

"HOT SHEET"



3RD QUARTER - 2025

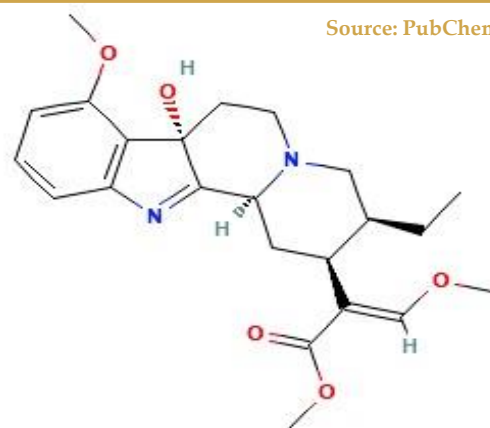
Objective: The goal of this, and subsequent bulletins, is to provide information regarding identified changes in drug trends, and/or to educate and forewarn about newly identified substances.

Subject Matter: This release provides information regarding the opioid compound 7-hydroxymitragynine (7-OH), a kratom-derived compound, readily available throughout American retail channels. Since its concentrated formulations remain accessible, this information is presented to provide guidance on understanding 7-OH, and its potential threat to public health and safety.

7-OH Defined

Natural kratom (*Mitragyna speciosa*) leaves have very small amounts of 7-OH.^[1] Scientists first discovered this compound in 1994, and it makes up less than 2% of the total alkaloid content in the plant.^[1] Mitragynine, kratom's main alkaloid, is much more common and makes up about 66% of the plant's alkaloids.^[2] The low natural levels make it impractical to extract high amounts of 7-OH from the kratom leaves. Rather than direct extraction, concentrated 7-OH is typically produced through chemical conversion, which involves the oxidation of mitragynine.^[1]

Research has demonstrated that this conversion occurs both in laboratory settings and within the human body after kratom consumption. Essentially, when consuming traditional kratom, a small amount of mitragynine is converted to 7-OH in your body. However, 7-OH products on the market contain this compound already converted and concentrated, bypassing the body's natural metabolic limitations.^[2]



Known Effects and Health Risks of 7-OH

In terms of potency, 7-OH demonstrates substantially greater mu-opioid receptor binding than mitragynine; mu-opioid receptors act as a docking station/switch in the brain for certain chemicals, like painkillers. In laboratory testing, 7-OH showed 13-fold higher potency than morphine and 46-fold higher potency than mitragynine.^[3] When consumed, this potent alkaloid creates various physiological responses, whose effects are essentially identical to conventional opioids^[1]:

- Pain relief (analgesia) through altered pain perception^[1]
- Euphoria and sedation, particularly at higher doses^[1]
- Respiratory depression at elevated doses, a dangerous effect shared with traditional opioids^[1]
- Nausea and dizziness reported as common side effects^[1]

Clinical investigations demonstrate substantial physiological hazards associated with 7-OH consumption, particularly as concentrated formulations become increasingly prevalent in consumer markets. Medical literature documents escalating incidences of adverse health events requiring immediate clinical intervention among users of this potent opioid compound.^{[1][4]}





Risks of Addiction – Dependence - Overdose

The addiction potential of 7-OH is a serious concern. Unlike whole-plant kratom, 7-OH appears to present substantially higher risks, as regular users often develop tolerance, requiring higher doses over time to achieve the same effects. ^[1] The FDA has cautioned against consumption due to potential severe health risks, including damage to the liver, convulsions, and substance use disorders (SUD). ^[4]

According to the FDA, there have been no dedicated clinical trials examining 7-OH independently. However, the organization's review of animal research indicates that 7-OH exhibits rewarding, reinforcing, and pain-reducing effects, while carrying risks of breathing difficulties, physical dependency, and withdrawal symptoms. ^[1] Kaitlyn Brown, PharmD, and clinical managing director at America's Poison Centers, explained, "A lot of people like to think 'plants, natural products' equal safer, but the reality is it has the same, if not higher, potency of the pharmaceutical opioids." ^[5]



