other stakeholders assess how well commercial insurance plans are performing with regard to mental health parity laws. The Illinois pilot shows widespread areas where parity violations are likely. The AMA is supporting a national expansion of the MHPI to be launched in 2026.
- Continued to support efforts, such as the Modernizing Opioid Treatment Access Act,[27] to increase access to methadone, including authorizing addiction medicine physicians and addiction psychiatrists to prescribe methadone outside of OTP settings to allow patients with OUD to obtain their prescriptions from community-based pharmacies.

Naloxone

Help save lives—prescribe and distribute naloxone

Increased access to and use of naloxone is one of the most important reasons why the nation's overdose death toll has thankfully decreased. Naloxone is proven to help prevent an opioid-related overdose, but only if it is administered in time.[28] Increased access to naloxone is supported by U.S. health agencies (CDC,[29] SAMHSA,[30] U.S. Surgeon General[31]), state laws and other policies,[32] and many patient, consumer and other advocacy groups.[33]

The AMA is proud that changing state laws to increase access to naloxone was among the first recommendations of the AMA Substance Use and Pain Care Task Force—and that AMA partnership with community-based organizations and the nation's medical societies was part of new and updated laws in all 50 states and the District of Columbia. While physicians' prescriptions for naloxone play an important role in preventing overdose, the AMA continues to strongly support community-based distribution, which for many years has been the primary source of naloxone to save lives. In 2024, for example, Remedy Alliance for the People helped distribute more than 2.1 million doses of naloxone across 45 states and Puerto Rico—unquestionably helping save thousands of lives.[34]

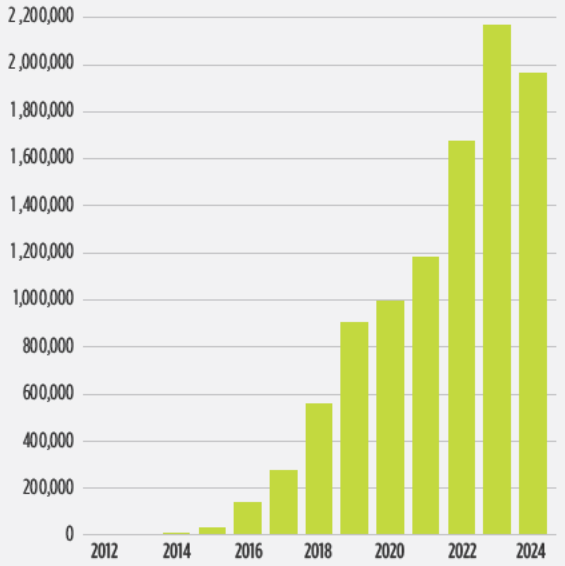
To continue the positive trends, the AMA recommends that:

- Physicians prescribe naloxone to anyone at risk of overdose, including dispensing naloxone in emergency departments and ensuring hospitalized patients at risk for overdose leave the hospital with naloxone (not just a prescription) in hand.
- Public health professionals provide ongoing community-based bystander training to recognize signs of overdose and how to administer naloxone.
- Public officials make naloxone available in public places, such as schools and other educational settings, libraries and concert venues; and also increase availability of naloxone in jails and prisons as well as for distribution upon release.
- Health insurance companies ensure naloxone is not subject to co-pays or cost-sharing.

> **"I talk with my patients and their families about naloxone the same way I discuss any other life-saving medication—with clear information, compassion, and take the time to address their questions and concerns. I hope they never need to use it, but just like an EpiPen or a rescue inhaler, being prepared can make all the difference."**
>
> **Elizabeth Salisbury-Afshar, MD, MPH**
> Addiction Medicine physician, Wisconsin

- Pharmacies make naloxone visible in front of the cash register and pharmacy counter.
- Employers and retailers consider making naloxone available alongside other first aid supplies—and ensure that naloxone is available with no cost on employee benefit health plans.

Trends in naloxone dispensed from retail pharmacies[33]
United States 2012–2024



Following a significant increase in naloxone dispensed from retail pharmacies since 2012, prescriptions have stabilized[35]

Access to naloxone has increased but still could be better[36]

- Despite studies showing the essential nature of community-based naloxone, there continues to be a great shortage of access to naloxone.[37]
- There is substantial, state-by-state variation in naloxone access.[38]
- New state laws to increase access to naloxone through civil protections for possession and administration by lay bystanders led to a 9–11% reduction in opioid-related deaths.[39]
- There is a need for emergency department distribution given that individuals who overdose and are saved rarely fill prescriptions for naloxone.[40]
- States with high overdose rates often have low-access to OTC naloxone.[41]
- Black people receive fewer naloxone prescriptions than other individuals.[42] Females receive naloxone by EMS less often than males.[43]
- In 2023, the FDA approved OTC naloxone, but high cost and stocking location(s) remain barriers.[44]

Prescribe naloxone to anyone at risk of overdose or in a position to save a life from overdose

The AMA strongly encourages physicians to consider prescribing or distributing naloxone to all individuals at risk of overdose or an individual who may be in a position to save a life from overdose. This is a decision to be made between the individual and physician and other health care professionals.[45] Factors that may be helpful in determining whether to prescribe naloxone to a patient, or to a family member or close friend of the patient, include:

Is the patient in the emergency department after an overdose?[46]

Does the patient have a history of substance use disorder or prior overdose?

Does the patient have an underlying mental health condition that might make them more susceptible to overdose?

Might the patient be in a position to aid someone who is at risk of overdose?

Are the patient's family or friends in a position to help save a life from an overdose?

Does the patient history demonstrate a risk of unintentional, opioid-related overdose?

Does the patient have a concomitant benzodiazepine prescription or other medication that might increase risk of overdose?

Does the patient have a medical condition, such as a respiratory disease, sleep apnea or other co-morbidities which might make him or her susceptible to opioid toxicity, respiratory distress or overdose?

Additional considerations when prescribing naloxone

Determining whether to prescribe or dispense naloxone or other opioid overdose reversal agents raises many issues, including initiating a discussion about the risk of overdose; the potential stigma a patient may experience; engaging the patient in broader discussions about treatment for a substance use disorder, if applicable; and how to ensure the patient (or close friend/family member) has the appropriate training in case of an overdose. Though prescribing or dispensing naloxone or other opioid overdose reversal agents is not a guarantee for an overdose reversal, it does provide a tangible option for care that otherwise may not be available in a timely manner.

- Prescribing naloxone has been found to reduce emergency department visits, and may help patients become more aware of the potential hazards of substance use, including risks of fentanyl contamination.[47]
- Prescribing naloxone does not increase liability risk.[48]
- Physicians and other health care professionals can help reduce stigma and increase appropriate use of naloxone through educating patients and families about risk and signs of overdose and how to administer naloxone.[49]
- Although it is recommended that naloxone be used in pregnant women in the case of maternal overdose,[50] pregnant women are less likely than men to receive naloxone during an opioid overdose-related emergency department visit.[51]
- Patients with cancer or hospice and palliative care needs benefit from discussions about overdose education and naloxone distribution.[52]
- In addition to current dosing for naloxone, the FDA has approved certain high-dose and long-acting opioid overdose reversal medications.[53] The AMA supports access to all FDA-approved opioid overdose reversal agents. Higher doses, however, have not demonstrated superior efficacy,[54] and some experts in public health, secondary prevention and emergency response have raised concerns about risks including precipitated withdrawal for the newer products.[55]

A note of caution: Naloxone and other opioid-overdose reversal agents do not reverse an overdose related to methamphetamine, cocaine or other non-opioid containing substances. They also do not work to counteract overdose related to alcohol, benzodiazepines or xylazine, which may increase the sedative effects of opioids, making the antagonist effects of naloxone appear not as rapid or sustaining.[56] Polysubstance use, moreover, may be intentional or unintentional as illicit substances may contain multiple adulterants, including illicitly manufactured fentanyl.[57] The CDC, SAMHSA, NIDA and many other leading health organizations, including the AMA, continue to counsel that in addition to immediately calling 911, it is still advised to administer naloxone or another FDA-approved overdose reversal agent if an overdose is suspected because it is likely an opioid is present, and naloxone has a low risk of harm to an individual. When in doubt, the AMA advises to administer the overdose reversal agent and give rescue breaths to help reduce respiratory depression.

Cannabis

Cannabis as a public health threat

Cannabis availability and use is increasing. The AMA continues to be concerned about increased access to cannabis, increased potency of cannabis products, and a growing body of research showing increases in cannabis use disorder as well as adverse effects on youth and vulnerable populations, including pregnant women.[58] Cannabis use also is increasing among older adults, increasing their risk of heart disease, stroke and cognitive harms.

As cannabis use has increased, the population prevalence of cannabis use disorder has risen in the U.S. In 2023, 6.8% of individuals aged 12 years and older (approximately 19.2 million people), and approximately 30% of those who reported using cannabis, met criteria for cannabis use disorder.[59]

Cannabis risks

According to the U.S. Substance Abuse and Mental Health Services Administration,[60] there are significant risks associated with cannabis use. Risks include adverse effects on brain health; associations between cannabis use and increased risk of depression, anxiety, suicide planning and psychotic episodes; harmful effects on timing and coordination; increased dangers when driving; and harms during pregnancy to the fetus, including fetal growth restriction, premature birth, stillbirth, and problems with brain development, resulting in hyperactivity and poor cognitive function.

40 of 50 states
3 territories and the District of Columbia
allow for medical use of cannabis [61]

More than 1/2 the U.S. population, 12 years and older, live in states where cannabis is legal for adult use [62]

Over 15% of people aged 12 years or older
(43.6 million people) used cannabis in the past month. Highest use is among young adults aged 18–25 years.

Key actions to reduce risk with cannabis

- **Research is needed:** Despite cannabis advocates' claims, there is limited data showing any meaningful benefit to cannabis. Adequate, well-controlled research studies to evaluate safety and efficacy are needed for cannabis, as well as related cannabinoids, including derived psychoactive cannabis products and hemp-derived intoxicating cannabinoids.
- **Prevention in high-risk populations is vital:**
  - **Youths:** Limiting access to cannabis products for minors/youths is critical to reduce risk of cannabis use. Additionally, limiting marketing to youths, including prohibiting the use of characterizing flavors that may enhance the appeal. Avenues for legal and financial penalties for marketing to youth are needed. Finally, the use of secure, child- and tamper-proof packaging and design, and safety labeling on all cannabis products will decrease risks of cannabis for children and youths.
  - **Pregnancy:**[63] Cannabis use in pregnancy is associated with adverse outcomes, including preterm birth, low birth weight and developmental delays. All pregnant women should be screened for cannabis use in pregnancy and lactation, and physicians should be prepared to counsel patients in a non-judgmental way on the risks of use during pregnancy and postpartum.
- **The AMA encourages states to review their regulations to ensure—at a minimum—the following requirements are present:**
  - Prohibit cannabis use in all places that tobacco use is prohibited, including in hospitals and other places in which health care is delivered
  - Apply the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople as well as avenues for legal and financial penalties for marketing to youth
  - Establishing manufacturing and product standards for identity, strength, purity, packaging and labeling with instructions and contraindications for use
  - Requiring transparency and disclosure concerning product design, contents and emissions
  - Ensure that a substantial portion of cannabis tax revenue is allocated for public health purposes, including substance use prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis and public health surveillance efforts.

The AMA Advocacy Resource Center has model state legislation to help states strengthen cannabis protections for public health.

AMA Cannabis Task Force

The AMA Cannabis Task Force (CTF) was formed in 2019 to evaluate and disseminate relevant scientific evidence to health care providers and the public. The CTF developed and launched a continuing medical education podcast series on AMA Ed Hub™ and the AMA Moving Medicine podcast series. The podcast series—free for physicians, public health officials and the general public—serves as a primer on cannabis products and their uses and potential health effects.

Podcast series topics

1. All about cannabis pharmacology[64]
2. Cannabis and pain management[65]
3. Cannabis use among pregnant persons[66]
4. Cannabis use and psychiatric disorders[67]
5. How addictive is cannabis?[68]
6. Preventing cannabis use among minors[69]
7. What to know about FDA-approved cannabis-derived products[70]

Stimulants

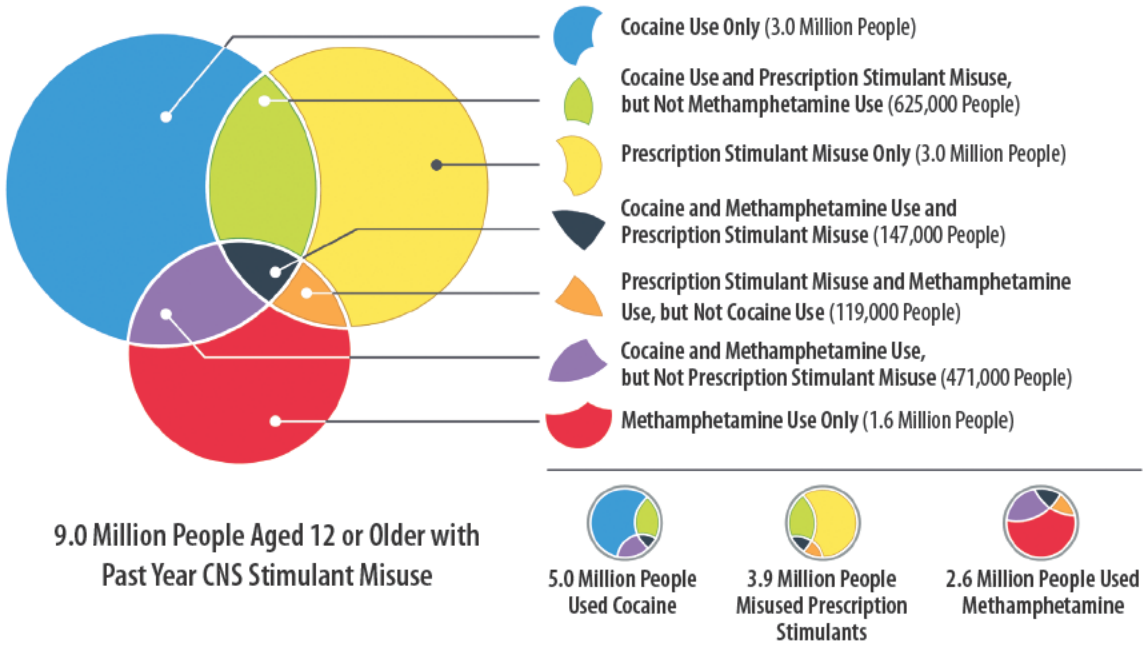
Stimulant use and risk for overdose deaths

Stimulant presence in overdose deaths—particularly methamphetamine and cocaine—has increased with the majority of overdose deaths involving stimulants, often mixed with opioids. The AMA is concerned with this increasing overdose trend given the beneficial role of stimulants for medical use as part of treatment for attention deficit hyperactivity disorder (ADHD) and other disorders. Prescription stimulant misuse has remained stable and even decreased in youth populations[71] despite increases in prescribing.[72]

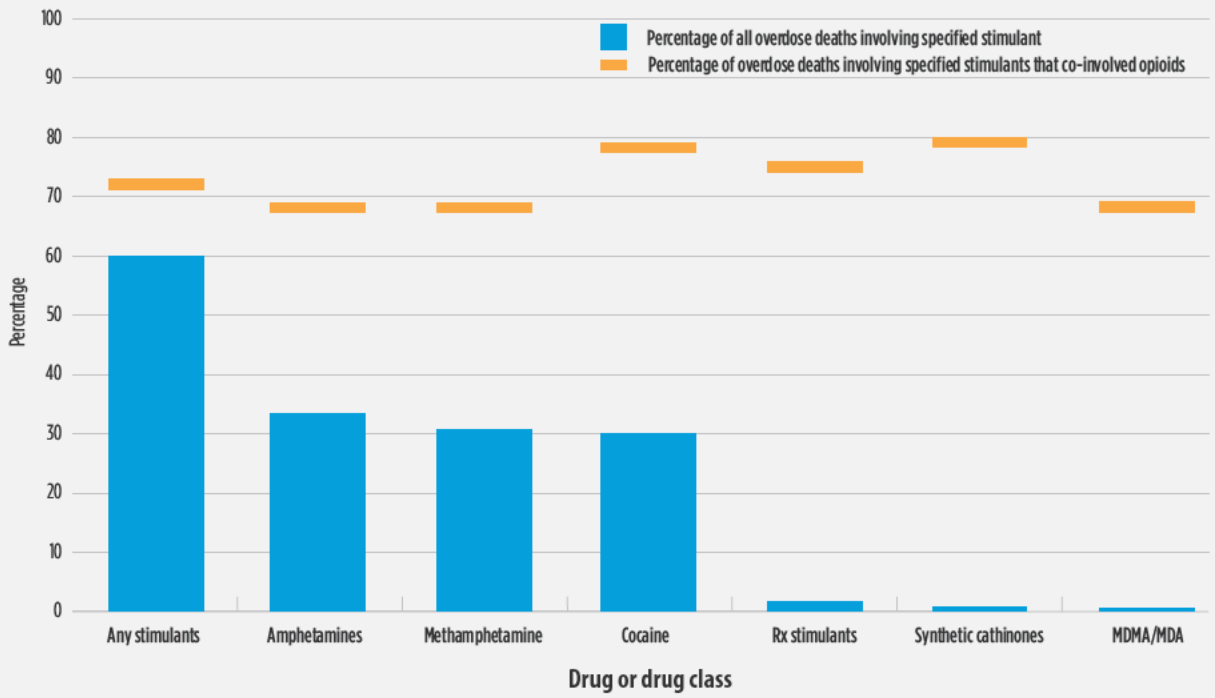
Stimulant use trends

- Cocaine use decreased from 1.7% in 2021 to 1.5% in 2024
- Methamphetamine use remained at less than 1% from 2021 to 2024
- From 2021 to 2024: [73]
  - 59.0% of overdose deaths involved stimulants
  - 43.1% co-involved stimulants and opioids
  - 15.9% involved stimulants and no opioids

Past Year Central Nervous System (CNS) Stimulant Misuse: Among People Aged 12 or Older; 2024 [74]



Percentage of overdose deaths (N=309,274) by type of stimulant involved and by combinations of stimulants involved–State Unintentional Drug Overdose Reporting System, United States January 2021–June 2024 [75]



Prescription stimulants

The AMA recognizes that FDA-approved stimulant drugs to help treat psychiatric and related conditions may be essential parts of a treatment regimen. Non-medical use, however, raises significant concerns. More than 15 million Americans are diagnosed with ADHD.[76] Prescription stimulants, such as amphetamine salts or methylphenidate, are treatment agents for ADHD, narcolepsy and other disorders. For nearly a century, prescription stimulants have been the cornerstone evidence-based treatment for ADHD.

- When taken as prescribed, prescription stimulant use has been shown to lower risks of self-harm, unintentional injury, traffic crashes and crime.[77]
- More research is needed across different populations to support positive outcomes and reduce harm.

Stimulant use disorder

The American Society of Addiction Medicine and American Academy of Addiction Psychiatry jointly developed a new clinical practice guide for Stimulant Use Disorder (StUD). According to the guide, StUD "can cause a range of serious and long-term health problems, including cardiac, psychiatric, dental, and nutritional complications. Injection stimulant use increases the risk of contracting human immunodeficiency virus (HIV), viral hepatitis, and other infectious diseases such as infective endocarditis. The stable or rising availability of stimulants, low prices, and potential contamination of stimulants with high potency synthetic opioids such as fentanyl and other components such as levamisole are expected to exacerbate risks." There are currently no FDA-approved medications to treat StUD.

Contingency management (CM) is an incentive-based health care intervention to motivate people to change behavior. CM is well studied in substance use disorder treatment, particularly StUD, with demonstrated superior benefits compared to other behavioral health interventions, including cognitive behavior therapy and 12-step models. The Substance Abuse and Mental Health Services Administration (SAMHSA) provides guidance on prize-based and voucher-based CM models for implementation.[78]

Hallucinogens

Hallucinogens

- Hallucinogen use increased from 2.7% in 2021 to 3.6% in 2024.[79]
- These include psilocybin, MDMA, ibogaine, ketamine, peyote and other entactogenic compounds.
- These agents may be used recreationally or advertised or marketed to treat psychiatric disorders or other conditions.

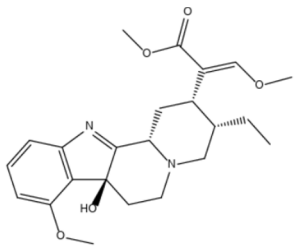
While some states are pursuing legislation to authorize the personal use of these compounds,[80] the AMA broadly recommends that individuals seeking to use these substances to treat a medical condition consult their physician.

The AMA also advocates against the use of any psychedelic or entactogenic compounds to treat any psychiatric disorder except those which have received FDA approval or those prescribed in the context of approved investigational studies.

Kratom

The U.S. Food and Drug Administration (FDA) estimates that approximately 1.7 million people used kratom in 2021.[81] A recent report and scheduling action by the FDA addressed concerns for 7-hydroxymitragynine (7-OH), a naturally occurring compound found in kratom.[82] The FDA cautioned[83] that "there are no FDA-approved 7-OH drugs, 7-OH is not lawful in dietary supplements and 7-OH cannot be lawfully added to conventional foods."

Figure: 7-Hydroxymitragynine (7-OH) chemical structure found in kratom[84]



The AMA recommends that states regulate kratom and ban over-the-counter sales. Before kratom can be marketed, purchased or prescribed:

- Research is needed to determine the safety and efficacy of kratom.
- Relevant regulatory entities need to evaluate kratom's appropriateness for sale before it can be marketed, purchased or prescribed.

Tianeptine

Tianeptine has opioid- and anti-depressant properties and is known as "gas station heroin" because it is commonly sold in gas stations, convenience stores and by online retailers. According to the FDA, tianeptine "is not approved by the FDA for any medical use, is not generally recognized as safe for use in food, and it does not meet the statutory definition of a dietary ingredient."[85] The FDA has issued multiple drug safety alerts because tianeptine products have been linked to serious harm, overdoses and death.

The AMA urges states to ban the sale of tianeptine directly to the public in the absence of research into the safety and efficacy of the substance.

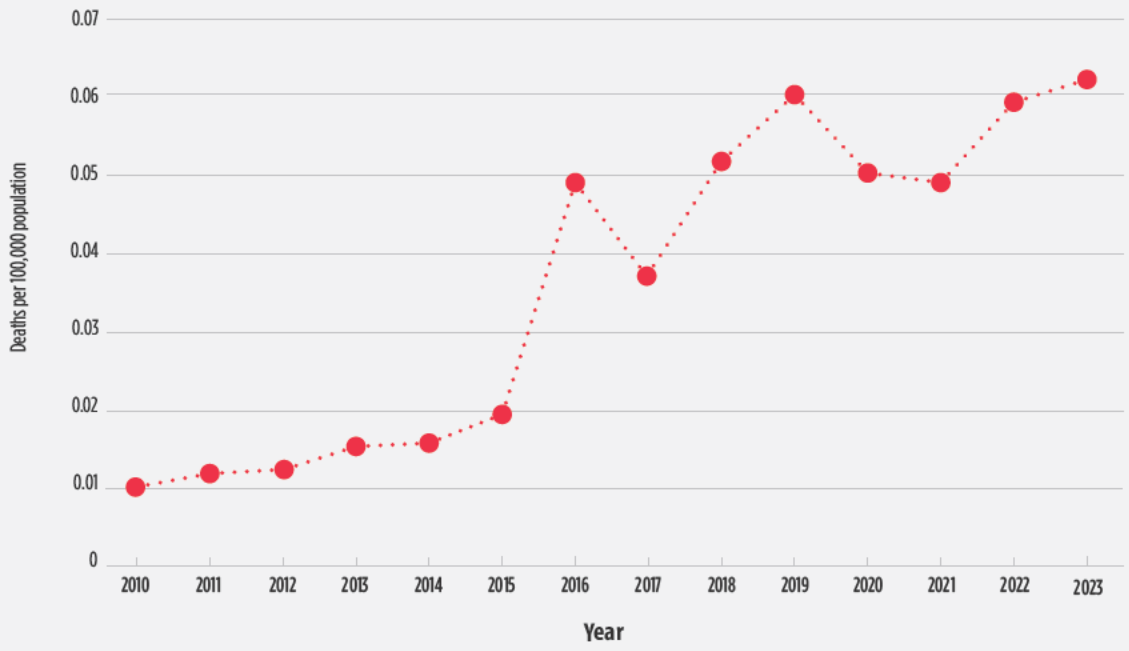
Inhalants

Inhalants are volatile substances in commonly used products such as paint thinner, hair sprays, computer keyboard cleaners and nitrous oxide (NO).[86] While NO can be safely used in medical settings as an anesthetic, when used recreationally, NO can cause severe neurological, cardiovascular and psychiatric complications. Adverse events, including death, associated with NO use is on the rise. The CDC reported, for example, that in Michigan in 2023, ED visits and EMS responses related to NO misuse increased four to five times compared to 2019.[87] Deaths due to NO have increased nearly 600% from 2010 to 2023.[88]

New AMA model state legislation can help states implement common-sense protections to prohibit the sale of dangerous kratom and tianeptine products.

The AMA highlights the need for education and awareness among medical professionals and the public of the health risks with inhalant use. The AMA also supports efforts to limit the ability of non-medical facilities to acquire NO for recreational inhalation purposes.

Figure: Crude nitrous oxide poisoning mortality rate in the U.S. from 2010 to 2023[89]



Stakeholder collaboration

Ending the nation's drug-related overdose and death epidemic—through improving care for patients with pain, mental illness or substance use disorder (SUD) and increasing access to primary and secondary prevention—requires partnership, collaboration and commitment. The AMA continues to urge action across multiple domains.

Increased access to treatment for substance use disorders

- Legislators and regulators at the state and federal levels need to increase support for legislative and other actions to remove administrative and other barriers faced by individuals with SUD. This includes prior authorization, step therapy, dosage caps for medications to MOUD and restrictions on access to methadone.
- The U.S. Drug Enforcement Administration (DEA) and other government agencies are urged to issue clear guidance that DEA's suspicious order reporting requirements will not be enforced against buprenorphine approved by the FDA for the treatment of opioid use disorder (OUD) until further notice.
- Jail and prison officials can implement screening, treatment and other programs that ensure individuals with an OUD—including pregnant women—are able to continue MOUD upon entry, during incarceration, and efforts are made to ensure connections to treatment upon release.

Protect patients with pain

- Medical and other health care professional licensing boards have the opportunity to help patients with pain by reviewing and updating opioid prescribing policies to reflect guidance from the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain.[90]
- Health insurers can show their commitment to ending the epidemic by increasing access to affordable, accessible non-opioid pain care options. Employers can review benefit plans to ensure employees have access to affordable, accessible non-opioid pain care options.

- Policymakers and public health officials can make clear that patients with pain deserve the same care and compassion as individuals with any other medical condition or disease, whether acute or chronic.

Primary and secondary prevention

- Public health officials, colleges, universities and other educational settings can adopt best practices to reduce overdose by supporting widespread overdose education and distribution of naloxone and fentanyl test strips as well as other measures to increase awareness of the contaminated, toxic, illicit drug supply.
- Policymakers are urged to help stop the spread of infectious disease by supporting sterile needle and syringe services programs, including removing restrictions on availability of sterile supplies.
- Faith leaders and community leaders can increase awareness about polysubstance use, availability of treatment and support networks, and overdose education and prevention resources.

Resources

Substance use in the United States: An issue brief from the American Medical Association providing updates on data, trends and policy directions.

CLICK HERE

Help save lives prescribe and distribute naloxone: Recommendations for physicians, policymakers and others to increase access to naloxone.

CLICK HERE

Support medical criteria for medical necessity determinations for mental health and substance use disorders: Specific legislative and regulatory recommendations to ensure health insurers are not allowed to use non-medical criteria when making medical necessity and other determinations.

CLICK HERE

Specific actions policymakers can take to end the nation's drug overdose epidemic.

CLICK HERE

Dispelling myths of bystander overdose: Highlights medical evidence and AMA strong support for primary and secondary overdose prevention efforts.

CLICK HERE

State snapshot of overdose epidemic: A state-by-state snapshot of news articles, public health reports and other information.

CLICK HERE

National snapshot of overdose epidemic: A collection of national news items, research and other information.

CLICK HERE

Prescribing trends

Opioids

CLICK HERE

Naloxone

CLICK HERE

Buprenorphine

CLICK HERE

Endnotes

1. The first report was issued in 2017. The 2018, 2019, 2020, 2021, 2022, 2023 and 2024 reports can be found on the AMA End the Epidemic microsite: www.end-overdose-epidemic.org
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4. Rodin R, Li L, McKendrick K, et al. The 2016 CDC Opioid Guideline and Analgesic Prescribing Patterns in Older Adults With Cancer. JAMA Netw Open. 2025;8(5):e259043.
5. 2025 Minnesota Statutes. 152.125 Intractable Pain; Also See 720 ILCS 570/315.7(c)
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8. On opioid labeling, FDA emphasizes patient-physician relationship. Statement by AMA President Bobby Mukkamala, MD. August 1, 2025. Also see AMA letter to the Honorable Martin Makary, MD, Commissioner U.S. Food and Drug Administration Re: Docket No. FDA-2024-N-5331 Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Amendment of Notice-Extended-Release/Long-Acting Opioid Analgesic Postmarketing Requirement. May 22, 2025.
9. See, generally, Substance Use Disorder Treatment Options, U.S. Substance Use Disorder Treatment Options; Medications for Opioid Use Disorder. National Institutes for Drug Abuse.
10. At a Crossroads: Opioid Use Disorder, the X-Waiver, and the Road Ahead Jaskaran Singh Dhillon, Leah Feulner, Ariya Beitollahi, Kelly Kossen, David Galarneau, Ochsner Journal Jun 2024, 24 (2) 108-117.
11. See discussion with Caleb Alexander, MD, and Michael Fingerhood, MD. Methadone Is an Effective Treatment for Opioid Use Disorder, So Why Aren't More Patients Using It?. Coulsen, Morgan. Johns Hopkins School of Public Health. Sept. 26, 2023.
12. 2024 National Survey on Drug Use and Health. Substance Use and Mental Health Services Administration. Available at https://www.samhsa.gov. "Among people aged 12 or older in 2024 who were classified as needing substance use treatment in the past year, about 1 in 5 (19.3% or 10.2 million people) received substance use treatment in the past year."
13. See, for example, Transmittal 24-16, "Suboxone and Buprenorphine-Containing Products Daily Dosing Limit Increase" from the District of Columbia Office of the Senior Deputy Director and Medicaid Director to D.C. Medicaid Providers, April 17, 2024. "With the rise in fatal overdoses in DC and the prevalence of fentanyl in opioid overdoses in the District, DHCF will eliminate the Medicaid PA requirement for Suboxone and Buprenorphine-containing products above 24mg (not to exceed 32mg)."
14. Suboxone and Buprenorphine-Containing Products Daily Dosing Limit Increase. Transmittal 24-16. Government Of The District Of Columbia. Department of Health Care Finance.
15. Ill. Comp. Stat. 103-1040.
16. The AMA joined the American Society of Addiction Medicine and other leading organizations to support "The Modernizing Opioid Treatment Access Act" (H.R. 1359 and S.644) which would (1) provide a legal mechanism for board-certified physicians in addiction medicine or addiction psychiatry, who do not work at OTPs, to prescribe methadone for OUD that can be dispensed from retail pharmacies, by creating a new registration process with the Drug Enforcement Administration for that purpose, so that such act is no longer criminalized at the federal level, and (2) establish additional federal safeguards for those prescribers.
17. For an excellent discussion and set of best practices across multiple state legislatures, see the "Model Substance Use During Pregnancy And Family Care Plans Act." Legislative Analysis And Public Policy Association. March 2023.
18. See, for example Some Mass. hospitals stop infant welfare reporting based solely on drug dependence." WBUR. April 3, 2023.
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28. Naloxone for Opioid Overdose: Life-Saving Science. National Institute on Drug Abuse; National Institutes of Health; U.S. Department of Health and Human Services. https://nida.nih.gov/publications/drugfacts/naloxone
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NEWS

ASAM: Sweeping Medicaid Reforms Could Weaken America's Addiction Treatment Efforts, Pose a National Security Threat

May 13, 2025

Download

To save lives and undermine the influence of drug cartels, ASAM urges Congress to exempt addiction-related treatment services from cost-sharing mandates and reject burdensome work requirements

Rockville, MD (May 13, 2025) - In response to Sunday's release of the House Energy & Commerce Committee's bill text to reform Medicaid funding, Stephen M. Taylor, MD, M

DFAPA, DFASAM, president of the American Society of Addiction Medicine (ASAM), issued the following statement:

“ASAM firmly opposes any harmful Medicaid reforms which threaten to make lifesaving addiction treatment less accessible to Americans. Should the out-of-pocket costs of treatment services for low-income Americans with addiction exceed the price of legal or illicit addictive substances due to health insurance loss or new Medicaid requirements, we risk losing valuable ground in our addiction and recovery efforts.

In particular, we are greatly concerned that proposals to impose cost-sharing requirements on Medicaid Expansion enrollees – including those with substance use disorders – could make addiction-related treatment services even more costly than cheaper tobacco products, alcohol, and illicit drugs. Further, while we deeply appreciate the Committee’s exemption of people with a substance use disorder from the proposed work requirements, we maintain serious concerns over how this and other exemptions will be implemented. Time and energy spent on excessive bureaucratic red tape and surveillance could be better used to ensure that more Americans with low incomes can readily access and afford the medical care they need and deserve, including through programs like Medicaid Expansion.

Medicaid Expansion is a powerful weapon against addiction and the drug cartels, because it can reduce demand for illicit substances and help more Americans with addiction enter treatment. It must be protected, especially as we continue to lose tens of thousands of lives each year to the nation’s addiction and overdose crisis.”

# # #

About the American Society of Addiction Medicine

The American Society of Addiction Medicine (ASAM), founded in 1954, is a professional medical society representing over 8,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addiction. For more information, visit www.ASAM.org.

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TAGS: **Medicaid**

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February 9, 2023

The Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
5600 Fishers Lane, Room 13-E-30
Rockville, MD, 20857

RE: Proposed Rulemaking 42 CFR Part 8 Medications for the Treatment of Opioid Use Disorder (RIN 0930-AA39)

To the Substance Abuse and Mental Health Services Administration (SAMHSA):

The Association for Multidisciplinary Education and Research in Substance use and Addiction (AMERSA) applauds SAMHSA's efforts to update federal regulations related to Medications for the Treatment of Opioid Use Disorder 42 Code of Federal Regulations (CFR) Part 8 Notification of Proposed Rule Making (NPRM).

AMERSA, founded in 1976, is a non-profit professional organization with a mission to improve health and well-being through interdisciplinary leadership and advocacy in substance use education, research, clinical care, and policy. Its membership consists of 450 experts in the field of addiction from multiple disciplines, including but not limited to, physicians, nurses, social workers, psychologists, dentists, pharmacists, and public health professionals. Many of us serve on the frontlines of the overdose crisis as federally funded scientists, teachers, treatment providers, and expert public health consultants, including to SAMHSA.

As an organization deeply committed to improving health and well-being among communities with substance use disorders, we have provided detailed comments on several topics related to the NPRM, as well as making several added considerations that are currently not included.

COMMENTS RELATED TO PROPOSED RULES BY TOPIC:

MAINTAIN AUDIO-ONLY TELEHEALTH FOR COUNSELING VISITS (42 CFR §8.12)

AMERSA supports the permanent provision of telehealth for both behavioral health and medical appointments in the OTP setting.

The new proposed changes require video-enabled telehealth for methadone treatments to avoid increasing methadone dosages for oversedated patients. As this concern is not applicable to counseling visits, we urge SAMSHA to support the permanent expansion for behavioral health appointments to take place by either audio- or video-based telehealth.

Under the state of emergency declared during COVID-19, a complex web of temporary changes enabled by payers, as well as by state and federal regulators, allowed OTP-based behavioral health (counseling) appointments to be conducted by video-based telehealth and, in some

cases, by audio-based telehealth.[1] However, federal regulations through the state of emergency maintained the requirement that medical intakes to OTPs for methadone treatment continue to occur in person, a requirement that curtailed enrollment into OTPs, especially during the early stages of the pandemic.[2] The provision of audio-only services (which do not require internet connectivity) for counseling has been documented to increase access to critical mental health services, especially for persons of color and low-income persons.[3] Early studies of audio-only "telemental health" show similar effectiveness with face-to-face mental health care.[4]

In addition, we support regulatory changes to authorize medical intake and "annual physical" appointments at OTPs to take place by video-based telehealth platforms. The physical evaluation required to ensure safe methadone initiation is safety-oriented and need not be a comprehensive, head-to-toe, in-person exam. Practitioners can safely and effectively complete a medical intake for patients by video, while onsite staff gather vital sign and toxicology data, like visits in primary care settings. The results of research studies performed during the expansion of telehealth for MOUD services demonstrate decreased rates of opioid overdose and improved retention in care for those receiving telehealth services compared to those not receiving them.[5] **We support the inclusion of OTPs in this expansion to further increase access to life-saving addiction services without undermining the quality of care.**

CLARIFY WHAT IS REQUIRED BY OTP PRACTITIONERS TO ENACT SPLIT DOSING (42 CFR §8.2 and §8.12)

AMERSA supports the expansion of split dosing for *all* OTP patients who, in the clinical judgment of the OTP practitioner, qualify for take-home doses. We further urge SAMSHA to clarify in its proposed changes that additional testing and submitting documentation for split dosing is not needed, as long as the OTP practitioner has made the clinical judgment and documented clearly in the medical record that the patient may benefit from split dosing.

Until now, split dosing has required the provider apply for an exception to SAMHSA, generally after having the patient undergo a peak and trough (P/T) laboratory measurement and then, only if the P/T demonstrates that they are a "rapid metabolizer" (P/T > 2.0). This process creates multiple barriers, including finding a laboratory that has the resources and expertise to perform this carefully timed measurement, the need for the patient to wait several hours while having two blood draws, and the administrative burden of applying for the exception. Pharmacokinetic studies support twice daily dosing in pregnant women based on their

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[3] Kleinman RA, Sanches M. Impacts of Eliminating Audio-Only Care on Disparities in Telehealth Accessibility. J GEN INTERN MED. 2022;37(15):4021-4023. doi:10.1007/s11606-022-07570-w

[4] Sugarman DE, Busch AB. Telemental health for clinical assessment and treatment. BMJ. 2023;380:e072398. doi:10.1136/bmj-2022-072398

[5] Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. JAMA Psychiatry. 2022;79(10):981-992. doi:10.1001/jamapsychiatry.2022.2284

increased metabolism and expanded blood volume.[6,7] Studies show improved fetal measures[8] and superior neonatal outcomes for pregnant women whose dose is split.[9] Moreover, many non-pregnant patients also state they feel better when their dose is split,[10] regardless of whether they are found by their peak/trough ratio to be "rapid metabolizers."

In our clinical experience (including as frontline OTP practitioners), exemptions during COVID-19 that allowed split dosing improved patient care experiences, autonomy, and decreased the frequency and intensity of opioid withdrawal without leading to increased diversion or worse patient outcomes. The proposed changes clarify that split dosing is allowed but does not specifically state that OTP practitioners may prescribe split dosing for patients without the need for additional lab testing. This lack of clarity may function as an additional barrier if OTP practitioners mistakenly believe that additional testing is still required. **Further clarification should be added stating that additional lab testing and submission of paperwork to SAMHSA is not needed to approve split dosing.**

APPLY ENFORCEMENT MECHANISMS TO ENSURE EQUITABLE ACCESS TO TAKE-HOME DOSES *(*42 CFR §8.12)

AMERSA supports the removal of the eight take-home criteria to allow for clinician discretion if a patient may benefit from additional take-homes.

Researchers who evaluated the impact of methadone-related COVID-19 exemptions found that patients with increased take-homes had better treatment experiences and retention, while feared increases in diversion and methadone-related overdoses did not emerge.[11] However, not all patients experienced the benefit of increased take-homes during COVID-19, because not all clinics and states applied for these exemptions.

To ensure that all patients receive equitable access and support to take-homes, SAMHSA should re-examine their enforcement mechanisms and consider the addition of metrics examining take-home receipt in their OTP certification processes. For example, OTPs that have significantly low offerings of take-home doses could be flagged for additional auditing measures and to encourage OTPs to maintain equitable take-home access.

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[6] Bogen DL, Perel JM, Helsel JC, et al. Pharmacologic evidence to support clinical decision making for peripartum methadone treatment. Psychopharmacology. 2013;225(2):441-451. doi:10.1007/s00213-012-2833-7

[7] Jarvis MA, Wu-Pong S, Kniseley JS, Schnoll SH. Alterations in methadone metabolism during late pregnancy. J Addict Dis. 1999;18(4):51-61. doi:10.1300/J069v18n04_05

[8] Jansson LM, Dipietro JA, Velez M, Elko A, Knauer H, Kivlighan KT. Maternal methadone dosing schedule and fetal neurobehaviour. J Matern Fetal Neonatal Med. 2009;22(1):29-35. doi:10.1080/14767050802452291

[9] McCarthy JJ, Leamon MH, Willits NH, Salo R. The Effect of Methadone Dose Regimen on Neonatal Abstinence Syndrome. *Journal of Addiction Medicine*. 2015;9(2):105. doi:10.1097/ADM.0000000000000099

[10] Haskew M, Wolff K, Dunn J, Bearn J. Patterns of adherence to oral methadone: Implications for prescribers. Journal of Substance Abuse Treatment. 2008;35(2):109-115. doi:10.1016/j.jsat.2007.08.013

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EXPLICITLY DESCRIBE HOW NEW INTAKE RULES MAY BE APPLIED (42 CFR §8.12)

We applaud SAMHSA for clarifying the roles of screening and full examination for OTP intake in the proposed rule change (pasted below in italics). In addition, we further urge that SAMHSA explicitly describe how these rules apply to specific clinical scenarios such as care transitions from hospitals or non-OTP settings to OTPs.

