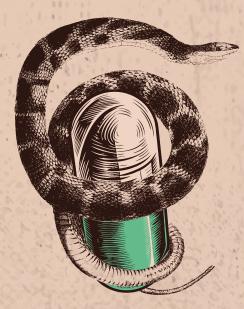
REGULATION OVER PROHIBITION

CONSUMER CHOICE



SINCE 2017 —

CENTER

SMARTER APPROACHES TO 7-OH AND KRATOM DERIVATIVES

7-Hydroxymitragynine (7-OH) is a natural compound from the kratom plant, long used in Southeast Asia for pain relief and recovery. Today, millions of Americans rely on kratom and its derivatives as safer alternatives for managing pain, anxiety, and opioid withdrawal.

Smart regulation-not prohibition-ensures safety, research, and consumer choice.

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INTRODUCTION

The Consumer Choice Center champions evidence-based policies that prioritize consumer choice, innovation, and harm reduction over prohibitionist measures that create unintended consequences.

Specific to drugs and consumer products like cannabis, nicotine, opiates, and even alcohol, we know from decades of <u>historical evidence</u> that legally regulated and supervised markets are overwhelmingly preferred to illicit markets where no such control can be effectively practiced.

For the sake of public health and responsible regulation, legal frameworks on these products are a <u>necessary component</u> of protecting consumers and reinforcing sound science. The same approach should be applied to novel products that have some potential for abuse.

The trade-offs implicit in evaluating public health and regulatory guidelines for such addictive drugs require evidence-based science, rational policy recommendations, and balancing those with a general approach of harm reduction.

The recent <u>proposal</u> by the Food and Drug Administration (FDA) to restrict 7-Hydroxymitragynine (7-OH), an alkaloid from the kratom plant (Mitragyna speciosa), by placing it on the list of Schedule 1 drugs according to the Controlled Substances Act (CSA) is one such policy shift that risks public health and will create more problems than it will solve.

Rather than judging novel drug usage through the prism of safety and efforts to curb uptake, we propose a regulatory framework that institutes control and supervision over wanton black markets.

By risking a shift of 1.7 million users of kratom and its derivatives in the United States toward potentially more harmful and illicit drugs, including those laced with fentanyl or cut with other dangerous substances, health regulators would stamp out one problem only to forge more in their wake. This would only exacerbate the existing drug crisis by expanding unsafe supplies, empowering <u>criminal syndicates</u> with no qualms about illicit trade, and robbing Americans of potential solutions.

What's more, Schedule 1 status would block the ability of any scientific or medical research into kratom, which would hinder <u>further education and review</u> necessary to advance public health. Similar restrictions on cannabis and psychoactive drugs over decades have <u>similarly stunted</u> our scientific understanding of the impact of these drugs, and clouded public policy debates about their therapeutic use and effective regulation.



FACTS ON 7-OH AND KRATOM DERIVATIVES

The drug 7-Hydroxymitragynine (7-OH) is a natural metabolite of the kratom plant, traditionally used in Southeast Asia for its stimulant and pain-relieving effects. Users report 7-OH alleviates chronic pain, anxiety, PTSD, and opioid withdrawal, with its potency surpassing mitragynine, the plant's primary alkaloid. Because these chemicals target the same brain receptors as opiates, many users take up these drugs as they aim to recover from opioid addictions. Researchers have also begun investigating whether kratom and its derivatives are helpful in alcohol withdrawal and recovery.

As detailed by the <u>few studies</u> we have from scientific journals and reports, these products are much more affordable than traditional prescription opioids, <u>reportedly</u> offering pain management over several days with smaller doses.

Among pharmacological researchers, there is a general consensus that these compounds have some medical application that would warrant further study. One guide for healthcare providers published in the journal Frontiers in Pharmacology concludes that "use of kratom as an effective substitute is supported by preclinical research, which is of particular interest in light of the current United States opioid crisis of rising dependence rates, emergency room visits, and overdose deaths".

An <u>initial pilot study</u> conducted by the FDA in February 2024 to document the effects of kratom and its metabolites found that users "appeared to be well tolerated" to the drug, and found minimal adverse effects even at high dosages. As a follow-up, the FDA has <u>opened</u> grant opportunities for additional studies.

