Students for Sensible Drug Policy
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July 31, 2026
To: Admiral Brian Christine, MD
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Ave, SW Room 716G
Washington, DC 20201

Public Comment Submitted on Behalf of Students for Sensible Drug Policy (SSDP) Regarding the OASH Request for Information On Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I (Docket HHS-OASH-2026-0232)

Students for Sensible Drug Policy respectfully urges the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) to reject the proposed temporary scheduling threshold for *7-hydroxymitragynine* (7-OH), which would ultimately classify 7-OH, a metabolite of the kratom plant, as a Schedule I controlled substance under the federal Controlled Substances Act. The available scientific evidence does not demonstrate that the proposed threshold is necessary to address an imminent hazard to public safety, nor does it establish that the selected threshold is scientifically justified or appropriately reflects real-world consumer use, pharmacology, or product formulations.

As the world's largest youth-led grassroots network dedicated to advancing evidence-based, public health–oriented approaches, SSDP supports thoughtful policy that protects health and safety. However, **the proposed threshold would effectively prohibit the vast majority of existing 7-OH products and, by triggering Schedule I placement, would produce serious unintended harms that are not supported by a comprehensive scientific assessment.** Rather than advancing public health, the proposed threshold would impede scientific research, drive consumers toward unregulated markets, and undermine the evidence needed to inform future policymaking. SSDP therefore opposes both the proposed threshold and the resulting Schedule I classification of 7-OH and urges HHS and the DEA to pursue a science-based regulatory approach grounded in the available evidence.

Scientific Background and Pharmacology of 7-Hydroxymitragynine (7-OH)

An Introduction to 7-Hydroxymitragynine (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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The kratom plant was introduced to the United States in the 1970s and has been used for pain relief and other purposes in Southeast Asia for hundreds of years. For many individuals — particularly those failed by conventional pain and substance-use treatment approaches — access to kratom-derived compounds, such as 7-OH, has been life-changing.

Pharmacology of 7-Hydroxymitragynine (7-OH)

The kratom plant (*Mitragyna speciosa*) contains numerous alkaloids, with mitragynine serving as its primary active alkaloid. Mitragynine is metabolized by the body into 7-hydroxymitragynine (7-OH), and both compounds interact with mu-opioid receptors (MORs).

Unlike traditional opioid medications, however, 7-OH functions as a partial agonist, meaning it binds to the same receptors targeted by prescription pain medications, but it 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, available preclinical evidence suggests that 7-OH may produce less respiratory depression than full opioid agonists — the primary cause of opioid overdose fatalities — compared to traditional opioids, although additional research is needed to fully characterize its safety profile in humans. These characteristics make 7-OH a **compound of genuine scientific interest,** particularly in the context of the ongoing search for safer pain management alternatives.

Research Harm

Emergency scheduling will create unnecessary obstacles for the scientific research needed to address the ongoing overdose crisis and perpetuate research harms — damage caused when government drug scheduling restricts or deters legitimate scientific inquiry by making it more difficult for researchers to access substances needed for scientific investigation.

Placing 7-OH in Schedule I of the Controlled Substances Act would substantially impede, delay, and deter ongoing scientific research by imposing significant regulatory barriers on investigators. These additional restrictions would slow or even prevent research into 7-OH's pharmacology, safety profile, therapeutic potential, toxicity thresholds, and appropriate regulatory framework precisely when additional evidence is most needed.

Restricting access to novel and emerging therapeutics through emergency Schedule I placement risks delays in urgently needed scientific breakthroughs. Schedule I placement would significantly impede research into 7-OH's pharmacology, safety profile, therapeutic potential, toxicity thresholds, and appropriate regulatory framework. Policymakers cannot make evidence-based decisions if the very research needed to answer these questions is effectively frozen.

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Ongoing Scientific Inquiry Regarding 7-Hydroxymitragynine (7-OH)

Adults report using 7-OH products in an effort to alleviate chemotherapy-related symptoms (Farkas et al., 2022), chronic pain (Spetea & Schmidhammer, 2019), and to reduce reliance on conventional opioids (Boyer et al., 2008). Continued research is necessary to better understand these reported uses, their effectiveness, and any associated risks.

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). Reductions in brain tumor cell viability, proliferation, and migration 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, stable interactions with a high affinity for 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, no significant genotoxic hazard was observed (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.

Opposition to Schedule I Designation for 7-Hydroxymitragynine (7-OH)

A 1MG Threshold Equates to a Ban

The proposed threshold for 7-hydroxymitragynine (7-OH) is **not supported by the available scientific evidence and is not necessary to address an imminent hazard to public safety.** HHS should therefore decline to recommend the proposed threshold to the Attorney General.

The proposed threshold of 0.050% or approximately 1 milligram per article would effectively eliminate the vast majority of 7-OH products currently available. That is not regulation; it is prohibition.

Any threshold should reflect how these products are actually used by responsible adults. A 1 milligram limit does not accomplish that. If limits are established, they should be based on real-world consumer use and scientific evidence, such as those outlined in the tens of thousands of comments that have been submitted in response to Docket HHS-OASH-2026-0232, not an arbitrary level that effectively bans an entire category of products.