Hospital-initiated methadone is an evidence-based strategy that can engage patients high-risk for overdose and other opioid-related death,[12] and more than double the likelihood of post-hospital treatment engagement.[13,14] However, real-time linkages to methadone from hospital to post-hospital care are commonly hampered by long community wait-times for new patient intakes by an OTP-clinician. These delays happen despite current federal rules *(42 CFR 8.12(f))* which permit OTPs to honor evaluations from "a primary care physician, or an authorized healthcare professional" (e.g., hospital physician). In states like Oregon, this means that a hospitalized patient who has started methadone during inpatient admission may have a 7-10 day wait-time to receive methadone after discharge, whereas in states like Massachusetts, patients routinely dose same- or next-day under a "direct admission status." These disparities exist because of varied interpretations of current federal rules by State Opioid Treatment Authorities (SOTAs) across the country. **Clarifying how rules apply in these specific clinical scenarios will assure appropriate rule interpretation:**

> *"Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner. The above can facilitate timely care transitions from a hospital (or other non-OTP setting) to OTP, wherein a DEA-licensed hospital clinician performs initial OUD assessment and initiates methadone and supports same- or next-day linkage to OTP care wherein a patient can dose before completing full intake or OTP physician assessment. Another example of how this rule can support care transitions includes methadone initiation in withdrawal management or ambulatory settings, consistent with "72-hour rule" (21 CFR 1306.07)."*

[12] King C, Cook R, Korthuis PT, Morris CD, Englander H. Causes of Death in the 12 Months After Hospital Discharge Among Patients With Opioid Use Disorder. J Addict Med. 2022;16(4):466-469. doi:10.1097/ADM.0000000000000915

[13] Englander H, Dobbertin K, Lind BK, et al. Inpatient Addiction Medicine Consultation and Post-Hospital Substance Use Disorder Treatment Engagement: a Propensity-Matched Analysis. *J GEN INTERN MED*. Published online August 13, 2019. doi:10.1007/s11606-019-05251-9

[14] Tierney HR, Rowe CL, Coffa DA, Sarnaik S, Coffin PO, Snyder HR. Inpatient Opioid Use Disorder Treatment by Generalists is Associated With Linkage to Opioid Treatment Programs After Discharge. J Addict Med. 2022;16(2):169-176. doi:10.1097/ADM.0000000000000851

EASE FIRST DAY DOSING RESTRICTIONS (42 CFR § 8.12)

We recognize that minimal changes were made to first day methadone dosing restrictions. We urge SAMHSA to address the subtherapeutic initial dosing of methadone in 42 CFR Part 8 by either eliminating restrictions on initial day dosing and deferring to clinician judgment, or providing further clarification in how higher doses, if clinically indicated and documented, could be enacted.

First day doses limiting to 40mg are not appropriate in the era with a ubiquitous fentanyl-contaminated drug supply. Many patients require higher initial and next day doses to avoid withdrawal and prevent treatment attrition.[15] Rapid up-titration is also particularly important in later pregnancy, where patients initiating may need higher doses given their rapid methadone metabolism. The current proposed regulations, while clarifying that "*provision for higher doses if clinically indicated and documented in the patient's record",* are too vague and non-specific. It is unclear if higher than 30mg initial doses are allowed, or if "higher doses" means additional doses should be administered in 10-20 mg increments at several hour intervals. Lack of clarity will lead to higher doses being underutilized, leading to reduced treatment retention. The current practice at most OTPs is that patients, particularly pregnant patients, remain on subtherapeutic doses with a titration schedule that is not adjusted to meet the physiological needs of pregnancy, hence placing patients and pregnancies at risk. A complete abolition of any stated cap in any current or future rulemaking would empower providers to use their clinical judgment. If complete abolition is not possible, **SAMHSA should add further clarification to what is needed for OTP practitioners to provide higher first day doses to patients, as currently proposed changes are not sufficiently clear.**

ADDITIONAL SUGGESTIONS FOR PROPOSED CHANGES:

INCLUSION OF MEDICALLY LICENSED JAILS AND PRISONS AS LONG-TERM CARE FACILITIES (42 CFR §8.11(3))

Incarcerated individuals who use opioids have among the highest risk of overdose death,[16,17] yet the proposed changes lack sufficient measures to facilitate methadone treatment within this population. Recent litigation and settlements by the Department of Justice have challenged inadequate access to OUD pharmacotherapy in jails, prisons, and long-term care facilities as a civil rights violation.[18]

Hospitals and long-term care facilities already have a waiver from OTP certification to administer methadone under *42 CFR* §8.11. Extending that "hospital waiver" to correctional

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[15] Buresh M, Nahvi S, Steiger S, Weinstein ZM. Adapting methadone inductions to the fentanyl era. J Sub Abuse Treat. 2022 Oct;141:108832. doi: 10.1016/j.jsat.2022.108832. Epub 2022 Jun 27. PMID: 35870437.

[16] Saloner B, Chang HY, Krawczyk N, et al. Predictive Modeling of Opioid Overdose Using Linked Statewide Medical and Criminal Justice Data. JAMA Psychiatry. 2020;77(11):1155-1162. doi:10.1001/jamapsychiatry.2020.1689

[17] Jon Berg, Breaking The Cycle: Medication Assisted Treatment (MAT) In The Criminal Justice System, Substance Abuse and Mental Health Serv. Blog, 15 Mar. 2019, https://blog.samhsa.gov/2019/03/15/breaking-the-cycle-medication-assisted-treatment-mat-in-the-criminaljustice-system.

[18] U.S. Attorney's Office, District of Massachusetts, U. S. D. of J. (2022). U.S. Attorney Rollins Announces Correctional Facilities Statewide to Maintain All Medications for Opioid Use Disorder. [https://www.justice.gov/usao-ma/pr/us-attorney-rollins-announces-correctional-facilities-statewide-maintain-all-medications]

facilities (including prisons and jails) is an expedient and safe way to allow correctional facilities to provide legally compliant medical care.

To rapidly address the public health crisis of overdose mortality that disproportionately impacts justice-involved individuals, we recommend the following changes to the proposed rule (new language underlined):

> *42 CFR* §8.11(3): Certification as an OTP under this part will not be required for the continuous medication treatment or withdrawal management of a patient who is admitted to a hospital or long-term care facility *or an individual residing in a correctional facility (prison or jail)* ~~*for the treatment of medical conditions other than OUD*~~ and who requires medication continuity or withdrawal management during the period of their stay in that ~~long-term care~~ facility when such treatment is permitted under applicable Federal law. The terms "long-term care facility" and "correctional facility" *are* ~~*is*~~ defined in § 8.2. Nothing in this section is intended to relieve ~~*long-term care*~~ *these* facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

A definition of qualifying correctional facilities should be added to 42 CFR §8.2, which would require the facility to have the necessary DEA registration to administer, store, and dispense scheduled prescription medications.

To align the waiver language for all three types of residential facilities, we removed the phrase "for the treatment of medical conditions other than OUD" regarding admitted patients and added "individuals residing" in qualifying facilities. Requiring that methadone administration inpatient be an "incidental adjunct" (secondary) to another medical condition does not make sense for a waiver expansion to jails and prisons. It is also unnecessary for long-term care facilities and hospitals. The DEA does not regulate the practice of medicine, so enforcing which patient condition is primary or secondary is simply not practical or feasible. A subsequent NPRM should eliminate references to this requirement also found in 21 CFR, Part 1306.07(c).

Much of the siloing of methadone treatment to OTPs was justified as being necessary to reduce diversion. Correctional facilities already have stricter diversion control infrastructure than hospitals as fully locked facilities with limited public access. Treating a jail differently than other facilities is not justified to reduce diversion.

Not all types of correctional facilities are expected to have the necessary staffing or structure to be able to administer all types of MOUD pharmacotherapy, and nothing in this rule change requires them to. They can still contract with a community OTP, or work with a mobile methadone unit to be able to offer MOUD in a collaborative arrangement. AMERSA supports reduced regulatory barriers to all those options as well. AMERSA also supports changes that will enable community pharmacies to collaborate with physicians, nurse practitioners, and physician assistants working in jails and prisons to offer all forms of OUD medication treatment. However, increasing OTP capacity in rural geographies through all these measures will take time as well as sufficient and sustained investments. Expanding the hospital waiver of OTP certification to jails and prisons is simply treating the people within these settings as deserving of the same medical care as those residing in other long-term care residential facilities. **Expanding the waiver of OTP certification will increase equitable access to OUD and opioid withdrawal treatment, deter the potential for civil rights violations, reduce the number of incarcerated people undergoing unnecessary forced tapers from evidence-**

based treatment, all while decreasing the incidence of painful, untreated opioid withdrawal.

EASE PATHWAYS FOR OPENING NEW OPIOID TREATMENT PROGRAMS (42 CFR §8.3-8.6 and §8.11-8.15)

In the United States, where less than 20% of US counties have access to an OTP,[19] the current limited supply of OTPs is insufficient to meet the demand for methadone treatment. Lack of access worsens patient outcomes, as patients accessing methadone treatment experience maximally disruptive care in OTP settings, such as having to drive long distances or face inclement weather to attend daily OTP visits with limited resources.[20]

Existence of federal, state, and local regulations create extraneous barriers to opening and sustaining new OTPs and aspiring OTP clinics must apply for burdensome accreditation processes with SAMHSA, DEA, state regulatory health agencies, as well as often facing direct neighborhood opposition voicing "not in my backyard" sentiments. While SAMHSA and DEA have expressed interest in easing regulations for medication mobile units to expand access for existing OTPs, this pathway is insufficient. Implementation of mobile medication units are expensive, with costs for each unit estimated between $250,000-500,000, plus additional requirements for the unit to return to/from the originating OTP daily, restricting community reach and impact.[21]

We urge SAMHSA to enact changes to ease or eliminate barriers for opening new OTP treatment programs.

For example, SAMHSA could extend the duration during which OTP certification is valid. SAMHSA could incentivize the opening of new OTPs through comprehensive federal funding opportunities and/or encourage operating new OTPs out of existing syringe service programs to help reduce costs of opening new facilities.

EXPAND METHADONE TREATMENT FOR OUD BEYOND OTP SETTINGS (42 CFR §8.12)

Allowing methadone treatment outside of OTP settings (e.g., allowing methadone prescribing in office-based settings or dispensing in community pharmacies) should be explored to further meet the urgent need of providing additional treatment access for patients with OUD.

As previously published, SAMHSA and the Drug Enforcement Administration (DEA) have the regulatory authority to allow methadone prescribing and dispensing to take place outside of OTPs.[1] Without expansion beyond the OTP setting, access to methadone for the treatment of OUD will remain limited due to geographic and rural disparities across the country, even with proposed changes in the above sections.

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[19] Duff JH, Carter JA. *Location of Medication-Assisted Treatment for Opioid Addiction: In Brief*. Congressional Research Service; 2019. https://sgp.fas.org/crs/misc/R45782.pdf

[20] Englander H, Gregg J, Levander XA. Envisioning Minimally Disruptive Opioid Use Disorder Care. J Gen Intern Med. Published online November 18, 2022:1-5. doi:10.1007/s11606-022-07939-x

[21] El-Sabawi T, Baney M, Canzater SL, Weizman SR. The New Mobile Methadone Rules And What They Mean For Treatment Access. Health Affairs Forefront. doi:10.1377/forefront.20210727.942168

Central to a vision for a more accessible and equitable methadone treatment system are the principles that:

1) Methadone regulations should prioritize patient health over other concerns
2) Methadone should be available in all treatment settings and communities
3) The structure of methadone treatment should be determined by the patient in collaboration with their practitioner, with recommendations based on empirical evidence - consistent with how we approach other chronic diseases.

As such, we recommend the current methadone treatment system be expanded beyond OTP settings to include office-based methadone prescribing and dispensing in community pharmacies, as has been successfully implemented, standardized, and normalized in other countries including the UK, Australia, and Canada.[22,23]

We urge SAMHSA to enact the following changes: 1) Work with the DEA to permit practitioners, including those in OTPs or in office-based settings, to prescribe methadone for OUD treatment. This should include any clinician authorized to prescribe controlled substances, as is the case with buprenorphine, or allow physicians with additional specialized addiction medicine training to do so in settings other than OTPs. 2) Permit methadone for OUD treatment to be dispensed by any pharmacy authorized to dispense controlled substances.

A model such as those described above would allow patients and clinicians to work together to determine the methadone treatment option that best fits a patient's needs, whether that means methadone dispensing and take-home doses at OTPs, methadone prescribing at OTPs, with pick up of doses at local pharmacies, or methadone prescribing by primary care and other non-specialist providers, with pick up of doses at local pharmacies.

CONCLUSION

Thank you again for your leadership and tireless work to finalize the proposed changes to 42 CFR Part 8, and for providing ongoing support to expanding treatment access which will affect hundreds of thousands of people across the country. If you have questions, or if our organization can be of further assistance, please contact Rebecca Northup at rebecca@amersa.org.

Sincerely,

Deborah S. Finnell, PhD, CARN-AP, FAAN
President, Association for Multidisciplinary Education and Research in Substance use and Addiction, on behalf of the 2022-2023 AMERSA Board of Directors

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[22] Calcaterra SL, Bach P, Chadi A, Chadi N, Kimmel SD, Morford KL and Samet JH. Methadone matters: what the United States can learn from the global effort to treat opioid addiction. J Gen Int Med. 2019. 34, 1039-1042.

[23] Board on Health Sciences Policy, Board on Health Care Services, Health and Medicine Division, Action Collaborative on Countering the U.S. Opioid Epidemic, National Academies of Sciences, Engineering, and Medicine. *Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop*. (Bain L, Norris SMP, Stroud C, eds.). National Academies Press; 2022:26635. doi:10.17226/26635

ADVOCATES | FOR OPIOID ADDICTION TREATMENT

Advocates for Opioid Addiction Treatment
Statement for the Record

House Energy & Commerce Health Subcommittee
Hearing on Policies to Protect Our Communities from Illicit Drug Threats
March 26, 2026

The Advocates for Opioid Addiction Treatment (AOAT) commends the Subcommittee for holding a hearing to examine policies addressing the addiction and overdose crisis in our country. However, **AOAT strongly opposes H.R. 5629, as it would reverse the significant progress made in our shared fight against the opioid overdose epidemic**. This legislation would likely lead to higher rates of opioid-related deaths and overdoses by restricting access to evidence-based treatment and eliminating patient-centered protocols that have proven effective.

AOAT represents more than 700 opioid treatment program (OTP) facilities and office-based opioid treatment (OBOT) providers across 46 states. Our health care teams provide lifesaving Medication-Assisted Treatment (MAT) to approximately 215,000 patients daily. Our facilities employ interdisciplinary teams—including physicians, pharmacists, nurses, counselors, peer support/recovery coaches, administrators, and clerical staff—to deliver comprehensive, evidence-based care to individuals living with opioid use disorder (OUD).

OTPs are highly regulated, structured, and comprehensive treatment facilities. We operate under strict federal, state, and local oversight—including the Substance Abuse and Mental Health Services Administration (SAMHSA), the Drug Enforcement Administration (DEA), state regulatory and Medicaid authorities, and pharmacy boards. Each facility must maintain continuous accreditation from a SAMHSA-approved body.

We support this rigorous regulatory framework and the patient and public safety protections it ensures. Most of our patients receive methadone, a Schedule II narcotic, as part of MAT. Methadone is highly effective when administered under physician supervision and diversion-control protocols. Without these safety measures, the risk of overdose is extremely high, as evidenced in the early 2000s, when physician-prescribed methadone for pain led to widespread overdoses, deaths, and diversion. Importantly, medication alone is not OUD treatment—it stabilizes patients by mitigating cravings and withdrawal symptoms, enabling engagement in the behavioral health therapies essential to recovery.

SAMHSA's reform of OTPs was the first comprehensive update since 2001 — a multiple decade gap during which the opioid crisis expanded and evolved dramatically. SAMHSA's revisions were based on published evidence, significant research, stakeholder and patient feedback, and public comments. They were designed to expand access to lifesaving care and modernize the delivery of OUD treatment by establishing a patient-centered model aligned with current medical and behavioral health standards, and removing outdated restrictions. These reforms intentionally support individualized care planning; allow clinicians to tailor treatment around employment, education, and recovery stability; and eliminate the burden of frequent in-person visits for individuals who lack reliable transportation or for whom an OTP is not geographically accessible.

AOAT strongly supported SAMHSA's recent overhaul of OTP regulations, which significantly expanded access to lifesaving treatment by:

- Allowing OTPs to admit patients via audio-visual telehealth under physician supervision;
- Removing the requirement that patients be addicted to opioids for at least one year before receiving OTP treatment; and
- Permitting health care professionals in mobile units to provide comprehensive care, not merely dispense medication.

These reforms also enhanced patient-centered care in OTPs, including:

- Allowing qualified patients to receive "take-home" methadone more quickly; and
- Permitting medically appropriate higher initial doses of methadone, supporting treatment for fentanyl addiction.

Our providers have worked tirelessly to implement these reforms, which have expanded treatment access—especially in rural and underserved areas. Telehealth and mobile units now allow patients to receive care where they live and work. These changes have also improved retention, treatment experience, and quality of care. Importantly, the safety and anti-diversion protocols in OTPs have prevented any increase in diversion associated with expanded take-home medication.

It is important to note that telehealth admissions at an OTP differ from typical telehealth arrangements: the patient is physically present at the facility — whether a clinic or mobile unit — while the medical provider participates remotely. The ability to utilize telehealth for intakes has proven especially valuable in addressing the health care workforce shortage in rural communities, where medical providers trained in addiction medicine often cannot be on-site at every facility for all operating hours and must instead divide their time across multiple facilities spanning large geographic areas. By enabling telehealth-based admissions, OTPs can admit patients timelier, rather than requiring them to wait several days until a provider is physically onsite — a delay that can mean the difference between someone entering treatment or a fatal overdose.

Not only have SAMHSA's OTP reforms increased access to treatment, they have also resulted in fewer emergency room episodes related to untreated withdrawal, relapse, or overdose; improved continuity of care; and helped saved countless lives.

H.R. 5629 would reverse these advances, reducing access for the 13% of the population without convenient OTP access and undermining gains in treatment retention, recovery, employment, and family stability.

The positive impact of SAMHSA's reforms is clear. For example, New Season, which operates 87 OTPs in 27 states and treats 33,000 OUD patients each day, reports:

- From 2023 to 2025, treatment compliance in the first month increased by more than 10%, with 12-month retention also rising;
- Patient employment rates improved across multiple treatment milestones in 2025 compared to 2023;
- In 2025, 14% of new patients accessed care via telehealth (29% in CO, 21% in FL), many of whom would not have received treatment otherwise;
- Take-home doses rose from 55% of patients in 2023 to 84% in 2025—a 53% increase;
- Starting methadone doses exceeding 30 mg increased from 7% in 2023 to 61% in 2025, allowing patients to reach therapeutic doses roughly 15 days faster than before; and
- Mobile units dramatically increased access: Portland, OR, the number patient visits to receive medication alone rose from 2,511 in 2024 to 11,671 in 2025 (365% increase), with continued growth in 2026. In fact, the number of patients using a New Season mobile unit has increase 300% since 2024.

Similarly, Behavioral Health Group, operating 99 OTPs across 20 states and DC, admitted nearly 1,600 patients via telehealth in the past six months alone—treatment that would not be possible under H.R. 5629.

It is also worth noting that Indiana has not implemented SAMHSA's regulatory changes. Therefore, H.R. 5629 would largely harm patients in the 43 states that have modernized their regulations, while leaving Indiana residents still unable to benefit from these lifesaving reforms.

SAMHSA's reforms have allowed OTPs to save more lives than ever. H.R. 5629 would reverse this progress, resulting in fewer patients receiving treatment, fewer individuals rebuilding their lives, and reduced access for rural and underserved communities. For these reasons, **we urge the Committee members to oppose H.R. 5629**.

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STATEMENT FOR THE RECORD

AMERICAN PSYCHIATRIC ASSOCIATION

FOR THE

HOUSE ENERGY AND COMMERCE COMMITTEE

SUBCOMMITTEE ON HEALTH

IN ADVANCE OF

March 26, 2026

LEGISLATIVE HEARING

The American Psychiatric Association (APA), the national medical specialty society representing over 39,200 psychiatrists, appreciates the opportunity to submit this statement for the record to the House Energy & Commerce Committee, Health Subcommittee. We commend the Committee's continued leadership in advancing policies that support timely, high-quality, and accessible mental health and substance use care and respectfully offer the feedback below on the legislation set to be heard before your Subcommittee.

H.R. 5629 - To provide that the final rule of the Department of Health and Human Services titled "Medications for the Treatment of Opioid Use Disorder" except for the portion of the final rule relating to accreditation of opioid treatment programs, shall have no force or effect.

The APA opposes H.R. 5629, which seeks to overturn the final rule "*Medications for the Treatment of Opioid Use Disorder"* (the "rule"). While the legislation reflects a well-intentioned effort to ensure that expanded access to treatment is accompanied by appropriate patient safety guardrails, it risks unintended consequences by elevating concerns about medication diversion over the well-established harms of untreated opioid use disorder. Evidence from recent years demonstrates that expanded access to medications for opioid use disorder improves engagement and reduces overdose risk, without clear increases in adverse outcomes.[1]

The current rule reflects a careful and evidence-based balance, expanding access to treatment for patients who may have historically faced barriers to care while maintaining necessary clinical oversight and continuity of care between patients and providers. Moreover, it does more than just increase access to medications for opioid use disorder; it allows treatment programs to tailor care to the patient's current situation and needs, such as use of telehealth services for screening and assessment, removing barriers patient admission criteria, and access to mobile medication units. Reinstating prior restrictions could unnecessarily disrupt care, limit access to treatment, and undermine patients' ability to maintain employment, pursue education, care for their families, and sustain recovery.

H.R. 7994 - The HERO Act

The APA supports The HERO Act, which would expand access to Naloxone and strengthen community-based overdose response systems. Timely intervention for an individual who has overdosed is often the determining factor between life and death. The rapid administration of naloxone is a well-established, evidence-based intervention that reduces mortality and preserves the opportunity for individuals to engage in treatment for opioid use disorder.

[1] Suen LW, Castellanos S, Joshi N, Satterwhite S, Knight KR. "The idea is to help people achieve greater success and liberty": A qualitative study of expanded methadone take-home access in opioid use disorder treatment. Subst Abus. 2022;43(1):1143-1150. doi: 10.1080/08897077.2022.2060438. PMID: 35499469; PMCID: PMC9710250.

Individuals who experience a nonfatal overdose remain at significantly elevated risk for subsequent overdose and death, underscoring the importance of rapid response and effective linkage to care. While overdose reversal alone is not a substitute for comprehensive, ongoing treatment, it is a critical component of a continuum of care approach to addressing substance use disorders. Expanding training and access across community settings, including first responders, schools, and other public-facing environments, can improve outcomes and reduce preventable deaths.

H.R. 1227 - The Alternatives to Pain Act

APA supports H.R. 1227, the Alternatives to Pain Act, which seeks to expand access to safe, effective, and evidence-based alternatives to opioid therapy. Advancing access to non-opioid pain management strategies is a critical component of a comprehensive approach to prevent substance use disorders. Many individuals with opioid use disorder are initially exposed to opioids through the treatment of acute or chronic pain; reducing reliance on opioid prescribing when clinically appropriate can help mitigate the risk of new cases of addiction.

Expanding access to multimodal pain treatment, including non-opioid pharmacologic therapies and non-pharmacologic interventions, can improve patient outcomes while reducing the risks of misuse, dependence, and associated psychiatric comorbidities. Given the well-established intersection between chronic pain and mental health conditions such as depression and anxiety, a more integrated and patient-centered approach to pain management is essential.

The APA thanks the Committee for its continued commitment to improving access to mental health and substance use care for millions of American's suffering from these chronic illnesses. We stand ready to collaborate and support the Committee's efforts to advance evidence-based solutions that strengthen access, quality, and safety in mental health services.

Edward W Boyer MD PhD
Edward Boyer LLC
387 South Parkview Ave
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August 16, 2025

STATEMENT OF EDWARD W BOYER MD PhD

QUALIFICATIONS

I am a board-certified emergency physician. Emergency medicine is an Accreditation Council for Graduate Medical Education (ACGME)-approved medical specialty that focuses on the first 30 minutes of any life-threatening condition. One notable aspect of emergency medical practice involves resuscitation of patients, identification of the cause of acute illness, and providing appropriate interventions.

I am a board-certified medical toxicologist. Medical toxicology is an ACGME-approved medical subspecialty that focuses on toxicity, poisoning, substance abuse, overdose, adverse effects, and drug interactions from all manner of potential intoxicants, including dietary supplements, herbal products, and medications. As a medical discipline, medical toxicology is particularly concerned with the adverse effects of psychoactive substances. A significant portion of medical toxicology practice and experience is related to the clinical effects of substances with mu-opioid receptor ("MOR") activity such as 7-hydroxymitragynine and other psychoactive substances, as well as the signs, symptoms and outcomes of diversion, misuse, abuse and withdrawal of each of these agents.

I have over 25 years of clinical practice experience (including internship, residency, and subspecialty training) in which I have treated several thousand patients with a wide variety of

adverse drug events, drug interactions, toxicities, and withdrawal symptoms. I have treated anticipated and unanticipated side effects of xenobiotics, including prescription medications, illicit substances, illegal drugs, dietary products, herbal remedies, and novel psychoactive substances, alone and in combination with each other. As a clinician focusing on the treatment of adverse effects of xenobiotics, I have treated several hundred patients with adverse effects, drug interactions, and toxicity from all manner of MOR agonists and their metabolites.

I have served on the medical staff of UMass Memorial Medical Center (2001-2016), Brigham and Women's Hospital (2016-2022), the Toxicology Service at Children's Hospital, Boston (1999-2021), and the Regional Center for Poison Control and Prevention Serving Massachusetts and Rhode Island (1999-2021). I now serve on the medical staff of The Ohio State University Wexner Medical Center (2021-present), Nationwide Children's Hospital (2024-present), and the Central Ohio Poison Control Center (2024-present).

I was a 2018 Fulbright Scholar funded to study the pharmacophysiologic outcomes in kratom users in Malaysia. In addition, I have received funding from the National Institute on Drug Abuse, part of the National Institutes of Health ("NIH"), to conduct original research investigations related to opioid analgesic medications (2001-present). I have also served as an NIH-funded research mentor for international trainees from Thailand, Malaysia, and Indonesia on kratom use. My research studies examine psychoactive substance use (including kratom), opioid abuse, innovative technologies, and HIV.

In addition, I have served as an expert consultant to the Community Epidemiology Work Group, the National Institute on Drug Abuse organization that monitors trends in substance use, including kratom (2004-2007). I have served on the scientific advisory board for the National Drug Early Warning System (2016-2020). I have conducted research for National Institutes on

Drug Abuse subcontractors related to opioid analgesic overdose, toxicity, misuse, and abuse (2004).

Because of my expertise, I have been invited to deliver expert lectures on kratom and the clinical effects of alkaloid components of kratom including 7-hydroxymitragynine at national conferences, including the North American Congress on Clinical Toxicology (2025), American Society of Addiction Medicine (2009), College on Problems of Drug Dependence (2018), Northeastern University's conference on Chemistry and Pharmacology of Drug Abuse (2019), to members of the United States Congress, and the University of Florida's International Kratom Symposium (2025). In 2024 I was invited to author the Kratom card for UpToDate, the leading medical information database. Finally, I was the 2008 NIH Distinguished Scientist in Natural Products Neuroscience for my formative work describing the clinical effects of kratom.

I have extensive experience in assessing the quality of medical literature as well as in determining whether published findings apply to specific patient care questions. I served on the Massachusetts Medical Society's Committee on Publications, which oversees the Editorial Board of New England Journal of Medicine (2016-2021). I have served as associate editor for the Journal of Medical Toxicology and been a member of the editorial board of ToxED, an online clinical database resource that assists clinicians in identifying adverse effects of numerous substances. In this capacity, I have reviewed the literature describing the toxicity, adverse events, and drug interactions of numerous substances, including kratom.

I have considerable expertise in the assessment of the scientific validity of research investigations. I have participated extensively in the NIH scientific review process—one of the most rigorous and objective scientific review processes in existence. I am a member of the College of CSR Reviewers, and in my service with NIH Scientific Review Groups I have examined grant

applications submitted to NIH that are related to behavioral and social science, substance abuse, and HIV (2005-present). The FDA has recognized my experience in medical toxicology and invited me to participate in Advisory Committees related to opioid REMS and to review the scientific validity of applications for funding of clinical trials (2004, 2022). I have also assessed the scientific validity of grant applications submitted to the US Centers for Disease Control ("CDC") related to HIV testing in emergency departments (2006). Related to these activities are my service as an expert reviewer for journals such as New England Journal of Medicine; Neuropsychopharmacology; Drugs, Drug and Alcohol Dependence; American Journal on Addictions; Academic Emergency Medicine; Journal of Medical Toxicology; Chest – Critical Care Medicine; Clinical Toxicology; Journal of Forensic Science; and Forensic Science International, among others.

I have expertise in the toxicology of MOR agonists including mitragynine, 7-hydroxymitragynine, mitragynine pseudoindoxyl, and other kratom alkaloids. This experience is drawn from education in medical school, internship, residency, post-graduate work, editorial assignments, continuous reading, teaching, and postgraduate instruction. I supervised the University of Massachusetts Medical Toxicology fellowship training program (2002-2015), where I was responsible for teaching fellows, residents, and clinical pharmacists from six different academic medical centers the adverse effects, drug interactions, and toxicity of all manner of potential intoxicants. I was a member of the Division of Toxicology of Harvard Medical School (2016-2021). In addition, I was a core faculty member of the Brigham and Women's Hospital Department of Psychiatry Training Program in Addiction Medicine (2020-2021). I am now Professor with Tenure at The Ohio State University and a member of the staff of the Central Ohio Poison Control Center (2024-present).

As part of these academic assignments, I teach basic and applied medical toxicology to medical students, residents, fellows, physicians-in-practice, behavioral science practitioners, Doctor of Pharmacy students, and pharmacy practice residents. I have taught courses on clinical presentations and outcomes of overdose at the Boston and Worcester campuses of the Massachusetts College of Pharmacy (1999-2003), and the Central Ohio Poison Center (2023-present). I have been invited to lecture to psychiatry physicians-in-training at Harvard Medical School teaching hospitals on pharmacology-related topics, including kratom toxicity (2005, 2019). As an instructor in CME courses offered by Harvard Medical School and Albert Einstein College of Medicine, I lectured on adverse effects of drugs with central nervous system ("CNS") activity, substance abuse, and addiction.

I have published in peer-reviewed journals. In particular, I have authored publications in Drug and Alcohol Dependence and Journal of Medical Toxicology that are related to human experience with 7-hydroxymitragynine. My work related to kratom has appeared in Addiction, Drug and Alcohol Dependence; American Journal on Addictions; Journal of Medical Toxicology; Current Topics in Medicinal Chemistry; Journal of Psychoactive Drugs, Journal of Addictive Diseases, Frontiers of Psychiatry, Journal of Toxicology and Pharmacology; Malaysian Journal of Medicine and Health Sciences; International Journal of Drug Policy; and Journal of Ethnopharmacology. My other original research, literature reviews, case reports, and perspectives have been published in the New England Journal of Medicine; Journal of the American Medical Association ("JAMA"); Pediatrics; Drug and Alcohol Dependence; and Academic Emergency Medicine, among others. Those articles have covered a range of issues pertaining to drug and dietary supplement toxicity, substance abuse, drug side effects, and behaviors of patients with chronic pain.

My general understanding of medical toxicology is based upon the length and scope of my graduate and post-graduate education, including the study of scientific methodology at Vanderbilt and Columbia Universities, pre-clinical pharmacology and neurosciences as well as clinical courses at Columbia College of Physicians and Surgeons, and the scope of my post-graduate training in medical toxicology at Children's Hospital Boston/Harvard Medical School. My ongoing study of medical toxicology continues with literature assessment and epidemiological analysis, including those instances where medications are involved in overdose and toxicity.

In my work as an academic physician, research scientist, and practicing toxicologist, I have compiled and analyzed data related to chronic pain and opioid analgesic overdose, toxicity, misuse and abuse, as well as the pharmacology and toxicology of numerous substances including 7-hydroxymitragynine. This work has enabled me to render conclusions about the likely factors that explain, to a reasonable degree of medical certainty, the toxicology of substances such as 7-hydroxymitragynine.

IDENTIFYING ADVERSE EFFECTS AND TRENDS

7-Hydroxymitragynine has long been recognized as being present in trace amounts in kratom leaf and as a metabolite of mitragynine due to action of cytochrome CYP3A4. Vendors now formulate the metabolite 7-hydroxymitragynine into commercial formulations. To identify emerging trends associated with use these formulations, clinicians review the medical literature and evaluate epidemiologic databases. While a clinician at the bedside can play an important role in identifying potential new adverse events, clinical observations are less important because emerging adverse events are typically rare events that demand population-based data.

Medical Literature

Initial descriptions of new adverse effects typically are published in case report form; these reports are often limited to 1-3 individuals presenting with a new adverse event. To identify these case reports, clinicians perform keyword searches using scientific publication databases (i.e., Pubmed, Google Scholar, Embase). Entering search terms into any of these search engines produces a list of citations that must be reviewed for relevance.

Results: To date, no published case reports in the peer-reviewed literature describe acute poisoning or overdose death from 7-hydroxymitragynine.

Assessment: A leading component of medical toxicology academic practice involves publication of case reports that highlight emerging adverse events and make other clinicians aware of these toxicities. Case reports also constitute the observation in the scientific method, that initial finding that serves as a means to generate one or more hypotheses to be tested. Case reports, therefore, can function as a signal; conversely, the absence of case reports might plausibly be considered to constitute a lack of signal.

Importance: The medical subspecialty that focuses on identifying new adverse effects from emerging use of substance, medical toxicology, has yet to publish acute poisoning or overdose death from 7-hydroxymitragynine. *Medical toxicologists are remarkably adept at identifying emerging adverse events from emerging substances.* For example, an oral anticoagulant poisoning outbreak among synthetic cannabinoid users from March 2018 was identified *within 2 weeks* by toxicologists at the Illinois Poison Control Center. Medical toxicologists are also adept at

prospectively identify poisoning cases. Medical toxicologists in New Jersey identified the onset of the 2023 tianeptine outbreak in June, followed by prospective surveillance for the next several months. This prospective surveillance found 4.6 tianeptine cases per month compared against a background rate of 0.5 tianeptine cases per year. *Given the proven skill of medical toxicologists in identifying adverse events from a wide variety of potential intoxicants including opioids, the lack of a published signal suggests not that 7-hydroxymitragynine poisonings are missed, but that a signal does not exist.* As both of these outbreaks entailed new substances, the argument that medical toxicologists must know about a new drug class before its outbreak can be identified lacks merit.

Epidemiologic Databases

Several data sources inform physicians, treatment clinicians, and policymakers regarding acute adverse effects, including overdose and death, from emerging substances. Each of them has advantages and disadvantages. Leading databases are:

1. National Poison Data System (NPDS). This system provides nearly nationwide reporting of overdose, interactions between substances, and adverse medication events. Data is derived from members of the public as well as bedside clinicians who seek up-to-date toxicologic information. A leading advantage of NPDS is that its data, being crowdsourced, is less prone to reporting bias. In addition, poison centers collect data such as the name, location, and contact information of the caller, all procedures that minimize the threat of spoofing. Unfortunately, NPDS has several disadvantages. First, calls made to a poison center are recorded as "exposures" because the actual ingestion of a specific

substance cannot often be proven to lead to the observed clinical findings.[1] Second, clinicians may misattribute clinical symptoms to an incorrect substance. Furthermore, the nurses and pharmacists who enter patient information may enter an inappropriate severity code that does not comport with degree of patient illness. Systemic misattribution can arise from programming errors. For example, for a physician who calls the poison control center, reports an event related to "7-hydroxymitragynine", and the specialist enters all data correctly, the NPDS data system in months past would default to "kratom" as the substance of interest. *This shortcoming was corrected on February 15, 2025 to make 7-hydroxymitragynine a specific substance in the NPDS; all poison control centers were notified of the correction to optimize accuracy of reporting.*

2. The National Drug Early Warning System (NDEWS). Now located at University of Florida, NDEWS expands the capabilities of the Community Epidemiology Working Group. Data inputs come from sentinel sites cast across the US bolstered with community-based experts, poison control data, 911 dispatch content, funeral directors, wastewater epidemiology, street intercepts, anonymous drug testing, web surveillance, as well as Canadian treatment sites. NDEWS can identify new substance use practices but may not identify the actual substance involved. In addition, NDEWS should be resistant to spoofing (for example, NDEWS is designed to identify new psychoactive substances, so the only way this surveillance system can miss an emerging problem is if no signal exists). Nonetheless, NDEWS has been aware of the difference between kratom and 7-hydroxymitragynine for several months

[1] For example, an individual found comatose in a room with empty bottles of sleeping pills would be classified as an exposure because ingestion is suspected but not proven, despite clinical signs and symptoms consistent with sleeping pill overdose.

(https://ndews.org/wordpress/files/2024/11/6.21.24_7-OH_PDF.pdf). While NDEWS monitors online threads for 7-hydroxymitragynine mentions, the system still lumps kratom and 7-hydroxymitragynine together in other surveillance efforts. This approach can lead to loss of precision in published NDEWS data and skewed interpretation of results.

3. FDA Adverse Event Reporting System (FAERS). A leading advantage of FAERS is that data is crowdsourced with minimal barrier to reporting. Unfortunately, FAERS has striking disadvantages: FAERS is highly susceptible to spoofing and factual inaccuracies. Submission of cases are anonymous; no confirmation of information or validation of report is performed. Researchers have noted that FAERS's data quality is "affected by the the…reporters' perception of the drug/natural product." (Li X, Ndungu P, Taneja SB et al. An evaluation of adverse drug reactions and outcomes attributed to kratom in the US Food and Drug Administration Adverse Event Reporting System from January 2004 through September 2021. Clin Trans Scie 2023; 16:1002-1011) *Importantly, FAERS does not identify a signal of an adverse event; FAERS suggests whether an investigation should be undertaken to determine if a signal exists*. Because of ambiguity in the FAERS dataset, the FDA correctly did not analyze FAERS data in their 7-hydroxymitragynine toxicologic assessment.[2] *Notably, none of the FAERS quarterly reports through Q1 2025—up to the time when the FDA 7-hydroxymitragynine report was being drafted—designate 7-hydroxymitragynine as presenting a safety signal for serious risk.*
4. DEA TOX. This DEA-funded, government-academic partnership (https://www.deadiversion.usdoj.gov/dea_tox/dea-tox.html) tests leftover or previously collected samples submitted voluntarily to a university laboratory for analysis. The

[2] *7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat* (Reissig et al, 2025)

academic lab is capable of detecting mitragynine and 7-hydroxymitragynine as well as other kratom alkaloids. DEA Tox details emerging toxicologic threats in its publicly available content.

5. State Unintentional Drug Overdose Reporting System (SUDORS). The US Centers for Disease Control and Prevention (CDC) funds 32 states and the District of Columbia to abstract into SUDORS detailed data on unintentional, intentional, and undetermined opioid overdose deaths from death certificates and medical examiner and coroner reports. SUDORS is heavily dependent on forensic testing; because few laboratories detect 7-hydroxymitragynine, SUDORS is of limited utility.
6. RADARS System. The RADARS System comprises an array of synergistic surveillance programs which offer a "mosaic" approach to understanding current trends in substance abuse, misuse, and diversion. The RADARS System programs systematically collect de-identified instances/reports for specific drug products occurring in a 3-digit ZIP code. Rates of abuse in each 3-digit ZIP code are then calculated based upon population and drug availability. RADARS System data is timely and allows for emerging trends to be discovered relatively quickly. RADARS System data have been used by manufacturers, regulatory agencies and medical/public health officials to characterize and monitor prescription drug abuse, misuse and diversion. RADARS System data have provided pivotal information for regulatory submissions and presented at several FDA advisory committee meetings and public hearings.

Results: While the number of 7-hydroxymitragynine exposures (N=118) reported in NDPS

increased by 58% between April 1-July 31, 2025[3], the number of kratom reports (N=1116) increased at a greater rate (69.9%) over the same period. The NPDS contains no reports of death attributable to 7-hydroxymitragynine, whereas 14 kratom deaths were reported April 1-July 31, 2025. No deaths identified by NPDS either before or after listing 7-hydroxymitragynine as a specific substance can plausibly be attributed to 7-hydroxymitragynine.[4] Even the NPDS August 12, 2025 alert ("Health Advisory: Serious Illnesses Associated with 7-OH Use") failed to identify a single death following ingestion of 7-hydroxymitragynine products.