LEGAL STATUS AND AVAILABILITY

In the United States, 7-OH products are <u>usually sold</u> at smoke shops, gas stations, and convenience stores in various forms, in drinks, powder forms, tablets, or gummies. Despite their availability, these products are sold without much regulatory oversight or labeling standards. There are no age restrictions, variability in strength and dosage, and no effective means for quality control.

Several states, including most recently Florida, have banned kratom products and its derivatives rather than dedicating resources to an effective regulatory structure. Other states are reportedly entertaining bans as well, demonstrating an effective coordination campaign allegedly led by various competing industry groups.

In July 2025, Rhode Island <u>reversed</u> its ban, introducing a regulatory framework for manufacturing and sales that will come into force in 2026.

The FDA's proposed restrictions on 7-OH contradict its risk profile and potential harm reduction qualities that are actively explored in the scientific community. Despite the negative headlines, quantitative data about uptake reveal a milder reality:

- Only 53 poison control calls (0.00009% of 600,000 total calls, February–May 2025), compared to 11% for OTC painkillers like Tylenol and 5% for cosmetics.
- No deaths solely attributed to 7-OH despite over 500 million doses consumed.
- Only 11 adverse events in the FAERS database



TURNING AWAY FROM PROHIBITION

The FDA's push to severely restrict and outright ban 7-OH disregards the very real scientific and medical evidence that warrant keeping this drug legal and available, albeit in a more regulated system. By favoring prohibition, the FDA threatens to replicate the harms of cannabis and alcohol prohibition by driving users to dangerous illicit markets where neither quality nor dosage can be effectively controlled.

Rather than a drastic Schedule 1 status for 7-OH and its similar kratom derivatives, our public health authorities must make the responsible decision of offering a smart regulatory framework to protect consumers, children, and allow legitimate medical research that could provide additional benefits to society. Rhode Island's recent law change supplicates this approach.

One such federal example is found in the Federal Kratom Consumer Protection Act (KCPA) introduced by Sens. Mike Lee (R-UT) and Cory Booker (D-NJ). This bill would create a national framework to ensure safety via testing, labeling, age restrictions, and require quality manufacturing practices. This appropriately recenters the supervision and regulation of these drugs at the federal level, providing uniform standards and control mechanisms to protect consumers in all 50 states.

Using smart regulatory policy to address 7-OH and similar kratom substances would help prevent overdoses, preserve legitimate access for pain and withdrawal management, and avoid needless criminalization and prohibition that would cause yet more societal harm.

KEY POINTS:

- Harm Reduction: Regulation ensures product testing, labeling, and age restrictions
 reducing risks compared to large-scale illicit markets.
- Consumer Choice: Criminalization denies adults safe and regulated access and drives use underground.
- Research & Innovation: Supporting medical research to discover potentially less harmful alternatives to opioids.

POLICY RECOMMENDATIONS:

- 1. Reject Schedule I classification for 7-OH.
- 2. Establish a regulated framework for Kratom and its metabolites
 - a. purity testing, transparent labeling, dosage standards, etc.
- 3. Encourage clinical research into therapeutic, medical, and recovery uses.
- 4. Implement age restrictions and consumer education rather than criminal penalties.

CONCLUSION

Restricting 7-OH ignores its safety profile and harm reduction benefits, risking a public health disaster by pushing users to illicit products that would jeopardize their health and safety.

Smart and responsible regulation through efforts such as the Kratom Consumer Protection Act, as proven with cannabis and nicotine and a host of other drugs, would ensure safer access for those who need these products while leaving enough room for legitimate medical and scientific research to take place.





The Consumer Choice Center is a non-profit organization dedicated to defending the rights of consumers around the world. Our mission is to promote freedom of choice, healthy competition, and evidence-based policies that benefit consumers. We work to ensure that consumers have access to a variety of quality products and services and can make informed decisions about their lifestyle and consumption.

As an independent nonprofit organization, the Consumer Choice Center relies on support and funding from private donors. As described in our Code of Ethics, we strictly maintain editorial independence and do not give our funders any influence on editorial decisions. Our support comes from corporations, individuals, and foundations. We have a tiered membership model available to members who support us on a yearly basis, equalling silver, gold, and platinum status.

In the past and currently, we have received funding from multiple industries, such as energy, fast-moving consumer goods, nicotine, alcohol, airlines, agriculture, manufacturing, digital, healthcare, chemicals, banking, cryptocurrencies, and fin-tech.

Find out more at www.consumerchoicecenter.org