The available evidence also does not demonstrate that products exceeding the proposed threshold constitute an imminent hazard to public safety. Nor does the record explain why the proposed threshold

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was selected over any other concentration or dosage metric. If HHS nevertheless determines that a threshold is appropriate, it should be based on scientifically validated measures of consumer exposure or standardized serving sizes rather than a fixed milligram-per-article threshold that fails to account for differences in product formulation and intended use.

The Available Evidence Does Not Support the Proposed Threshold

The available scientific evidence does not demonstrate that products exceeding the proposed threshold present an imminent hazard to public safety requiring emergency action. Rather, the available evidence demonstrates significant uncertainty that should be addressed through additional research rather than prohibition.

What is clear is that 7-OH does not meet the standards of Schedule I classification under the Controlled Substances Act. Schedule I classification is reserved for substances with *no accepted medical use* and *no pathway for safe study*. In contrast:

- No known lethal overdose threshold for 7-OH has been established in the scientific literature.
- Adverse reports involving 7-OH are rare, especially when not combined with other substances.
- Available evidence indicates that serious adverse outcomes associated with kratom-derived compounds are most commonly linked to polysubstance use, contamination, or other confounding factors rather than 7-OH alone.
- Increased doses do not produce proportionally stronger opioid-like effects.
- Emerging research continues to investigate the therapeutic potential of mitragynine and its metabolites, including possible applications in pain management, opioid use disorder, and other areas of medicine. Additional preclinical research has also identified promising anticancer activity and a favorable genotoxicity profile, underscoring the importance of allowing this work to continue.

Expected Public Health and Public Safety Outcomes of Schedule I Placement

Criminalization has repeatedly failed as a strategy for increasing public safety, and nothing in the current record demonstrates that the proposed threshold would produce a different outcome.

Adding 7-OH to Schedule I of the Controlled Substances Act will not improve public health or safety. Instead, it will divert resources away from treatment, education, and regulatory oversight — evidence-based approaches — and toward enforcement.

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. It will also expose 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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As a public policy strategy, **criminalization has repeatedly failed to eliminate consumer demand**. Rather than reducing use, prohibition pushes consumers into unregulated, illicit markets where products are more likely to be adulterated, mislabeled, and hazardous. Consumers lose access to quality-controlled products and accurate information, while regulators lose visibility into emerging market trends. Ordinary Americans who are simply trying to improve their quality of life will face devastating consequences.

Available evidence indicates that severe adverse outcomes associated with kratom-derived compounds, such as 7-OH, are consistently linked to polysubstance use, contamination, or a prior history of substance abuse — not typical use alone (United Nations Commission on Narcotic Drugs, 2021). By driving consumers away from regulated markets and evidence-based education about safer consumption practices, Schedule I enforcement would increase the likelihood of unsafe use.

A Sensible Path Forward

Regulation, Not Prohibition

The United States continues to face unprecedented rates of overdose and chronic pain, underscoring the urgent need for safer analgesics and more effective medications for opioid use disorder. Consumers across the country rely on kratom-derived products, including 7-OH, to manage chronic pain, withdrawal symptoms, improve their quality of life, and reduce reliance on opioids, alcohol, and illicit substances.

At a time when millions of Americans continue to struggle with chronic pain, addiction, and limited access to affordable healthcare, scheduling 7-OH will put patients at great risk.

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 meeting specific statutory criteria.

Based on the current record, the available evidence does not establish that the proposed threshold is necessary to avoid an imminent hazard to public safety. 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.

Additional scientific research — not "emergency" prohibition — is needed to determine appropriate regulatory safeguards.

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A Sensible, Evidence-Based Approach

SSDP continues to strongly oppose the proposed threshold scheduling of 7-OH and instead calls for a science-based, public health–centered approach that protects consumers, supports continued research, and preserves legal access for responsible adults.

We do not need to choose between inaction and prohibition. Instead, HHS and the DEA should work alongside Congress to pursue an evidence-based regulatory framework that includes:

- Product testing and accurate labeling
- Good Manufacturing Practice (GMP) standards to ensure product consistency and purity
- Age verification through valid identification at the point of purchase
- Licensing requirements for manufacturers and retailers
- Clear dosage information and consumer education standards
- Adverse event reporting requirements to improve ongoing safety surveillance
- Continued access for legitimate scientific research and ongoing evaluation of the emerging evidence regarding 7-hydroxymitragynine

These practical safeguards reduce risk, ensure product consistency, preserve opportunities for scientific research, keep consumers out of illicit markets, and address legitimate public health concerns without repeating the well-documented harms of prohibition.

For these reasons, Students for Sensible Drug Policy opposes the DEA's proposed emergency scheduling of 7-OH and respectfully urges HHS to conclude that the proposed threshold is not supported by the available scientific evidence and is not necessary to address an imminent hazard to public safety.

The current record does not establish that the selected threshold reflects real-world consumer exposure, product formulation, or pharmacological evidence, nor does it adequately explain why alternative approaches would be insufficient.

Rather than recommending emergency prohibition, HHS should encourage continued scientific research and the development of an evidence-based regulatory framework that protects public health while preserving opportunities for scientific inquiry.

Thank you for your consideration.

Sensibly,

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