Publicly available content on DEA Tox describes increased kratom and 7-hydroxymitragynine findings since 2020 (the laboratory conducting the analyses can detect 7-hydroxymitragynine, mitragynine pseudoxindoxyl, speciociliatine, as well as other kratom alkaloids). DEA Tox details emerging toxicologic threats in its publicly available content such as tianeptine, xylazines, and other substances, but 7-hydroxymitragynine, even after oral single-product formulations entered the marketplace, has never received comparable recognition. Because of dramatic selection bias in case identification, DEA Tox is not useful as an epidemiologic source, but certain trends appear. For example, the measured concentration of 7-hydroxymitragynine is comparable to or lower than mitragynine, suggesting that 7-

[3] The dates in this analysis are different from those in the FDA assessment "*Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicologic Concerns Around an Emerging Opioid Threat"* (Reissig et al., 2025). A specific product code for 7-hydroxymitragynine was added on 2-15-2025 to Toxicall (and added to NDPS on 7-16-2025). This document compares kratom and 7-hydroxymitragynine mentions in the NPDS for the period April 1-July 31. This range of dates was selected in this analysis to allow full training of poison center staff to the new product codes and become familiar with its use. The method in this report is intended to produce greater precision in the data than the methods in the FDA report; by selecting a range of dates when 7-hydroxymitragynine could not be properly coded, the FDA has adopted a methodology that exaggerates the rate of rise of 7-hydroxymitragynine exposures reported to poison centers.

[4] A single death was recorded in the NPDS 7-hydroxymitragynine dataset in June 2025, but this individual had ingested clonidine, amphetamines, gabapentin, benzodiazepines, and 7-hydroxymitragynine. Reported clinical effects in this patient included (among others) hematemesis, cerebrovascular accident, and fever, as well as hyperventilation and alkalosis. The last two findings, in particular, are inconsistent with opioid effect from kratom and mitragynine, either alone or used together. Because of the number of involved substances and the clinical findings that are unrelated with known toxic effects of opioids, this case is not included in this analysis.

hydroxymitragynine was not the ingested substance.[5]

NDEWS content related to 7-hydroxymitragynine is heavily related to reporting of online material, research publications, and background material. One NDEWS data collection effort focusing on EMS run data combines kratom and 7-hydroxymitragynine. NDEWS releases do not describe acute poisoning and overdose deaths.

Assessment: No clear signal for overdose death from 7-hydroxymitragynine exists. This finding holds true across multiple nationwide overdose surveillance systems.

The lack of a signal is important. In general, multiple overdoses do not go unnoticed; multiple overdoses generate signals. (MMWR 2008; 57:793-796; New England Journal of Medicine 2018; 379:1216-1223; MMWR 2024; 73:89-90) The lack of signal from even a single 7-hydroxymitragnine overdose death is important. Prior research has identified that notification of upcoming scheduling of a substance leads to increased overdose from that substance; for example, the DEA announcement in 2001 that gamma-hydroxybutyrate (GHB) as a Schedule I substance led to an immediate surge of severe GHB overdoses in the weeks prior to scheduling. (Journal of Toxicology-Clinical Toxicology 2001; 39:541-542). Paradoxically, NPDS data demonstrates that the July 25 FDA warning letter has not triggered a comparable surge of severe 7-hydroxymitragnine poisoning, overdose, or death.

[5] Very little, if any, ingested 7-hydroxymitragynine reverts to mitragynine, but 7-hydroxymitragynine is unstable in biological matrices. In vitro studies in human plasma treated to prevent destruction of the 7-hydroxymitragynine identified that some 7-hydroxymitragynine rearranges to form mitragynine pseudoindoxyl. This finding seems to suggest that a more reasonable measure of ingested 7-hydroxymitragynine exposure might involve the sum of potential metabolites—but this represents a hypothesis that awaits testing. Nonetheless, any finding where more mitragynine is present than 7-hydroxymitragynine is likely to be from kratom ingestion; cases where more 7-hydroxymitragynine (along with mitragynine pseudoindoxyl) is present than mitragynine suggests ingestion of a substance other than mitragynine.

The argument that data collection systems being unaware of 7-hydroxymitragynine leads to missed adverse events lacks merit. Leading surveillance systems (i.e., poison control centers, DEA Tox, and NDEWS) are well aware of the distinction between kratom and 7-hydroxymitragynine. Furthermore, the way in which NPDS operates *increases* the accuracy of identifying death from a specific chemical. For example, poisoning death in a patient in a healthcare facility (i.e., the sort of individual about whom NPDS collects data) is rarely immediate. The period from presentation to death allows medical toxicologists time to obtain substantial information about the intoxication; this, in turn, leads to greater precision in attributing poisoning death—and minimizing underreporting—to a specific substance. NPDS has not identified a single death solely attributable to 7-hydroxymitragynine. Furthermore, NDEWS investigators knew of the differences between the two compounds but provided only aggregated data of "kratom/7-OH" exposure. This research strategy potentially overrepresents the impact of 7-hydroxymitragynine in their reporting.

Summary: A signal arising from overdose death from 7-hydroxymitragynine is absent. Based upon data available at this time, the lack of findings suggests that 7-hydroxymitragynine carries no undue or unreasonable risk of overdose death.

Comments on the 2025 FDA report on 7-hydroxymitragynine entitled

"7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicologic Concerns Around an Emerging Opioid Threat"

The FDA document entitled "7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicologic Concerns Around an Emerging Opioid Threat" contains several misstatements of science and epidemiology.

Science: The FDA report conflates 7-hydroxymitragynine MOR receptor affinity with lack of safety. *Exposure, not potency of binding alone, predicts toxicity.*[6] As FDA guidance documents flatly state, "[e]xposure-response information is at the heart of any determination of…safety…." ("Guidance for Industry. Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications, published 11/30/2024, available at: https://www.hhs.gov/guidance/document/exposure-response-relationships-study-design-data-analysis-and-regulatory-applications) While binding of a substrate to its receptor is useful to know, it is but one aspect of considering potential adverse effects including acute poisoning and overdose death.[7] The FDA not only overlooks the importance of assessing human exposure to 7-hydroxymitragynine following ingestion of that substance in its analysis, but they also disregard existing data that could better inform policymaking decisions.

The FDA assessment, recognizing that data related to administration of 7-hydroxymitragynine in humans are limited, relied upon existing studies and animal models to infer

[6] "Exposure" in this context is different from NPDS usage; here, exposure refers to the concentration and persistence of a substance in the body. The amount of drug that is absorbed into the body, how long the body takes to metabolize and excrete it, metabolite-to-parent ratio, protein binding, and how long a substance persists in target organs, among other parameters, all contribute to extent of exposure to that substance. Response can be assessed in terms of therapeutic effect or safety.

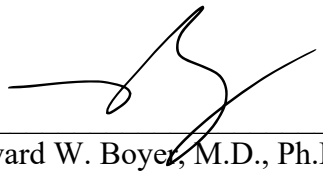
[7] The same features that make 7-hydroxymitragynine difficult to detect in forensic testing—its instability in plasma—*also limit the exposure of the person ingesting 7-hydroxymitragynine*. 7-Hydroxymitragynine contains a conjugated methyl ester that is of heightened chemical reactivity, hence the observed instability of 7-hydroxymitragynine in plasma, blood, urine, and gastric fluid. The stability of orally administered 7-hydroxymitragynine is actually worse than research suggests; incubation of 7-hydroxymitragynine without protease inhibitors led to greater-than-expected destruction of the molecule than from simple ester hydrolysis alone. Moreover, this analysis (ACS Pharmacol Transl Sci 2020; 3:1063-68) did not include the impact on hepatic metabolism—a recognized pathway for 7-hydroxymitragynine metabolism. Together, these effects, unconsidered by the FDA, limit human exposure to ingested 7-hydroxymitragynine.

(rather than prove) the potential for toxicity in humans. Unfortunately, the FDA makes in their assessment two errors. First, the FDA attempts to extend information derived from *kratom* administration studies to oral 7-hydroxymitragynine. Substantial differences exist in several pharmacokinetic and pharmacodynamic parameters in animal models between 7-hydroxymitragynine from kratom administration and oral administration of 7-hydroxymitragynine. Many of these parameters arising from oral 7-hydroxymitragynine administration in animal models (e.g., the limited bioavailability of <3%, limited volume of distribution, short elimination half-life, brief Mean Residence Time (the time a molecule such as 7-hydroxymitragynine spends in the body), and poor brain penetrance could contribute to an understanding of the observed lack of signal for acute poisoning and overdose death. Second, the FDA relies upon animal studies with unclear translational value to identify respiratory depression. The relied-upon study compared intravenous 7-hydroxymitragynine administration—a route of administration of 7-hydroxymitragynine that has not been observed among consumers. At no point does the FDA 7-hydroxymitragynine assessment acknowledge the importance of pharmacokinetic and pharmacodynamic parameters that limit exposure and mitigate toxicity from 7-hydroxymitragynine, or rely upon optimal scientific methodology in attempts to demonstrate toxicity.

Epidemiology: The FDA in their 7-hydroxymitragynine toxicology assessment notes considerable shortcomings of several epidemiologic datasets—and ignore some appropriate ones. For example, the FDA notes, correctly, that FAERS is not worthy of further analysis. Notably, however, the FDA assessment ignores that none of the FDA's own quarterly reports through Q1 2025 describe 7-hydroxymitragynine as presenting a safety signal for serious risk

(https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event-reporting-system). The FDA places greatest emphasis on NPDS data but report only 7-hydroxymitragynine exposures. This approach contains considerable bias because of the lack of a comparator. A more scientifically rigorous approach would have compared the number and rate of change of NPDS-reported exposures to 7-hydroxymitragynine versus another psychoactive substance—such as ingestible delta-9 tetrahydrocannabinol (Δ-9 THC) formulations. For example, between April 1 and July 31, Δ-9 THC edibles were reported in NDPS over 7900 times—with six deaths (and no 7-hydroxymitragynine exposures in the cohort). Comparing the reports for 7-hydroxymitragynine to other substances would likely have identified a much stronger signal for other substances than 7-hydroxymitragynine.

I am able to defend rigorously these conclusions, made within a reasonable degree of medical and toxicologic certainty. I reserve the right to supplement, amend, or addend these conclusions based upon new information, including other expert reports.



Edward W. Boyer, M.D., Ph.D.

August 18, 2025

To: Members of the Sub-Committee on Health; House Energy and Commerce Committee

RE: HR 5629

In March 2020, SAMHSA let states request blanket exceptions so OTPs could dispense up to **28 days of take-homes for "stable" patients** and up to **14 days for "less stable" patients**. In the 2024 final rule, HHS/SAMHSA said the COVID experience and subsequent research supported making key take-home flexibilities permanent, while shifting decisions more toward clinician judgment and less toward rigid time-in-treatment rules.[1]

The evidence to date suggests little in the way of harmful outcomes and some evidence of improved retention of people in treatment and less evidence of relapsing behavior. HR 5629 would therefore likely reduce treatment retention with little to no impacts on diversion of methadone and no clear impact on overdoses involving methadone.

Some of the existing evidence is summarized below.

The U.S. evidence from the COVID-flexibility period points in a fairly consistent direction: **more flexible take-home methadone was associated with improved convenience and patient autonomy, generally similar or better treatment retention, and no clear signal of increased overdose at the population level**.[2]

A 2023 *Lancet Public Health* evidence synthesis, which reviewed the early peer-reviewed U.S. literature, similarly concluded that studies had **not shown increased overdose, serious adverse events, or clear evidence of major diversion-related harms** after take-home flexibilities were introduced.[3]

In fact, overdose deaths involving methadone declined from 2019 to 2021. And analyses showed no differences among states adopting more flexible approaches and those that did not.[4]

Several studies suggest that relaxing take-home rules helped people **stay in treatment** or at minimum did **not worsen retention**. A retrospective study in Pennsylvania reported that expanded take-home dosing was associated with **reduced attrition** and favorable toxicology changes at one OTP.[5]

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[1] Federal Register :: Medications for the Treatment of Opioid Use Disorder

[2] Krawczyk N, Rivera B, Levin E et al. **Synthesising evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy**, The Lancet Public Health, 8, e238-e246

[3] ibid

[4] Roy V, Buonora M, Murray-Krezan C **U.S. states opting out of expanded methadone take-home policies and associated mortality,** Journal of Substance Use & Addiction Treatment, 2025; 179

[5] Op cit note 2

A 2023 *Lancet Regional Health – Americas* study of new methadone patients in an urban OTP found that exposure to extended take-home schedules was **not associated with worse retention or more adverse events**, though measured opioid use while in care was somewhat higher in one comparison. The overall interpretation was that relaxed guidelines were **not associated with measurable increases in harms**.

Diversion: This is the area with the weakest evidence base, but the available evidence is reassuring rather than alarming. SAMHSA's final rule states that, based on available evidence and state reports during the PHE, there was **no significant change in diversion** and that survey evidence suggested diversion among patients receiving take-homes was low.[6]

Richard G Frank

Leonard D Schaefer Chair in Economic Studies and Director of the Center on Health Policy

The Brookings Institution.

[6] Federal Register :: Medications for the Treatment of Opioid Use Disorder

House Committee on Energy and Commerce

Subcommittee on Health

Legislative Hearing

Submitted by Congressman Ted W. Lieu (CA-36)

March 26, 2026

Chairman Griffith and Ranking Member DeGette, thank you for holding this hearing and for allowing me to speak in support of my legislation H.R. 2004, Tyler's Law. I am proud to have re-introduced this bipartisan legislation alongside my colleagues Representatives Latta, Kamlager-Dove, and Barragan.

Tyler's Law would direct the Department of Health and Human Services (HHS) to issue guidance on fentanyl testing in emergency rooms.

About Fentanyl Testing in Emergency Rooms

Currently, many drug screenings in emergency rooms only test for marijuana, cocaine, amphetamines, opiates, and PCP – but not fentanyl. This means that when a patient comes to the hospital to be treated for an overdose, the hospital may not have identified the presence of fentanyl in their system. That patient could then be discharged without knowing that the drugs they took were contaminated, and without being provided the resources to combat an opioid addiction, resulting in additional adverse outcomes, including death.

Adding fentanyl testing to routine drug screenings in emergency rooms could prevent many fentanyl-related deaths, which continues to be the leading cause of overdose deaths.

About Tyler's Law

A standard like this could have made the difference in the case of Tyler Shamash. Tyler was a teenager who lost his life at the age of 19 to a fentanyl overdose, in part because -- unbeknownst to the physician there -- he was not tested for fentanyl in the emergency room. Tyler was discharged from the hospital with no knowledge that he had fentanyl in his system. The next day, he took drugs that he did not know were contaminated with fentanyl – this time, his overdose was fatal. His mother, Juli, has been advocating for this legislation and sharing her son's story to prevent others from experiencing the same tragedy. I have been honored to work with Juli, a tireless advocate, for the past few years.

Tyler's Law would direct HHS to complete a study to determine how frequently emergency rooms are currently testing for fentanyl when patients come in for an overdose, as well as the

associated costs, benefits, and risks, and would direct HHS to then issue guidance to hospitals on implementing fentanyl testing in emergency rooms.

Conclusion

I am proud that Tyler's Law has 50 bipartisan cosponsors and is supported by the Emergency Nurses Association and the American College of Emergency Physicians. On Tuesday, March 24th, this measure passed out of the U.S. Senate on a unanimous basis.

Tyler's Law will help prevent these tragedies by promoting fentanyl testing in hospital emergency departments. Illicit fentanyl has taken too many American lives, and getting this legislation into law could prevent other families, like Juli's, from experiencing such a devastating tragedy. I respectfully request that the Subcommittee support Tyler's Law and I thank you again for the opportunity to testify before you.

Letter of Support for Tyler's Law (H.R. 2004)

Submitted for the Record

Health Subcommittee Hearing

U.S. House Committee on Energy and Commerce

We are mothers and family members who have lost loved ones to fentanyl poisoning and overdose. Each of us has experienced firsthand the devastating consequences of a drug supply that is increasingly contaminated with fentanyl.

We are writing to express our strong support for Tyler's Law (H.R. 2004), which addresses an important gap in overdose care by examining fentanyl testing practices in hospital emergency departments.

Many families, like ours, only learned after the death of a loved one that fentanyl had been present or that it may not have been detected during medical treatment. In some cases, patients arrive at emergency departments after suspected overdoses, but standard toxicology screens may not detect fentanyl because it requires a separate test.

Ensuring that clinicians have clear guidance on fentanyl testing could help provide critical information when treating overdose patients and may help inform decisions about follow-up care and treatment.

Several of us have worked to address this issue at the state level:

- Gretchin Murray, whose son Gage died from fentanyl poisoning, helped pass Gage's Law in Florida to improve toxicology reporting in overdose deaths.
- Thurraya Barnwell Kent, whose son Malcolm died after fentanyl exposure went undetected in the emergency room, helped pass Malcolm's Law in Virginia to improve fentanyl testing practices in hospitals.
- Melanie Yates, whose fiancé Josh Siems died from fentanyl poisoning, helped pass the Josh Siems Act in Maryland to improve fentanyl testing and reporting.
- Jacob Towe, whose 3-year-old son Leo died after fentanyl exposure went undetected during a child welfare investigation and is currently trying to get Leo's Law passed in Oklahoma

Other families across the country continue to advocate for change after similar losses:

- Megan Le Doux, whose son Wade died from fentanyl poisoning
- Perla Mendoza, whose son Elijah died after unknowingly ingesting fentanyl
- Mareka Cole, who son Marek died after unknowingly ingesting fentanyl

While our experiences come from different states and circumstances, we share a common goal: preventing other families from suffering the same loss.

Tyler's Law represents an important step toward better understanding how fentanyl testing is currently used in emergency departments and whether national guidance could help improve care for overdose patients.

We respectfully urge the Committee to support Tyler's Law and continue working toward policies that help clinicians identify fentanyl exposure and save lives.

Sincerely,

Gretchin Murray

Thurraya Barnwell Kent

Melanie Yates

Jacob ToweHR2004

Megan Le Doux

Perla Mendoza

Mareka Cole

Statement for the Record

Submitted by:
Teresa Miller, JD
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Before the U.S. House Energy and Commerce Subcommittee on Health

March 26, 2026 Hearing

"Policies to Protect Our Communities from Illicit Drug Threats"

The Legal Action Center is a law and policy organization that works to fight discrimination, build health equity, and restore opportunity for people with substance use disorders (SUDs), arrest and conviction records, and HIV or AIDS. We urge the House Energy and Commerce Health Subcommittee to bolster public health responses to the ongoing overdose crisis in this country that help stem the tide on overdose deaths and increase access to SUD care rather than revert to outdated punitive and other failed policies of the past.

While the overall drug overdose death rate in this country has declined recently, we are still losing more than 200 people a day to fatal overdose, and certain groups of people continue to experience significantly higher mortality rates. Meanwhile, mental health needs continue to rise across most populations as we lose nearly 135 people a day to suicide. Ensuring people's access to substance use and mental health (MH) care couldn't be more important— not only to build on the progress made in reducing fatal overdoses but also to address the ever-growing mental health crisis.

Of the nearly 50 million people in the United States with an SUD, only about 20% access treatment in a given year, and that's before the impacts of recent federal rollbacks to key pillars of care access including Medicaid, SAMHSA, and Marketplace plans. Of the adults who needed SUD treatment and did not receive it, 30% pointed to a lack of health coverage or affordable health coverage as the reason why.

Millions of Americans are bracing for the impact of the One Big Beautiful Bill Act (OBBBA)'s nearly $1 trillion in cuts to Medicaid -- the single largest payer of mental health and SUD services in the nation -- which the Congressional Budget Office (CBO) estimates will cause 10 million people to lose access to health care coverage, including 7.5 million people being forced off Medicaid.

Medicaid is a crucial lifeline for those who are struggling with SUD. Nearly 40% of Medicaid enrollees live with SUDs and/or MH conditions, and over 20% of U.S. adults with any SUD are covered by Medicaid. Compared to other types of insurance, Medicaid consistently yields the highest rates of treatment access to quality care for opioid use disorder (OUD), underscoring the program's indispensable role in addressing the continuing overdose crisis. For example, after Kentucky expanded its Medicaid program, the number of enrollees accessing SUD treatment grew by a remarkable 700%.

Over the years, prior to the OBBBA, Congress and CMS had made substantial progress in improving access to SUD and MH care by expanding Medicaid eligibility, SUD treatment coverage, and SUD/MH parity protections, but we are concerned that current congressional and administration actions aimed at further gutting Medicaid will reverse these important gains.

In total, there are nearly 14 million nonelderly adult Medicaid enrollees with SUDs and/or MH conditions nationwide who rely on Medicaid to access lifesaving medications,

services, and support. Many formerly incarcerated individuals and those with SUDs or MH conditions rely on Medicaid in the first place because of pervasive discrimination and stigma in many areas of life, including employment, education, housing, and commercial insurance. The federal government's current actions, including Medicaid policy changes like the OBBBA's work reporting requirements, are only reinforcing and extending this stigma and discrimination deeper.

While data shows that at least 92% of adult Medicaid enrollees already meet either the work requirement or one of the exemptions, CBO estimates that more than 25% will lose coverage, many due solely to the bureaucratic red tape associated with these requirements rather than ineligibility. This loss of coverage will only compound the barriers that people with SUDs, MH conditions, and arrest/conviction histories already face, reducing their care access and significantly worsening their health. While the President and Congress intentionally included critically important exemptions in the law to ensure vulnerable populations, like those with SUDs, were not unintentionally harmed by these new work requirements, the reality and experience of states that have adopted such requirements is one of massive coverage loss, including among vulnerable populations.

Georgia and Arkansas are crucial examples of the barriers to coverage and coverage loss that results from work reporting requirements. In Georgia, as of the end of February 2026, just shy of 15,000 people accessed coverage through the state's Pathways to Coverage program, out of about 240,000 predicted to be eligible – a meager 6 percent. And, in Arkansas, where Medicaid work reporting requirements were promised to increase employment, 18,000 people – or 1 in 4 - lost their Medicaid coverage in less than a year, with no increase in employment.

On top of the massive cuts contained in the OBBBA, Congress and the Administration have sent letters to more than 10 states purporting to investigate fraud in their Medicaid programs, specifically targeting SUD treatment in many cases. CMS even went so far as to freeze federal Medicaid funding to Minnesota for entire categories of services. These overly broad actions do nothing to address actual fraud and instead jeopardize people's access to lifesaving care.

As part of this hearing, the Subcommittee is considering a series of bills, including H.R. 5629**. LAC opposes H.R. 5629 and urges Congress not to pass this legislation. On top of the Medicaid cuts mentioned previously, this bill would have a devastating impact on access to medications for opioid use disorder (MOUD). The 2024 42 CFR Part 8 Final Rule importantly established more flexibilities for states to increase access to MOUD. These medications are widely recognized as the gold standard of care for treating OUD but are only accessed by a small fraction of individuals.** Modernizing the Part 8 standards, as SAMHSA did in 2024, was a critical step to increasing access to MOUD and must be continued to increase overall engagement and address remaining stark disparities. For individuals living in rural communities, access to opioid treatment programs (OTPs) and office-based MOUD is particularly limited. Further, despite some

prisons and jails offering MOUD, the majority of incarcerated people remain unable to access MOUD, contributing to the significantly higher overdose rates for people reentering the community. Rolling back the recent improvement in the revised Part 8 rule would also create significant confusion and service disruption for people receiving SUD treatment and the people who serve them.

The Part 8 rule changes came nearly 30 years after the Institute of Medicine observed that the OTP regulatory scheme should reinforce the lifesaving and public safety benefits of methadone, one of the three FDA-approved types of MOUD, as opposed to "put[ting] too much emphasis on protecting society from methadone." The changes crucially removed stigmatizing regulatory language with the goal of reinforcing a standard of patient-centered and dignified care that all patients deserve and all OTPs should provide. The 2024 updates to Part 8 importantly give patients at OTPs more flexibility with their SUD treatment, which minimizes disruptions to "employment, education and other daily activities for patients," and removed barriers to engaging in care in OTPs. The changes also importantly foster patient wellbeing, public health and safety, and more equitable access to MOUD at large. The changes are consistent with research findings that show that increased methadone treatment regulatory flexibilities extended during the COVID pandemic led to no significant increase in methadone-involved overdose fatalities or severity in methadone poisoning exposure and increased patient quality of life. Congress should be looking for more opportunities to increase support and access to SUD treatment consistent with this goal of enabling individuals to live their lives to the fullest while participating in treatment.

Further, H.R. 5629 would roll back progress towards increasing access to SUD treatment in carceral settings, a priority that more than half of all states have been working toward. The 2024 Part 8 changes provided important clarification that a carceral facility that is not an OTP can still provide methadone for the initiation or continuation of treatment for OUD or withdrawal management to a patient if certain conditions are met. This is especially important as formerly incarcerated people are 130 times more likely to die from an overdose in the first two weeks after release than the general population.

The OBBBA's significant cuts to Medicaid already threaten access to lifesaving health coverage and care for people with SUD. We urge the Subcommittee not to exacerbate the harm by passing legislation that will further reduce care access and create additional barriers to people's wellbeing and stability. If we want to continue the progress we have made in reducing overdose deaths, we should be enhancing and building on the public health policies that have yielded results, like reducing barriers to SUD treatment and services and increasing access to healthcare coverage. The Legal Action Center stands ready to partner in these efforts and appreciates the opportunity to provide this statement.

May 26, 2026

Regarding: H.R. 8000, END 7-OH Act (Rep. Bilirakis)

The Honorable Morgan Griffith
Chairman, Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana Harshbarger
Vice Chair, Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana Degette
Ranking Member, Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Griffith, Vice Chair Harshbarger, Ranking Member Degette and Members of the Subcommittee on Health:

I write to you regarding H.R. 8000, END 7-OH Act which proposes to place 7-hydroxymitragynine (7-OH) within Schedule I of the Controlled Substances Act (CSA).

As attested to by my attached curriculum vitae, my research on kratom use in the U.S. began in 2017 and was advanced during my 4-year postdoctoral training at the National Institute on Drug Abuse (NIDA) Intramural Research Program (IRP) beginning in 2019. Following my postdoctoral training at NIDA IRP I continued researching kratom as a faculty member at the Johns Hopkins University School of Medicine in the Department of Psychiatry and Behavioral Sciences and undertook pilot survey projects examining use of 7-OH products among U.S. adults. I am one of the few clinical researchers in the United States who has presented and published in the areas of kratom and 7-OH, with several additional publications currently under peer review.

My aim in writing this letter is to provide some basic information that may help inform the Committee's decision-making on this proposed bill.

Products containing 7-OH are derived from the botanical *Mitragyna speciosa*, commonly referred to as kratom in the U.S. Among kratom's constituents, mitragynine is the most abundant alkaloid, and 7-OH is mitragynine's active metabolite—that is, the human body (mostly the liver and intestines) converts some mitragynine to 7-OH, which then has its own effects.[1] 7-OH also forms in small amounts in the kratom leaf itself, through oxidization, when leaves are stored dry.[2] As the amount of 7-OH that forms in kratom leaf is negligible, it is appropriate to consider 7-OH products as distinct from kratom products.[3] In the U.S., products with 7-OH as the primary constituent have been sold in the U.S. since early 2023, but have not been widely studied.[4] Oftentimes these products are referred to as "synthetic" but they are not; rather they are made from organic kratom material.

When 7-OH products appeared several years ago, I and others voiced over the possibility that they could result in public health harms.[5] These assumptions rested largely on limited basic research findings (i.e., binding affinity studies, non-human animal studies) elucidating opioidergic mechanisms of action and behaviorally reinforcing properties. Concerns about concentrated kratom product formulations more generally (but not specific to 7-OH) were also previously made, largely for similar reasons.[6]

I believe that concerns about kratom and 7-OH products were and are warranted, as are concerns with *any* psychoactive substance with rewarding properties. However, concerns specific to

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[1] Ganasan, J., Karunakaran, T., Marimuthu, Y., Rusmadi, N. N., Firouz, N. S., Jenis, J., & Kumar, U. S. U. (2024). Chemistry and toxicity of 7-hydroxymitragynine (7-OHMG): an updated review on the oxidized derivative of mitragynine. *Phytochemistry Reviews*, 1-14; Kruegel, A. C., Uprety, R., Grinnell, S. G., Langreck, C., Pekarskaya, E. A., Le Rouzic, V., ... & Sames, D. (2019). 7-Hydroxymitragynine is an active metabolite of mitragynine and a key mediator of its analgesic effects. *ACS Central Science*, *5*(6), 992-1001; Tanna, R. S., Nguyen, J. T., Hadi, D. L., Manwill, P. K., Flores-Bocanegra, L., Layton, M. E., ... & Paine, M. F. (2022). Clinical pharmacokinetic assessment of kratom (Mitragyna speciosa), a botanical product with opioid-like effects, in healthy adult participants. *Pharmaceutics*, *14*(3), 620.

[2] Chakraborty, S., Uprety, R., Slocum, S. T., Irie, T., Le Rouzic, V., Li, X., ... & Majumdar, S. (2021). Oxidative metabolism as a modulator of kratom's biological actions. *Journal of Medicinal Chemistry*, *64*(22), 16553-16572.

[3] Sharma, A., Smith, K. E., Kuntz, M. A., Berthold, E. C., Elashkar, O. I., Guadagnoli, N., ... & McCurdy, C. R. (2025). Chemical Analysis and Alkaloid Intake for Kratom Products Available in the United States. *Drug Testing and Analysis*; Zhang, M., Sharma, A., León, F., Avery, B., Kjelgren, R., McCurdy, C. R., & Pearson, B. J. (2022). Plant growth and phytoactive alkaloid synthesis in kratom [Mitragyna speciosa (Korth.)] in response to varying radiance. *PLoS One*, *17*(4), e025932

[4] Hill, K., Boyer, E. W., Grundmann, O., & Smith, K. E. (2025). De facto opioids: Characterization of novel 7-hydroxymitragynine and mitragynine pseudoindoxyl product marketing. *Drug and Alcohol Dependence*, *272*, 112701.

[5] Smith, K. E., Boyer, E. W., Grundmann, O., McCurdy, C. R., & Sharma, A. (2025). The rise of novel, semi-synthetic 7-hydroxymitragnine products. *Addiction*, *120*(2), 387-388.

[6] Grundmann, O., Garcia-Romeu, A., McCurdy, C. R., Sharma, A., Smith, K. E., Swogger, M. T., & Weiss, S. T. (2024). Not all kratom is equal: the important distinction between native leaf and extract products. *Addiction*, *119*(1), 202-203.

kratom and 7-OH with respect to fatalities, adverse events, overdose, and addiction have largely not been realized. Neither "kratom" nor "7-OH" are household words, nor emblematic of a public health crisis. Insofar as there are *risks* associated with kratom and 7-OH use, these can be best addressed with continued research and stringent regulation (as distinct from prohibition). It is my concern that scheduling 7-OH under the CSA or by other procedures prior to more research being conducted would not be in the interest of public health given the widespread reasons that consumers have for using both kratom and 7-OH, including for the purpose of harm reduction from substances such as fentanyl.[7]

The recommendations of scheduling of kratom, mitragynine, or 7-OH in the U.S. have long been confusing and fraught.[8] This current recommendation is a continuation of a seeming misunderstanding or lack of consideration of the science. Since 7-OH products have proliferated in the U.S. it has become increasingly evident that non-human animal models using routes of administration and doses uncharacteristic of human 7-OH use may not translate to real-world consumption patterns.[9] The pharmacology of kratom and its constituent alkaloids and metabolites, along with the pharmacology of kratom-derived products such as 7-OH, are complex and sometimes misunderstood. For instance, in humans, we do not know how strongly 7-OH activates mu opioid receptors (the receptors responsible for most the well-known effects of opioids), but we know that only 2.7% of 7-OH taken orally (which is the way consumers take it) survives the digestive tract and enters the bloodstream and brain where it can reach receptors. This *low oral bioavailability* differentiates 7-OH from morphine and commonly used opioid analgesics, and it contradicts the now widespread assertion that 7-OH is "more potent than morphine."[10] That assertion reflects what 7-OH and morphine can do when they reach mu opioid receptors in an intravenously injected rat—not what they do when taken orally by a person. This is one of several examples of how talking points around 7-OH are not always accurate or straightforward.

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[7] Smith, K. E., Panlilio, L. V., Feldman, J. D., Grundmann, O., Dunn, K. E., McCurdy, C. R., ... & Epstein, D. H. (2024). Ecological momentary assessment of self-reported kratom use, effects, and motivations among US adults. *JAMA Network Open*, *7*(1), e2353401-e2353401; Smith, K., Zamarripa, A., Zeilinger, N., Rattenni, R., & Boyer, E. (2026, January). When a Botanical Breaks Bad: Initial Characterization of 7-hydroxymitragynine (7-OH) product use among U.S. Consumers. In *Neuropsychopharmacology* (Vol. 51, No. SUPPL 1): Springer Nature; Hill, K., Piercy, C.J., Epstein, D.H., Rattenni, R., Zeilinger, N., Boyer, E.W., Zamarripa, A, Smith K.E. (Under Review). Consumer Perspectives on Policy and Marketing for Novel 7-hydroxymitragynine (7-OH) Products: Regulation Is Recommended over Prohibition.

[8] https://cdn.prod.website-files.com/61858fcfc6543059f0617522/620c13ac9741c266fb08af52_HHS%20Rescission%20Letter%20Dr.%20Giroir%20Aug%2016%202018%20highlighted.pdf

[9] Gonzalez, J. D. Z., Alexandria, R. K., Mukhopadyay, S., McCurdy, C. R., McMahon, L. R., & Wilkerson, J. L. (2025). Assessment of abuse liability and respiratory effects of mitragynine and 7-hydroxymitragynine in rats. *Journal of Pharmacological and Toxicological Methods*, *133*, 107624

[10] Chiang, Y. H., Kanumuri, S. R. R., Kuntz, M. A., Senetra, A. S., Berthold, E. C., Kamble, S. H., ... & Sharma, A. (2025). In Vitro and In Vivo Pharmacokinetic Characterization of 7-Hydroxymitragynine, an Active Metabolite of Mitragynine, in Sprague-Dawley Rats. *European Journal of Drug Metabolism and Pharmacokinetics*, *50*(3), 205-218.

The report issued by the U.S. Food and Drug Administration in July 2025 couched concerns on 7-OH from basic science findings, presenting few clinical accounts of 7-OH evincing harm.[11] Policy on 7-OH requires an understanding of 7-OH use in humans through clinical research which has, to date, not been conducted apart from self-report surveys and qualitative interviews that my colleagues and I are in the process of publishing. Such self-report data are a first step, but there needs to be significantly more research to inform scheduling decisions around 7-OH products and other kratom-derived products. Ideally, such research findings would be weighed alongside possible public health harms that could occur if these substances were to become inaccessible to consumers.

In the absence of safety and tolerability studies or human abuse potential studies, signals of risk related to 7-OH may be gleaned from monitoring and surveillance, adverse event reporting, or case reports. There are few such signals of risk related to 7-OH and nearly all are ambiguous, coming from cases that are confounded (meaning that too many possible causes of events are present, so firm conclusions cannot be drawn).[12] This was discussed in my attached report provided to FDA in August 2025 as part of a larger response to Warning Letters they had issued.[13] There is also no indication that 7-OH is causing harm for most consumers or that unwanted effects associated with 7-OH use have resulted in the need to seek medical care, although 7-OH use, similar to kratom use, is not without concern for the risk of development of physical dependence or substance use disorder (SUD).[14] To be clear, abuse liability or addiction potential remains for *any* rewarding psychoactive substance, with kratom, 7-OH, and many other products marketed as dietary supplements no exception. That *possibility* does not mean most will actually develop a severe SUD characteristic of addiction related to their use.

In the months since FDA recommended that the U.S. Drug Enforcement Administration schedule 7-OH under the CSA, there has not been a substantive change in the situation with respect to SUD that can be discerned by publicly available information. For instance, the FDA acted appropriately in issuing letters to healthcare professionals about 7-OH risks. They have issued other public-facing material that, in addition to correctly reiterating that kratom and 7-OH are not FDA-approved therapies,[15] may have overstated risks related to kratom and 7-OH in humans based on available data.[16] Despite these warnings, most clinicians that I have interacted or

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[11] Reissig, C. J., Chiapperino, D., Seitz, A., Lee, R., Fadin, R., & McAninch, J. (2025). *7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat*. U.S. Food and Drug Administration Center for Drug Evaluation and Research.

[12] National Drug Early Warning System. (2025, May). *Special Report: EMS encounters for kratom/7-OH-related overdoses (nonfatal or fatal) in the US January 1, 2023 - April 30, 2025*. National Drug Early Warning System (NDEWS). https://ndews.org/wordpress/files/2025/05/5.30.25_NDEWS-2025-kratom-related-overdoses.pdf

[13] https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-firms-marketing-products-containing-7-hydroxymitragynine.

[14] Smith, K.E., Zeilinger, N., Rattenni, R., Feldman J., Boyer, E.W., Zamarripa A. (Under Review) Toward an understanding of 7-hydroxymitragynine (7-OH) products: Initial characterization of use patterns and consumer perceptions.

[15] https://www.fda.gov/media/187913/download?attachment

[16] https://www.fda.gov/news-events/public-health-focus/fda-and-kratom

consulted with have either not heard of 7-OH or have articulated that problems involving kratom and 7-OH are rare among their caseloads, with 7-OH less common than kratom-related presentations. SUD related to kratom, which has been better studied, is seldom severe with most kratom consumers highly functioning and productive people.[17]

For 7-OH specifically, there have been a total of five published case reports or case report series to date on SUD or physical dependence (i.e., tolerance, withdrawal) with primarily mild 7-OH withdrawal symptoms and SUD confounded by the contemporaneous co-use of kratom and/or prior SUDs for other substances.[18] The abuse potential or risk of kratom or 7-OH, relative to those of traditional opioids and illicitly manufactured fentanyl, seems to be low, most notably with respect to respiratory depression. Nonetheless, safety and human abuse potential studies for both kratom and 7-OH are needed to inform decisions around scheduling in the absence of other data showing clear harms caused as a result of using these products and with the products themselves not bereft of benefit.

It is my hope that research into kratom and 7-OH will continue with findings informing a coherent public policy. In the meantime regulatory actions can be taken to reduce the possibility of harm. These include age gating, tamper-resistant packaging, restrictions on sales near schools or college campuses, clear and accurate labels, product audits and testing, limits on concentrations or doses, and requirements that formulations be oral route of administration only.

For now, published research by myself and other investigators suggests that kratom appears to be a net benefit rather than a net detriment to most of its consumers, and while the ratio of benefit to detriment is not yet defined for most 7-OH consumers, it would be imprudent to leap to prohibiting it through the CSA. That action may place many consumers in a position of risk of returning to illicitly manufactured fentanyl or other dangerous substances. This is a job for regulation and oversight, not criminalization. It is my opinion that both kratom and 7-OH products should remain available for the U.S. adult consumers who wish to take them but with oversight and enhanced public health monitoring.

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[17] Smith, K. E., Epstein, D. H., & Weiss, S. T. (2024). Controversies in assessment, diagnosis, and treatment of kratom use disorder. *Current Psychiatry Reports*, *26*(9), 487-496.

[18] Lybik, N., Cone, B., Skelton, S., & Elfessi, Z. (2026). Management of acute withdrawal from 7-hydroxymitragynine following high-dose chronic use: A case report. *Journal of the American Pharmacists Association*; Reif, B., Adkins, A., Boyer, E. W., Kanumuri, S. R. R., Sharma, A., & Smith, K. E. (2025). Substance use disorder following consumption of a novel synthetic 7-hydroxymitragynine product. *Journal of Addiction Medicine*; Sherrick, R. C. (2026). Treatment of kratom use disorder with methadone in an opioid treatment program. *Journal of Addiction Medicine*; Sivakumar, D., Pascual, J., Kennedy, M., Clark, K. T., Mason, J. M., Walfield, A. L., Hayes, B. D., & Maldonado, G. (2025). The successful use of buprenorphine to manage kratom withdrawal secondary to self-treatment of opioid withdrawal. *Clinical Toxicology, 63*(11), 1018–1019; Smith, K. E., Kanumuri, S. R. R., Sharma, A., Rattenni, R., LeComte, R., McCurdy, C. R., Boyer, E. W., & Strain, E. C. (2025). Complicating factors surrounding concurrent use of kratom and a novel 7-hydroxymitragynine product among a participant enrolled in a kratom clinical trial. *Addiction*; Wightman, R. S., & Hu, D. (2025). A case of 7-OH mitragynine use requiring inpatient medically managed withdrawal. *Journal of Addiction Medicine*.

I respectfully urge the Committee to not advance H.R. 8000 or any bill that would seek to schedule 7-OH or any other kratom alkaloid, metabolite, or kratom-derived compound without adequate clinical research being conducted first.

Thank you for your time and consideration.

Respectfully,

Kirsten E. Smith, Ph.D., L.M.S.W.