Poison center documentation indicates that individuals experiencing 7-OH overdose often display typical opioid overdose symptoms. "Looking at our reported data, we see patients that have some agitation, nausea, vomiting, fast heart rates," Brown stated. She emphasized that severe cases have shown depression of central nervous system function or respiratory difficulties. Additional reported symptoms included mental confusion, excessive sweating, elevated blood pressure, breathing difficulties, drowsiness or unconsciousness, and convulsions. ^[5]

Mashal Khan, MD, an addiction psychiatrist and assistant professor at Weill Cornell Medicine, and Sotiris Chaniotakis, MD, and a psychiatrist at a substance use facility, both highlighted concerns regarding 7-OH's addictive nature. "Essentially the potential for dependence and withdrawal that we associate with opioids is more or less the same," Khan explained regarding 7-OH. ^[5]

However, unlike controlled opioids or illicit substances, 7-OH remains freely accessible to consumers. Chaniotakis highlighted how easily one can purchase a standardized, potent supply legally for just \$15 to \$30. "The only message that I want to get out there is that it's strong, it's available over the counter, it's given in pill form, and it's being synthesized in labs that are not being regulated," Chaniotakis emphasized. "And based on my personal experience as a doctor and from the studies, it is highly addictive." ^[5]

"HOT SHEET"



3RD QUARTER - 2025

Consumer Exposure Through Unregulated Products

Regulatory oversight gaps permit widespread distribution of concentrated 7-OH formulations through conventional commercial channels, creating exposure risks for uninformed purchasers. [1]

Availability in Gas Stations, Vape Shops, and Online

Distribution networks for 7-OH products extend beyond specialized botanical retailers into mainstream commercial establishments. Gas stations, corner stores, and vape shops maintain inventory of concentrated 7-OH products alongside conventional merchandise. [6] FDA Commissioner Marty Makary identified this expansion pattern, stating "vape stores are popping up in every neighborhood in America, and many are selling addictive products like concentrated 7-OH." [6]

Mislabeling and adulteration in kratom products

Commercial kratom products frequently contain artificially enhanced 7-OH concentrations exceeding natural alkaloid profiles found in raw kratom leaf material. [1] This adulteration practice creates deceptive product presentations, whereby consumers purchasing seemingly natural kratom products actually receive synthetically modified or concentrated 7-OH formulations. [1]

Youth-targeted formulations: gummies and shots

Particularly concerning product development trends involve 7-OH formulations designed to appeal to younger demographics. Federal health officials have documented increasing availability of youth-oriented products, these products have been characterized as "appealing to children and teenagers" through "fruit-flavored gummies and ice cream cone" products. [6]

Contemporary youth-targeted product categories include:

- Flavored beverage mixtures containing 7-OH [7]
- Chewable formulations available multiple varieties (i.e., blue raspberry and pink strawberry) [7]
- Concentrated liquid "shots" containing elevated compound levels [7]



"HOT SHEET"



3RD QUARTER - 2025

FDA Launches Investigation into Synthetic 7-OH

The FDA has launched an investigation into synthetic 7-OH products, marking a new chapter in the agency's approach to kratom-derived substances. On July 29, 2025, the FDA announced it was recommending a scheduling action to control certain 7-OH products under the Controlled Substances Act (CSA).^[6]

A "disturbing rise in reports of overdoses, poisonings and emergency room visits linked to products containing 7-OH" primarily triggered the FDA's investigation said Health and Human Services (HHS) Deputy Secretary Jim O'Neill.^[8] Health officials expressed growing concern about novel potent opioid products increasingly available to American consumers through various retail channels. According to FDA Commissioner Marty Makary, "7-OH is an opioid that can be more potent than morphine," highlighting the serious nature of the agency's concerns.^[6]

The investigation followed a thorough medical and scientific analysis by the FDA, which found that 7-OH has significant potential for abuse because of its ability to bind to opioid receptors. Health officials are especially alarmed by how easily consumers can purchase products with concentrated levels of 7-OH.^[6]

Which products are under scrutiny?

The FDA is specifically targeting concentrated forms of 7-OH, including:

- Tablets and capsules^[1]
- Fruit-flavored gummies^[6]
- Drink mixes and shots^[1]
- Products marketed in ways appealing to children, such as ice cream cones^[6]



Notably, many products under investigation are not clearly or accurately labeled regarding their 7-OH content, with some actively disguised or marketed as kratom. This misrepresentation creates significant confusion for consumers who may not understand what they are purchasing.^[1]

How does this differ from traditional kratom regulation?