CURRICULUM VITAE

Kirsten E. Smith

March 2026

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Education and Training

2010-2014	Bachelor of Social Work, minors History and Psychology. University of Kentucky, Lexington, KY Summa Cum Laude
2014-2015	Master of Social Work, University of Kentucky. Lexington, KY. Summa Cum Laude *Primary mentor, Michele Staton, Ph.D.*
2015	Postbaccalaureate Independent Study. University of Kentucky, Department of Behavioral Science Lexington, KY *Primary mentor Robert J. Walker, M.S.W.*
2016-2019	Doctor of Philosophy in Social Work, Kent School of Social Work. Louisville, KY *Co-mentors Robert J. Walker, M.S.W., Michele Staton, Ph.D., Martin T. Hall, Ph.D.*
2019-2023	Postdoctoral Fellowship, National Institute on Drug Abuse Intramural Research Program. Baltimore, MD *Primary mentor David. H. Epstein Ph.D., co-mentor Lorenzo Leggio, M.D., Ph.D.*

Professional Experience

2013	Clinical Internship, Hope Center Men's Recovery Program. Lexington, KY
2013	Undergraduate Clinical Practicum, Chrysalis House. Lexington, KY
2014	Undergraduate Community Practicum, United Way of the Bluegrass. Lexington, KY
2014-2015	Graduate Clinical Practicum, Hope Center Men's Recovery Program. Lexington, KY
2015-2016	Research Assistant, University of Kentucky College of Medicine. Lexington, KY
2015-2016	Senior Data Coordinator, University of Kentucky Center on Drug and Alcohol Research. Lexington, KY
2016-2018	Research Assistant, University of Louisville. Louisville, KY
2018-2019	Data Coordinator/Analyst, University of Kentucky Center on Drug and Alcohol Research. Lexington, KY
2019-2023	NIDA IRP Postdoctoral Training Fellow, Translational Addiction Medicine Branch. Baltimore, MD
2023-2025	Assistant Professor, Johns Hopkins University School of Medicine, Department of Psychiatry and Behavioral Science, Behavioral Pharmacology Research Unit, Baltimore, MD
2026-present	Consultant, Dial Square LLC, Kansas City, KS; Westminster, MD

PUBLICATIONS

***Designates corresponding author status, <u>underline</u> designates a mentee, †designates equal contribution authorship**

Original Research

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44. Ware O, Strickland JC, **Smith KE**, Blakey SM, Dunn KE (2023) Factors associated with high-risk substance use in persons receiving psychiatric treatment for a primary trauma- and stressor-related disorder diagnosis *Journal of Dual Diagnosis*
45. Panlilio LV, Burgess-Hull A, Feldman J, Rogers JM, Tyburski, M, **Smith KE**, Epstein DH (2024) Activity space during treatment with medication for opioid-use disorder: Relationships with personality, mood, and drug use. *Journal of Substance Use and Addiction Treatment*
46. **Smith KE***, Rogers JM, Sharma A, McCurdy CR, Weiss ST, Dunn KE, Feldman JD, Kuntz MA, Mukhopadhyay S, Raju KSR, Taylor RK, Epstein DH (2023) Reponses to a "typical" morning dose of kratom in people who use kratom regularly: A direct-observation study. *Journal of Addiction Medicine*
47. **Smith KE***, Panlilio LV, Feldman JD, Grundmann O, Dunn KE, McCurdy CR, Garcia-Romeu A, Epstein DH (2024). Ecological momentary assessment of self-reported kratom use, effects, and motivations among US adults. *JAMA Network Open*

48. Zamarripa, CA, Spindle, TR, Panlilio, LV, Strickland, JC, Feldman, JD, Novak, MD, Epstein, DH, Dunn, KE, McCurdy, CR.,...**Smith KE*** (2024) Effects of kratom on driving: A cross-sectional, ecological momentary assessment, and simulated driving study. *Traffic Injury Prevention*
49. Bergeria CL, Gipson CD, **Smith KE**, Stoops WW, Strickland JC (2024) Opioid craving does not incubate over time in clinical research: Is the preclinical incubation of craving model lost in translation? *Neuroscience and Behavioral Reviews*
50. Hill K, Grundmann O, **Smith KE**, Stanciu CN (2024) Prevalence of kratom use disorder among kratom consumers. *Journal of Addiction Medicine*
51. Rogers JM, Weiss ST, Epstein DH, Grundmann O, Hill K, **Smith KE*** (2024) Kratom addiction per DSM-5 SUD criteria, and kratom physical dependence: Insights from dosing amounts versus frequency. *Drug and Alcohol Dependence*
52. Rogers JM, Colvin K, Epstein DE, Grundmann O, McCurdy CM, **Smith KE*** (2024). Growing pains with kratom: Experiences discussed in subreddits contrast with satisfaction expressed in surveys. *Frontiers in Pharmacology*
53. Hill K, Grundmann O, Panlilio L, Epstein DE, **Smith KE*** (2024) Use of cannabinoids by people who consume kratom in the United States. *Journal of Addiction Medicine*
54. Hill K, Rogers JM, Grundmann O, Epstein, DH, **Smith KE*** (2024) At least four "strains" of kratom consumers in the United States: Latent-class analysis of motivations for kratom use. *The American Journal of Drug and Alcohol Abuse*
55. **Smith KE***, Panlilio LV Sharma A, McCurdy CR, Feldman JD, Mukhopadhyay S, Raju KSR, Kuntz MA, Hill K, Epstein DH (2024) Time course of kratom effects via ecological momentary assessment by product type, dose amount, and assayed alkaloid content. *Drug and Alcohol Dependence*
56. Mun CJ, Epstein DH, Panlilio LV, Dunn KE, Thrul J, McCurdy CM, **Smith KE*** (2025) Kratom (*Mitragyna Speciosa*) use for pain management: Insights from cross-sectional and ecological momentary assessment data. *Journal of Pain*, 26, 104726
57. **Smith KE***, Feldman J, Freinberg C, Shade S, Grundmann O (2025) Systematic review of clinical case reports involving tianeptine products: "Gas station heroin" hype or fact? *Current Addiction Reports*
58. Sharma A, **Smith KE,** Kuntz MA, Berthold EC, Elashkar OI, Guadagnoli N, Raju KSR, Mukhopadhyay S, Panlilio LV, Epstein DH and McCurdy CR (2025) Chemical analysis and alkaloid intake for kratom products available in the United States. *Drug Testing and Analysis*
59. Hill K, Boyer EW, Grundmann O, **Smith KE*** (2025) De facto opioids: Characterization of novel 7-hydroxymitragynine and mitragynine pseudoindoxyl products. *Drug and Alcohol Dependence*
60. **Smith KE***, Kanumuri Raju KSR, Sharma A, Rattenni R, LeComte R, McCurdy CR, Boyer EW, Strain EC (2025) Complicating factors surrounding concurrent use of kratom and a novel 7-hydroxymitragynine product among a participant enrolled in a kratom clinical trial. *Journal of Addiction Medicine*
61. Piercey CJ, Cameron J, Ahern, R, Packwood I, Bruning C, Henry D, Ruehrmund J, Weldon K, **Smith KE**, Karoly HC (2025) Kratom use among ethnobotanical tea bar patrons in Colorado: Subjective drug effects, adverse reactions, and perceived benefits of use. *Drug and Alcohol Dependence Reports*
62. Herberholz ES, Wolchok RE, Rogers JM, Selenou-Yemgang S, Beckwith BD, **Smith KE**, Epstein DH (2025) Latent classes of adverse childhood experiences (ACEs) and adult substance-use problems and psychosocial outcomes: complex and heterogenous associations. *International Journal of Mental Health and Addiction*
63. **Smith KE***, Hill K, Bergeria CL Strickland JC (2025) Tianeptine products: Public health threat or niche substance use? *Journal of Psychoactive Drugs*
64. Reif B, Adkins A, Boyer EW, Kanumuri Raju KSR, Sharma A, **Smith KE*** (2025) Substance use disorder following consumption of a novel 7-hydroxymitragynine product. *Journal of Addiction Medicine*
65. Hill K, Anderson A, Sharma A, Kanumuri Raju KSR, Mukhopadhyay S, Veltri C, **Smith KE**, McCurdy CR, Grundmann O (2025) Diversification of kratom in US markets: Results form an online survey and chemical assay of products. *Substance Use and Misuse.*
66. Mun CJ, Timmons P, Panlilio LV, Verrico CD, Thomas YT, Zamarripa AC, Epstein DH, **Smith KE*** (2025) Is bedtime use of kratom (*Mitragyna speciosa*) a sleep aid or disruptor?: Examining its daily effects and individual differences. *Experimental and Clinical Psychopharmacology*
67. Pierce-Messick Z, **Smith KE**, Acuff SF, Reed DD, Epstein DH, Strickland JC (2025) Association of behavioral economic demand for kratom and DSM-5 use disorder: Quantity and likelihood-based demand approaches. *Addictive Behaviors Reports*
68. Kowalczyk WJ, **Smith KE**, Rogers JM, Bertz J, Epstein DH (Under Review) Demographics and self-perceptions of the broad population of the involuntarily celibate: They are more than just incels. *The Journal of Sex Research*
69. Singh D, Mathandaver D, Müller CP, **Smith KE** (2025) Kratom (Mitragyna speciosa) as a replacement for alcohol among a sample of Malaysian adults with a history of alcohol use problems
70. Hill K, Boyer EW, **Smith KE*** (2025) Clinically characterizing US adults who use kava or kratom: Substance use disorder assessment challenges for increasingly popular botanical products. *Drug and Alcohol Dependence Reports*

71. Timmons P, Hill K, **Smith KE**, Riley A, Mun CJ (2026) Akuamma seed (*Picralima nitida*) use in the US: Findings from a web-based survey. *Journal of Psychoactive Drugs*.
72. Piercey CJ, Bunch J, Cameron J, Ahern, R, Packwood I, Bruning C, Henry D, Ruehrmund J, Weldon K, Bunch J, **Smith KE**, Karoly HC (2026) Characteristics of adverse reactions to kratom and implementation of harm reduction strategies in a sample of ethnobotanical tea bar patrons in Colorado. *Harm Reduction Journal*
73. Epstein DH, Stull S, **Smith KE** (Under Review) Drug use without addiction in people with "a stake in the conventional life": Lessons from an online pilot test of a classic sociological concept
74. Hill K, Piercy CJ, Karoly H, **Smith KE*** (Under Review) Kava (*Piper methysticum*) consumption patterns and conceptualizations: Results from an online survey of experienced consumers
75. **Smith KE**, Zeilinger N, Rattenni R, Feldman J, Boyer EW, Zamarripa A* (Under Review) Toward an understanding of 7-hydroxymitragynine (7-OH) products: Initial characterization of use patterns and consumer perceptions
76. Kanumuri Raju KSR, Sharma A, **Smith, KE**, Zeilinger N, McCurdy CR (In Preparation) UPLC-MS/MS-based quantification of major kratom alkaloids and metabolites in human plasma and its application to clinical samples analysis
77. Hill K, Piercy CJ, Epstein DH, Rattenni R, Zeilinger N, Boyer EW, Zamarripa A, **Smith KE*** (Under Review) Consumer Perspectives on Policy and Marketing for Novel 7-hydroxymitragynine (7-OH) Products: Regulation Is Recommended over Prohibition
78. Piercy CJ, Hill K, **Smith, KE**, Epstein DH, Rattenni R, Zeilinger N Boyer EW, Zamarripa A (In Preparation) Use or misuse?: An initial characterization of 7-hydroxymitragyine (7-OH) product experiences

Book Chapters, Monographs

1. **Smith KE,** Grundmann O, Swogger MT, Garcia-Romeu A (2023) Kratom (Mitragyna speciosa): Pharmacology and Use of a Naturally Occurring Atypical Opioid. *The Oxford Handbook of Opioids and Opioid Use Disorder, 1st edition.*
2. **Smith KE*,** Grundmann O, Singh D (In Press) Kratom-related Physical Dependence and Addiction (Elsevier) *Kratom*
3. Durkin R, Grundmann O, **Smith KE** (In Press) Regulation and policy regarding kratom-derived dietary supplements and direct-to-consumer sales (Elsevier) *Kratom*

Letters, Correspondence

1. Grundmann O, Babin JK, Henningfield JE, Garcia-Romeu A, Kruegel AC, Prozialeck WC, Raffa RB, Singh D, and **Smith KE** (2021). Kratom use in the United States: a diverse and complex profile. *Addiction*, *116* [Letter to the Editor]
2. Stull SW±, **Smith KE**±, Vest N, Effinger DP, and Epstein DH (2021). Potential value of the insights and lived experiences of addiction researchers with addiction. *Journal of Addiction Medicine* [Commentary]
3. Strickland JC and **Smith KE** (2021) Comment on Heilig et al.: The centrality of the brain and the fuzzy line of addiction. *Neuropsychopharmacology*, 46, 1703-1704 [Research Highlight]
4. Grundmann O, McCurdy CR, Singh D, **Smith KE**, Swogger MT (2022). The pharmacology of kratom and its alkaloids. Frontiers in Pharmacology [Editorial].
5. **Smith KE***, Dunn KE, Epstein DH, Feldman J, Garcia-Romeu A, Grundmann O, Henningfield J, McCurdy CR, Rogers JM, Schriefer D, Singh D, Weiss (2022) Need for clarity and context in case reports on kratom use, assessment, and intervention *Substance Abuse*, [Letter to the Editor]
6. **Smith KE*** (2022) Disease and decision. *Journal of Substance Abuse Treatment*, [Commentary]
7. **Smith KE***, Sharma A, Grundmann O, McCurdy C (2023). Kratom alkaloids: A blueprint? *ACS Chemical Neuroscience* [Invited Viewpoint]
8. Henningfield JE, Chawarski MC, Garcia-Romeu A, Grundmann O, Harun N, Hassan Z, McCurdy CR, McMahon L, Sharma A, Shoaib M, Singh D, **Smith KE**, Swogger MT, Vicknasingam B, Walsh Z, Wang D, Huestis MA (2023) Kratom withdrawal: Summary and conclusions of a virtual scientific forum. *Drug and Alcohol Dependence Reports* [Commentary]
9. Grundman O, Garcia-Romeu A, McCurdy CR, Sharma A, **Smith KE**, Swogger MT, Weiss ST (2023) Not all kratom is equal: the important distinction between native leaf and extract products. *Addiction* [Letter to the Editor]
10. McCurdy CR, Sharma A, **Smith KE**, Veltri, C, Weiss ST, White C, Grundman O (2024) An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations" *Expert Review of Clinical Pharmacology* [Invited Review]
11. Grundmann O, **Smith KE**, Prozialeck WC, Veltri CA, Boyer E (2024) "Presence of kratom in opioid overdose deaths: Findings from coroner postmortem toxicological report" *Frontiers in Pharmacology* [Commentary]
12. Henningfield JE, Huestis MA, Grundmann O, **Smith KE** (2024) "Kratom safety and toxicology in the context of public health: Research needs to better inform regulation" *Frontiers in Pharmacology* [Review]

13. Acuff SF, Strickland JC, **Smith KE**, Field M (2024) Heterogeneity in choice models of addiction: The role of context. *Psychopharmacology 241*(9), 1757-1769 [Review]
14. **Smith KE***, Epstein DE, Weiss ST (2024) "Controversies in kratom use disorder" *Current Psychiatry Reports,* 1-10 [Invited Review]
15. Hill K, Grundmann O, **Smith KE**, Stanciu CN (2024) "Response to Gorelick" *Journal of Addiction Medicine* [Invited Response]
16. **Smith KE,** Boyer EW, Grundmann O McCurdy CR, Sharma A (2025) "The rise of novel, semi-synthetic 7-hydroxymitragynine products" *Addiction* [Letter to the Editor]

Google Scholar H Index: 25

Media Releases or Interviews

Print/Online

2018 *Clinical Psychiatry News*, Randy Dotinga "For Some SUD Patients, Kratom May be a Self-treatment Tool"
2022 *Filter*, Doug Johnson "People's Reasons for Using Kratom are Rapidly Diversifying"
2022 *Addiction Treatment Forum*, Barbara Goodheart "Lived Experience: A Refreshing New Voice"
2022 *VICE*, Manisha Krishnan "'Gas Station Heroin' is Causing Intense Withdrawals: It's Legal in Most States"
2023 *The Messenger*, Sheila Baylis "Herbal Supplement Kratom is Being Bought and Sold in a 'Wild West' Marketplace"
2024 *Los Angeles Times*, Emily Alpert Reyes "Kratom products have gone unregulated in California, unnerving both fans and critics
2024 *Natural Products Insider*, Josh Long "Kratom groups, researchers sound alarm over 7-hydroxymitragynine products"
2024 *Bloomberg,* Fiona Rutherford & Immanuel John Milton "FDA pulls back its study into kratom plant's effects"
2024 *The Guardian,* Shayla Love, "The wellness drink for sober people that some say they can't stop drinking"
2024 *The New York Times,* Jan Hoffman "Rethinking addiction as a chronic brain disease"
2024 *Bloomberg* Fiona Rutherford & Immanuel John Milton "Kratom appears safe in early FDA study that excluded popular drinks"
2024 *Bangkok Post* "Kratom now a $1-billion industry in US"
2024 *Dallas Morning News* Hojun Choi, "Kratom advocates says illegal, synthetic products are being sold in North Texas"
2024 *SupplySide Supplement Journal* Hank Schultz, "Kratom experts raise 7-OH alarm-again"
2025 *Johns Hopkins Magazine*, Ashley Stimpson, "Unknown Substance: Assistant Professor Kirsten Smith has become a leading voice on the herbal supplement kratom
2025 *PS* Chandler Plante, "TikTokers are sounding the alarm on kratom-but what is it?"
2025 *Missouri Independent*, Rebecca Rivas "FDA warns Kansas City manufacturer it is marketing illegal pain-relieving pills"
2025 *Supply Side Supplement Journal* Han Schultz, "FDA moves against 7-OH products"
2025 *New York Times*, Christina Jewett "Kennedy announces plan to restrict some kratom products"
2025 *The Wall Street Journal*, Sumathi Reddy "What you need to know about kratom"
2025 *Forbes*, Andrew DeAngelo "The science behind the fight over 7-OH"
2025 *CNN*, Kristen Rogers "Why a drink called Feel Free has many saying they're trapped in addiction, debt, and rehab
2025 *The Kansas City Star*, David Hudnall "It's addictive, and it's everywhere': KC company's pills hook users across US"
2025 *The Pitch*, Joe Elliott " Inside the kratom industry's 7-OH tug of war between profits and public safety"
2025 *GQ*, Samantha Leach "How kratom, formerly known as 'gas station heroin,' went mainstream
2025 *The Guardian*, Xi Chen "From bank robber to scholar: the Knoxville dropout fighting to challenge how we see addiction
2026 *High Times*, Skye Hawthorne "The fight over 7OH is splitting the kratom industry"

Podcasts

2021 *Kratom Science* hosted by Brian Gallagher, "Dr. Kirsten Smith of National Institute on Drug Abuse"
2022 *Psychoactive* hosted by Ethan Nadelmann, "Kirsten Smith on Kratom"
2022 *The Addiction Psychologist* hosted by Samuel Acuff and Noah Emery, "Kirsten Smith and Kratom"

2022 *Kratom Science* hosted by Brian Gallagher, "Dr. Kirsten Smith of NIDA Returns"
2024 *AirTalk* hosted by Larry Mantle (Los Angles NPR 89.3 FM) "...And a Look into Addiction"
2025 *The Addiction Psychologist* hosted by Samuel Acuff and Noah Emery, "Kirsten Smith and Kratom Part II"
2026 *SMART Policy Podcast* hosted by Jeremy Kourvelas, "What the Brain Disease Model of Addiction Gets Right and What it Misses"
2026 *American Society of Addiction Medicine (ASAM) Practice Perils*, hosted by Dr. Stephan Taylor, "Kratom and 7-OH: What Clinicians Need to Know"

Television/Video

2023 NewsNation "Gas station heroin' is addictive, and in some cases, deadly"
2023 ABC WMAR "Maryland man's death linked to kratom; herbal substance center of heated debate"
2024 NBC WBIR "From robbing banks to becoming a Johns Hopkins professor: Knoxvillian hopes to help others by studying addiction"
2025 NBC WBIR "What is kratom? Knoxville police officer accused of shoplifting kratom while on duty: A professor at Johns Hopkins University studies kratom, and says a new form, 7-OH, acts only on opioid receptors, raising substance abuse concerns"

Popular Writing, Invited

2022 CLOSLER Johns Hopkins Medicine "Afraid to Tell the Truth"
2022 The American Psychological Association Division 50 *SoAP Box* Newsletter-Clinical Translation Column "Cucumbers and Pickles"

FUNDING

Extramural Funding

6/1/2021 Real-world momentary assessment of kratom use and laboratory-based observed cessation accompanied by product assays: Toward an interdisciplinary characterization of kratom use and pharmacology.
K99 DA055571-01
Total Direct Costs: NA (Due to award being given to NIDA IRP postdoctoral fellow)
*****Note that NOA is not given for grants awarded to IRP fellows.
Role: Principal Investigator
Impact Score: 20

4/1/2024 Real-world momentary assessment of kratom use and laboratory-based observed cessation accompanied by product assays: Toward an interdisciplinary characterization of kratom use and pharmacology.
R00 DA055571-02
Total Costs: $747,000
Role: Principal Investigator
Impact Score: 20

10/1/2024 Mentoring in advanced mHealth technologies and machine learning for HIV/drug abuse research
DA037109-10 Subaward
Total Direct Costs: $18,518
PI: Edward Boyer

9/15/2025 Evaluating kratom extract using a human drug development methodology: Single ascending dose safety and tolerability-human abuse potential
1R01 DA061809-01
Total Direct Costs: $3,623,143
Role: Principal Investigator
Impact Score: 22
Notice of Award: 9/15/2025

2/12/2025 Momentary and Longitudinal Effects of Kratom Use in Adults with Chronic Pain: A 12-Month EMA-Burst Study with Product Assays
1R01DA064929-01
Total Direct Costs: $2,478,443
Role: Multiple Principal Investigator
Impact Score: 41

Educational Intramural Funding

03/01/2017 Alternative psychoactive substances: Prevalence and emerging trends in a sample of drug-using individuals enrolled in community-based treatment
University of Louisville Graduate Student Research Fund Grant
Total Direct Costs: $1,000
Indirect Costs: $500
Role: Co-Investigator

CLINICAL ACTIVITIES

Certification
Active Licensed Masters Social Worker (LMSW) Maryland; License #30641

EDUCATIONAL ACTIVITIES

Teaching

Classroom instruction

2018 (Spring) Teaching Practicum, Undergraduate and Graduate hybrid, Substance Use and Substance Use Disorders. University of Louisville

Virtual classroom instruction

2019 (Spring) Adjunct Instructor, Psychopathology II for Clinical Practice, Graduate Course, University of Kentucky
2020 (Spring) Adjunct Instructor, Psychopathology II for Clinical Practices, Graduate Course, University of Kentucky.

Mentoring

Pre-doctoral Research Mentees

2019-2024 Jeffrey M. Rogers, B.A., B.S., enrolled Clinical Psychology Doctoral Student, Pre-doctoral Trainee (NIDA DA031098), San Diego State University and the University of California San Diego
2020-2022 Salma Pont-Fernandez, B.S., Postbaccalaureate Training Fellow, NIDA IRP
2019-2022 Destiny Schriefer, B.A., enrolled Master of Science Candidate in Epidemiology, the Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD
2021-2023 Jeffrey Feldman, B.S., Postbaccalaureate Training Fellow, NIDA IRP
2022-2025 Katherine Hill, M.P.H., enrolled Doctoral student, Yale School of Public Health, Department of Epidemiology of Microbial Diseases
2024-2025 Cianna Piercey, B.A., enrolled as Doctoral student in, Colorado State University Clinical Psychology Program

PROFESSIONAL ACTIVITIES

Appointments and Editorial Activities

2019-2022 Non-physician Scientist, National Institutes of Health Institution Review Board
2021-2022 Guest Associate Editor, *Frontiers in Pharmacology* Special Issue: The Pharmacology of Kratom and Its Alkaloids
2022-2024 Editorial Board, *Experimental and Clinical Psychopharmacology*
2022-Present Editorial Board, *Substance Abuse: Research and Treatment*
2022-Present Section Editor, *Current Addiction Reports*
2022-Present Consulting Editor, *Experimental and Clinical Psychopharmacology*
2023-Present Editorial Board, *Neuropsychopharmacology-Digital Psychiatry and Neuroscience*
2025-Present Editorial Board: *Substance Abuse Treatment, Prevention, and Policy*

Journal Peer Review Activities

2017-2018	Journal of Ethnopharmacology
2017-2018	Substance Abuse, Treatment, Prevention and Policy
2017-2025	Journal of Psychoactive Drugs
2018	Journal of Pain Research
2018-2024	Addiction
2018-2025	Drug and Alcohol Dependence
2019	Journal of Correctional Healthcare
2019	The American Journal of Public Health
2019	Tobacco Use Insights
2019-2024	The American Journal of Drug and Alcohol Abuse
2019-Present	Substance Abuse: Research and Treatment
2020	BMJ Open
2020	International Journal of Drug Policy
2020	Journal of Cannabis Research
2020	Alcohol and Alcoholism
2020	American Journal of Preventive Medicine
2020-Present	Substance Use and Misuse
2020-2021	Experimental Neurology
2020-2025	Experimental and Clinical Psychopharmacology
2021	Annals of Medicine
2021	Expert Opinion on Drug Metabolism and Toxicology
2021	Drug and Alcohol Dependence Reports
2021-2024	Journal of Addiction Medicine
2022	International Journal of Medical Sciences
2022-2025	JAMA
2022-Present	Current Addiction Reports
2023	Life Sciences
2023	The American Journal on Addictions
2023-Present	JAMA Network Open
2024	Harm Reduction Journal
2024	Psychopharmacology
2025	Social Science and Humanities Open
2025	Medical Reports

Advisory Committees, Review Groups/Study Sections

2022-2023	Advisor on NIDA "Kratom Drug Facts" webpage development.
2022-Present	The College on Problems of Drug Dependence, Travel Awards Committee
2023-2025	Organizing Committee Member International Symposium on the Science of Kratom
2024-Present	Dissertation Committee, KJ Jannie, DrPH Candidate (HPM-QPS), Johns Hopkins University
2024-Present	Johns Hopkins University Department of Psychiatry and Behavioral Sciences, Strategic Planning Committee: Expand Research Activities
2024-Present	NIH Early Career Reviewer Program
2025-Present	Dissertation Committee, Cianna Piercey, Clinical Psychology Doctoral Candidate, Colorado State University

Professional Societies

2014-2016	Member, National Association of Social Workers
2015-2016	Member, Students for a Sensible Drug Control Policy
2016-2019	Member, Sociologists for Women in Society
2017-2019	Member, Society for Social Work and Research
2017-2021	Member, American Society of Criminology
2017-Present	Member, Academic Consortium on Criminal Justice Health
2018-Present	Regular Member, College on Problems of Drug Dependence
2020-Present	Member, American Psychological Association

- APA Division 28-Psychopharmacology & Substance Use Member, Executive Board

- APA Division 50- Society of Addiction Psychology Member

2021-Present Member, American Society of Addiction Medicine
2023-Present Member, International Society for Substance Use Professionals
2023-Preseent Member, Doctors for Drug Policy Reform
2024-Present Member, Society for the Study of Addiction
2025-Present Member, National Association of Social Workers #886968163

National Session Chair

2018 "Is there a downside? Harm reduction", 81st College on Problems on Problems of Drug Dependence Annual Meeting, Oral Session Co-Chair

2021 "Addiction researchers with their own lived experiences of addiction: Implications for the science, the scientists, and the public", 83rd College on Problems of Drug Dependence Annual Meeting, Forum Co-Chair.

2022 "From bench to bedside to policy: Updating our understanding of kratom" 84th CPDD Annual Meeting, Symposium Chair

2023 "The tightrope of substance abuse potential: The preclinical and clinical factors that make or break the scheduling of a substance, using kratom (Mitragyna Speciosa) as an example" 2023 Annual Meeting of the American College of Clinical Pharmacology, Symposium Co-Chair

2025 "When does reductionism limit our perspective? The role of psychosocial and contextual determinants in substance use disorders" 87th College on Problems of Drug Dependence Annual Meeting, Symposium Chair

CONSULTANTSHIPS

2017-2018 Death penalty mitigation specialist-in-training consultant, Kentucky Department of Public Advocacy
2023-2024 Scientific Advisor, The Kratom Coalition
2023-2025 Consultant, International Plant and Herbal Alliance
2024 Consultant, Barnes & Thornburg, LLP
2024-Present Consultant, Kilpatrick Townsend & Stockton LLP
2024-Present Consultant, Snell & Wilmer
2025-2025 Consultant, Amin Wasserman Gurnani
2025-2025 Consultant, Todd, Brown, Frost
2026-Present Consultant, Porto Law Firm
2025-2026 Consultant, Michael Best
2025-Present Consultant, Pierce, Davis & Perritano LLP
Pending Consultant, NIDA R01 "Reducing Stigma About Receiving Treatment for Opioid Use Disorder" (PI Sudie Back)

AWARDS & HONORS

2012-2013 Academic Excellence Scholarship, University of Kentucky
2012-2013 Virginia Lane Award, full undergraduate scholarship, University of Kentucky Women's Club
2013-2014 Academic Excellence Scholarship, University of Kentucky
2013-2014 Virginia Lane Award, full undergraduate scholarship, University of Kentucky Women's Club
2017 IDEA Festival competitive graduate student travel award
2018 American Consortium on Criminal Justice Health (ACCJH) competitive doctoral travel award, Academic and Health Policy Conference on Correctional Health
2018 Society for Social Work and Research competitive doctoral travel award
2018 The College on Problems of Drug Dependence (CPDD) Travel Award for Early Career Investigators, competitive travel award
2019 ACCJH competitive doctoral travel award, Academic and Health Policy Conference on Correctional Health
2020 ACCJH competitive early career investigator travel award, Academic and Health Policy Conference on Correctional Health
2021 NIDA-NIAAA R-13 competitive travel award, American Psychological Association Annual Convention
2022 CPDD Female Opioid Research and Clinical Experts (FORCE) Junior Investigator, competitive travel award.

2022 NIDA-NIAAA R-13 competitive travel award, American Psychological Association Annual Convention
2024-2026 NIH/NIDA Loan Repayment Program (LRP) Award
2025 *Journal of Addiction Medicine* Author Recognition Award: The Most Downloaded Article Published in 2024

INVITED TALKS

Regional

12/2020 "So, what exactly is kratom?" National Institute on Drug Abuse IRP Clinical Rounds, Baltimore, MD
10/2021 "Is kratom use *mis*use?" National Institute on Drug Abuse IRP Fellows Research Lunch (Virtual)
10/2021 "Real-world momentary assessment of kratom use accompanied by product assays", National Institute on Drug Abuse IRP, Translational Addiction Medicine Branch (Virtual)
11/2022 "Candid conversations about drug use, addiction, and recovery," National Institute on Drug Abuse IRP (Virtual)
5/2023 "A Crash course on kratom," Science for Non-Scientists, National Institute on Drug Abuse IRP (Baltimore, MD)
9/2023 "No longer niche: The rise and increasing popularity of kratom," 14th Annual Johns Hopkins University Road to Recovery Annual Conference (Baltimore, MD)
10/2024 "How engagement with people with lived experience of addiction can inform innovative SUD interventions" I4SUD (Baltimore, MD)
12/2024 "Overview and update on kratom use in the United States: Implications for clinical practice, science, and policy" Johns Hopkins University Department of Psychiatry and Behavioral Sciences Seminar Series
5/2025 "Baltimore Neuroscience Community Spotlight and Discussion" University of Maryland, Baltimore
7/2025 "Kratom-derived Products and Public Health" Invited Generation Tomorrow Lecture, Johns Hopkins Medicine Division of Infectious Disease, Baltimore, Maryland
2/2026 "Update on kratom and 7OH: Implications for Policy" MedChi Opioid, Pain & Addiction Committee (virtual meeting)

National

03/2018 "Profile of kratom use among a sample of polysubstance users enrolled in residential drug treatment" Graduate Student Regional Research Conference, Louisville, KY
06/2018 "Kratom use patterns among opioid users in the United States: A novel form of harm-reduction?" CPDD Annual Meeting Media Forum ("blitz"), San Diego, CA
04/2021 "Introduction to kratom and its clinical implications", START Kentucky Clinical Consortium (Virtual)
10/2021 "Clinical potential or clinical concern?: Characterizing the complexities of kratom use among humans" Department of Pharmacodynamics, Early Career Neuroscientist Seminar Series, Gainesville, FL (Virtual)
3/2022 "Kratom 101: Overview of the increasingly used plant-based product with mu opioid and other bioactive properties" University of Kentucky Neuroscientists Interested in Addiction Series, Lexington, KY.
3/2022 "Characterizing kratom use among humans: Implications for research and practice" University of Kentucky Department of Behavioral Science Grand Rounds Series, Lexington, KY.
8/2022 "Kratom: Should we be concerned?" ToxTime: United States Drug Testing Laboratories Webinar Series (Virtual)
11/2022 "Clinical issues for SUD treatment: Kratom" Yale School of Medicine, Division of Sciences, Department of Psychiatry (Virtual)
12/2022 "Clinical issues for SUD treatment: Kratom: Ecological momentary assessment preliminary findings" Yale School of Medicine, Division of Sciences, Department of Psychiatry (Virtual)
1/2023 "Neurodiversity in academia" panel speaker, Princeton University Wintersession (Virtual)
7/2023 "The emerging science and clinical perspective on kratom" International Plant and Herbal Alliance, Las Vegas, NV.
8/2023 "The role of journals in reducing stigma, and the role of people with lived experience in addiction research and publishing" International Society of Addiction Journal Editors (Boulder, CO)
11/2023 "Kratom: The unregulated and uncontrolled botanical product at the corner store" National Association of State Controlled Substances Authorities, Webinar (virtual)
12/2023 "Kratom Use Patterns and Clinical Trends in the United States" Congressional Briefing on Kratom Science and Policy (Washington, DC)

3/2024 "The curious case of kratom: Update on the science and clinical implications of this not-so-novel drug" Cure Addiction Now (Los Angeles, CA)

3/2024 "Current profile of kratom use in the United States: What you need to know." Cure Addiction Now. National Webinar (virtual).

4/2024 "No longer novel: the enduring presence of kratom in the US and implications for clinical practice" Divisions of Addictions at Yale (DAY), Department of Psychiatry Seminar (Los Angeles, CA)

5/2024 "Researchers with Lived/Living Experience Involving Substance Use" Webinar, The College on Problems of Drug Dependence (virtual)

5/2024 "Ecological momentary assessment and lab-based pilot study of kratom use: What it tells us about consumption patterns and cognitive, physiological, and subjective effects" International Plant and Herbal Alliance (San Diego, CA)

8/2024 "Kratom consumers in the United States: What clinicians need to know" American Osteopathic Academy of Addiction Medicine (AOAAM), Opioid Research Network (ORN) Consortium National Webinar (virtual)

9/2024 "US clinical research on kratom: Overview of findings and policy implications" Congressional Briefing on Kratom Science and Policy (Washington, DC)

10/2024 "Overview of clinical research on kratom use in the United States" Arkansas Health Services Subcommittee of Public Health, Scientific Briefing (Little Rock, AK)

12/2024 "Implications of pre-mixed kratom and kava products" Utah Department of Agriculture and Food (Salt Lake City, UT)

2/2025 "Clinician-focused overview of kratom product use in the United States" New York Society of Addiction Medicine (virtual)

4/2026 "Kratom, 7-hydroxymitragynine, and mitragynine pseudoindoxyl: Research updates to better understand relative addiction risk profiles" University of Arizona Addiction Medicine Fellowship Guest Lecture (virtual)

4/2026* "Chasing kratom: Lessons learned from investigations into the real-world use of emerging psychoactive substances," Brown University, Center for Alcohol and Addiction Studies Colloquium Series (Providence, RI)

5/2026* "Update on the diversification of kratom-derived products: 7-hydroxymitragynine, pseudoindoxyl, and beyond" American Osteopathic Academy of Addiction Medicine (AOAAM), Opioid Research Network (ORN) Consortium National Webinar (virtual)

International

3/2023 "Summary findings from investigation into kratom product use in the United States" side panel speaker, 66th United Nations Commission on Narcotic Drugs (virtual)

8/2024 "Kratom use trends in the United States of America" National Research and Innovation Agency (BRIN; Jakarta, Indonesia)

8/2024 "Kratom use in the United States" Indonesia Ministry of Health & Ministry of Trade (KEMENKES; Jakarta, Indonesia)

3/2025 "Update of findings from clinical research on kratom" side panel speaker, 67th United Nations Commission on Narcotic Drugs (Vienna, Austria)

SCIENTIFIC CONFERENCE PRESENTATIONS

Posters

1. **Smith KE**, Shalash S, Bunting A, Staton M, Walker R, Winston EM, and Pangburn K (April 2016) "Profile of synthetic drug users in corrections-based substance abuse treatment" Center for Clinical and Translational Science Spring Conference, Lexington, KY
2. **Smith KE**, Bunting A, Golder S, Hall MT, Higgins GE, and Logan TK (January 2018) "Prevalence and features of Social Security Disability Insurance utilization in a sample of women on community corrections" Society for Social Work Research Conference, Washington, DC
3. **Smith KE**, Bunting A, Golder S, Hall MT, Higgins GE, and Logan TK (April 2018) "Prevalence and correlates of disability among a sample of women on probation and parole" Academic and Health Policy Conference on Correctional Health, Houston, TX
4. **Smith KE** and Bunting A (March 2019) "Chemical bedfellows: Illicit use of prescription opioids and buprenorphine associated with methamphetamine use among a sample of polydrug users in Kentucky" Substance Use Research Day, Lexington, KY
5. **Smith KE** and Epstein DH (June 2020) "My name is peer-led recovery, and I need a moral inventory: Toward an ethics audit of recovery support services in the US" CPDD Annual Meeting (Virtual)

6. **Smith KE**, Rogers JM, Strickland, JC, and Epstein, DH (March 2021) "From trivia to trend: Use of tianeptine and other emerging drugs in an online sample of adults" Substance Use Research Event (Virtual)
7. **Smith KE**, Epstein DE, Rogers JM, and Strickland JC (June 2021) "Drug use without addiction in people with a 'stake in the conventional life': A classic ethnographic idea examined in nationwide crowdsourced data" CPDD Annual Meeting (Virtual)
8. **Smith KE**, Staton M, Archuleta A, and Winston E (April 2021) "Social dissatisfaction and suicidal ideation associated with high-risk opioid use following corrections-based drug treatment and reentry among a sample of adults in Kentucky" Academic and Health Policy Conference on Correctional Health (Virtual)
9. **Smith KE**, Dunn KE, Garcia-Romeu A, Grundmann O, Rogers JM, Swogger MT, Epstein DH (August 2021) "Psychological and substance use correlates of lifetime kratom use in a large online sample" American Psychological Association Annual Conference (Virtual)
10. **Smith KE**, Dunn, KE, McCurdy C, Rogers JM, Grundmann O, Strickland JC, Garcia-Romeu A, Epstein DH (November 2021) "The launch of an interdisciplinary set of studies on kratom, a widely used plant product with mu opioid and other bioactive properties", NIDA-NIAAA Mini-Convention Frontiers in Addiction Research (Virtual)
11. Kaiser S, Rague J, **Smith KE**, and Weiss S (September 2021) "A secondary analysis of adverse events and naloxone administration in intentional kratom exposures from 2013-2020 using the Toxicology Investigators Consortium (ToxIC) registry" North American Congress of Clinical Toxicology" (Virtual)
    Published abstract: *Clinical Toxicology,* 59, 1130-1131
12. **Smith KE,** Rogers JM, Dunn KE, McCurdy C, Strickland JC, Epstein DE (December 2021) "Opioid, cup of coffee, or antidepressant? The perceived functions of kratom among current and former users" American College of Neuropsychopharmacology Annual Meeting, San Juan, PR
    Published abstract: *Neuropsychopharmacology,* 46, 431-432
13. **Smith KE**, Panlilio LV, Schriefer D, Leggio L, Phillips KA, Preston KL, Kramer MS, Fossler MJ, Shaham Y, Epstein DH (June 2022) "TRV734 as a potential medication for opioid use disorder: Protocol for a dose-finding pilot and proof-of-concept human laboratory study" CPDD Annual Meeting, Minneapolis, MN
14. **Smith KE,** Feldman, JD, Rogers JM, Dunn KE, McCurdy CR, Weis ST, Sharma A, Grundmann O, Epstein DH. (April 2023) "Effects after kratom self-administration of typical kratom dose among regular kratom-using adults" American Society of Addiction Medicine Annual Conference, Washington DC
15. **Smith KE,** Rogers JM, Sharma A, Zamarripa A, Weiss ST, Feldman JD, Spindle TR, Dunn KE, McCurdy CR, Epstein DH. (December 2023) "Physiological, subjective, and cognitive effects from a typical morning 'dose' of kratom among adults who use regularly: Findings from a direct-observation pilot study" American College of Clinical Neuropsychopharmacology Annual Meeting, Tampa, FL
16. **Smith KE**, Sharma A, Panlilio LV, McCurdy CR, Feldman JD, Epstein DE. (April 2024) "Ecological momentary assessment study of US adults who use kratom accompanied by product assay" Oxford International Conference on the Science of Botanicals, Oxford, MS
17. Weiss ST, Culbreth, R, Falise A, Aldy K, **Smith KE**, Wax PM, Campleman S, Brent J (September 2024) "The increasing evidence of serious adverse effects associated with the use of kratom" North American Congress of Clinical Toxicology
18. **Smith KE** & Hill K (April 2025) "Tianeptine "gas station heroin" products: Public health concern or niche substance use?" American Society of Addiction Medicine Annual Conference, Denver CO
19. **Smith KE**, Hill K, Piercey C, Karoly H (June 2025) "Twining of two botanicals: Clinical characteristics and assessment challenges of contemporaneous kava and kratom use among US adults" College on Problems of Drug Dependence, New Orleans, LA
20. **Smith KE,** Zamarripa A, Zeilinger N, Rattenni R, Boyer EW (Accepted; January 2026) "When a botanical breaks bad: Initial characterization of 7-hydroxymitragynine (7-OH) product use among US consumers" American College of Neuropsychopharmacology, Nassau Bahamas

Oral/Podium Presentations

21. **Smith KE**, Bunting A, Walker R, Hall MT, Grundmann O, Castillo O (June 2018) "Kratom use patterns among opioid users in the United States: A novel form of harm-reduction?", CPDD Annual Meeting, San Diego CA
22. **Smith KE**, Tillson MD, Staton M, and Winston EM (April 2019) "Prevalence and correlates of past-year non prescribed buprenorphine use among a sample of adults entering Kentucky Department of Corrections drug treatment programs, Academic Health Policy Conference on Correctional Health, Las Vegas, NV.

23. Vest N, **Smith KE**, Stull S, Effinger D, Epstein DH, Cleveland H, Faulkner M (June 2021) Forum talk, "Experiential knowledge and the phenomenology of the addiction-remission continuum: Not a theory of anything, but a means to help modify theories of everything within addiction science", CPDD Annual Meeting (Virtual)
24. Weiss S and **Smith KE** (April 2022) Focused Session, "Clinical characterization of kratom: Is it a craze or here to stay?" American Society of Addiction Medicine Annual Conference, Hollywood, FL
25. **Smith KE** (Chair), Grundmann O (Co-chair), McCurdy C, and Henningfield J, Dunn KE (Moderator) (June 2022) Full Symposium, "Real-world and clinical characteristics of kratom use" CPDD Annual Meeting, Minneapolis MN
26. Henningfield J, Huestis M, **Smith KE,** Kingston R (April 2023) Full Session, "Advancing Kratom Science: New Data on Kratom's Pharmacology, Safety, Pharmacokinetics, Abuse Potential, And Real-World Surveys, Oxford International Conference on the Science of Botanicals, Oxford, MS
27. McCurdy C, Grundmann O, **Smith KE**, Weiss S (Co-Chair, August 2023) Full Symposium, "An Interdisciplinary Overview on the Increasing Clinical and Scientific Relevance of Kratom" American Psychological Association Annual Meeting, Washington DC
28. **Smith KE** (Co-chair), Henningfield J, Grundmann O (September 2023) Full Symposium, "Preclinical and clinical data on kratom as predictors for abuse liability" Annual Meeting of the American College of Clinical Pharmacology, Bellevue, WA
29. **Smith KE** (February 2024) "Findings from a direct-observation substudy of chronic kratom consumers" 3rd International Scientific Symposium on Kratom, Orlando, FL
30. **Smith KE** (February 2024) "A day in the life: Momentary and daily dosing patterns of US kratom consumers" 3rd International Scientific Symposium on Kratom, Orlando, FL
31. **Smith KE** (April 2024) Full Symposium, "Ecological momentary assessment and classification of kratom use patterns among US adults. Comprehensive Perspectives on Addiction Annual Meeting, Denver, CO
32. **Smith KE** (February 2025) "Current perspectives on kratom physical dependence and addiction" 4th International Scientific Symposium on Kratom, Orlando, FL
33. **Smith KE** (February 2025) "7OH uptake among kratom consumers: What we know from clinical trials screenings" 4th International Scientific Symposium on Kratom, Orlando, FL
34. " 4th International Scientific Symposium on Kratom, Orlando, FL
35. **Smith KE**, Weiss S, Latham I, Levy R, Swart BB (April 2025) Focus Session, "Complexities and controversies in assessing, diagnosing, and managing kratom use" American Society of Addiction Medicine Annual Conference, Denver, CO
36. **Smith KE** & Boyer E (September 2025) Symposium "De facto opioids and the new addiction: 7-OH, 'pseudo,' and speciociliatine" 2025 North American Congress of Clinical Toxicology, Chicago, IL
37. Boyer EW, Smith KE, Babu KM (*****March 2026) Symposium "Kratom, 7OH, and kratom combination products: It is far more than just a plant now" American College of Medical Toxicology Annual Scientific Meeting, Boston, MA
38. Hill K, **Smith KE**, Boyer E (*****April 2026) Focus Session "Beyond kratom: Novel products containing 7-hydroxymitragynine, mitragynine pseudoindoxyl, MGM, and kava" American Society of Addiction Medicine Annual Meeting, San Diego, CA
39. Vest N, Ostacher M, **Smith K**, Hoaston T, Humphreys K (*****June 2026) Symposium "Lived experiences across career stages: "Proving them wrong (and right)" CPDD Annual Meeting, Portland Oregon

COMMUNITY SERVICES

2012	Volunteer, Lexington Rescue Mission, Lexington KY
2012-2019	Volunteer Instructor, Hope Center Men's Recovery Program, Lexington, KY
2013	Volunteer, AIDS Volunteers of America, Lexington, KY
2014	Volunteer, United Way of The Bluegrass, Lexington, KY
2014-2016	Guest speaker, University of Kentucky College of Social Work Undergraduate Program
2016-2017	Volunteer, Disability Resource Center, University of Louisville
2017	Volunteer, Bluegrass Reentry Council, Louisville KY
2018-2019	Volunteer Instructor, Hope Center Women's Recovery Program, Lexington, KY
2020-2022	Volunteer, NIH Intramural Research Program "Postbac Poster Day" Judge
2021-2023	Volunteer, NIDA IRP Stigma Awareness & Reduction Team (StART), Baltimore, MD
2022-2023	Volunteer mentoring NIDA Undergraduate Research Internship Program
2023-2025	Division 28 Psychopharmacology & Substance Use Newsletter Editor
2022-present	Volunteer NIDA Speaker's Bureau
2024-2026	Westminster, MD Board of Elections

ATTACHMENT: My individual report submitted to the U.S. Food and Drug Administration in August 2025 as part of a larger former response packet from Shaman Botanicals after receiving FDA Warning Letters. This signed report is dated August 18, 2025.

EXPERT REPORT OF KIRSTEN E. SMITH, Ph.D.

I am providing this report on kratom, mitragynine (MG), 7-hydroxymitragynine (7-OH), and mitragynine pseudoindoxyl (MGP) based on my review of the published literature and publicly available information from public health monitoring systems. This review is an overview and is not exhaustive. My expert opinion is also based on my ongoing work and direct experience I have as a researcher in this area, including interactions with my scientific colleagues. Likewise, it includes interactions with people who use or sell kratom, MG, 7-OH, and MGP and clinicians who would be expected to interact with consumer populations.

The views expressed in this opinion are my own. They do not necessarily reflect the views or positions of Johns Hopkins Medicine or any professional or non-professional organization to which I belong.

Based on my evaluation of the relevant existing evidence on kratom, MG, 7-OH, and MGP, there is inadequate information to assert that products containing these ingredients present a significant or unreasonable risk of illness or injury in the oral forms currently marketed to consumers in the United States.

Relevant Background Training, Expertise, and Experience

I earned my bachelor's degree in social work, with minors in psychology and history, from the University of Kentucky in 2014. In 2015, I graduated from the University of Kentucky with a clinical master's in social work (MSW). My undergraduate and graduate clinical training included clinical practicums at addiction treatment centers in Kentucky. I was a legally certified MSW in Kentucky (CMSW; License #7399), and I am a licensed MSW in Maryland (LMSW; License #30641).

After earning my MSW, I assisted with data projects at the University of Kentucky's Center on Drug and Alcohol Research (CDAR). During that time, I was involved in volunteer work in local substance use disorder (SUD) treatment programs, working with adults seeking help with SUDs related to opioids, stimulants, alcohol, and cannabis, among others. Most of the clients I worked with exhibited complex polydrug use and had psychiatric health histories.

During my graduate clinical training in 2015, I first became aware of the botanical, *Mitragyna speciosa*, commonly referred to in the United States as "kratom." A 27-year-old male client who was in early remission from opioid use disorder (OUD) informed me that he was consuming kratom tea to help with opioid cravings and anxiety. He reported that kratom made him feel good, but not "high," which has important clinical significance. During this time, I continued to

work at CDAR and continued my volunteer work. I encountered more individuals in recovery who were using kratom. This use of kratom as a form of harm-reduction and self-management of mood and well-being piqued my interest, just as I was beginning a joint Ph.D. program in social work at the University of Louisville-University of Kentucky. In that program, I focused on social determinants of health related to drug use and criminal justice involvement. My doctoral thesis examined patterns of high-risk opioid and stimulant use among corrections-involved adults using a behavioral economic framework. Throughout my Ph.D. program, I continued to hear from clients in the centers where I volunteered that they were using kratom as a substitute for illicit opioids and alcohol. As such, I decided to conduct a preliminary investigation into kratom use among adults with SUD histories enrolled in treatment to better understand motivations for and patterns of use (Smith & Lawson, 2017).

After completing my Ph.D. in 2019, I began a 4-year postdoctoral training fellowship at the National Institute on Drug Abuse Intramural Research Program (NIDA IRP) in Baltimore, Maryland. As few at NIDA IRP had heard of kratom, I was asked to speak about the substance. During this time, I began collaborating with other researchers in the United States who wanted to better understand how kratom was being used. As kratom use in the United States appeared to be increasing, I wanted to better understand why people were consuming it. In 2020, while still at NIDA IRP, I began focusing more of my time and attention on kratom, conducting or collaborating on other survey studies and on social media analyses.

Concurrently with my increased research into kratom at NIDA IRP, I also served as the Lead Associate Investigator on a double-blind, randomized, placebo-controlled clinical trial investigating the opioid withdrawal-suppressing effects of an experimental opioid agonist medication. In this capacity, I received training in human laboratory research that I now apply to my ongoing kratom research.

During this time as a postdoctoral fellow at NIDA IRP, I also advised on the initial development of NIDA's webpage on kratom, served on the National Institutes of Health Institutional Review Board, and accepted an invitation to join the NIDA Speaker's Bureau in order to help communicate the current known science of kratom upon request. During this time as a postdoctoral fellow, I was also an adjunct instructor for the University of Kentucky, where I taught a (virtual) graduate level psychopathology course that included training students in the assessment, diagnosis, and treatment of SUDs and other psychiatric or behavioral disorders.

I was awarded my first NIDA research grant (K99DA055571) in 2021 to investigate kratom as part of my postdoctoral fellowship. This consisted of the first ecological momentary assessment study ever conducted on kratom use among a national sample of adults who consumed kratom regularly. Samples of the kratom products used during the study by participants were obtained and assayed for their chemical composition. This grant included a pilot laboratory-based sub-study in which kratom consumers self-administered their typical kratom product under direct observation. Physiological, subjective, and cognitive outcomes were evaluated, along with adverse events (NCT05457803). These studies were conducted at NIDA IRP in collaboration with the University of Florida College of Pharmacy and the Johns Hopkins University School of Medicine. Some of the findings are discussed further below.

I completed my postdoctoral fellowship in July 2023 and began a research faculty position with the Johns Hopkins University School of Medicine. I am currently an Assistant Professor in the Department of Psychiatry and Behavioral Sciences, Behavioral Pharmacology Research Unit (BPRU). Within BPRU, I work nearly exclusively on kratom and kratom-derived products, though I have also published on topics related to cannabis, opioids, kava, tianeptine, and on addiction theory more broadly. After my second NIDA grant (R00DA05571-02) to study kratom was funded, I formed the Kratom Research Unit within BPRU. This unit specializes in kratom research and is intended to attract students, postdoctoral fellows, or others interested in collaborating on kratom projects and engage public, industry, and government. I hope to grow the scope of the Kratom Research Unit in the coming years to encompass kratom-derived products or constituents of kratom, such as 7-OH and MGP, and to also focus on other botanicals.

My ongoing research at Johns Hopkins is comprised of several projects. The largest is an inpatient (3-day, 2-night) human laboratory study of adults who use commercial kratom products regularly. Specifically, I am conducting a full pharmacokinetic and behavioral pharmacology characterization of kratom's effects over an approximately 36-hour period. This period is then followed by a period of kratom cessation, during which time I systematically evaluate kratom withdrawal symptoms using validated and novel objective and subjective measures (over an approximately 48-hour period). This is the first empirical, direct-observation study of kratom withdrawal and the first full pharmacokinetic (PK)/behavioral pharmacology study of commercial kratom products that includes whole leaf and extract products (NCT06089980). This study is funded by NIDA and Johns Hopkins University departmental start-up funds.

I am also conducting a pilot study investigating the acute effects of leading commercial kratom extract products (NCT06640569). This project is funded through departmental start-up funds from Johns Hopkins University.

I have two recently completed survey projects. The first is on kratom and other botanical-derived products, such as kava and akuamma seed (funded by departmental funds), and another survey and qualitative interview study on 7-OH products funded by Johns Hopkins University departmental start-up funds, with some support from a NIDA subaward (K24 DA037109-10). No industry or philanthropic funds were used for this study, directly or indirectly.

I currently have under review three NIDA R01 grant applications. These include an R01 grant application for over $5.3 million in total costs that was competitively scored (score of 22; 10.0 percentile) on April 7, 2024. If awarded, it would support a rigorous, two-part study comprised of a single ascending dose safety, tolerability, PK, and dose-finding study for a broad-spectrum kratom extract to be followed by a human abuse potential study on the same. This grant includes a subaward to the University of Florida College of Pharmacy. Communication from the NIDA Project Officer is active and ongoing, and a funding decision is expected before the end of the fiscal year.

Since 2023, I have served as a paid scientific advisor and consultant to the International Plant and Herbal Alliance, which is a nonprofit 501(c)(3) organization concerned with advancing the science and policy on kratom. Between October 1, 2023, and March 1, 2024, I served as a paid

scientific advisor and consultant to The Kratom Coalition, a 501(c)(4) organization concerned with advancing science and policy on kratom. I have provided oral or written testimony or have made presentations on the subject of kratom and 7-OH for state legislative or regulatory bodies, law firms, and at committee hearings.

In the United States, I am one of very few clinical researchers and trained clinicians focused on the study of kratom and kratom-derived products. To date, and to my knowledge, I am the only researcher at a university funded by NIDA to examine both the PK and clinical and behavioral pharmacology of kratom products in humans. In addition to several book chapters, I have approximately 76 peer-reviewed papers either published or in press, 11 others are currently under review, and 8 others are in active preparation for submission. Most pertain to kratom directly with several others indirectly related. To date, I have been involved with all published research-based assessments of kratom-related physical dependence or DSM-5 SUD diagnostic criteria for kratom. I have also published systematic reviews of clinical case reports on kratom-related physical dependence, SUD, and morbidities.

Related background on my qualifications includes having been accepted as an NIH Early Career Reviewer Program and being an active member of several professional organizations. These include the American Psychological Association (APA; including as an Executive Committee member for APA Division 28 Psychopharmacology and Substance Use and as a member of APA Division 50 Society of Addiction Psychology), Academic Consortium on Criminal Justice Health, the College on the Problems of Drug Dependence, International Society for Substance Use Professionals, National Association of Social Workers, the American Society of Addiction Medicine and the Society for the Study of Addiction. I am also on the organizing committee for the Scientific Symposium on Kratom held annually at the University of Florida Lake Nona Campus. I currently serve on four editorial boards for peer-reviewed academic journals, am a consulting editor for *Experimental and Clinical Psychopharmacology*, and also serve as a Section Editor on kratom for *Current Addiction Reports*. I recently received an author recognition award from the *Journal of Addiction Medicine*, the flagship journal for the American Society of Addiction Medicine, for their most downloaded peer-reviewed paper in 2024, which was on kratom's acute effects.

I regularly present on kratom to students, clinical groups, health departments, professional organizations, and at scientific annual meetings, including over 40 professional talks or presentations on kratom. In doing this, and in the general course of being an expert in the field of kratom, I am often engaged in conversations with medical practitioners who encounter kratom use among their patients or clients. I am also contacted by people who have used or who use kratom or 7OH. I have spoken on kratom at two side panels accepted for the United Nations Commission on Narcotic Drugs (2024 and 2025) and have participated in two data briefings for members of Congress. Since leaving NIDA IRP, I have remained on the NIDA Speaker's Bureau, and I generally welcome any engagement with policymakers, regulators, industry, clinicians, academics, or consumers, as I have found that there is a tremendous amount to both communicate but also a tremendous amount to continually learn.

As I discuss further below, even though I am an appointed research faculty member within the Johns Hopkins School of Medicine, I have always been (and will remain) proactive in seeking

information from all available sources. I have found that continued exposure to real-world situations is invaluable for keeping abreast of new phenomena and trends in the use of bioactive substances that often are sold as dietary ingredients or natural products. For instance, I regularly visit vape shops and just recently returned from a self-funded trip to a trade show where kratom, MG, 7-OH, and MGP (among many other products) were sold. As noted, I have recently completed surveys on kava, tianeptine, akuamma seed, kratom whole leaf, kratom extract, 7-OH, and MGP and have another survey project in development. I have spoken at length with people who use these kratom, mitragynine, 7OH, and MGP products. Given this, I am qualified to discuss them based on the knowledge available to date. My *curriculum vitae* is attached as Exhibit "A" hereto. As new data or knowledge is acquired, my impressions and views will likely be continually refined.

Background on Kratom

In Western nations, including the United States, "kratom" refers to the fast-growing tree, *Mitragyna speciosa,* and to the products derived from its harvested leaves (Grundmann et al., 2024; Cinosi et al., 2015; Singh, Narayanan, & Vicknasingam, 2016). Kratom is indigenous to Southeast Asia, primarily Malaysia and Thailand, and is being cultivated throughout Southeast Asia, particularly in Indonesia (Ahmad & Aziz, 2012; Charoenratana, Anukul, & Aramrattana, 2021; Kantor Staf Presiden, 2022; Reuters, 2024). Kratom has been used for centuries in Southeast Asia by chewing the fresh leaves or by boiling them into a tea or juice decoction (Singh, Narayanan, & Vicknasingam, 2016). Kratom is consumed orally in both the United States and Southeast Asia.

The bioactive alkaloids in kratom leaves are approximately 2-4% of the leaf material weight (Leksungnoen et al., 2022; Sengnon et al., 2023). Kratom and kratom products can vary in terms of their alkaloid composition, which can be impacted by agricultural, environmental, or other factors (Laforest et al., 2023; Prozialeck et al., 2020; Sengnon et al., 2023; Smith et al., 2024; Zhang et al., 2022). Commercial kratom products include dried leaf/dried leaf powder consumed loose or encapsulated, leaf material pressed into pellets, gummies, prepared seltzers or teas, concentrated liquids, and other extract formulations that range in their content of kratom's major alkaloid, MG, and minor alkaloids per container and per serving (Grundmann et al., 2024; Sharma et al., 2025). Kratom raw or dried leaf generally contains fewer alkaloids by weight than other forms; however, alkaloids from kratom leaf can be extracted by water (e.g., brewed tea, which is an aqueous extract) and deliver more alkaloids for absorption than by eating the leaf material itself.

Kratom alkaloids have been explored as candidates for therapeutic or drug-development pathways separate from kratom as a natural product, food, dietary supplement, dietary ingredient, etc. (Alford et al., 2025; Gutridge, 2021; McCurdy et al., 2024; Smith et al., 2023; Vijeepallam et al., 2019). The National Institutes of Health has invested in both basic science and clinical research on kratom and kratom alkaloids.

Preclinical (binding affinity in vitro and/or non-human animal in vivo) studies have found that kratom alkaloids have opioidergic, dopaminergic, alpha-adrenergic, serotonergic, and possible adenosinergic activity all of which may interact in complex and differing ways across species

(Berthold et al., 2022; Boyer et al., 2007; Gutridge et al., 2020; Hiranita et al., 2020; Hiranita et al., 2022; León et al., 2021; McCurdy et al., 2024; Obeng et al., 2022; Ramanathan et al, 2021). Because MG is the most abundant alkaloid in kratom, it has been the best studied, and many kratom effects have been attributed to it.

Brief overview of chemical composition and basic pharmacology:

Products in U.S. commerce derived from *Mitragyna speciosa* (kratom) contain MG (McCurdy et al., 2024; Smith et al., 2023; Sharma et al., 2025). Additional alkaloids found in kratom products tested include: paynantheine, speciogynine, mitraciliatine, corynantheidine, corynoxine, corinoxine-B, and 7-OH (Smith et al., 2024; Sharma et al., 2025). 7-OH develops at low percentages by weight within kratom leaves post-harvest as an artifact of temperature, heat, and oxidization (Chakraborty et al., 2021; Smith et al., 2024; Sharma et al., 2025; Zhang).

MG metabolizes in the human body into 7-OH, and 7-OH is then metabolized into MGP, meaning that both 7-OH and MGP are kratom metabolites (Angyal et al., 2023; Chiang et al., 2025; Chakraborty et al., 2021; Hiranita et al., 2020; McCurdy et al., 2024; Wilson et al., 2021). The MOR (μ-opioid receptor) potency, in terms of in vitro binding affinity is greater than for MG or morphine, although the activity of MG, 7-OH, and MGP in humans has not been elucidated (Kruegel et al., 2016; Obeng et al., 2021).

Both MG and 7-OH have been characterized as partial agonists at MOR, although 7-OH has also been characterized more recently as a full MOR that is highly selective, but with potentially lower plasma protein binding compared to some other kratom constituents and less blood brain barrier permeability relative to MG (Chiang et al., 2025; Kruegel, et al., 2019; Obeng et al., 2020; Obeng et al., 2021; Yusof et al., 2019). As noted in a recent review (Ganasan et al., 2024), "[b]oth MG and 7-[OH] share structural features with morphine, a classic opioid, enabling them to interact with the MOR. The key similarity among these three compounds is the presence of nitrogen atoms and ring structures, which allow them to bind to opioid receptors." However, the structural variations between 7-OH and MG result in differing MOR binding affinity, with 7-OH a generally recognized higher MOR affinity partial agonist relative to MG (Ganasan et al., 2024). Presently it is unclear if 7-OH is better characterized as a partial or full MOR agonist or if MG and 7-OH bind to all available MOR receptors. MG and 7-OH may have complex receptor expression that is not fully known. Indeed, the mechanisms, including downstream in vivo mechanisms across a variety of outcomes for kratom, MG, 7-OH, and MGP, are not fully elucidated within or across species.

MG and 7-OH (and other kratom alkaloids) can be administered in animals at well-tolerated doses, and at no observable effect levels with toxicity expected to be dose-dependent (Obeng et al., 2021; Zurath Gonzalez et al., 2025). MG, 7-OH, and MGP may have unique safety profiles given that they do not recruit the β-arrestin pathway and have been recognized as generally having a lower risk profile compared to molecules derived from typical opioid compounds (Chakraborty et al., 2021; Ganasan et al., 2024; Kruegel et al., 2016; Sakamoto et al., 2022; Turnaturi et al., 2023; Váradi et al., 2016). However, the safety profile between kratom or MG

extract containing a broad array of alkaloids compared to MG isolate (which metabolizes into 7-OH and MGP) requires continued study (Sabetghadam et al., 2013) if compounds are advanced for drug development rather than as constituents of natural products.

With respect to the clinical and behavioral pharmacology of MG and 7-OH evinced in animal models, it remains unclear if findings will translate to humans who consume kratom, MG, 7-OH, and MGP orally in real-world conditions at self-selected serving sizes and for a variety of reasons. But, to this point, animal testing does not show serious potential safety concerns.

As noted above, in U.S. kratom products, 7-OH is not a major constituent (Smith et al., 2024; Smith et al., 2025; Sharma et al., 2025), which is why 7-OH and MGP may be more appropriately considered kratom-derivatives formed via MG metabolism. It is also why they should be understood as distinct from products comprised of a broad spectrum of kratom alkaloids or from products with high levels of MG in terms of their clinical evaluation.

Clinical data on kratom:

Self-report on the perceived benefits of kratom use among U.S. consumers is well documented (Garcia-Romeu et al., 2020; Grundmann, 2017; Smith et al., 2022; Smith et al., 2022a; Smith et al., 2024a). There are currently limited data on kratom's effects derived from human laboratory studies. Two studies that primarily focused on MG pharmacokinetics (with some additional outcomes) conducted in Southeast Asia involved males who consumed fresh kratom leaf tea preparations (Trakulsrichai et al., 2015; Vicknasingam et al., 2020). No clinically significant adverse events occurred.

Another recently published study (Huestis et al., 2024) examined the PK for MG alkaloid and 7-OH metabolite levels among healthy adults following a single oral dose of kratom leaf powder and 15 consecutive daily doses. Servings ranged from 500-4,000 mg of leaf material (6.7-53.2 milligrams MG). Although not all study data appear to be published, there were no serious adverse events or adverse events reported in initial findings.

Another PK study conducted in the U.S. examined 6 healthy adults who were not active kratom consumers (3 male/3 female) and evaluated PK differences between kratom alkaloids (Tanna et al. 2022). This study reported two adverse events of nausea/vomiting when 2g of whole leaf kratom was consumed on an empty stomach. A recent study conducted in the Netherlands (Prevete et al., 2024) examined PK and safety of an MG extract across 5, 10, and 20 milligrams among 8 kratom-naïve adults; 40 milligrams of MG was consumed among 7 participants. No serious adverse events occurred. Of the minor adverse events that occurred in both the placebo and active conditions three had onset after MG administration and resolved. Vitals had some statistically but not clinically significant changes from baseline.

The U.S. Food and Drug Administration has also completed a single ascending dose (SAD) safety and tolerability study among 40 healthy adults with a past-month history of some polydrug use (Reissig et al., 2024). Based on data presented publicly, this study involved administration of a well-characterized kratom powder preparation across 5 cohorts with 8 participants each (2 placebo, 6 active kratom) at doses of 1g, 3g, 8g, 10g, and 12g. No serious adverse events

occurred. Two minor adverse events of GI upset/vomiting occurred at a rate greater than placebo, and at a serving of 8 grams or more (Reissig et al., 2024). No doses showed a strong indicator of subjective ratings related to abuse potential and did not significantly differ from the placebo. Subjective ratings for feeling "high" or "drunk" were highest at 12g but still quite low at 33.7/100 and 15.7/100, respectively. To be clear, this was not a human abuse potential study, and these results are preliminary. However it appears that, overall, kratom was well-tolerated. The U.S. FDA is moving forward with a human abuse potential study on kratom (Department of Health and Human Services, 2024).

Lastly, one small pilot study examined subjective, physiological, and cognitive outcomes related to kratom consumption. In this study, participants who self-administered their typical kratom product serving under observation were regular kratom consumers (Smith et al., 2024b). Serving sizes ranged between 1.1-10.9 grams of kratom whole-leaf powder. These consumers had been using kratom between 1-13 years and some reported the development of tolerance to kratom, which some managed by taking occasional breaks (Smith et al., 2024; 2023a). Plasma samples collected from participants following kratom dosing included: MG, 7-OH, speciogynine, speciociliatine, mitraciliatine, paynantheine, corynantheidine, mitraphylline, corynoxine, and corynoxine-B (Smith et al., 2024b). There were no statistically or clinically significant physiological changes from baseline among any participants apart from miosis; specifically, pupil diameter showed a statistically significant decrease 40-80 minutes post-dosing and remained below baseline >160 minutes post-dosing. All vitals were within normal ranges at all times during the study (Smith et al., 2024b). In this study, abuse liability indicators measured using the Drug Effect Questionnaire (DEQ) found that ratings for "feeling effects" from kratom were 40.0 out of 100 (with 100 being "extremely" and 0 "not at all," measured using visual analogue scale [VAS]) at 40 minutes post-dose. These "feeling effects" peaked at a mean of 72.7 out of 100 approximately 80-90 minutes post-dose. For "liking" kratom effects, the mean scores were 63.4 out of 100 at 40 minutes post-dose. For "wanting more" kratom, the mean score was 19.3 out of 100 at 40 minutes post-dose; by >160 minutes, this had increased, indicating that that the acute peak effects of kratom were beginning to dissipate. For "feeling high," the mean score was quite low at 15.2 out of 100 at 40 minutes after taking kratom, remaining constant at the group level thereafter (Smith et al., 2024b). In this study, psychomotor effects measured using validated computer tasks showed that overall response accuracy was high before and after kratom use (i.e., no psychomotor slowness before or after kratom use). Outcomes that indicated impaired driving did not significantly change pre- or post-kratom dosing and at no point during the study was impairment observed or suspected (Zamarripa et al., 2024). No adverse events occurred during this study.

Physical Dependence and Substance Use Disorder Related to Kratom

Some preclinical considerations:

Nonhuman animals will self-administer both MG and 7-OH (Harun et al., 2021; Hemby et al., 2019; Yusoff et al., 2016). Harun et al. (2021) found that MG at 0.3, 1.0, and 3.0 mg/kg/infusion maintained lever-press responding in rats previously trained to self-administer fentanyl, however, Hemby et al. (2019) found that intravenous self-administration was demonstrated for 7-OH, but not MG, in morphine-maintained and drug-naïve rats. The preclinical literature, while mixed,

provides a scaffold for understanding safety and risks of not only MG-containing kratom products sold in the United States. but also kratom-derived products that contain higher amounts of MG, 7-OH and/or MGP constituents than is found in the natural kratom leaf. Understanding the pharmacology of MG, 7-OH, and MGP is important to understanding how MG, 7-OH, and MGP as alkaloid or metabolite ingredients can be safely consumed by U.S. adults without an unreasonable risk of illness or injury.

Preclinical findings suggest that both MG and 7-OH have some indicators of physical dependence and rewarding properties with some seemingly mediated by MOR agonism (e.g., MG-seeking, MG-conditioned place preference, MG withdrawal, MG and 7-OH reinstatement of morphine-seeking) although the profile between the two differ, with findings indicating that relative to MG, 7-OH may have greater relative abuse liability or adverse effects, but not always (Hassan et al., 2021; Hiranita et al., 2021; Japarin et al., 2023; Yunusa et al., 2024). Yue et al. (2022) found that MG dose-dependently suppressed naloxone precipitated withdrawal signs in a manner similar to that for heroin but with lower potency (Yue et al, 2022). In a series of studies by Behnood-Rod et al. (2020) using an intracranial self-stimulation (ICSS) procedure MG, 7-OH, and morphine all affected reward systems of the brain. Findings from this series of ICSS experiments indicate that MG, 7-OH, and morphine affect the brain reward systems, though the authors concluded that using this well-established procedure for evaluating rewarding or aversive effects, both MG and 7-OH were not rewarding and that "these kratom alkaloids do not have abuse potential."

Manus et al. (2025) examined MG and 7-OH effects on phasic dopamine release in mice nucleus accumbens. The authors noted: "Many psychostimulants, such as cocaine and amphetamine, inhibit DAT and dramatically increase the synaptic half-life of evoked dopamine, but [MG] does not appear to share this mechanism." In terms of binding, the findings suggest that MG acts as a D2 agonist at low doses in males. No sex differences were found for 7-OH but dose-dependent effects were found with low doses of 7-OH significantly increasing dopamine release although "not to the extent of known drugs of abuse" and high dose conditions of 7-OH decreasing dopamine release with 7-OH not altering dopamine auto receptor functioning. The authors concluded: "Findings suggest that [MG and 7-OH] can alter phasic dopamine release, but potentially not to the extent and not in the same patterns as traditional drugs of abuse."

Some clinical considerations:

Ultimately, the understanding of the pharmacology of kratom, MG, 7-OH, and MGP remains ongoing and of great interest to scientists. Although animal studies are important for understanding mechanisms, they do not always translate directly to real-world human use. It is unclear if findings of the relative abuse liability of MG or 7-OH translate to humans who, unlike animals, have access to myriad drug and non-drug reinforcers which influence choice and decision-making (Acuff et al., 2024; Bickel et al., 2014; Heather et al., 2022; Pickard & Ahmed, 2019; Venniro et al., 2018; Witkiewitz & Tucker, 2025).

What is now clearly demonstrated is that humans will readily orally self-administer kratom, MG, 7-OH, and MGP compounds. This fact is evinced by patterns of kratom leaf and extract product consumption both in the United States and by historical use of kratom in Southeast Asia (Coe et

al., 2019; Grundmann, 2017; Singh et al., 2016; Singth et al., 2018; Smith & Lawson, 2017; Talek et al., 2021). It is also evident by the sale and use of 7-OH and MGP products in the United States over the past 2-3 years (Hill et al., 2025; Smith et al., 2005). As such, demonstrating self-administration, conditioned place preference, discriminative stimulus effects, or other outcomes indicative of some abuse potential for kratom, MG, 7-OH, or MGP in nonhuman animal models across various routes of administration, while scientifically interesting, does not for me (as a clinical researcher) carry as much weight as human abuse potential studies using these compounds as comparators to one another and against MOR or stimulant comparators.

Kratom, MG, 7-OH, and MGP have been used for years now in the United States, but there appears to be limited evidence for any widespread development of severe SUD or addiction even though it is indeed possible for a person to develop a physical dependence or SUD for any of these. Indeed, rewarding and behaviorally reinforcing compounds or ingredients confer some potential for "misuse" or "abuse" that is typically dose-dependent. Substances with the potential to produce tolerance or withdrawal, including kratom, MG, and 7-OH, also likely confer some abuse liability. It is important to be aware of these characteristics as potential risks, but they cannot be considered a certainty or inevitability given that each product would have its own conditions of use, labeling, recommended serving sizes, etc. Likewise, the consumer will have their own person-level and environmental factors that will influence consumption patterns, including use with other supplements, products, medications, or illicit drugs.

Given the scale and long history of kratom use, there are remarkably few published case reports of kratom-related physical dependence or SUDs globally or in the United States, though they are not absent (Singh et al., 2019; Smith et al., 2023b). Given the millions of kratom consumers in the United States alone (Grundmann et al., 2025), the absence of published medical reports or commentaries from clinicians discussing public health threats related to addiction is striking.

Regarding case reports describing kratom-related physical dependence symptoms (tolerance, withdrawal), "misuse," or "abuse," there are approximately 80-90, with the DSM-5 framework only applied in a minority of cases (Broyan et al., 2022; Kiyokawa et al., 2023; Smith et al., 2022b; Smith et al., 2023b; Stanciu et al., 2019; Schmuhl et al., 2020; Swart, Reznikoff, & Steen, 2024). Some cases have shown that kratom is used nonproblematically or to achieve some benefit (Boyer et al., 2007; Gnanasegaram, Sexton, & Stanciu, 2024; Müller et al., 2020).

As discussed below, I am unaware of any published case report on 7-OH or MGP. Such case reports would have been likely to have been presented or published over the past 2-3 years since these products began being sold in the United States.

One source of information on kratom-related dependence and SUD symptoms comes from social media data (Smith et al., 2021; Rogers et al., 2024a). There are significant challenges and limitations to examining social media data. Still, many posts convey some experiences related to kratom use, kratom-related problems, and discontinuation of kratom use that are not adequately captured in case reports or on surveys. However, as with surveys there is self-selection and recall bias in social media posts. Such limitations notwithstanding, descriptions of perceived or professed kratom problems and kratom-related addiction have been described in some Reddit

posts, albeit among a seeming minority (Rogers et al., 2024a). Data related to 7-OH or MGP from social media posts have not yet been fully analyzed and published. However, having personally looked over a significant amount of Reddit data for 7-OH and MGP it appears, at least provisionally, that there are similarities to kratom: there are many consumers who are satisfied with their experiences and others who have quit or stopped using for a variety of reasons, including those related to adverse events or SUD (Grundman et al., 2022b; Rogers et al., 2024a; Smith et al., 2021). For instance, there are subreddits devoted to quitting or stopping kratom and 7-OH. SUD for kratom evaluated via survey has been mostly mild to moderate (Garcia-Romeu et al., 2020; Hill et al., 2024; Smith et al., 2022c). Continued study of kratom online posts is needed along with analysis of posts related to 7-OH and MGP experiences.

In a survey completed before a 15-day ecological momentary assessment (EMA) of kratom use patterns among 357 regular kratom consumers enrolled into the study, 66.7% had ever met SUD criteria for kratom during their lifetime (Smith et al., 2024a). Commonly DSM-5 symptoms included withdrawal and tolerance, using more than intended, and craving. More frequent kratom consumers within the sample tended to adjust or titrate their kratom consumption to meet their goals, such as focus and productivity, self-managing symptoms of OUD, relieving pain, increasing energy, and improving mood (Mun et al., 2025; Smith et al., 2023a; Smith et al., 2024a). Daily diaries conducted via smartphone app during the EMA phase found that contrary to impaired control or social problems, participants largely rated kratom's acute effects as being both helpful for and compatible with meeting daily roles and obligations (Smith et al., 2024a). This was found even among participants who met SUD criteria for kratom. The psychosocial functioning seems to remain intact among most U.S. kratom consumers studied to date including those who meet SUD criteria. The authors concluded that most kratom use was instrumental and conferring some beneficial effects.

A more detailed analysis of baseline data from this same study examined data for all enrolled participants (N=395; Rogers et al., 2024b) with 46.6% meeting DSM-5 criteria for past-year SUD for kratom, meaning that some who previously met criteria had remitted. When withdrawal was assessed retrospectively, some global withdrawal symptoms (*e.g.*, irritability) as well as more kratom-specific symptoms (*e.g.*, restless legs) were mostly mild-moderate.

As part of this survey and EMA study, 341 commercial kratom products were provided by participants. This study for which participants provided products was conducted between July-November 2022, which largely predates widescale 7-OH and MGP use. All products included in the final analyses were whole-leaf products, not extracts (Sharma et al., 2025). The total milligrams of MG and other alkaloids were estimated per serving with the average milligrams of MG per serving 31.3 (range of 2.0-205.9 milligrams; Sharma et al., 2025). Total alkaloids (MG plus other alkaloids) was 63.9 milligrams per serving on average. The estimated daily intake of MG was 134.6 on average (Sharma et al., 2025). Principle components analysis showed that 7-OH was the most stable and consistent, reflecting its exceptionally low variability. As a minor alkaloid in the kratom leaf products tested, 7-OH was below the lower limit of quantification in several kratom products, with the mean content 0.01% w/w or w/v. The content of 7-OH ranged from BLLOQ-0.21% (w/w or w/v) with a median of 0.01% w/w or w/v. Results indicate that 7-OH, as an alkaloid, is not a major component of the dried kratom leaf products in the United States. As such, 7-OH products converted from kratom or MG extract may be better considered a

metabolite and should not be considered kratom (Smeith et al., 2025) or as the authors note, "kratom derivatives" (Sharma et al., 2025).

As with any other substance that has rewarding properties, kratom-related SUD must be assessed on a case-by-case basis and differentiated from normative and nonproblematic consumption patterns. Ideally, the total alkaloids per serving and the frequency of consumption would be considered along with motivations for use and benefits, which the DSM-5 assessment does not include. Aggregate assessments of U.S. kratom consumers provide signals that an SUD for kratom can develop but such aggregate data are not a replacement for individual assessments that consider comorbidities, health history, other substance use, motivations for use, and other trait or state characteristics needed to contextualize the etiology and trajectory of an SUD. To date, many U.S. adults who use kratom regularly can develop tolerance or withdrawal risks, but most kratom consumers appear to be highly functioning. Normative use and SUD related to kratom, MG, 7-OH, and MGP products require continued scientific study along with clinical assessment of presenting patients. Given significant differences in kratom-derived products, researchers and clinicians must improve assessment methods to account for the variation (Grundmann et al., 2024; Smith, Epstein, & Weiss, 2024; Smith et al., 2025).

Respiratory Depression

Respiratory depression: Some preclinical considerations

Given the MOR activity of MG and 7-OH it is important to consider possible respiratory depressant effects. In one study investigating this possibility for MG, none of the three blood gas parameters indicating respiratory depression significantly deviated from baseline at the therapeutic 6.75 mg/kg for the oxycodone positive control dose (Henningfield et al. (2022). However, doses of 60 mg/kg and 150 mg/kg oxycodone produced respiratory depressant outcomes as well as behavioral effects and lethargy consistent with prototypical opioids; moreover, 1 death occurred at each oxycodone dose. The large 400 mg/kg MG dose produced milder observable signs, relative to the oxycodone doses, but included changes in locomotor behavior, lethargy, and/or incoordination in a majority (5 of 6); this slowed behavior indicates potentially decreased respiratory rate at 2 and 4 hours in five rats. Approximately 40 minutes after the 400 mg/kg MG dose, one rat displayed "full body spasms" when handled and removed from the home cage. Under observation at approximately 1 hour post-MG dosing, the animal exhibited "seizure-like activity." Henningfield et al. (2022) concluded that MG did not yield significant dose-related respiratory depressant or life-threatening effects and that sedative-like effects of MG, produced at the highest 400 mg/kg dose, were milder than those produced by oxycodone. All findings were dose related.