The FDA has explicitly stated that this regulatory action "is not focused on natural kratom leaf products."^[6] Instead, it specifically targets concentrated 7-OH, which is a byproduct of the kratom plant.^[6] This marks a significant shift from previous regulatory approaches.

Historically, the DEA attempted to classify kratom as a Schedule I controlled substance in 2016 but withdrew this action after considerable public opposition, including a letter signed by more than 60 members of Congress.^[9] Currently, while the FDA continues to warn consumers against using kratom products generally, this new investigation draws a clearer distinction between natural kratom and synthetic derivatives.

From a legal standpoint, the differences are substantial. The FDA has determined that "there are no FDA-approved 7-OH drugs, 7-OH is not lawful in dietary supplements and cannot be lawfully added to conventional foods."^[6]

“HOT SHEET”



3RD QUARTER - 2025

Poison Center Data

America's Poison Centers recorded 53 exposure cases with 7-hydroxymitragynine between February and April 2025. ^[1] The breakdown shows:

- 24 cases (45%) from intentional abuse ^[1]
- 8 cases (15%) linked to withdrawal ^[1]
- 16 cases involved only 7-OH exposures ^[1]

Several cases led to serious medical problems that needed hospital care. This data shows just a small part of the problem since specific 7-OH tracking codes only started in early 2025. ^[1]



Poison centers logged 165 exposures to 7-OH in the first 7 months of 2025. From these, 35% caused serious health issues and 67% needed medical treatment. ^[10] Additionally, 1,690 exposure cases involving kratom were reported, which surpasses the total from the entirety of 2024. ^[10] The increase of these cases could also potentially be attributed to the effects and prevalence of 7-OH products.

EMS Encounters

From January 2023 to April 2025, EMS responded to 4,233 kratom/7-OH overdose incidents, with “1,071 cases (25.3%) in western states, 1,191 cases (28.1%) in central states, and 1,971 cases (46.6%) in eastern states.” ^[11] The statistics reveal a notable upward trend in kratom/7-OH-related emergency responses both regionally and nationwide. ^[11] In the central states region, which all of the Midwest HIDTA states are located within, two counties in Kansas, Sedgwick and Johnson, were among the top 10 counties “with the highest rates of EMS encounters for kratom/7-OH-related overdoses (nonfatal and fatal) per 10,000 population”, at 0.52 and 0.44, respectively. ^[11]

Legal Status of 7-OH in Midwest HIDTA States

Neither Kratom nor 7-OH are currently scheduled under the federal CSA. However, the FDA has recommended the DEA classify 7-OH as a Scheduled 1 controlled substance, their decision regarding this scheduling is still pending. ^[6]

Iowa – Legislation (**Senate File 367**) is being considered to classify all parts of the *Mitragyna speciosa* plant, which would include 7-OH and mitragynine, as a hallucinogenic Schedule I controlled substance. ^[12]

Kansas – 7-OH and kratom are currently legal. A bill (**HB 2230**) seeking to regulate kratom like a food product, set age restrictions, and prohibit adulterated or contaminated products was introduced in 2025, but has not been passed. ^[13]

Missouri – 7-OH and kratom are currently legal. A proposed bill (**HB 1037**), known as the “Kratom Consumer Protection Act”, primary purpose was to regulate the sale of kratom products by establishing specific safety and labeling standards and restricting sales to minors; the bill died in a Senate committee. ^[14]

Nebraska – In May 2025, the Kratom Consumer Protection Act (**LB 230**) was passed, key components included making it illegal to sell to anyone under 21, packaging cannot be enticing to children, and 7-OH must be less than 2% of the alkaloid composition of the kratom products. ^[15]

North Dakota – 7-OH and kratom are currently legal; a bill crafted to make it a Schedule I substance failed to pass in early 2025, but a study (**HB 1566**) is being done to explore the risks associated with them. ^[16]