In Zuarth Gonzalez et al. (2025), MG doses larger than 17.8 mg/kg produced overt signs of toxicity in rats and were not fully tested. This highest dose produced no significant respiratory depression and resulted in seizure-like activity in two out of three male rats, with one rat sustaining physical injury. This adverse reaction established 10 mg/kg the upper safety limit for testing. MG doses were 5.6 and 10 mg/kg administered intravenously. Using whole body plethysmography, MG produced significant increases in respiration but not respiratory depression in the rats tested. The authors found that 7-OH at 1mg/kg dose administered intravenously, the 1 mg/kg 7-OH dose did not produce respiratory depression outcomes, though

some indicators were found at higher 3.2 and 10 mg/kg doses administered intravenously. Respiratory frequency decreased for the higher 7-OH doses administered intravenously at 30 minutes and 60 minutes. Post hoc analysis showed that these 3.2 mg/kg and 10 mg/kg 7-OH doses significantly reduced respiratory frequency (i.e., number of breaths per minute) at 30 minutes but that effects were not maintained at 60 minutes. For one respiratory depressant indicator (tidal volume; amount of air inhaled or exhaled per single breath), 7-OH did not reach statistical significance at 30 minutes or at 60 minutes post-dose. 7-OH statistically significantly reduced minute volume (i.e., total volume of air inhaled or exhaled per minute calculated by multiplying the tidal volume and respiration rate) at 30 minutes, but not 60 minutes, post-dose. Overall, indicators of 7-OH respiratory depressant outcomes resolved in less than an hour, unlike morphine, which persisted at 60 minutes. At 10 mg/kg of 7-OH, the 7-OH x saline administration significantly differed from the 7-OH x naloxone administration, with naloxone successfully antagonizing 7-OH (Zurath Gonzalez et al., 2025).

Elsewhere, the antinociceptive and other effects of MG have been reversed by both opioid (naloxone) and alpha-2 adrenergic receptor antagonists (yohimbine and idazoxan; Harun et al. 2015; Hiranita et al., 2021; Matsumoto et al., 1996; Kruegel et al., 2019; Foss et al., 2020). In mice, naltrexone has also been shown to fully antagonize the antinociceptive effects of MG at 293 mg/kg and to antagonize increases in the maximum possible effect of 7-OH (Berthold et al., 2022). In one seminal paper by Obeng et al. (2021), naltrexone antagonized morphine and 7-OH effects and antagonized MG discriminative stimulus effects.

Hill et al. (2022) examined the respiratory depressant effects of MG, 7-OH, and morphine via oral administration in mice. Although the 1mg/kg of 7-OH administered intravenously by Gonzalez and colleagues (2025) failed to produce respiratory depressant effects, Hill et al. (2022) found that an oral 1.9 mg/kg dose of 7-OH produced effects. For MG administered at doses of 5.6 mg/kg and 10 mg/kg, Gonzalez et al. (2025) found increased respiration rate whereas Hill et al. (2022) demonstrated clear and sustained respiratory depressant effects of oral MG at 5.5 and 10.0 mg/kg with a ceiling effect at 10 mg/kg. Oral administration at equipotent doses for MG (5.5 mg/kg), 7-OH (1.9 mg/kg), and morphine (3.8 mg/kg) induced significant respiratory depression, and this was maintained for the entire 90-minute post-dose observation period. Although some time points differed across respiratory depression outcomes, area under the curve analysis of these equi-effective doses of MG, 7-OH, and morphine did not show significant differences in the overall degree of respiratory depression induced over the observation period. Moreover, all three MOR agonist compounds did not significantly differ at any time point in their degree of antinociception and duration of action (Hill et al., 2022). Although kratom has complex non-opioid mechanisms of action related to analgesia or anti-nociception (Henningfield et al., 2023; Kruegel & Grundmann, 2018; Mat et al., 2023; McCurdy et al., 2024), it is apparent that MG and 7-OH have shown some MOR-mediated effects, including the behavioral effects described above and again below.

The abovementioned findings help explicate possible activity of MG and 7-OH at various doses when administered intravenously in rats and orally in mice, with each study having tradeoffs in terms of understanding potential risks of these molecules. Given the oral bioavailability of 7-OH is quite low, possibly as low as ~2.7-3.0%, (Chiang et al., 2025), the Gonzalez et al. (2025) study likely fails to translate to products containing large amounts of 7-OH, as humans consume 7-OH

and MGP products orally. Although rats are generally superior to mice in terms of the species when modeling some physiological outcomes that we wish to extrapolate to humans, the intravenous route of administration makes the findings of unclear practical value for understanding products taken orally which may not have the same systemic exposure. At high enough doses, kratom, MG, and 7-OH may produce toxic or adverse effects (Macko et al., 1972; Manda et al. 2014; Hill et al. 2022; Sabetghadam et al., 2013; Torrico et al. 2024; Zurath Gonzalez et al., 2025), as would be expected with nearly any bioactive compound.

Again, a nontrivial point is that the 7-OH doses tested in animals may not reflect serving sizes chosen and consumed by humans, for which there will be variety of other considerations to take into account (age, weight, sex, polysubstance use, etc.). As has been shown with kratom (and other substances) most consumers tend to titrate how much they consume in order to achieve desired effects (Smith et al., 2023a; Smith et al., 2024; Smith et al., 2024a). I have come to learn that those decisions may be made by consumers individually in the absence or presence of product labels, serving size recommendations, or other information (Smith et al., 2023a).

There is one interesting point for consideration that has not been widely discussed. MG-related adverse effects or toxicity may not be readily identified in humans nor reversed due to the complex and still not fully elucidated promiscuous pharmacology of MG and kratom. By comparison, the MOR selectivity of 7-OH makes the identification, prevention, mitigation, and reversal of any MOR-mediated adverse event related to 7-OH possible if it were to occur among human consumers. Although the risk of illness or injury for products containing kratom, MG, 7-OH, or MGP appears to be quite low, if a severe adverse event for 7-OH were to occur than those could reasonably be expected to be more easily prevented, identified, and mitigated. It is presently unclear what a kratom or MG toxidrome presents as. Again, adverse events for kratom, MG, 7-OH, and MGP are not widespread, but it is important to consider the full breadth of public health implications for all of these compounds or ingredients.

Respiratory depression: Some clinical considerations

To my knowledge there have been no confirmed cases of kratom-induced respiratory depression in humans where it was demonstrated that kratom or its constituents, including MG and 7-OH, were causally related. However, the few cases that do exist merit comment as they mention the possibility of respiratory depression related to kratom.

One case report of a purported kratom overdose that included a low respiration rate describes the administration of naloxone in an emergency department setting which, according to the authors, reversed respiratory effects they associated with kratom followed by patient agitation upon naloxone administration (Overbeek et al., 2019). The patient screened positive for MG without medications, alcohol, or other MOR-acting compounds detected.

Jarka & Gregoire (2023) published a case report of precipitated withdrawal from kratom whole-leaf powder after naloxone wherein the patient reported extreme agitation and presented to the emergency department. Toxicology screens were negative save for a small amount of alcohol.

Palasamudram Shekar et al. (2019) submitted a patient case report in 2018 of an adult male who had been consuming a "green colored herbal supplement" with increasing daily dosage prior to being found unresponsive and with miosis, slowed breathing, and Glasgow Coma Scale of 3; the patient was administered naloxone. The patient was managed in the intensive care unit until he stabilized and was discharged after two weeks to an acute physical rehabilitation center. Suspecting kratom overdose, the patient's urine was tested for kratom and the authors reported that the urine sample was found to have 500 ng/ml of 7-OH which they suggested indicated a kratom "overdose." As the total volume of urine excreted and last kratom serving amount were unknown, this numerical value has little context or meaning other than to indicate that the patient had likely been consuming kratom. However, for comparison, other crude qualifications to identify the presence of 7-OH in urine can be found in one small observational human laboratory study (Smith et al., 2024c). In this study (which did not involve pharmacokinetic modeling), 7-OH in urine of adult participants who used kratom regularly ranged from 2418.2–88063.5 ng/ml following self-administration of kratom powder at doses between 1.1-10.9 grams (Smith et al., 2024c); pre-dosing of kratom, 7-OH in participant urine ranged from 2587.220–94640.910 ng/ml. In the Palasamudram Shekar et al. (2019) case, the authors did not report testing (or testing results) for other substances in the patient's urine or plasma. As such, this case report of severe adverse event following ingestion of kratom provides little insight into illness or injury related to kratom as a whole or 7-OH in particular.

To my knowledge there have been no reported nor confirmed clinical cases of respiratory depression in humans induced by 7-OH or MGP where it was demonstrated that products containing these constituents were causally related. At this time, I am also unaware of any published case report even correlating 7-OH or MGP with respiratory depression with or without causality being attributed. To date, no cases of 7-OH-related respiratory depression exist in the medical literature.

Consideration of Other Available Data in Relation to Illness or Injury

In 2018, Dr. Brett Giroir, the former Assistant Secretary for Health within the Department of Health and Human Services proposed to the Drug Enforcement Administration that further research into MG and 7-OH should be undertaken to inform any scheduling decision of kratom, MG, or 7-OH. There remains what he described back in 2018 as a relative lack of evidence. At the time of this writing, there remains a relative lack of evidence on the risk of kratom, MG, 7-OH. The signal of public health harm in the form of illness or injury has not yet appeared for these or for MGP.

Indeed, there are few morbidities that can be causally attributed to kratom, MG, 7-OH, or MGP. Kratom cases are the only ones published, and many of them involve preexisting physical or psychiatric pathologies or polydrug exposures (Alsarraf et al., 2019; Feldman et al., 2023; Stanciu et al., 2023).

There are 12 cases of MG-only positive mortalities well described with MG toxicity listed as the cause of death; in these cases, blood concentrations ranged from 730 to 5900 ng/ml (median concentration of 2000 ng/ml; Papsun et al., 2023; Brower, 2022). More broadly, ng/ml of MG has ranged from 5.0 to 11,000 in postmortem samples. As no other kratom alkaloids have been

widely used as markers of kratom use and quantified, it is unclear what role they may have played in toxic or fatal outcomes. There is no known lethal dose of kratom to my knowledge.

Some kratom metabolites, including 7-OH, are unstable in blood, particularly relative to MG and are metabolized more quickly (Osawa & Johnson, 2025 Smith et al., In Press; Tanna et al., 2022). As a metabolite, 7-OH has a shorter half-life compared to MG (Huestis et al., 2024). It should be expected that both MG and 7-OH could be found in people using kratom or 7-OH products, with possible intermediary or residual chemicals and secondary metabolites also possibly found, depending on the kratom or 7-OH product and the frequency of consumption (single versus daily). Until clinical and forensic testing improve, collateral information and self-report are critical to understanding all adverse events related to kratom, MG, 7-OH, and MGP. Although there are some published case reports of morbidities or mortalities associated with kratom and MG, they are few and number and confounded by myriad factors (Stanciu et al., 2023; Papsun et al. 2019; Papsun et al., 2023).

I am unaware of any published case reports on 7-OH or MGP products involving mortalities.

I have not, in my role as an academic, been asked to review any clinical case report or data manuscript submitted for peer review publication involving 7-OH or MGP related to morbidities or mortalities.

With respect to monitoring systems, it is unclear if there are trend-level data for either use rates or morbidities related kratom, MG, 7-OH, or MGP, since terms are often combined. Prevalence estimates for kratom use vary considerably (Henningfield et al., 2024), though more recent estimates suggest up to possibly 9.1% past-month consumers (Grundmann et al., 2025).

There are no prevalence estimates for 7-OH or MGP use among U.S. adults. However, based on data that I have collected as part of screening for my two ongoing studies at Johns Hopkins University of active kratom consumers, approximately 16% have reported past-month 7-OH product use at the time of their initial screening. I do not believe it is appropriate to extrapolate from these data as many who screen for my studies are primarily kratom whole-leaf consumers and the prevalence of co-use of kratom with 7-OH may differ between kratom whole-leaf and extract consumers, with use possibly higher among kratom extract consumers. Given the millions of kratom consumers in the United States (Grundmann et al., 2025) if even 16-20% were also using 7-OH then it would be reasonable to estimate that 7-OH use is occurring on a large scale numbering in the millions. Such widespread 7-OH use would, if resulting in widescale illness or injury, be expected to be detected clearly on monitoring systems.

The National Drug Early Warning System (NDEWS) reported 4,233 instances of emergency medical service (EMS) contacts related to what they reported as fatal and nonfatal “kratom/7-OH” overdoses, with a statistically significant increase between January 1, 2023, and April 30, 2025. However, because terms were combined the data are difficult to interpret with respect to use of either kratom or 7-OH or co-use of both. Kratom/7-OH-related EMS encounters were included if the chief complaint/narrative in the narrative text search contained US product names, trade names including “kratom” (or “kratum”, “Cratom”), “Gratom”, “kratom extract”, “kratom shot”, “kratom capsule”, “Mitragyna speciosa”, “7-hydroxymitragynine”, “7-OH”, “7OH”, “7HMZ”, “7(omega)MZ”, “7OHMZ”, “Ketum”, “Thang”, “Thom”, “Kakuam”, “Biak”,

"Katawn" or "Kedemba." As noted by the NDEWS, limitations of their data methods are reflected by the fact that they reflect pre-hospital EMS encounters "and do not include hospital outcomes, toxicology confirmation, medical history, or prescription information," and that "much of the data relies on clinical impressions, self-report, or bystander accounts. Additionally, kratom/7-OH-related overdoses may be underreported or misclassified."

At the time of this writing FDA's Adverse Event Reporting System ("FAERS") shows 13 cases of adverse events and 2 fatalities that were suspected to involve 7-OH. However, the contributing or causal role of 7-OH was ambiguous due to the lack of characterizations of 7-OH products and the possible role of other factors, such as polysubstance exposure or existing health conditions. In their recently released report on 7-OH, *7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat* (Reissig et al., 2025), FDA acknowledged limitations with existing epidemiological data sources on 7-OH and how these limitations and issues "may complicate real-world assessment of risks associated with use of 7-OH containing products as distinct risks associated with kratom and other mitragynine-containing products" (Reissig et al., 2025).

As also noted in the recently released FDA report, queries to the Drug Enforcement Administration Toxicology Testing Program (DEA TOX) database for an approximately 6-year period between 2019-2025 returned 103 cases related MG, 7-OH, or MGP. Samples are submitted to DEA TOX voluntarily based on suspected overdoses involving novel psychoactive substances. The utility of DEA TOX is limited in this respect. Moreover, the biospecimens that contained 7-OH also contained MG at far higher levels than 7-OH, likely indicating that these cases involved kratom or possibly co-use of kratom and 7-OH (see DEA TOX quarterly reports available https://www.deadiversion.usdoj.gov/dea_tox/dea-tox.html). Using DEA TOX to determine if there is a signal is ultimately challenging, and any signal will be ambiguous at best.

Likewise the National Poison Data System (NPDS) data can be problematic for estimating illness or injury at the population level due to the nature of self-report, which may not be confirmed by assay of either patient biospecimens or the product purportedly used. NPDS data indicate that there are only 37 single-substance exposures for 7-OH between the period for which there are data (2/1/2025-4/30/2025) with most cases resulting in clinically moderate or minor outcomes or outcomes that were not followed but for which "minimal clinical effects" were possible. As the 7-OH product names are not provided, nor serving sizes of 7-OH listed, the data are of limited value.

The aforementioned monitoring and surveillance systems have limitations, but they nonetheless provide indicators when clear public health threats emerge from a particular substance. In the past two years, we have not seen a clear and consistent public health signal emerge for kratom, mitragynine, 7-OH, or MGP.

As public health surveillance systems are updated to better capture both kratom leaf and extract products as well as kratom-derived products containing 7-OH or MGP metabolite ingredients, I have attempted to gain an understanding of 7-OH and MGP use in any way I can. For instance, as part of my job as a clinical researcher focused on kratom, I often interact with practicing clinicians. This occurs at scientific meetings or when I am asked to give a talk on kratom or 7-

OH. Over the years, some providers have emailed or called me directly to inquire about kratom. Although I am an LMSW, I do not currently practice and do not give clinical advice, but rather provide information to clinicians based on available data. In my interactions with medical providers who encounter kratom in their practice, it appears that the rate at which SUD for kratom is presenting is generally low relative to other substances (e.g., alcohol, methamphetamines, opioids), and the severity at which it is presenting is mild or moderate relative to other substances. This is not to say that physical dependence and SUD related to kratom leaf and extract products does not exist but rather that it does not appear to be widespread or consistently severe, as noted above. In giving talks over the past few years, I have been struck by how many public health officials or clinicians do not know what kratom, MG, 7-OH, or MGP are. Although kratom is more widely recognized than MG, 7-OH, or MPG, most people I talk to do not know much about it. This anecdotal account does not reflect hard numbers, but it does reflect the fact that, broadly speaking, kratom, MG, 7-OH, or MGP are not household words.

Since mid-2022/early 2023, which is the time period that that 7-OH products first began to appear on the market at scale, I have had only two healthcare providers reach out to me regarding 7-OH use disorder and/or withdrawal, with one of them contacting me recently after reading a recent media story regarding the proposed scheduling of 7-OH.

Again, in my role as an academic, I have not been asked by any journal to peer review any case report manuscript involving 7-OH or MGP for publication. In clinical talks that I have given, I have urged clinicians to write up case reports on kratom, MG, 7-OH, and MGP.

I am, however, a co-author on two recent case reports describing 7-OH and kratom. Their existence reflects a concerted effort by me and my colleagues to find and write up confirmed 7-OH use. I note this because it underscores the fact that 7-OH-related clinical cases are simply not widespread nor particularly easy to find.

These two cases that I have co-authored have been accepted for publication, both in the *Journal of Addiction Medicine*. These reports have undergone full peer review and are in press, I will provide short overviews.

The first case report involving a 7-OH product describes a patient who doctors based in Ohio identified through the Central Ohio Poison Center (Reif et al., In Press). The patient was a 35-year-old man who presented with supraventricular tachycardia (SVT) and urinary retention. After hospital admission, he described using a 7-OH product. The patient had a history of untreated SVT characterized by recurrent episodes that abated with Valsalva maneuver developed palpitations. After learning of the SVT history, ongoing care by cardiology, and scheduled ablation, emergency providers administered diltiazem (18 mg). The first recorded vitals in the Emergency Department were: a pulse 122 beats per minute; a blood pressure 124/77 mg Hg; a respiratory rate 18 breaths per minute; and he was afebrile. The SVT was the reason for his hospitalization.

At the time of admission, the patient vaped cannabis and nicotine and reported heroin use a decade earlier. He used kratom approximately 6 months before trying the 7-OH product, which began 10 weeks before hospitalization. The patient described tolerance developed from his 7-OH

product; within two weeks he was using one 7-OH film every 1-2 hours. The patient met criteria for severe DSM-5 SUD related to his 7-OH product use and was inducted onto buprenorphine by the treating physician. When we evaluated him for SUD, the patient did not report psychosocial impairments related to use and was actively employed as a business owner at the time of his assessment. As part of the case report, 7-OH in the product and blood samples that we obtained from the patient was confirmed. Ultimately, we considered the likelihood of this patient's cardiac findings being attributable to 7-OH as quite low. The patient had an extensive history of SVT managed by a cardiologist, but he was nonadherent to treatment. However, we did attribute the urinary retention (2.3 liters) to the 7-OH product use along with the SUD, albeit neither were what he sought medical treatment for.

The second case report involving a 7-OH product is of a participant who enrolled in one of my studies on kratom at Johns Hopkins University. In this case report, we presented a 23-year-old man who had been using kratom whole-leaf powder for 3 years and who was enrolled into my ongoing clinical trial evaluating kratom PK, behavioral pharmacology, and withdrawal. This study takes place over 3 days and 2 nights in a locked clinical research unit. This participant typically used 1.5-2g of kratom whole-leaf powder six times/day. At the time of screening (weeks prior to study admission) the participant was evaluated and met DSM-5 criteria for severe SUD for whole leaf kratom but had no prior diagnosis or treatment for other substances. The participant used 30 mg prescribed lisdexamfetamine (Vyvanse) for attention deficit hyperactivity disorder. Urine assay on the participant's study screening and admission days confirmed this and were negative for other substances. No noteworthy conditions were identified during the health and physical screening. Following the participant's scheduled kratom product self-administration during the study, several outcomes were atypical, including blunted subjective kratom effects. For the 7-day period before study admission, the participant was using his kratom powder approximately six times per day. In the afternoon of his first study day, the participant reported recent initiation of what he referred to as a new kratom that was, we found out upon further questioning, a 7-OH product; he reported using the product 20 mg three times/day for four days prior to study admission. The participant reported withdrawal symptoms that he did not wish to tolerate and requested early discharge from the study. At discharge, the participant's Subjective Opiate Withdrawal Scale ("SOWS") and Clinical Opiate Withdrawal Scale ("COWS") scores were 11 (moderate) and 7 (mild), respectively. Because the participant was concurrently using kratom whole leaf and a 7-OH product it is not possible to determine what withdrawal symptoms were attributable to which substance, although the participant had been using whole leaf kratom for a far longer period of time and more frequently than any other substance. A sample of the kratom leaf product used by the participant was obtained along with biospecimens. From the nine blood draws collected prior to the participant's discharge, MG (29.7 ng/ml) plasma concentration peaked at 1.5 hours post-dosing, while 7-OH C_{max} (11.7 ng/ml) occurred before his kratom product self-administration, providing support for his reported prior ingestion of a 7-OH product at 23:30 the night before study admission. Vitals remained stable at all time points during the study.

To my knowledge these are the only two case reports related to 7-OH product use accepted for peer-review publication. In only one of the two cases were adverse events related to 7-OH evident and unambiguous (severe SUD for 7-OH; urinary retention). In the other case, severe SUD for kratom whole leaf was evident. These cases are, in my opinion, reflective of the

literature I described above, which is that an SUD for any rewarding substance is possible, including for kratom leaf or extract, MG, 7-OH, and MGP, but that in the past 20 years of use of kratom-derived products in the United States, we have not seen a widescale public health threat emerge.

I have also recently completed an online convenience sample survey of U.S adults who had ever consumed 7-OH products, with a final sample size of 278 valid survey responses. As data are not yet published and as more data are not yet analyzed, I provide only a high-level description of general methods. No kratom or 7-OH industry funds were directly or indirectly involved in this study.

Data were collected between March and May 2025, and the study was approved by the Johns Hopkins University Institutional Review Board ("IRB"). Kratom and 7-OH advocacy groups and vendors promoted the study online and through email. Recruiting materials were also posted on social media, including on subreddits devoted to kratom and 7-OH generally, or quitting 7-OH. Recruitment was as broad and inclusive as possible, though many respondents reported hearing about the study from Reddit (46.8%), the American Kratom Association (23.7%), and online retailers who sell 7-OH products (6.5%).

Prior to enrollment, candidates completed a short online screening questionnaire designed to determine eligibility and protect against bots or malicious actors. Screeners not automatically excluded underwent manual review to ensure the following criteria were met: completed attestations (e.g., agreeing to participate and being contacted); ≥18 years of age; residing in the United States (with verifiable email address and zip code cross-referenced); being English-language proficient; having ever used 7-OH. We did not require any minimum exposure for study inclusion (as some may have only recently tried 7-OH for the first time or may have not used regularly); we wanted to capture a range of use experiences while not inadvertently excluding people who had stopped using. Candidates also had to pass 9 validity checks (e.g., math problems, fake responses). If a screener passed all checks, the candidate was emailed a unique survey link. The survey was hosted on a Qualtrics platform. Respondents were compensated automatically with a $10 digital gift card following survey completion.

In addition to the online survey, a qualitative interview sub-study was conducted. For this I personally interviewed 23 adults with 7-OH experience for approximately 1.5-2.0 hours per interview. Most were active 7-OH consumers at the time of the interview. The audio and text from this sub-study is actively being analyzed. We have approximately four manuscripts that are expected and in preparation. We believe there are likely some self-selection and recall bias, as is the case with many cross-sectional surveys, but we hope these preliminary data provide some signal to help refine research moving forward.

Indeed, I am now working to develop another survey exploring 7-OH and MGP product use among active (past-month) consumers that will also be independently conducted with colleagues at Johns Hopkins University. This survey will be 100% supported using departmental start-up funds; no funds directly or indirectly related to industry or to non-profits concerned with kratom or 7-OH will be used. This includes any philanthropic donations (none of which have been made at this time of this writing). I do hope to gather support from kratom and 7-OH stakeholders,

consumers, advocates, or industry in helping recruit for the study, and this will be noted in my study protocol, which is a standard practice in recruiting for survey-based research.

Lastly, as a person genuinely wanting to better understand 7-OH and MGP use, I find it necessary to go out into the community to have conversations with people who use and sell these products, including people at vape shops or industry trade shows. Between the interviews on 7-OH that I have done for research purposes and informal conversations that I have had with 7-OH consumers and sellers, I have not developed an impression that, to date, 7-OH or MGP should be considered a public health crisis resulting in widespread illness or injury. What I have found through my preliminary research and conversations is that kratom, MG, 7-OH, and MGP are providing many quality-of-life benefits to many people along with some risk.

Overall, it is my opinion that kratom, MG, 7-OH, and MGP are, for those who use them, providing more of a net benefit rather than a net detriment. As science evolves and more data are collected, that opinion is subject to change. Kratom, MG, 7-OH, and MGP are not without risk nor are they devoid of benefit.

To conclude, based on all of my work to date that appears on my CV, both published, in press, and in preparation, and based on my now years' long direct interaction with U.S. adults who use kratom, MG, 7-OH, and MGP, it is my opinion that people who consume these kratom-derived products do so with their own risk-benefit frameworks in mind. It is also my opinion, as evinced by the overall lack of epidemiological and forensic data, that kratom, MG, 7-OH, and/or MGP do not pose an unreasonable risk of illness or injury, particularly relative to many other available substances. Risks that have been identified and therefore are foreseeable, can be mitigated through continued scientific study, good manufacturing processes, and appropriate regulation that will necessarily include adequate labeling based on a product's conditions of use.

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Summary of FY 2026 Legislative Proposals

The FY 2026 budget includes several legislative proposals that support agency efforts to protect American consumers and patients. The proposals include enhanced authorities to address the import of problematic medical devices and ensure data quality in medical product applications. The proposals would change labeling requirements for active pharmaceutical ingredients to include original manufacturer and supply origin and enhance the utility of drug manufacturing amount information to be reported to the Agency. The Agency also seeks authority to ensure that data supporting application and non-application medical products are reliable and verifiable for as long as the product may be legally marketed and has sufficient tools to act on findings of fraudulent or unreliable data. The budget would also expand the type of information required to prevent drug shortages and resolve a statutory distinction between biosimilar products and interchangeable biosimilar products. The budget would also give FDA the authority to require an importer to destroy any FDA-regulated product(s) refused entry into the United States that presents a significant public health concern, thus removing their option to export such product(s).

Disrupt the Flow of Problematic Imported Medical Devices

Despite extensive efforts utilizing all of FDA's existing oversight authorities, the United States continues to see an influx of problematic imported devices from China and other nations that puts patients and healthcare providers at substantial risk of harm. This compromises the U.S. healthcare system and the supply chain for critical medical devices upon which our hospitals, providers, and patients depend. This risk from problematic imported devices is particularly concerning in outbreak situations when supplies are limited and the U.S. healthcare system is more vulnerable to reliance on foreign suppliers and imported products that may not meet premarket and postmarket requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This poses a substantial national security risk and diminishes U.S. preparedness. FDA is seeking additional authorities that would give the Agency greater assurances that foreign firms are manufacturing devices intended for import into the United States in compliance with quality systems requirements. In addition, FDA is seeking additional authorities to address when the Agency becomes aware that shipments of devices from a particular country, territory, or region may be adulterated, misbranded, or otherwise violative, and pose a threat to U.S. healthcare providers and patients. These new authorities will enhance FDA's ability to ensure safety, effectiveness, and quality of medical devices entering the U.S. market, support patient health and safety, and advance U.S. preparedness and national security.

Require Labeling to Include the Original Manufacturer and Supply Chain Information

Transparency regarding the drug supply chain is critical for FDA, industry, and other stakeholders. FDA needs additional supply chain information to investigate quality and safety problems. Manufacturers, compounders, and purchasers such as hospitals and patients could make better-informed decisions when evaluating and selecting suppliers and manufacturers with this additional information. FDA proposes to amend section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to clearly require that the label and any accompanying certificate of analysis for an active pharmaceutical ingredient (API) for use in drug manufacturing, including

human drug compounding, identify the name, address, and unique facility identifier of the API's original manufacturer. In addition, FDA proposes to amend section 502 to clearly require that the label for a finished drug product identify the name, address, and unique facility identifier of the finished drug product's original manufacturer. FDA also proposes to amend section 502 to clearly require that the labeling for a finished drug product or API identify the original manufacturer of each API, each manufacturer involved in the production of a finished drug product (if different from the original manufacturer), and the packer or distributor, if any. Finally, FDA proposes to amend section 502 to require that the label for certain excipients designated as high-risk by the Secretary identify the excipient's original manufacturer. The Secretary may provide for reasonable variations or an alternative placement for certain drug product labeling requirements, including by electronic means. We anticipate that information about API sources, other manufacturers, and packers and distributors could be provided on a website or other electronic format.

Enhance the Utility of Drug Manufacturing Amount Information Required to be Reported to FDA

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) requires drug manufacturers registered under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to report annually to FDA the amount of each listed drug they manufactured, prepared, propagated, compounded, or processed ("manufactured") for commercial distribution. However, this information is not sufficient to allow FDA to assess the extent of a manufacturer's reliance on suppliers used in the manufacture of a listed drug, which is critical to better understand potential vulnerabilities of the drug supply chain. Accordingly, FDA seeks to expressly require registrants to provide, by a statutory deadline, data identifying the suppliers they relied on to manufacture the listed drug and the extent of such reliance in each annual report. These authorities will help FDA utilize our limited resources more efficiently to address potential drug shortage risks and enable timely action against companies that fail to comply with this reporting requirement.

Require Retention of Data and Records Supporting Marketed Medical Products and Marketed Medical Product Applications and to Act Upon Submissions Containing Fraudulent or Unreliable Data

FDA is increasingly identifying instances of fraudulent or unreliable data provided in premarket submissions for medical devices, in marketing applications for drug and biological products, and in support of non-application medical products (e.g., OTC monograph drugs), including during inspections and remote regulatory assessments of manufacturing establishments. In many instances, the fraudulent or unreliable nature of the data is not discovered until after marketing authorization is granted or a non-application medical product is distributed. This may be because the nature of the unreliable data is not apparent until after an inspection is conducted or a pattern is discovered. As a result, FDA seeks express authority to ensure that data supporting application and non-application medical products are reliable and verifiable for as long as the product may be legally marketed, including throughout the lifetime of the application or market authorization, and to ensure that FDA has appropriate tools to act on findings of fraudulent or unreliable data, including untrue statements of material fact, during premarket review and across the total product life cycle. These new or clarified authorities would help protect the public from medical products that have not been shown to be safe and effective.

Eliminate the Statutory Distinction Between the Approval Standard for Biosimilar and Interchangeable Biosimilar Products and Deem that Approved Biosimilars are Interchangeable

The statutory distinction between biosimilar products and interchangeable biosimilar products has led to confusion and misunderstanding, including among patients and healthcare providers, about the safety and effectiveness of biosimilars and about whether interchangeable biosimilars are safer or more effective than other biosimilars. Interchangeability pertains to pharmacy substitution of an interchangeable biosimilar for its reference product. However, both biosimilars and interchangeable biosimilars are just as safe and effective as their respective reference products and can be used in place of their respective reference products. Accordingly, FDA seeks to amend section 351 of the Public Health Service Act to no longer include a separate statutory standard for a determination of interchangeability and to deem all approved biosimilars to be interchangeable with their respective reference products. This proposal would make the U.S. biosimilar program more consistent with current scientific understanding, as well as with the approach adopted by other major regulatory jurisdictions such as the European Union that permit interchangeability of biosimilars with their respective reference products upon approval. This proposal is expected to increase uptake of biosimilars, with potential downstream effects of increasing competition, access, and affordability.

Require Destruction of Imported Products that Pose a Significant Public Health Risk

Under section 801 of the Federal Food, Drug, and Cosmetics Act, importers have the option to export an entry refused by FDA within 90 days of the refusal regardless of the seriousness of the public health concern posed by the product. FDA proposes to amend section 801 to give the Agency authority to require an importer to destroy any FDA-regulated product(s) refused entry into the U.S. that presents a significant public health concern, thus removing their option to export such product(s). The Agency has observed importers exporting or attempting to re-import commercial-sized shipments that pose a significant public health concern including food contaminated with *Salmonella*, *Listeria* and carcinogenic unapproved animal drugs; human drugs such as hand sanitizer contaminated with methanol; and misbranded or adulterated devices such as contact lenses, COVID-19 test kits, and personal protective equipment. In May 2023, a high-volume importer/wholesaler pled guilty to attempting to re-import 2100 cartons of frozen eels from China that were refused by FDA because testing confirmed contamination with a carcinogenic unapproved animal drug. FDA believes this new authority would prevent re-importation of refused products and would deter importers from seeking to import products they know or have reason to believe would pose a significant public health risk and could be ordered destroyed. This authority would also increase efficiency by reducing the need to involve the Customs and Border Protection in the seizure of unsafe FDA-regulated products and allow the Agency to require importers to pay the destruction costs up front, thereby avoiding additional legal action to recoup such costs.

The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

IACC International AntiCounterfeiting Coalition

NADDI National Association of Drug Diversion Investigators

NASCSA National Association of State Controlled Substances Authorities

NCL National Consumers League

ASOP Global | Alliance for Safe Online Pharmacies

Rx 360 The International Pharmaceutical Supply Chain Consortium

ISMP Institute for Safe Medication Practices
An ECRI Company

ECRI The Most Trusted Voice in Healthcare

September 4, 2025

The Honorable Bill Cassidy
455 Dirksen Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Bernard Sanders
332 Dirksen Senate Office Building
United States Senate
Washington, D.C. 20510

The Honorable Brett Guthrie
2161 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
2107 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

RE: FDA FY26 Legislative Proposals Enhance Patient Safety

Dear Chairman Cassidy, Ranking Member Sanders, Chairman Guthrie and Ranking Member Pallone:

As organizations committed to protecting patient safety and securing the integrity of the United States supply chain, we write to express our support for one of the U.S. Food and Drug Administration's (FDA) proposed legislative priorities for Fiscal Year 2026. This proposal could significantly strengthen the FDA's ability to detect, deter and respond to the growing threat of counterfeit and illicit pharmaceutical products entering the country.

FDA PROPOSAL: REQUIRE DESTRUCTION OF IMPORTED PRODUCTS THAT POSE A SIGNIFICANT PUBLIC HEALTH RISK

Streamlining the seizure and destruction processes for unapproved and adulterated medicines and medical devices by border inspectors from either CBP or FDA must be a priority in order to protect patients from malicious bad actors who aim to harm American patients and consumers. The current requirement to hold and adjudicate these obviously dangerous products sometimes results in their return to the rogue manufacturers, allowing these rogue

manufacturers to port shop. After this return, the **rogue manufacturers simply reship them back to the United States**, again aiming to breach our pharmaceutical border security and harm American patients.

We applaud FDA's efforts to disincentivize rogue manufacturers from attempting to sneak their products by customs by making them subject to seizure.

> *FDA legislative proposal text: "Under section 801 of the Federal Food, Drug, and Cosmetics Act, importers have the option to export an entry refused by FDA within 90 days of the refusal regardless of the seriousness of the public health concern posed by the product. FDA proposes to amend section 801 to give the Agency authority to require an importer to destroy any FDA-regulated product(s) refused entry into the U.S. that presents a significant public health concern, thus removing their option to export such product(s). The Agency has observed importers exporting or attempting to re-import commercial-sized shipments that pose a significant public health concern including food contaminated with Salmonella, Listeria and carcinogenic unapproved animal drugs; human drugs such as hand sanitizer contaminated with methanol; and misbranded or adulterated devices such as contact lenses, COVID-19 test kits, and personal protective equipment. In May 2023, a high-volume importer/wholesaler pled guilty to attempting to re-import 2100 cartons of frozen eels from China that were refused by FDA because testing confirmed contamination with a carcinogenic unapproved animal drug. FDA believes this new authority would prevent reimportation of refused products and would deter importers from seeking to import products they know or have reason to believe would pose a significant public health risk and could be ordered destroyed. This authority would also increase efficiency by reducing the need to involve the Customs and Border Protection in the seizure of unsafe FDA-regulated products and allow the Agency to require importers to pay the destruction costs up front, thereby avoiding additional legal action to recoup such costs."*

Bad actors continue to exploit gaps in our import enforcement system, using legal loopholes to reintroduce dangerous, rejected products into the U.S. market. The current process – **allowing these products to be returned to the sender rather than seized and destroyed** – creates a revolving door that puts American patients at risk. Granting FDA authority to mandate the destruction of high-risk, noncompliant imports is a critical step toward closing this loophole. It will help prevent repeat offenses, deter malicious manufacturers, and ensure that our pharmaceutical border security is not a point of vulnerability in the fight to keep unsafe, counterfeit or substandard medicines and medical devices out of our healthcare system.

We urge Congress to advance this commonsense, patient-focused reform to strengthen the FDA's ability to protect Americans from unsafe and counterfeit medicines and medical products. This proposal represents a critical opportunity to close dangerous loopholes, reinforce our pharmaceutical border security, and uphold the integrity of our supply chain.

We stand ready to support efforts that prioritize patient safety and ensure that only safe, effective and FDA-approved products reach American patients.

Sincerely,

Shabbir Safdar
Executive Director, The Partnership for Safe Medicines

Carrie Harney
Board Chair, Alliance for Safe Online Pharmacies (ASOP)

Travis D. Johnson
Vice President - Legislative Affairs, Senior Counsel, The International AntiCounterfeiting Coalition

Charlie Cichon
Executive Director, National Association of Drug Diversion Investigators

Katherine Keough
Executive Director, National Association of State Controlled Substances Authorities

Nancy Glick
Director, Food and Nutrition Policy
National Consumers League

Rita K. Jew, Pharm.D., MBA, BCPPS, FASHP
President, Institute for Safe Medicine Practices

Dheerendra Kommala, MD
Chief Medical Officer, ECRI

Jim Fries
Chief Executive Officer, Rx-360

cc: U.S. Senate Health, Education, Labor, and Pensions Committee Members
U.S. Senate Appropriations Committee Members
U.S. House of Representatives Energy and Commerce Committee Members
U.S. House of Representatives Appropriations Committee Members
Dr. Martin Makary, Commissioner, U.S. Food and Drug Administration

February 23, 2026

Senator Bill Cassidy, MD
Chairman,
U.S. Senate Committee on Health,
Education, Labor, and Pensions

Senator Bernie Sanders
Ranking Member,
U.S. Senate Committee on Health,
Education, Labor, and Pensions

Representative Brett Guthrie
Chairman,
House Committee on Energy
and Commerce

Representative Frank Pallone
Ranking Member,
House Committee on Energy
and Commerce

Re: The *Destruction of Hazardous Imports Act*, H.R. 2715 and S.3213

Dear Chairman Cassidy, Chairman Guthrie, Ranking Member Sanders, and Ranking Member Pallone:

According to U.S. Food and Drug Administration (FDA) documentation, the United States imports 94 percent of the seafood that Americans consume annually.[1] Given the substantial volume of seafood entering the U.S. market each year, even a small share of unsafe imports presents significant public health risks to American consumers.

Each month, the FDA reports refusing entry lines of foreign seafood that have been contaminated with banned veterinary drugs, pesticides, poisonous substances, salmonella, listeria, E. Coli, and other human pathogens occurring from bacteria or viruses.[2] Because of these findings, the FDA maintains and actively administers Import Alerts in order to prevent contaminated seafood from entering the U.S. market.[3]

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[1] U.S. Government Accountability Office, Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply, GAO-25-107571 (Jan. 8, 2025) p.22 n.3; *see also* U.S. Food and Drug Administration, Activities for the Safety of Imported Seafood, (Feb. 2023) p.4.

[2] *See* U.S. Food and Drug Administration, "Import Refusal Report" (search results for "Refusal Actions by FDA as Recorded in OASIS for 16-Fishery/Seafood Products) https://www.accessdata.fda.gov/scripts/importrefusals/.

[3] *See* U.S. Food and Drug Administration, "Import Alert for Industry Fishery/Seafood Prod" https://www.accessdata.fda.gov/cms_ia/industry_16.html. Specifically, the FDA maintains and administers Import Alerts on ready-to-eat seafood contaminated with Listeria monocytogenes (Import Alert 16-39), seafood contaminated with salmonella (Import Alert 16-81), cooked seafood products contaminated with E. Coli (Import Alert 16-121), aquaculture seafood products contaminated with unapproved drugs (Import Alert 16-124), seafood contaminated with chloramphenicol (Import Alert 16-127), seafood contaminated with nitrofurans (Import Alert 16-129), seafood contaminated with viruses (Import Alert 16-137), foods (including seafood) contaminated with pesticides (Import Alert 99-08), foods (including seafood) contaminated with chemicals (poisonous) (Import Alert 99-48), and foods (including seafood) contaminated with radioactive chemicals (Cs-137) (Import Alert 99-51).

Under existing law, whenever the agency refuses entry to imported seafood – whether as the result of an inspection or the operation of an Import Alert – the FDA must provide the importer with the option to re-export the contaminated product rather than destroy it. The re-exportation option creates the risk that unscrupulous exporters and/or importers may nevertheless seek to enter the unsafe seafood through another port, a fraudulent practice referred to as "port-shopping."[4]

The FDA has recognized this weakness in government oversight of foreign seafood and, as part of its budget request for fiscal year 2026, has asked that Congress provide the agency with "the authority to require an importer to destroy any FDA-regulated product(s) refused entry into the United States that presents a significant public health concern, thus removing their option to export such product(s)."[5] In explaining its need for this authority, the FDA noted that the agency "has observed importers exporting or attempting to re-import commercial-sized shipments that pose a significant public health concern including food contaminated with Salmonella, Listeria and carcinogenic unapproved animal drugs . . ." The FDA cited to a specific example of an importer that attempted to re-import seafood that had been refused by the agency after testing established that it was contaminated "with a carcinogenic unapproved animal drug." As the agency explained, "FDA believes this new authority would prevent reimportation of refused products and would deter importers from seeking to import products they know or have reason to believe would pose a significant public health risk and could be ordered destroyed."

The undersigned agree with the FDA that this authority would safeguard the health of the American public through the destruction of contaminated seafood as well as the establishment of a powerful incentive for exporters to prevent the shipment of unsafe product in the first instance. To this end, we have strongly supported the *Destruction of Hazardous Imports Act*, bipartisan legislation introduced by Representative Clay Higgins (R-LA) and Representative Troy Carter (D-LA) in the House (H.R. 2715), and by Senator Rick Scott (R-FL) in the Senate (S.3213). The *Destruction of Hazardous Imports Act* would provide the agency with the authority to destroy FDA-regulated goods that pose a "significant public health concern," including seafood contaminated with banned veterinary drug residues, pesticides, poisons, or with dangerous human pathogens. Revised bill language under consideration would clarify that the FDA will require importers to destroy refused FDA-regulated products presenting a significant public health concern. Once modified, the *Destruction of Hazardous Imports Act* substantially strengthens oversight of foreign seafood sold in the U.S. market while minimizing burdens on U.S. taxpayers.

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[4] *See, e.g.* J. Spink and D. Moyer, Defining the Public Health Threat of Food Fraud, *Journal of Food Science* Vo. 76, Nr. 9, 2011 ("fraudsters may shift ports of entry by conducting strategic 'port shopping' and by shipping fraudulent product through less-monitored entry points.").

[5] U.S. Food and Drug Administration, Summary of FY 2026 Legislative Proposals https://www.fda.gov/media/187068/download?attachment.

For these reasons, we ask for your support of the *Destruction of Hazardous Imports Act* and for swift action to enact this important legislation into law. We thank you in advance for any consideration given to these comments.

Sincerely,

Alaska Longline Fishermen's Association
https://www.alfafish.org/

Apostleship of the Sea of the United States of America
https://aos-usa.org/

Chesapeake Bay Seafood Industries Association
http://www.cbsia.org/

East Coast Shellfish Growers Association
https://ecsga.org/

Gulf of America Reef Fish Shareholders' Alliance
www.shareholdersalliance.org

Hawaii Longline Association
https://www.hawaiilongline.org/

Louisiana Crawfish Processors Alliance

Louisiana Farm Bureau Crawfish Advisory Committee
https://lafarmbureau.org/

Maine Coast Fishermen's Association
https://www.mainecoastfishermen.org/

North American Marine Alliance
https://www.namanet.org/

North Carolina Fisheries Association
https://ncfish.org/

Oregon Trawl Commission
https://www.oregontrawl.org/

Port Arthur Area Shrimpers Association
https://www.facebook.com/PAShrimpers/

Southeastern Fisheries Association
https://www.sfaonline.org/

Southern Shrimp Alliance
https://shrimpalliance.com/

Texas Shrimp Association
https://www.facebook.com/TexasShrimpAssociation/

cc:

Senator Angela Alsobrooks
Senator Susan Collins
Senator Maggie Hassan
Senator Tim Kaine
Senator Andy Kim
Senator Ed Markey
Senator Ashley Moody
Senator Lisa Murkowski
Senator Christopher Murphy
Senator Patty Murray
Senator Lisa Blunt Rochester
Senator Rick Scott
Senator Tim Scott
Senator Tommy Tuberville

Representative Jake Auchincloss
Representative Cliff Bentz
Representative Gus Bilirakis
Representative Kat Cammack
Representative Buddy Carter
Representative Troy Carter
Representative Kathy Castor
Representative Neal Dunn
Representative Lizzie Fletcher
Representative Russell Fry
Representative Clay Higgins

BHG
Behavioral Health Group℠

March 20, 2026

The Honorable Diana DeGette

Ranking Member, Subcommittee on Health
Committee on Energy and Commerce
US House of Representatives
Washington, DC 20515

Dear Ranking Member DeGette,

I am writing as a healthcare provider operating an Opioid Treatment Program (OTP) serving patients in your district. I applaud the Health Subcommittee for holding a hearing on the important issue of addressing illicit substances. However, I am writing to urge the House Energy and Commerce Subcommittee on Health to carefully consider the real-world impact of H.R. 5629 and to oppose any effort to repeal the Substance Abuse and Mental Health Services Administration (SAMHSA) Final Rule modernizing 42 CFR Part 8, which took effect in April 2024.

At Behavioral Health Group, we operate six opioid treatment facilities serving over 1,900 patients in the state of Colorado, including one in Downtown Denver. Most of these patients receive methadone as part of their treatment plan. Let me begin with a point of full agreement: safety must remain the top priority in the provision of methadone and other medications for opioid use disorder (OUD). The current Final Rule does not weaken that standard. In fact, it preserves, and in many ways strengthens, the clinical safeguards necessary for safe, appropriate treatment, while allowing providers to respond more effectively to the realities we are seeing on the ground.

Responding to a More Dangerous Drug Supply

The rise of fentanyl and other high-potency synthetic opioids has fundamentally changed the clinical profile of OUD. Patients often require more individualized and, in some cases, higher induction dosing strategies to stabilize safely and reduce the risk of continued illicit opioid use.

The Final Rule provides the clinical flexibility needed to respond to this reality while maintaining appropriate medical oversight. Repealing it would push providers back toward more rigid protocols that may no longer reflect current patient needs or best practices.

Telehealth Flexibility: Expanding Safe Access, Especially in Rural Areas

Telehealth provisions, particularly the ability to conduct admissions remotely, have allowed us to safely and efficiently expand access to care.

In our program, these flexibilities have:

- Enabled timely admissions across multiple locations by leveraging qualified providers at larger or centralized programs
- Allowed for daily admissions capacity, even in smaller or rural sites that may not always have an on-site physician
- Demonstrated that a full in-person physical exam is rarely the determining factor in whether a patient should be admitted to treatment

These changes have significantly reduced delays in care, which is critical given the high risk of overdose. In the last 6 months, we performed 35 telehealth admissions in Colorado. That is 35 individuals who were able to access life-saving treatment at exactly the time they were ready and willing to get help.

Take-Home Medications: Flexibility Within a Strong Safety Framework

The Final Rule's approach to take-home methadone doses is both cautious and practical. Importantly:

- Clear limits on take-home quantities remain in place, though they are more flexible than before
- OTPs are still required to maintain robust diversion control plans
- Clinical decision-making is entrusted to credentialed providers operating within a defined regulatory framework

This approach allows us to determine when the benefits of take-home medication outweigh the risks for a given patient without removing the guardrails that ensure safety.

Just as importantly, when take-home doses are not clinically appropriate, we retain the ability to provide daily observed dosing without disrupting care or forcing unnecessary transitions. The system remains fully capable of adjusting to patient needs in either direction.

Preserving Stability and Progress

Since the rule took effect in April 2024, providers and patients have adapted to a more responsive, patient-centered model of care that maintains safety while improving access. Repealing these provisions would create unnecessary disruption, reduce access,

particularly in rural areas, and undermine the progress we have made in engaging and retaining patients in treatment.

A Data-Informed, Patient-Centered Approach

The inclusion of telehealth in the SAMHSA Final Rule reflects lessons learned during the COVID-19 public health emergency and is supported by growing evidence that telehealth can safely and effectively expand access to OUD treatment.

Rather than eliminating these tools, Congress should support ongoing evaluation and refinement to ensure they continue to serve patients effectively and responsibly.

As a provider serving individuals and families in Denver and throughout Colorado, I respectfully urge the Committee to oppose repealing or weakening the telehealth flexibilities and telehealth admission pathways established under the modernized 42 CFR Part 8 rule.

These policies are not theoretical. These policies are actively saving lives in our communities by making treatment more accessible, timely, and sustainable.

I would welcome the opportunity to discuss how telehealth has improved care for patients in your district and to share additional data from our program.

Thank you for your leadership and your commitment to addressing the opioid misuse and overdose crisis.

Sincerely,

Matt Perdue, MD
Regional Medical Director – Colorado
Behavioral Health Group
5250 Leetsdale Dr, Suite 220
Denver, CO 80246
303.629.5293
matthew.perdue@bhgrecovery.com

Congressman Morgan Griffith
House Energy & Commerce Committee
Chairman, Subcommittee on Health
2110 Rayburn HOB
Washington, DC 20515

Dear Chairman Griffith,

We write to thank you for holding a hearing and soliciting public input on HR 8000. We respectfully ask that you consider the serious unintended consequences this legislation would impose on American families, particularly adult consumers who lawfully and responsibly use 7-hydroxymitragynine (7-OH) as a harm reduction tool and a less harmful alternative to traditional opioids.

For those reasons, we urge you to oppose HR 8000 as written and instead allow Congress to craft a sensible regulatory framework that protects children while preserving access for informed adults.

Millions of Americans rely on 7-OH to reduce and often end their use of illicit opioids. Many adult consumers have turned to it in place of prescription pain pills to manage chronic pain.

Outright prohibition would not make these people disappear — it would push them back toward opioids, whether legally prescribed or obtained through the black markets that invariably form in the wake of blanket bans like the one proposed here. Congress has seen this story before, and it does not end well.

Equally troubling is the speed with which this ban is being pursued. The scientific literature on 7-OH is still developing, and several medicinal trials are actively underway. A Schedule I classification would not only terminate those trials, but it would make them illegal.

Scheduling a substance used safely and effectively by millions of adults, without adequate scientific justification, sets a troubling precedent and adds unnecessary burden to both consumers and the healthcare system.

The initial data from federal agencies supports a regulatory framework for 7-OH rather than criminalization and an outright

ban. The FDA's own data[1] show only 40 adverse health events – fewer than those associated with soap – despite more than a million Americans[2] having consumed 7-OH to the tune of more than 1 billion servings. That is not a public health emergency. That is a substance in need of proper oversight.

Independent researchers agree. Consistent with FDA's initial data, prominent researchers from Johns Hopkins, Harvard, and UCLA[3] emphasize that 7-OH should not be treated as a public health emergency, noting that existing evidence reveals no documented cases of fatal overdoses, respiratory depression, or broad-scale dependence.

No lethal oral dose has been identified in animal studies. This is a meaningful distinction from the well-documented toxicity profiles of opioids and even common over-the-counter medications like acetaminophen.

We welcome the ability to have a more substantive conversation with your staff on a strong regulatory approach to 7-OH that keeps underage Americans safe while preserving lawful access for adult consumers.

Such a framework would include a minimum purchase age of 21, age-verification at points of sale, clear labeling and packaging restrictions, regular manufacturing inspections, and meaningful advertising restrictions. These are sensible and smart policies that would avoid needless criminalization and government bureaucracy.

Congress should not rush to schedule a substance used by millions of Americans without any scientific or public health justification to support it. We respectfully urge you to take the more measured and more effective path. Thank you for your thoughtful consideration.

Sincerely,

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[1] *FDA Adverse Event Reporting System (FAERS) Public Dashboard*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (last visited Mar. 25, 2026).

[2] Marwood Group, *Marwood Report* (June 24, 2025), https://8zk4yr9arpcn-u6814.pressidiumcdn.com/wp-content/uploads/2025/07/Marwood-Report-Final-6-24-25.pdf.

[3] *Leading Researchers Reject FDA's Position, Find No Evidence of Harm from 7-OH*, Hart Supporter, https://hartsupporter.com/leading-researchers-reject-fdas-position-find-no-evidence-of-harm-from-7-oh-in-response-from-shaman-botanicals-to-fda/ (last visited Mar. 25, 2026).

Consumer Choice Center

Consumer Action for a Strong Economy (CASE)

End It For Good

Hispanic Leadership Fund

Moms For America

Taxpayers Protection Alliance

STATEMENT FOR THE RECORD

Health Subcommittee Hearing

U.S. House Committee on Energy and Commerce

March 26, 2026

Regarding Tyler's Law (H.R. 2004)

Submitted by

Juli Shamash

Founder, Drug Awareness Foundation

KEY POINTS

• Many standard hospital toxicology screens do not detect fentanyl, even though fentanyl is now involved in the majority of overdose deaths in the United States.

• Because fentanyl is a synthetic opioid, it typically requires a separate test that may not be routinely ordered.

• As a result, clinicians treating overdose patients may not know that fentanyl exposure has occurred.

• Tyler's Law (H.R. 2004) directs the Department of Health and Human Services to study fentanyl testing practices in emergency departments and develop national guidance to help close this gap in overdose care.

STATEMENT

My name is Juli Shamash, and H.R. 2004, Tyler's Law, is named for my son, Tyler. Tyler died after fentanyl exposure went undetected in the emergency department, just hours before his death. Tyler was kind, thoughtful, and brilliant. He had a big heart and was deeply loyal to his

friends and family, always going out of his way to help others. Like many young people struggling with addiction, Tyler was working hard to rebuild his life and was living in a sober living home at the time.

On October 21, 2018, Tyler died in the bathroom of that sober living home after ingesting fentanyl. He was just 19 years old.

The night before he died, Tyler was taken by ambulance to an emergency department for a suspected overdose. He told medical staff that he had accidentally taken too much Imodium for an upset stomach. As a parent of someone struggling with addiction, I understood that people battling substance use disorder sometimes hide the truth about what they have taken. Because of that, I asked the treating doctor three separate times whether Tyler had been tested for everything, including fentanyl. Each time, the doctor assured me that the hospital's toxicology screen tested for opioids and would detect fentanyl.

After Tyler died, we learned that this was not correct. The standard hospital toxicology screen does not detect fentanyl because fentanyl is a synthetic opioid that requires a separate test. Tyler was discharged back to the sober living that night. Less than 24 hours later, Tyler died after using drugs again. Had we known that fentanyl was present in Tyler's system that night, we would have sought a higher level of care for him, such as detox or residential treatment.

Unfortunately, Tyler's story is not unique. Many clinicians are unaware that fentanyl is not included in standard toxicology screens. Recently, I spoke with a friend who is an obstetrician and regularly orders toxicology screens when he suspects drug use during pregnancy. Like the emergency physician who treated Tyler, he was surprised to learn that the standard five-panel toxicology screen does not detect fentanyl and that a separate test must be ordered.

This gap in testing is particularly concerning given the scale of the fentanyl crisis. According to the Centers for Disease Control and Prevention, synthetic opioids such as fentanyl are now involved in the majority of overdose deaths in the United States. Yet many hospitals continue to rely on toxicology screens that do not detect fentanyl unless a specific test is ordered. Improved fentanyl detection in emergency departments can:

- Identify fentanyl exposure early
- Inform patients when substances are poisoned with fentanyl
- Enable timely intervention and connection to addiction treatment
- Improve public health data and response to the overdose crisis

Tyler's Law (H.R. 2004) addresses this critical gap in overdose care. The bill directs the Department of Health and Human Services to study fentanyl testing practices in hospital emergency departments and develop national guidance on whether patients presenting with overdoses should routinely be tested for fentanyl and other synthetic opioids. The study would examine current hospital practices, costs and implementation considerations, patient safety and

privacy concerns, and how improved fentanyl detection could enhance treatment decisions and overdose prevention.

Tyler's Law gives Congress an opportunity to address a clear gap in overdose care by ensuring that policymakers and clinicians understand when and how fentanyl testing should be used in emergency departments. Earlier detection can help guide appropriate care and may help prevent future overdoses.

As the Committee examines overdose care in emergency departments, an important question is whether clinicians consistently have the information they need to identify fentanyl exposure. Because fentanyl is not included in many standard toxicology screens, emergency physicians may not know when it is present unless a separate test is ordered. Understanding how hospitals currently approach fentanyl testing and whether national guidance could help close this gap could be an important step toward improving care for patients experiencing overdoses.

Tyler's Law is a practical, bipartisan step toward ensuring that clinicians have the information they need when treating patients who may have been exposed to fentanyl. Fentanyl does not discriminate. It affects families in every community and across the political spectrum.

No parent should ever learn after their child's death that a critical test was not performed.

I respectfully urge the Committee to support Tyler's Law so that other families do not experience the same preventable loss that mine has endured.

Thank you for your attention to this important issue.

Juli Shamash

Founder, Drug Awareness Foundation

LEGAL ACTION CENTER

February 14, 2023

Miriam Delphine-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use, U.S. Department of Health and Human Services
Administrator, Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Medications for the Treatment of Opioid Use Disorder - RIN 0930-AA39

Dear Assistant Secretary Delphine-Rittmon,

Thank you for the opportunity to submit comments on the proposed rule for Medications for the Treatment of Opioid Use Disorder, 42 C.F.R. Part 8. I am writing on behalf of the Legal Action Center, a law and policy organization that works to fight discrimination, build health equity, and restore opportunity for people with substance use disorders, arrest and conviction records and HIV or AIDS. The Center co-chairs the Coalition for Whole Health, a broad coalition of local, State, and national organizations in the mental health and substance use disorder prevention, treatment, rehabilitation, and recovery communities.

We commend SAMHSA for proposing revisions to the Part 8 regulations that will expand access to medications for opioid use disorder (MOUD), facilitate retention in care by reducing burdensome program participation requirements for individuals who are prescribed methadone, allow for more decentralized care delivery, and incorporate harm reduction practices into opioid treatment program (OTP) practices. We applaud SAMHSA for removing stigmatizing regulatory language with the goal of reinforcing a standard of patient-centric and dignified care that all patients deserve and to which all OTPs should be held. The proposed regulations build on important lessons from the COVID-19 pandemic related to treatment initiation and service delivery via telehealth, provision of unsupervised medication dosing early in treatment, and reduced urine drug testing requirements. Nearly 30 years after the Institute of Medicine observed that the OTP regulatory scheme should reinforce the life-saving and public safety benefits of methadone, as opposed to "put[ting] too much emphasis on protecting society *from* methadone,"[1] SAMHSA's proposed regulations strike the right balance to better ensure patient wellbeing, public health and safety, and more equitable access to MOUD.

[1] Institute of Medicine 1995. *Federal Regulation of Methadone Treatment.* Washington, DC: The National Academies Press, at 3. https://doi.org/10.17226/4899 (hereafter IOM 1995 Report).

Modernization of the Part 8 standards is essential as the country responds to the worst opioid epidemic in our history – one that has disparately harmed communities of color. As the proposed regulation recognizes, Black, LatinX, American Indian and Alaska Native people have experienced the highest rates of overdose during the pandemic, and Black men 65 years and older are seven times more likely than white men to die of overdose. While only a small fraction of individuals with OUD access medication, Black and Hispanic patients have disparately lower rates of participation in MOUD care than white individuals, and OTPs are concentrated in urban and low-income communities and counties with highly segregated Black populations.[2] For individuals living in rural communities, access to OTPs and office-based MOUD is particularly limited.[3] People incarcerated in prison and jail often are unable to access MOUD and rates of overdose death for people reentering the community from incarceration are 129 times higher than those in the general public.[4]

The following comments offer suggestions to:

- Expand the definition of harm reduction services;
- Develop patient-centric drug testing requirements and ensure results are used for therapeutic purposes;
- Clarify the use of telehealth service delivery post-treatment initiation;
- Define specific criteria for assessing patient eligibility for unsupervised medication doses and build in consumer education and protection standards related to program determinations;
- Authorize for-profit programs to provide interim treatment; and
- Clarify the scope of entities that can serve as a medication unit.

In addition, to ensure that the proposed regulations translate into improved access and better care for all individuals regardless of race, ethnicity, age, sexual orientation, gender identity, or geographical location, we urge SAMHSA to:

- Adopt data reporting requirements, including patient demographic data to track OTP implementation of unsupervised medication dosing rules, use of drug testing, and telehealth service delivery and then publicly share that data to better ensure equitable and non-discriminatory practices;

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[2] National Academies of Sciences, Engineering, and Medicine, 2022. *Methadone Treatment for Opioid Use Disorder: Improving Access Through Regulatory and Legal Change: Proceedings of a Workshop,* at 18. (hereafter NASEM 2022 Report).

[3] Tanvi Rao, et al., *Exploring Urban-Rural Disparities in Accessing Treatment for Opioid Use Disorder* (Nov. 19, 2021), https://www.air.org/resource/equity-focus/exploring-urban-rural-disparities-accessing-treatment-opioid-use-disorder; Paul J. Joudrey, et al., *Drive Time to Opioid Treatment Programs in Urban and Rural Counties in 5 US States*, 322 JAMA 1310-11 (Oct. 1, 2019), https://jamanetwork.com/journals/jama/fullarticle/2752051.

[4] Ingrid A. Binswanger, et al., *Release from Prison – A Hight Risk of Death for Former Inmates,* 356 NEJM 157, 161 (2007) https://perma.cc/L49X-7MZ7.

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- Develop, in collaboration with OTP patients, a patient survey of treatment experience that the SOTA would disseminate annually and then issue a report of findings and recommendations for programmatic improvements; and
- Adopt funding and other incentives to ensure that State and local government do not undermine Part 8 programmatic reforms by retaining and adopting more restrictive standards.

Finally, we view the proposed regulations as an important and long-overdue step to better integrate MOUD care delivered by OTPs into a more mainstream medical care delivery model. With the elimination of the x-waiver requirement and imposition of more universal SUD and OUD education requirements, we expect access to MOUD will improve over time. Building on this foundation, **we urge SAMHSA and NIDA to conduct research and pilot care delivery models that better integrate MOUD care into medical care delivery across different patient populations, including office-based prescribing of methadone for individuals who meet clinical criteria for stability**.[5]

I. Patient Admission Criteria and Treatment Initiation

We support the proposed admission criteria that are based on standardized diagnostic criteria for MOUD eligibility, require a patient's informed consent and, for individuals under 18 years of age (or younger as permitted under state law), consent by a responsible adult. We also support the removal of two requirements that are a barrier to MOUD: demonstration of a one-year history of OUD and, for individuals under age 18, documentation of two unsuccessful treatment attempts in a non-MOUD program within the previous 12-month period.

We fully support the proposed clarification of the treatment initiation process, including the two-part medical examination framework that will permit treatment initiation following the screening examination that confirms satisfaction of the eligibility criteria and no MOUD contraindication. Sec. 8.12(f)(2). This framework will allow for more rapid initiation into treatment and take advantage of telehealth services to screen individuals and initiate treatment.

We also support the expansion of the non-OTP practitioners who may conduct the medical screening and full examination. Sec. 8.12(f)(2)(B)(ii). By authorizing any appropriately licensed practitioner to conduct the examination (i.e. physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife, consistent with state law), the rule would greatly expand the opportunity for individuals to be referred to OTPs for immediate treatment engagement. This standard would allow far more licensed practitioners in medical practices, emergency departments, hospital bridge clinics and inpatient services, carceral or other settings to conduct the required medical examination, reducing the burden on OTP medical personnel and avoiding delays and duplicative examinations that can deter patients from entering MOUD care.

We also appreciate the description of the records that must be provided to the OTP practitioner for verification (e.g. written results and narrative of the examination and available lab testing results). We have learned in our work with OTP practitioners that questions have been raised about the sufficiency of the medical examination information prepared by medical staff in some carceral settings. **We read the OTP verification standard of "true and accurate" to be based**

[5] *See* NASEM 2022 Report at 75-77.

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on a review of the medical records alone and not require a second medical examination by OTP practitioners. **We urge SAMHSA to clarify whether any specific documentation is required to satisfy the proposed "true and accurate" standard to avoid confusion and administrative burden.**

Finally, as the proposed rule sets out, practitioners have used telehealth throughout the pandemic to safely initiate treatment with buprenorphine yet have not been permitted to initiate care with methadone via telehealth. **We fully support the adoption of the proposed standard for both initiation of buprenorphine and methadone,** permitting both audio-visual and audio-only telehealth for patients admitted to treatment with buprenorphine and audio-visual platforms for methadone, except to extent a patient is in the presence of a licensed practitioner who is registered to prescribe and dispense controlled substances. Sec. 8.12(f)(2)(v)(A) and (B).

Beyond treatment initiation, we urge SAMHSA to clarify that telehealth, including audio-only telehealth, is appropriate for continuous medication treatment including with methadone. While the proposed definition of "telehealth or telemedicine" clearly includes counseling, education and health information services, **an explicit standard will avoid confusion, particularly for reimbursement purposes.** As states begin to adopt telehealth standards post-public health emergency, it is essential that federal law authorize the continuation of telehealth care for OUD, which has allowed for far greater flexibility, reduced barriers to continuous treatment and greater patient satisfaction. Authorizing audio-only telehealth post-treatment initiation with methadone is essential to ensure equity for patients who cannot afford audio-visual technology, including Black, LatinX and Native-American patients, reside in locations with limited broad-band capacity or do not have accessible technology appropriate for their disability.

II. Counseling and Psychoeducational Services

We fully support the proposed counseling standards that are more singularly focused on each patient's clinical needs and their active involvement to identify the training, education and employment services that are to be provided. We also support the specific inclusion of harm reduction education and recovery-oriented counseling. Sec. 8.12(f)(5). **We note that the definition of "harm reduction" (Sec. 8.2), while expansive, does not specifically reference "identification of syringe services programs" or "distribution of fentanyl test strips."** We urge SAHMSA to add these additional components of harm reduction practices to the definition.

We commend SAMHSA on clearly articulating that an OTP may not deny MOUD to a patient who refuses counseling. Sec. 8.12(f)(5). The support for this evidence-based standard is set out in the 2019 National Academy of Science, Engineering and Medicine report, MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, which concludes that the lack of "behavioral interventions is not sufficient justification to withhold medication to treat OUD."[6] We agree that an OTP's counseling and supportive services offer significant benefits, particularly for patients with limited support systems, yet counseling mandates should not be a

[6] National Academy of Science, Engineering and Medicine, MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES (Alan I. Leshner & Michelle Mancher, eds., 2019) at 3, Box S-2. Setting out research that concludes that, with the exception of medication-adjunct contingency management intervention, "behavioral therapies themselves do not generally improve retention or reduce opioid use in individuals with OUD receiving methadone treatment." *Id*. at 48.

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barrier to MOUD.[7] These same principles support the proposed expansion of interim treatment.

III. Drug Testing Services

We recognize that drug testing serves a function in SUD treatment, as one measure of an individual's treatment progress. We are concerned, however, that the proposed rule retains a blanket requirement of no less than eight random drug tests per year (with exceptions at an individual patient level), which is at odds with the proposed regulatory standard for a testing frequency that is based on both generally accepted standards of clinical practice and tailored to the patient's response and stability in treatment. Sec. 8.12(f)(6). The 8-test standard does not take into consideration the lessons of reduced drug testing during COVID and retains a tool with "notable drawbacks" for patient-centric care.[8] Patients with long-standing participation in OTPs, those who are stable, and individuals who are doing well in their education, family and/or employment, but may not have abstinence as their goal, should not be subject to surveillance as a "reflexive" response.[9] Such practices are not required of individuals who are prescribed Schedule II medications for other medical conditions.

More fundamentally, the proposed rule does not offer guidance on the implications for on-going program participation for patients who have one or more positive test results. **The proposed rule has appropriately removed consideration of positive drug test results in determining a patient's unsupervised medication dosing schedule, (*see* Sec. 8.12(h)(4)(i)), but it does not limit OTP use of test results to purely therapeutic decision-making.** We know that some OTPs discharge patients based on positive test results and impose other program participation requirements that are inconsistent with the goal of retaining patients in care. Such actions also have direct and adverse consequences for individuals who are in treatment as a result of a criminal charge or other state supervision by the criminal legal or child protection service systems. Indeed, the criminal legal system often requires the OTP to "participate" in its surveillance via drug test reporting and offers patients little choice but to consent to the disclosure of drug test results as a condition of treatment participation. This cascade of consequences can adversely affect Black patients who are involved in the criminal legal and

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[7] In an evaluation of Missouri's Medication First treatment approach for OUD, Winograd and colleagues noted:

> We underscore that agencies should continue to offer, promote, and even assertively encourage psychosocial services as appropriate for individual clients – just not make continued MOUD contingent upon participation in those services. We also stress how sessions with nurses, physicians, and other medical professionals can themselves be therapeutic and are valuable for more than just the medication provided, as pharmacotherapy facilitates rather than obstructs mutual support, engagement, and psychosocial rehabilitation.

Rachel P. Winograd, et al, *Implementation and Evaluation of Missouri's Medication First Treatment Approach for Opioid Use Disorder in Publicly Funded Substance Use Treatment Programs*, 108 J. SUBSTANCE ABUSE TREATMENT, 55, 56 (2020).

[8] Utsha G. Khan & Shoshana V. Aronowitz, *Considering the Harms of Our Habits: The Reflexive Urine Drug Screen in Opioid Use Disorder Treatment*, 123 J. SUBSTANCE ABUSE TREATMENT 108258 (2021) (noting the negative impact that drug testing has on the clinician-patient relationship by sending a message of mistrust, reinforcing the hierarchical nature of the relationship, and risking trauma with observed drug testing).

[9] "[A]s we have learned [during COVID], reflexively and routinely mandating [urine drug testing] for stable patients is not necessary to continue their engagement in care." *Id.*

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child protective services systems at racially disparate rates.

We urge SAMHSA to develop drug testing standards that:

- Reduce the number of random and scheduled drug tests based on objective indicators of a patient's progress in treatment and treatment goals;[10]
- Allow for drug testing only when the result is needed to inform a change in the treatment
- regimen.[11]
- Ensure drug test standards give primacy to the dignity and health needs of the patient.
- Require OTPs to use test results exclusively for therapeutic treatment decisions so that the program is not perceived to be an arm of state surveillance and can apply harm reduction standards that do not require abstinence and are consistent with individual patient goals.

IV. Unsupervised Medication Dose Standards and Schedule

We commend SAMHSA for significantly improving the criteria a program may consider when evaluating a patient's eligibility for unsupervised medication doses and establishing a more rapid schedule for receiving unsupervised medication doses. In-person dosing requirements have long been one of the most onerous aspects of methadone treatment, and daily attendance requirements, which create a constant patient flow, have contributed to community opposition to the siting of OTPs. We support the adoption of criteria that are based on the lessons and research gleaned from the COVID experience in which patients received a larger number of take-home doses on a more rapid schedule and did not experience higher overdose rates or worse treatment outcomes or result in greater diversion of medication. **We urge SAMHSA to adopt several additional requirements to help guide clinical decision-making and ensure optimal and consistent application of the proposed standards.**

We fully support SAMHSA's decision to remove specific criteria that date back to the 1980 regulations and appear to be more concerned about medication diversion[12] than patient and public health. These include the absence of recent drug use, regularity of clinic attendance, absence of recent criminal activity, stability of the patient's home environment and social relationships, and length of time in treatment. The updated proposed criteria are more appropriately tied to a patient's progress in treatment, with the goal of patient retention, rather than external factors that penalize individuals based on their socio-economic status and law enforcement practices that target communities of color.

We note that the criteria do not explicitly require OTPs to evaluate alternatives to in-person supervision of medication administration, which could allow for remote supervision of patients who may not be otherwise eligible under the proposed criteria. For example, a study of technology-assisted methadone take-home dosing, using an electronic pillbox to provide

[10] As several clinicians noted, "Preserving the therapeutic nature of the [clinician-patient] relationship must be prioritized over blind adherence to outdated and potentially harmful clinical habits, such as reflexive [urine drug testing]. *Id.*

[11] *Id*.

[12] IOM 1995 Report at 93-94.

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real-time monitoring, found that remote management of methadone take-home doses is a way for OTPs to dispense under supervision without the patient being in person, even for patients who would not be otherwise eligible for take-home medication.[13] Remote supervised dosing with technological assistance may offer a way to increase program capacity and increase patient satisfaction, thereby expanding access and retention.[14] **We urge SAMHSA to include a consideration of remote monitoring in the criteria for unsupervised medication dosing, provided such technology complies with Part 2 and HIPAA privacy standards.**

A. Additional Implementation Guidance

We are concerned that several terms are not defined and will allow program personnel to exercise significant discretion that could lead to inconsistent decisions within and across programs and result in discriminatory practices. We urge SAMHSA to issue guidance on:

- how programs should determine the existence of an "active substance use disorder" that would increase the patient's risk of harm; and
- the types and severity of "behavioral problems" that may affect a patient's eligibility for unsupervised medication doses.

We also note that a for-profit OTP's financial interests may be linked to its determination of unsupervised medication doses. To the extent reimbursement is based on a patient's physical presence at the program site, the OTP's financial interests may conflict with a patient's eligibility for extended take-home medication. While we do not read the proposed criteria to permit consideration of reimbursement requirements, **SAMHSA may need to address payer reimbursement standards that do not align with an expanded take-home medication schedule and work with payers to decouple billing standards with on-site program attendance.**

B. Consumer Education and Protections

With a fundamentally new clinical orientation, **we urge SAMHSA to adopt several consumer protections to ensure that (1) patients gain the benefit of greater take-home dose flexibility;[15] (2) rules are applied equitably without discrimination based on race, ethnicity, age and other factors; and (3) program practices are appropriately monitored and, as necessary, corrected to achieve the regulatory goals**. We offer the following suggestions:

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[13] Kelley E. Dunn, Robert K. Brooner & Kenneth B. Stoller, *Technology-Assisted Methadone Take-Home Dosing for Dispensing Methadone to Persons with Opioid Use Disorder During the COVID-19 Pandemic*, J. SUBSTANCE ABUSE TREATMENT (2021).

[14] Michael Kidorf, et al., *Use of an Electronic Pillbox to Increase Number of Methadone Take-home Doses During the COVID-19 Pandemic*, 126 J. SUBSTANCE ABUSE TREATMENT (July 2021).

[15] During the pandemic, a minority of patients with OUD received extended take-home doses. NASEM 2022 Report at 30 and 38; Mary C. Figgatt, et al., *Take-home Dosing Experiences Among Persons Receiving Methadone Maintenance Treatment During COVID-19*, JR. SUBST. ABUSE TREATMENT 123 (2021) 108276 (clinic-level percentage of participants receiving a take-home medication for a week or longer during COVID varied from 11% to 56%).

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- All licensed OTPs should be required to inform program participants of the new unsupervised medication dose criteria and schedule through general education programs following patient admission and at regular intervals.
- OTPs should be required to discuss the new criteria with each patient individually as part of treatment planning and articulate how the medical director or medical practitioner evaluates their eligibility under the criteria. The program's decision and rationale should be included in the patient's record, and the patient should be permitted to file a grievance to dispute the decision without suffering adverse consequences.
- As part of the OTP's record keeping obligations, it should be required to demonstrate that it is applying the revised criteria and collect data that track its decisions on quantity and frequency of unsupervised medication and grievances/appeals of such decisions, including data on patient demographics (e.g. age, race, ethnicity, gender, gender identity, time in treatment).

The State Opioid Treatment Authority (SOTA) should be responsible for reviewing program data and patient files to evaluate implementation of the new standards and identify opportunities for education and improvement. Patient grievances should be included in the program information that the SOTA evaluates.

V. Interim Treatment

Studies show that providing interim treatment when an OTP reaches patient capacity, as opposed to a spot on a waitlist, reduces drug-related risks and costs for the patient and public: delayed access to methadone puts patients at risk for continued drug use, infectious disease, overdose, and reduced likelihood of eventual treatment.[16] **We support the proposed standards for interim treatment which address some, but not all, regulatory standards that have limited uptake of interim treatment.**

Specifically, we support the proposed revisions that extend the timeframe for participation in interim treatment from 120 days to 180 days and allow for unsupervised medication doses as opposed to daily program attendance. Sec. 8.12(j). **Just as additional guidance on the take-home dosage criteria will improve OTP implementation for patients in comprehensive treatment, guidance on these standards for interim treatment will be essential.** With far more limited contact with program staff, it is unclear how a medical director or practitioner will make the necessary determinations for take-home medications. Failure to allow for more flexible medication dosage could result in limited utilization of this important treatment access opportunity.

The proposed regulations continue to restrict interim treatment availability to non-profit or public OTPs and bar for-profit OTPs from providing interim treatment. Sec. 8.11(f). This restriction limits access to interim treatment, as more than half of the OTPs operate as for-profit entities and some states do not have non-profit programs.[17] **We urge SAMHSA to authorize for-profit**

[16] Dennis McCarty, et al., *Interim Methadone – Effective but Underutilized: A Scoping Review*, 225 DRUG & ALCOHOL DEPENDENCE (2021).
[17] *Id.*

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OTPs to offer interim services under the proposed standards that include documentation that the SOTA does not object to providing interim treatment in the State and that the OTP meets other regulatory requirements. Sec. 8.11(f).

VI. Medication Units

We fully support the proposed expansion of medication units to deliver the full complement of services that are provided at the OTP. Treatment with methadone, as envisioned by Dr. Vincent Dole, contemplated a "hub and spoke" model to expand the availability of medication outside the OTP.[18] The proposed standard adopts a sensible approach that would allow for off-site settings – whether brick-and-mortar or mobile – to deliver all MOUD services that are available at the OTP, allowing for more convenient and less centralized care delivery. Sec. 8.2 and 8.11(h). While the rule allows for continuous medication treatment in long-term care facilities for patients requiring non-OUD medical care (Sec. 8.11(h)(3)), adoption of medication units in skilled nursing and long-term care facilities will allow for more patient-centric OUD care for such patients.

We are particularly supportive of the identification of "community pharmacists" as having a role in the operation of a medication unit. *See* Sec. 8.2. **We seek clarification from SAMHSA as to its intent to allow "community pharmacies" to serve as a medication unit, as opposed to having a non-OTP pharmacist provide services at a separate entity "that is established as part of, but geographically separate from an OTP…."** Sec. 8.2. Based on studies in the United States and abroad, **we urge SAMHSA to explicitly permit "community pharmacies" to serve as a medication unit that dispenses and/or administers methadone based on the OTP's order.** A 2021 study out of Raleigh, North Carolina, in which an OTP provider wrote prescriptions to be dispensed by pharmacists,[19] found "indicators of medication adherence and intervention fidelity were successful," with no evidence of diversion and high participant satisfaction.[20] Two additional U.S. studies that examined the feasibility of office-based prescribing and pharmacy dispensing of methadone also confirm the feasibility and success of the model for patient who have participated successfully in OTP care.[21] Canada,[22] Ireland,[23]

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[18] Vincent P. Dole, *Methadone Maintenance Treatment for 25,000 Heroin Addicts*, 215 JAMA 1131, 1132 (1971).

[19] Li-Tzy Wu, et al. *Opioid Treatment Program and Community Pharmacy Collaboration for Methadone Maintenance Treatment: Results for a Feasibility Clinical Trial*, ADDICTION RESEARCH REPORT (2021), doi:10.1111/add.15641. "While pharmacy administration/dispensing of methadone could have been accomplished under a physician order as part of an OTP medication unit, the purpose of this study was a proof of concept to permit the prescribing of methadone under a research permit, which otherwise would not have been permitted under US regulations." *Id*. at 2.

[20] *Id*. at 11.

[21] Drucker, Ernest, et al., *The Lancaster Office Based Opiate Treatment Program: A Case Study and Prototype for Community Physicians and Pharmacists Providing Methadone Maintenance Treatment in the United States*, 6 ADDICTIVE DISORDERS & THEIR TREATMENT 121 (Sept. 2007); Ellen Tuchman et al., *Safety, Efficacy, and Feasibility of Office-based Prescribing and Community Pharmacy Dispensing of Methadone: Results of a Pilot Study in New Mexico*, 5 ADDICTIVE DISORDERS & THEIR TREATMENT 43 (2006). *See also*, 20222 NASEM Report at 75-76 (summarizing research on office-based methadone treatment).

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Britain[24] and Australia[25] implement care models that include pharmacy dispensing and/or administration of methadone. **Allowing community pharmacies to serve as a medication unit is an important first step to test and authorize office-based prescribing of methadone, particularly for patients who have met their treatment goals in OTP settings and do not require interaction with a structured treatment setting.**

VII. State and Local Restrictions and Standards for Treatment of MOUD in OTPs

The regulatory standard that permits state and local governments to "regulate the use of MOUD in the treatment of OUD" (sec. 8.11(e)) allows any state or locality to limit access to MOUD by imposing standards that SAMHSA has now rejected as inconsistent with evidence-based, patient centric care. Examples of state standards[26] that would be inconsistent with the proposed Part 8 standards, as proposed, include: restrictions on opening new OTPs; authorization of administrative discharge; prohibitions on take-home medications and more stringent criteria for assessing eligibility for unsupervised medication doses; counseling mandates and requirements linking counseling with unsupervised medication doses; and urine testing requirements in excess of eight tests per year.[27] **Without significant engagement with State and local officials and funding incentives, we are concerned that many jurisdictions will undermine important reforms related to initiation of treatment via telehealth, delinking MOUD and counseling requirements, more flexible and expanded unsupervised medication dosing, increased access to interim treatment, and care delivery in medication units, among other practices**.

As with other FDA-approved medications – particularly one that has been so heavily regulated and so thoroughly studied – federal officials must take affirmative steps to incentivize States across the nation to adhere to the updated Part 8 standards and ensure that access to MOUD is not limited by a lack of awareness of federal standards or stigmatizing attitudes and non-therapeutic motivations of state policymakers. We recommend the following steps as a starting point to establishing a uniform national standard based on federal standards for OTP regulation:

- SAMHSA, in collaboration with the SOTA, should assess state and local OTP requirements and identify those that are more restrictive than federal Part 8 standards;

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[22] Paul J. Joudrey, et al., *Methadone Access for Opioid Use Disorder During the COVID-19 Pandemic Within the United States and Canada*, 4 JAMA NETWORK OPEN (July 23, 2021); *see* Graham Gauthier et al., *Improved Treatment Retention for Patients Receiving Methadone Dosing Within the Clinic Providing Physician and Other Health Services (onsite) Versus Dosing at a Community (offsite) Pharmacy*, 191 J. DRUG & ALCOHOL DEPENDENCE 1 (2018) (moderately better retention for patients who received medication at a specialty clinic than a pharmacy where patients at pharmacy received a low peak dose of 65 mg of methadone).

[23] S.L. Calcaterra, *Methadone Matters: What the United States Can Learn from the Global Effort to Treat Opioid Addiction*, J. GEN INTERN. MED (2019).

[24] Lisa Luger et al., *Involvement of Community Pharmacists in the Care of Drug Misusers: Pharmacy-Based Supervision of Methadone Consumption*, 11 INTL. J. DRUG POLICY 227, 230 (2000).

[25] NASEM 2022 Report at 77-78.

[26] NASEM 2022 Report at 41-43; Pew Charitable Trusts, Overview of Opioid Treatment Program Regulations by State (Sept. 19, 2022), https://www.pewtrusts.org/-/media/assets/2022/09/overview-of-opioid-treatment-program-regulations-by-state.pdf .

[27] NASEM 2022 Report at 41-43.

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- SAMHSA should require the SOTA to provide an evidence-base and needs justification for any standard that is more restrictive than Part 8 standards;
- SAMHSA should adjust the State's federal Substance Abuse Prevention and Treatment Block Grant allocation to the extent the SOTA cannot demonstrate the need for a more restrictive requirement;
- CMS should establish Medicaid reimbursement models that incentivize the removal of OTP requirements that do not align with Part 8.

We urge SAMHSA to incorporate the State review requirements in the Part 8 SOTA reporting standards and adopt funding guidelines to the extent States fail to align their standards with federal Part 8 requirements.

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Thank you for considering our views and we look forward to working with SAMHSA as it adopts patient-centric and evidence-based OTP standards.

Sincerely,

Ellen M. Weber. J.D.
Sr. Vice President for Health Initiatives
eweber@lac.org

Memorandum

TO: Health Subcommittee, House Energy and Commerce Committee

FROM: Haiden Huskamp, Harvard Medical School

DATE: March 26, 2026

RE: Observations Relevant to Telehealth Provisions of HR5629

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1. Beginning with the start of the COVID-19 pandemic, a notable share (approximately 15%) of initiations of medications that treat opioid use disorder have occurred via telemedicine, facilitated by flexibilities introduced during the Public Health Emergency in telehealth prescribing of controlled substances including buprenorphine and methadone (evidence-based treatments for opioid use disorder). Telemedicine reduces key barriers to treatment for some patients, and patients report advantages over in-person care.

   References:

   a. Barsky et al, "Use of Telemedicine for Buprenorphine Inductions in Patients with Commercial Insurance or Medicare Advantage," JAMA Network Open, January 4, 2022.

   b. Patel et al., "Patient and Clinician Characteristics Associated with Use of Telemedicine for Buprenorphine Induction among Medicare Beneficiaries," Journal of General Internal Medicine, November 2022.

   c. Sousa et al., "Perspectives of Patients Receiving Telemedicine Services for Opioid Use Disorder Treatment: A Qualitative Analysis of User Experiences," Journal of Addiction Medicine, Nov-Dec 2022.

2. Initiation of medications for opioid use disorder via telemedicine has generally been associated with better retention in care.

   References:

   a. Krawczyk et al, "Pandemic Telehealth Flexibilities for Buprenorphine Treatment: A Synthesis of Evidence and Policy Implications for Expanding Opioid Use Disorder Care in the United States," Health Affairs Scholar, June 20, 2023.

   b. Jones et al., "Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose among Medicare Beneficiaries Before and During the COVID-19 Pandemic," JAMA Psychiatry, October 2022.

3. Clinical outcomes were similar among patients with opioid use disorder who were treated by clinicians with high vs. low telemedicine use during the pandemic, suggesting that telemedicine is a comparable alternative to in-person treatment.

   Reference:

   a. Hailu et al., "Telemedicine Use and Quality of Opioid Use Disorder Treatment in the U.S. during the COVID-19 Pandemic," JAMA Network Open, January 2023.

The Honorable Lindsey Graham
U.S. Senate
211 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Jeff Merkley
U.S. Senate
531 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Jodey Arrington
U.S. House of Representatives
204 Cannon House Office Building
Washington, D.C. 20515

The Honorable Brendan Boyle
U.S. House of Representatives
507 Cannon House Office Building
Washington, D.C. 20515

January 29, 2025

Re: Protect Medicaid for People with Mental Health Conditions and Substance Use Disorders

Dear Chairman Graham, Chairman Arrington, Ranking Member Merkley, and Ranking Member Boyle:

The Mental Health Liaison Group (MHLG), a coalition of national organizations representing people with mental health conditions and substance use disorders, family members, mental health and addiction providers, advocates and other stakeholders, is committed to strengthening Americans' access to mental health and substance use disorder care. We are writing to urge Congress to protect Medicaid, including in any reconciliation efforts. Cutting Medicaid funding or benefits, as well as imposing burdensome work requirements, would disproportionately harm people with mental health (MH) conditions and substance use disorders (SUD), who make up approximately 40% of nonelderly adults on Medicaid. In the midst of our nation's ongoing mental health crisis, including its devastating impact on youth, and our ongoing overdose epidemic, we cannot reduce access to community- and school-based life-saving services.

Our organizations are deeply concerned by policy proposals under consideration that would change Medicaid's financing structure, shift costs to the states, reduce eligibility or benefits, or impose additional barriers to coverage and enrollment. Any of these policy changes or cuts would take away quality, affordable MH/SUD care from approximately 80 million Americans who rely on Medicaid, including low-income children, pregnant women, people with disabilities, and seniors. However, the need for MH/SUD services would not go away. Many people would be forced to forgo community-based and routine MH/SUD care, such as medications for opioid use disorder (MOUD), therapy, and prescription MH medications. This would lead to people's conditions worsening until they require more costly and more intensive treatment at a point of crisis. Moreover, limiting access to Medicaid threatens to undermine gains in reducing overdose mortality rates, and could lead to increasing rates of incarceration and hospitalization.

Medicaid is the single largest payer of MH and SUD services, and we fear the devastating consequences to our nation if the federal Medicaid program were to be weakened. All people, regardless of their economic circumstances, deserve access to evidence-based MH and SUD care, and we all pay a high cost when that care is unattainable. We strongly urge you to reject any cuts to the Medicaid program. If you have any questions or would like to discuss this issue, please do not hesitate to contact Hannah Wesolowski, Chief Advocacy Officer at the National Alliance on Mental Illness (hwesolowski@nami.org), or Deborah Steinberg, Senior Health Policy Attorney at the Legal Action Center (dsteinberg@lac.org).

Sincerely,

National Alliance on Mental Illness (NAMI)
Legal Action Center
American Academy of Nursing
American Association for Marriage and Family Therapy
American Association for Psychoanalysis in Clinical Social Work
American Association of Child and Adolescent Psychiatry
American Association of Psychiatric Pharmacists
American Association on Health and Disability
American Foundation for Suicide Prevention
American Psychiatric Association
American Psychiatric Nurses Association
American Psychological Association Services
American Society of Addiction Medicine
Anxiety and Depression Association of America
Association for Behavioral Health and Wellness
Bazelon Center for Mental Health Law
Children and Adults with Attention-Deficit/Hyperactivity Disorder
Clinical Social Work Association
Crisis Text Line
Depression and Bipolar Support Alliance
Epilepsy Foundation of America
Global Alliance for Behavioral Health and Social Justice
Huntington's Disease Society of America
Inseparable
International OCD Foundation
International Society of Psychiatric-Mental Health Nurses
Maternal Mental Health Leadership Alliance
Mental Health America
NAADAC, the Association for Addiction Professionals
National Association for Rural Mental Health (NARMH)
National Association of County Behavioral Health and Developmental Disability Directors (NACBHDD)
National Association of Pediatric Nurse Practitioners
National Association of School Psychologists
National Association of Social Workers
National Association of State Mental Health Program Directors
National Council for Mental Wellbeing
National Federation of Families
National Health Law Program
National League for Nursing
National Register of Health Service Psychologists
National Women's Shelter Network, Inc.
Network of Jewish Human Service Agencies
Postpartum Support International
Psychotherapy Action Network
School Social Work Association of America
SMART Recovery
The Kennedy Forum

The National Alliance to Advance Adolescent Health/Got Transition
UnidosUS
Vibrant Emotional Health
Western Youth Services
Youth Villages

Cc: House and Senate Leadership; Chairs and Ranking Members of E&C and Finance

SAFER FOUNDATION

A ROAD TO A BETTER FUTURE

April 30th, 2025

The Honorable Brett Guthrie, Chairman
The Honorable John Joyce, Vice Chairman
U.S. House of Representatives Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: Medicaid Cuts

Dear Chair Guthrie, Ranking Member Dr. Joyce, and members of the House Energy and Commerce Committee,

On behalf of Safer Foundation, I write to express our strong support for the continued protection of Medicaid and to highlight its essential role in supporting successful reentry for individuals involved in the criminal justice system.

Safer Foundation is a nonprofit organization dedicated to reducing recidivism by helping people with criminal records reintegrate into society and lead productive lives. Through comprehensive support services—including job readiness training, employment placement, long-term career development, and policy advocacy—we empower our clients to become employed, self-sufficient, and law-abiding members of their communities.

Medicaid is critical to achieving this mission. Approximately two-thirds of the individuals we serve live with chronic health conditions such as diabetes, heart disease, asthma, HIV, or cancer. Additionally, around 70% struggle with substance use disorders, and 15–30% experience serious mental illness.[i,ii,iii,iv,v,vi] Individuals with these conditions have higher rates of re-arrest and re-incarceration than those without.[v,vi,vii,viii,ix,x] Before Medicaid expansion, many of these individuals only accessed care during crises—through emergency rooms or incarceration.[x]

Since the launch of CountyCare in Cook County in 2013 and the statewide expansion of Medicaid in Illinois in 2015, Medicaid has provided a reliable source of treatment for individuals returning to the community after incarceration. Over the past decade, the criminal justice and treatment systems have come to depend on Medicaid as a lifeline for individuals with behavioral health needs who encounter law enforcement, the courts, or reentry services.

Any reduction in Medicaid funding or coverage would disproportionately impact this expansion population—particularly access to mental health and substance use treatment—and would likely lead to increased costs for the criminal justice system. These services are not only vital for health but are also foundational for successful reintegration and public safety.

In 2024, 64% of the individuals who sought reentry support from Safer Foundation were referred to primary care, mental health, or substance use treatment to address critical unmet needs following release from incarceration. These interventions were key to

SAFER FOUNDATION
A ROAD TO A BETTER FUTURE

stabilizing their lives and enabling employment.

For example, one client from southern Illinois, a skilled welder, initially struggled to regain employment due to untreated substance use issues. After failing a drug test for a promising job, he entered residential treatment with our partner, Healthcare Alternative Systems, and then transitioned to recovery housing provided by the Salvation Army. With the stability that came from treatment and housing, he not only returned to welding but eventually chose to give back by becoming a recovery support worker.

Another client, after months of joblessness, engaged with our Supportive Reentry Network Collaborative and Working-4-Peace programs. With the help of Medicaid, he accessed mental health services and completed life skills training. With support from his job developer, he quickly secured employment and began rebuilding his life.

These stories are just two among thousands that underscore the importance of Medicaid for reentry success. We respectfully urge you to oppose any policy changes that would undermine access to care, such as Medicaid block grants, per capita caps, or restrictions that lead to the loss of coverage or reduced benefits for mental health and substance use treatment.

Thank you for your attention to this critical issue. We appreciate your leadership and continued efforts to protect Medicaid and the individuals who rely on it—not only for medical care but for the stability needed to live productive, law-abiding lives. We stand ready to work with Congress to implement reforms to Medicaid that reduce costs, eliminate overly burdensome regulations, improve patient outcomes, and ensure access to care.

If we can be of any assistance to you or your staff, please do not hesitate to contact me at victor.dickson@saferfoundation.org.

Sincerely,

Victor Dickson
President & CEO

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NEWS, PUBLIC VIEW

NASADAD COMMENTS ON NPRM 42 CFR PART 8

| FEBRUARY 21, 2023 | LACY ADAMS

On December 13, 2022, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Notice of Proposed Rule Making (NPRM) to revise the regulations governing the accreditation and operation of opioid treatment programs (OTPs), clinics that are specially authorized to use methadone as a treatment for opioid use disorder (OUD). These are the most significant revisions to these regulations since 2016, and reflect experience gained from waivers and exceptions granted during the Public Health Emergency, as well as a need to expand access to medication for opioid use disorders (MOUD) due to the ongoing rising epidemic of opioid overdose deaths. The proposed regulations underscore support for the provision of comprehensive individualized treatment services for individuals receiving treatment in OTPs.

To understand the potential impact of the NPRM, NASADAD worked with State Directors and the Opioid Treatment Network (OTN), a NASADAD component group of State Opioid Treatment Authorities (SOTAs). NASADAD staff hosted meetings with the OTN Executive Committee and the Board of Directors Policy Committee to develop a response to the proposed rule on behalf of the Association. The response was submitted on February 14, 2023.

Below are highlights of the proposed regulations and NASADAD's corresponding comments to the rule:

- **NPRM proposal regarding take-home medications.** Under the Public Health Emergency, SAMHSA issued guidance allowing states to permit considerable flexibility to OTPs in providing take-home medication to patients to reduce patient and staff exposure to COVID-19. These flexibilities allow less stable patients to take home up to 14 days of medication and more stable patients to take home up to 28 days of medication. The *proposed* regulations would allow up to seven days of take-home medication during the first 14 days of treatment, up to 14 days of take-home medication after the 15th day of treatment, and after 31 days of treatment, the patient could be allowed to take-home medication for 28 days.

NASADAD comments. NASADAD noted that the proposed schedule for take home medications is more liberal than the schedule permitted during the Public Health Emergency (PHE), and while the PHE flexibilities were evaluated regarding safety and efficacy, the proposed schedule has not been evaluated. NASADAD recommended, therefore, that each patient be evaluated for their ability to safely manage take home medications and that this evaluation be documented in the patient's clinical record.

- **NPRM proposal regarding admission restrictions.** The proposed regulations would remove both the requirement that a person be addicted at least one year before admission, and the prohibition against treating individuals under the age of 18 without two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a twelve-month period. The proposed regulations would replace these restrictions with requirements that are focused on medical assessments, and in the case of a person younger than 18 years of age, the proposed rule would require approval by a parent, guardian, or relevant state authority unless state law specifies that their approval is not needed.

NASADAD Comments. NASADAD strongly supported these changes, as they focus on specific needs of individual patients during a time of unprecedented risk of addiction or overdose.

- **NPRM proposal regarding initiation of medication, screening and assessment.** Under the proposed regulations, patients could begin utilizing medication for opioid use disorder (MOUD) after a screening (before the assessment is completed), and both the screening and the assessment could be provided by a non-OTP practitioner, provided that the OTP practitioner verified the screening and assessment. The proposed regulations describe the elements that must be included in a screening or assessment, and under certain conditions, these could be provided by audio-visual telemedicine or by audio device.

NASADAD Comments. NASADAD shared a concern that non-OTP practitioners may lack necessary knowledge to adequately assess opioid use disorders. In addition, the OTP practitioner may not have reviewed outside screenings and assessments before initiating the medication. We noted that many of our members are actively working to enhance the knowledge of community providers, such as Federally Qualified Health Centers and emergency room bridge programs. NASADAD recommended that the final regulation include a requirement that the OTP Medical Director, or his qualified proxy, document in the clinical record that the written patient evaluation conducted by a non-OTP practitioner has been reviewed and approved within a reasonable time period after initiating medication.

NASADAD also expressed that using audio-only devices to screen new patients for MOUD should be the exception, and only allowed in situations where there is a lack of access to in-person or telehealth assessment. NASADAD recommended that these situations should be documented in the patient record and examples should be provided in the final regulations. In addition, NASADAD recommended that the written assessment be verified by the OTP Medical Director within a reasonable time of initiating medication.

Several definitions were added, eliminated, or revised, including the following:

- The proposed definition of *Practitioner* would include mid-level practitioners.
- The term *medication-assisted treatment* would be replaced by the term *medication for opioid use disorder.*
- The terms d*etoxification treatment, maintenance treatment,* and *opioid agonist treatment* were eliminated.

- New terms proposed to be added include *behavioral health services*, *care plan, continuous treatment,* and *harm reduction.*

NASADAD Comments. NASADAD concurred with the changes to the definitions, with the exception of the addition of the term "behavioral health services," which was defined very generally with no to reference to substance use disorders or recovery support services in OTPs. NASADAD recommended that the final regulations include specific definitions for mental health services and substance use disorder services, and that recovery support services be included in these definitions.

In summary, NASADAD was pleased to provide input on these important proposed rule revisions and look forward to working with SAMHSA to implement the final rule.

Download (PDF, Unknown)

NASADAD National Association of State Alcohol and Drug Abuse Directors

February 13, 2023

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration (SAMHSA)
5600 Fishers Lane, Room 13-E
Rockville, MD, 20857

Re: 42 CFR Part 8, RIN 0930-AA39

SUBMITTED VIA PORTAL ON February 13, 2023

Dear Assistant Secretary Delphin-Rittmon:

Thank you for the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) 42 CFR Part 8, published in the December 16, 2022, Federal Register. The National Association of State Alcohol and Drug Abuse Directors, Inc. (NASADAD) is the national association representing the government agencies that administer the publicly-funded prevention, treatment and recovery systems in the 50 states, District of Columbia, and U.S. territories. We have worked collaboratively with the Substance Abuse and Mental Health Services Administration (SAMHSA) for many years, and this partnership has been further strengthened during the current national opioid crisis. One critical aspect of this partnership is the work between our association's component group, the Opioid Treatment Network (OTN), which consists of the State Opioid Treatment Authorities (SOTAs), to ensure that patients in Opioid Treatment Programs (OTPs) have access to safe and effective medication and services. We believe many of the proposed rule changes will further strengthen this goal.

Comments on the Proposed Rule:
We support the emphasis in the proposed rule on treatment that is clinically focused and patient-centered, and that requires assessment and treatment planning that is tailored to meet the needs of individual patients. Additionally, NASADAD supports removing the eligibility requirement that individuals seeking medication for opioid use disorder (MOUD) be addicted for one year, and removing restrictions to treatment for individuals who are younger than 18 years of age to remove barriers to MOUD in OTPs. We strongly agree with the NPRM explicit requirement to give priority admission for pregnant patients to all OTPs and the accompanying requirements concerning the care of these patients. We concur with the emphasis in the proposed rule that the Medical Director is ultimately responsible for oversight of patient care, and the attention given to mid-level providers in the definitions.

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NASADAD supports updating terminology consistent with public health practice (e.g., MOUD and withdrawal management).

We also support the strengthened communication between the accrediting bodies and SAMHSA, the inclusion of a physician experienced in treating Opioid Use Disorder (OUD) on the survey team, and the increased role of the provider in making treatment decisions in the OTP application process.

Schedule for Take-Home Medication.

NASADAD understands the utility of the proposed schedule for take home medications, especially in certain situations in which the patient is not able or free to move around in the community, or where patients who previously demonstrated responsible use of MOUD have had to stop MOUD and are returning to treatment, or who are in living situations that do not support frequent visits to the OTP. Examples might include patients who are returning to treatment after incarceration and who are otherwise stable, a patient who is anticipating a short period of incarceration in a jail facility that will cooperate with safely storing medication for the patient to self-administer, or a patient who needs to be in a residential program for additional therapeutic support where the program can provide safe storage of medication for the patient to self-

administer. In addition, we are aware that states and OTPs may institute their own policies regarding access to take-home medications.

We note that the NPRM is proposing a more liberal take-home schedule than is allowed under the Public Health Emergency (PHE). We also note that while the revised take home policies allowed under the PHE were evaluated, we know of no similar set of evaluations of the proposed take home policies outlined in the NPRM. Therefore, we suggest that the **regulations require that all patients have an individual documented evaluation for their ability to safely manage take-home medications and that this documented evaluation be a required part of the clinical record.** This requirement would safeguard against blanket policies that prevent an individual assessment of a patient's ability to safely manage or inability to currently self-manage their medications.

Screening and Evaluation.

We appreciate the intent to r
medical provider is not available to
MOUD. However, we are concerned
knowledge regarding substance use disorders and the skills necessary to screen or evaluate someone to initiate MOUD prior to the OTP Medical Director reviewing the results of the

A NEW PATH
Parents for Addiction Treatment & Healing

Congressman Brett Guthrie
Chairman of the House Committee on Energy and Commerce
Congressman Morgan Griffith
Chairman of the House Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

March 25, 2026

Dear Committee Chairman Guthrie, Subcommittee Chairman Griffith, and Members of the Committee:

We are Moms United to End the War on Drugs, a project of A New PATH, and we use our voices as mothers (and others) to stop the stigmatization and criminalization of people who use drugs or who have a substance use disorder, and to urge policy makers to eschew punitive policies in favor of public health treatment and recovery responses to drug use and substance use disorders.

We want to register our concern about several bills being considered during your upcoming hearing on "Policies to Protect Our Communities from Illicit Drug Threats."

First, an overarching observation: our examination of the agenda of the hearing leads us to conclude that your efforts are more weighted toward interdiction and punishment than in prevention and treatment (the bills prevailingly have titles including words like "Stop" and "End" and "Fight" rather than "treat" or "heal" or "care"). We demand that the government reaction to dangerous drugs that can harm our children be rooted in compassion and science, not prohibition and punishment. We believe your hearing is missing critical components necessary to "Protect Our Communities from Illicit Drug Threats." We urge the Committee and the Subcommittee to explore non-punitive responses, and to fund the care that is needed to support families struggling with drugs.

The specific bills we wish to comment on individually are as follows:

- H.R. 5629 – to provide that the final rule of the Department of Health and Human Services titled "Medications for the Treatment of Opioid Use Disorder", except for the portion of the final rule relating to accreditation of opioid treatment programs, shall have nor force or effect; and
- H.R. 5630 – to amend the Public Health Services Act to require additional information in state plans for Substance Use Prevention, Treatment, and Recovery Services block grants.

The first bill, H.R. 5629, would nullify parts of SAMHSA's 2024 42 CFR Part 8 Final Rule (the SAMHSA Rule), which took historic steps to loosen restrictions around medications for opioid use disorder and opioid treatment programs (OTPs). For example, the SAMHSA Rule allows patients to receive take-home doses of Methadone, allows for telehealth flexibilities for initiation of buprenorphine, and other changes that helped people access care. Reversing these important policies would have devastating impacts on people trying to access Medication for Opioid Use Disorder (MOUD), especially in rural areas. Based on the evidence, MOUD is one of the most effective tools we have to reduce the risk of overdose. Unfortunately, access is still constrained by laws that dictate which medications clinicians can prescribe and in which settings they may do so, needlessly limiting our uses of the best tools available.

The second bill, H.R. 5630, purports to address misuse of drugs for medication assisted treatment, but we are deeply concerned that this bill would make it harder for patients to access medication-assisted treatment so essential to their care. We are opposed to any policies that impose unnecessary barriers on people seeking treatment for opioid use disorder. Indeed, the availability of treatment, including MOUD, is an important factor in the recent reductions in overdose deaths. We fear tightening regulations will lead to more deaths due to lack of access to medications that could prevent them.

Many Moms United to End the War on Drugs representatives have a son or daughter who has been negatively affected by incarceration for substance use or have died from an overdose, so our families are the casualties of punitive prohibitionist policies. We have a lived experience perspective on this policy issue and would be happy to provide testimony attesting to the importance of protecting our children from harm from drugs through honest drug education, reducing stigma, and access to evidence-based treatment for our children who need it, not incarceration.

Sincerely,

Gretchen Burns Bergman
Lead Organizer, Moms United to End the War on Drugs
Website: www.momsunited.net 619-884-3561 (cell)

Students for Sensible Drug Policy
1800 M St NW, #33051
Washington, DC 20033
ssdp.org

March 26, 2026

To: The Honorable Chair and Members
House Committee on Energy and Commerce
Health Subcommittee
2123 Rayburn House Office Building
45 Independence Ave SW, Washington, DC 20515

Statement of Opposition to H.R. 8000 "End The Needless Distribution of 7-OH" Act

To The Honorable Chair and Members of the House Energy and Commerce Health Subcommittee:

My name is Brooke Sanders and I am a Neuroscience PhD researcher at the University of South Florida, where I study the epigenetic impacts of various substances on the human genome, as well as Director of Network Relations at Students for Sensible Drug Policy (SSDP).

Students for Sensible Drug Policy respectfully urges the Subcommittee to oppose H.R. 8000, which would classify 7-hydroxymitragynine (7-OH) as a Schedule I controlled substance under the federal Controlled Substances Act.

As the world's largest youth-led nonprofit dedicated to advancing evidence-based, public health–oriented approaches, SSDP supports thoughtful policy that protects health and safety. However, **scheduling 7-OH as Schedule I would have serious unintended harms and is not grounded in a comprehensive scientific assessment.**

Summary of Evidence and Harms

What is 7-OH?

7-hydroxymitragynine (7-OH) is a naturally occurring alkaloid found in the kratom plant (*Mitragyna speciosa*), a tropical tree native to Southeast Asia. **It is not a novel synthetic drug, nor is it a laboratory invention.** Like many plant-derived compounds — from morphine in poppy plants to caffeine in coffee — 7-OH exists as part of a complex botanical profile that humans have interacted with for centuries. It can be present naturally in kratom leaves or produced through simple oxidation processes, similar to how other botanical compounds are stabilized or concentrated for consistency.

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How 7-OH Works in the Body

7-OH is a partial agonist at the mu-opioid receptor, meaning it binds to the same receptors targeted by prescription pain medications, but does so in a fundamentally different way. Unlike full opioid agonists such as oxycodone or fentanyl, partial agonists have a natural ceiling effect — beyond a certain dose, additional amounts do not produce proportionally greater receptor activation. This pharmacological distinction is significant from a safety and policy standpoint. Importantly, 7-OH appears to act through pathways that may produce less respiratory depression — the primary cause of opioid overdose fatalities — compared to traditional opioids. These characteristics make 7-OH a **compound of genuine scientific interest,** particularly in the context of the ongoing search for safer pain management alternatives.

7-OH products are used by adults seeking

- Alleviation of chemotherapy side effects (Farkas et al., 2022)
- Relief from chronic pain (Spetea & Schmidhammer, 2019)
- A reduced dependence liability on opioids (Boyer et al., 2008)

For many individuals, access to kratom-derived compounds has been life-changing — particularly for those failed by conventional pain and substance-use treatment systems.

Current Scientific Evidence

A 2023 study showed that the viability, proliferation, and migration of cancer cells is directly inhibited by mitragynine and its active metabolites, such as 7-OH (Viwatpinyo et al., 2023). The reduction of brain tumor cells were observed via mitragynine and its metabolites ability to induce targeted cell death, cell cycle arrest, and cell migration of C6 rat glioma, SHSY-5Y human neuroblastoma, and HT22 mouse hippocampal neuronal cells. The evidence presented by Viwatpinyo and colleagues represents mitragynine and its active metabolites' unique ability to induce antitumor effects in three different organisms.

7-OH has been noted as a novel therapeutic agent for the treatment of Human Epidermal Growth Factor Receptor 2 (HER2) positive breast cancer (Akbar et al., 2025). 7-OH exhibited strong and stable interactions in high affinity to HER2, which is a classic pharmacological identifier of a drug with chemotherapeutic properties. Akbar and colleagues present significant data which supports 7-OH as a “viable candidate for HER2-targeted breast cancer therapy”.

When assessing the genotoxicity risk of 7-OH enriched mitragynine, there is no significantly observed hazard (Harnkit et al., 2026). In in-silico genotoxicity, 7-OH was inactive in a model of micronucleus activity and non-genotoxic. In addition, this work exemplifies the compound's low risk profile for chromosomal damage. Computational analysis concluded that the assays conducted were “quite trustworthy” in the lack of genotoxic evidence found with 7-OH.

Research Harm

Placing 7-OH in Schedule I of the Controlled Substances Act would put an immediate freeze on all research currently being conducted on 7-OH and negatively impact the ability of researchers to continue scientific and medical research into this compound, its potential uses, and any existing safety concerns.

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Federal Legal Status

At the federal level, 7-hydroxymitragynine and kratom broadly remain legal and unscheduled under the Controlled Substances Act. The most significant federal action came in 2016, when the DEA announced its intent to temporarily place kratom's primary alkaloids, including 7-OH, into Schedule I of the Controlled Substances Act. Following substantial public comment and congressional concern, the DEA withdrew the proposal and opened a formal public comment period to gather more information. Since then, the FDA has continued to raise questions about the safety profile of kratom products, issuing import alerts and warning letters to certain manufacturers, while stopping short of pursuing federal scheduling. The result is a federal status that remains unresolved — kratom and its alkaloids are neither approved nor prohibited at the federal level, leaving consumers, researchers, and manufacturers operating without a clear or consistent regulatory framework.

The Facts Do Not Justify Schedule I Prohibition

While there are legitimate concerns about 7-OH products sold without clear labeling or regulatory oversight, these findings support regulation—not criminalization. Schedule I classification is reserved for substances with *no accepted medical use* and *no pathway for safe study*. Applying it here would shut down urgently needed research into pharmacology, novel therapeutics, toxicity thresholds, safer formulations, and appropriate regulatory controls—leaving policymakers blind to the very risks they seek to address. And it would negatively impact consumers who would now seek alternatives from the illicit market, risking overdose and death.

Criminalization Will Increase, Not Reduce, Public Health Risk & Public Safety Concerns

Adding 7-OH to Schedule I of the Controlled Substances Act will not improve public safety, but it will divert resources from treatment, education, and oversight — evidence-based practices — into enforcement.

H.R. 8000 is entitled the 'End Needless Distribution of 7-OH Act,' but if H.R. 8000 passes, demand for 7-OH will not disappear. Instead, it will be pushed into illicit markets, where products are more likely to be adulterated, mislabeled, or dangerously potent.

Available evidence indicates that severe adverse outcomes associated with kratom-derived compounds are consistently linked to polysubstance use, contamination, or prior history of substance abuse—not typical use alone (United Nations Commission on Narcotic Drugs, 2021). Schedule I enforcement would drive consumers away from regulated environments and education about safer consumption practices, increasing the likelihood of unsafe use.

Criminalizing 7-OH will not eliminate its production or demand; it will instead displace regulated small businesses—those with clear incentives to comply with safety standards and oversight—and cede the market to unregulated actors operating outside the reach of public health protections and accountability, while further exposing thousands of Americans—particularly young people and communities already over-policed under harmful drug war policies—to arrest, prosecution, and incarceration.

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A Sensible Path Forward

H.R. 8000 would expand criminalization, suppress research, and drive risk underground—all while failing to address the root causes of harm associated with 7-OH products.

For these reasons, **Students for Sensible Drug Policy respectfully urges the House Committee on Energy and Commerce Health Subcommittee to OPPOSE H.R. 8000** and instead adopt a sensible approach to reasonable public health concerns.

We do not need to choose between inaction and prohibition. SSDP urges the Subcommittee to reject H.R. 8000 and instead pursue evidence-based safeguards, including:

- Product testing and accurate labeling
- Clear dosage and consumer education standards
- Ongoing research access for universities and medical institutions
- Age verification through valid ID at the point of purchase
- Good Manufacturing Practice (GMP) standards to ensure product consistency and purity
- Adverse event reporting requirements so regulators and researchers can track safety data over time

Rather than criminalization, these measures address the real risks associated with unsafe formulations of 7-OH products while preserving opportunities for research, informed use, and public safety policies that reflect evidence.

Thank you for your consideration.

Sensibly,

Brooke Sanders, MS
Director of Network Relations & Strategic Expansion
brooke.sanders@ssdp.org
202-393-5280

NAMI News

Statement of Leading Mental Health and Substance Use Disorder Organizations on Medicaid

NAMI | March 17, 2026

House Energy and Commerce Committee, O&I Subcommittee "Protecting Patients and Safeguarding Taxpayer Dollars: The Role of CMS in Combatting Medicare and Medicaid Fraud"

The undersigned national organizations represent people with mental health and substance use disorders, family members, mental health and addiction providers, advocates, and other stakeholders who recognize the importance of efforts to maintain program integrity for Medicaid and all programs funded at taxpayer expense. Claims of fraud, waste, abuse, or improper payments should always be investigated, but broadly undermining the Medicaid program does not address these and only harms Americans, particularly those with mental health and substance use disorders. We urge Congress not to make further cuts to Medicaid, which will harm individuals who depend on lifesaving care.

Our nation is already bracing for the impact of the nearly $1 trillion of Medicaid cuts resulting from passage of Pub. Law 119-21 (H.R. 1 or OBBBA), which the Congressional Budget Office (CBO) projects will result in **10 million people** becoming uninsured, including 7.5 million losing Medicaid coverage. Additional cuts to Medicaid will exacerbate this damage, especially for the **nearly 40%** of Medicaid enrollees with mental health (MH) conditions and/or substance use disorder (SUD). In the midst of our ongoing **MH crisis** and **opioid overdose public health emergency**, we need to stop cutting off access to the services and supports people need.

More Medicaid cuts will reduce access to lifesaving services. Congress and the Centers for Medicare and Medicaid Services (CMS) have made laudable progress in helping the most vulnerable people in our country access health care by expanding eligibility, MH/SUD parity protections, and coverage of medications for opioid use disorder in Medicaid. But now, Congress and CMS are targeting numerous states' Medicaid funding under the guise of investigating fraud. This unprecedent approach will not address program integrity: instead it prevents states from delivering the lifesaving care that Medicaid recipients need. This broad and untargeted strategy will harm the very people that Medicaid is intended to help, particularly the community our organizations represent and serve. Further, this strategy is unlikely to save costs, as cutting critical services will result in expensive and avoidable hospitalizations, emergency room stays, nursing facility admissions, and other costly interventions

Rather than protecting people with MH conditions and SUD, these cuts directly target them. When passing Pub. Law 119-21, members of Congress kept repeating

they were not going to cut care for people with MH conditions, SUD, and/or disabilities. However, the very services Congress and CMS are targeting are those that people with these conditions rely on to stay healthy and remain in their homes and communities. Our organizations can point to thousands of stories of people with **MH conditions** and **SUD** whose lives were saved because they had Medicaid, not the least of which because Medicaid has the highest rates of treatment access of quality care for **MH conditions** and **opioid use disorder** compared to other types of insurance. Congress and CMS cannot purport to be protecting individuals with these conditions while their current actions attack the services they need.

Although deaths of despair in this country have declined somewhat recently, we are still losing more than 200 people a day to drug overdose and nearly 135 people a day to suicide. Access to MH and SUD care couldn't be more important. We urge Congress not to make further cuts to Medicaid under the pretext of combatting fraud and abuse. Instead, we believe CMS should partner with states and stakeholders to continue to improve access to lifesaving MH and SUD care.

If you would like to discuss our comments, please contact Deb Steinberg at **dsteinberg@lac.org** and Jennifer Snow at **jsnow@nami.org**.

American Association on Health and Disability
Bazelon Center for Mental Health Law
Lakeshore Foundation
Legal Action Center (LAC)
National Alliance on Mental Illness (NAMI)
National Association for Rural Mental Health (NARMH)
National Association of County Behavioral Health and Developmental Disability Directors (NACBHDD)
NHMH – No Health without Mental Health
SMART Recovery
The Jed Foundation
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THE UNITED STATES CONFERENCE OF MAYORS

May 9, 2025

The Honorable Brett Guthrie
Chair
Energy and Commerce Committee
United States House of Representatives
(Sent Via Email)

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
United States House of Representatives
(Sent Via Email)

RE: Preserving Medicaid Is Essential to Maintaining Public Safety in Our Cities

Dear Chairman Guthrie and Ranking Member Pallone:

We write on behalf of America's mayors to urge you to preserve and strengthen the Medicaid program, not cut it, as you markup the reconciliation bill. The cuts being considered by Congress will not only hurt Medicaid beneficiaries and our health system, but also jeopardize public safety and the progress we have made in reducing violent crime. As you stand in support of our police during Police Week, please bear in mind that the Medicaid cuts and eligibility changes you are considering will limit the ability of our police officers to focus on violent crime. Medicaid cuts will exponentially increase the instances of officers responding to people suffering from mental health crises, substance abuse addiction, housing instability, and more who otherwise would have had access to healthcare services through Medicaid ensuring their stability.

We have made great progress in reducing violent crimes over the last few years. A Violent Crime Survey of 68 cities released May 6 by the Major Cities Chiefs Association showed that homicides declined by 20% during the first quarter of 2025 compared with the same period last year. Rape was down 14%, robbery 20%, and aggravated assault 11% in the survey cities. America's mayors are proud of the decline in crime we have seen and are doing everything possible to reduce crime further in our cities, to make our cities safe.

Our police officers and EMTs are often the first on the scene when someone is experiencing a mental health crisis, struggling with addiction, or suffering from a preventable health condition that has gone untreated. These are not simply public health issues—they are public safety challenges. Without access to the ongoing care that Medicaid provides, these challenges grow more severe, more dangerous, and more costly for local governments.

In our cities, Medicaid:

- Supports Crisis Response and Diversion: It funds behavioral health and substance use treatment that help reduce 911 calls, emergency room visits, and jail bookings—allowing police to focus on true public safety threats and reimburses some of the costs of EMT calls.

- Reduces Recidivism: Access to healthcare, especially during reentry from incarceration, reduces the likelihood that individuals will cycle back through the justice system.

- Protects First Responders: Medicaid-funded services help prevent dangerous confrontations by providing community-based care and stabilizing individuals before they reach a point of crisis.

- Stabilizes Families and Neighborhoods: By addressing underlying health and social challenges, Medicaid helps create safer, more resilient communities.

The healthcare, mental health support, substance abuse prevention, and other services provided by Medicaid help prevent and reduce homelessness which has a major impact on public safety. Homeless people are disproportionately victims of crimes and commit crimes at a disproportionate rate.

Medicaid supports those experiencing homelessness by:

- Providing access to those with poor health and limited access to care which is a primary cause of homelessness.

- Providing for services that ensure the most chronically homeless are stabilized.

- Supporting medical services that provide much needed healthcare which reduces the economic burden that allows households to afford housing.

If these services are reduced or eliminated, we may well see an increase in homelessness, and that may also lead to an increase in crime.

America's mayors urge you to recognize Medicaid as not only a health program, but as a vital public safety tool and to oppose any cuts to Medicaid as you markup the reconciliation bill. Thank you for your leadership and for standing with America's cities on this critical issue.

Sincerely,

Andrew J. Ginther
Mayor of Columbus, OH
President

Tom Cochran
CEO and Executive Director

Cc: Members, House Energy and Commerce Committee

March 25, 2026

Dear Members of the E&C health subcommittee, US House of Representatives:

My name is Edward Boyer MD PhD, and I am a medical toxicologist focusing on the management of opioid overdose, toxicity, and abuse. In July 2025 I wrote a letter to the US Food and Drug Administration in response to their July 29 report entitled; “7-Hydroxymitragynine: An Assessment of the Scientific Data and Toxicologic Concerns Around an Emerging Opioid Threat. I am writing today to update my findings of my letter to the FDA, attached here for reference.

Since July 2026, no additional deaths have been observed by medical toxicologists, the group of medical specialists who supervise poison control centers. Similarly, no reports have been published in the peer reviewed literature, nor have deaths been reported by surveillance forensic toxicology efforts such as DEA TOX.[1]

In the period since the FDA report, a single case report of 7-hydroxymitragynine overdose requiring naloxone (the antidote for opioid overdose) has been published. This publication has serious scientific deficiencies, the most notable of which is the failure to prove that the individual in question ingested 7-hydroxymitragynine, as well as the failure to disprove ingestion of opioids such as fentanyl—a substance to which the patient in question had previously abused. Overall, this case report contains too many deficiencies to contribute to the body of medical knowledge.

Summary: As in July 2025, the available data demonstrates that no significant signal exists for public health concerns from 7-hydroxymitragynine.

Sincerely,

Edward W Boyer MD PhD

[1] A The Los Angeles County Medical Examiner’s Office has claimed to have identified several cases of death from 7OH. These cases all have serious deficiencies in reporting as well as cause of death determination—and were disseminated via press release, not the peer reviewed medical literature. They have yet to be published.