South Dakota – Kratom and 7-OH are legal to possess by individuals over 21. However, 7-OH may be no more than 2% of the alkaloid composition, labels must include the amount of mitragynine / 7-OH in the product along with a specific warning statement and bans products that contain synthetic forms of kratom alkaloids (**HB 1056**). ^[17]

“HOT SHEET”



3RD QUARTER - 2025

Conclusion

The FDA's investigation into synthetic 7-OH products marks a significant shift in regulatory approach, making a distinction between natural kratom and highly concentrated synthetic derivatives.^[6] This separation proves crucial as evidence mounts regarding the extraordinary potency of 7-OH—with its opioid binding affinity being approximately 13 times stronger than morphine and 46 times that of mitragynine.^[3] Perhaps most alarming, many consumers remain unaware they're purchasing synthetic opioids rather than traditional kratom products, largely due to misleading marketing tactics.^[1]

Manufacturers have exploited regulatory gray areas, marketing products containing up to “500% more 7-OH than would be expected naturally.”^[7] These concentrated forms present serious health risks, including respiratory depression, addiction potential, and withdrawal symptoms resembling conventional opioids.^[1]

Key Takeaways

Understanding the serious health risks and regulatory concerns surrounding 7-OH is crucial for public safety and informed decision-making.

- These dangerous products remain widely available in gas stations, vape shops, and online despite FDA warnings, often marketed as harmless kratom supplements.^[6]
- Youth-targeted formulations like gummies and flavored shots pose particular risks, with some products containing up to 60mg or more of this potent opioid compound per package.^{[6][7]}
- The FDA has recommended Schedule I classification for concentrated 7-OH products and issued warning letters to manufacturers selling these illegal substances.^[6]
- Physical dependence and withdrawal symptoms occur with regular use, meeting criteria for substance use disorder according to clinical studies.^{[1][4][5]}

FAQs

Q1. How do synthetic 7-OH products differ from natural kratom? Natural kratom contains only trace amounts (0.01-0.04%) of 7-OH^[1], while synthetic products can contain up to 500% more 7-OH.^[7] This makes synthetic products much more potent and potentially dangerous compared to traditional kratom leaf.

Q2. Are 7-OH products legally available in the United States? While the FDA has not approved any 7-OH products for medical use, these substances remain widely available in gas stations, vape shops, and online retailers.^[6] However, the FDA has issued warnings and initiated steps toward enforcement actions against companies selling these products.^[6]

Q3. What are the main health risks associated with 7-OH use? The primary health risks include liver toxicity, seizures, respiratory depression, and the potential for substance use disorder. Users may experience severe liver damage, neurological effects, and symptoms similar to opioid dependence.^{[1][4][5]}

Q4. Can using 7-OH lead to addiction or withdrawal symptoms? Yes, regular use of 7-OH can lead to physical dependence and withdrawal symptoms similar to those of traditional opioids. Studies have shown that a significant percentage of users meet the criteria for substance use disorder, experiencing cravings, tolerance, and difficulty quitting.^{[1][2][5][7]}

Q5. Is naloxone effective against a 7-OH/Kratom overdose? YES. “Due to its opioid-like properties, patients who overdose on kratom do respond to naloxone administration.”^[18]

"HOT SHEET"



3RD QUARTER - 2025

References:

1. Reissig, C. PhD, Seitz, A. PhD-MPH, Lee, R. Pharm.D., Radin, R. PhD, McAninch MD-MPH-MS, Food and Drug Administration (July 29, 2025), "7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat;" <https://share.google/PAuKBkys6RBsi9VQm>
2. Lydecker AG, Sharma A, McCurdy CR, Avery BA, Babu KM, Boyer EW. Suspected Adulteration of Commercial Kratom Products with 7-Hydroxymitragynine. J Med Toxicol. 2016 Dec;12(4):341-349. doi: 10.1007/s13181-016-0588-y. Epub 2016 Oct 17. PMID: 27752985; PMCID: PMC5135684; <https://pubmed.ncbi.nlm.nih.gov/27752985/>
3. Eastlack SC, Cornett EM, Kaye AD. Kratom-Pharmacology, Clinical Implications, and Outlook: A Comprehensive Review. Pain Ther. 2020 Jun;9(1):55-69. doi: 10.1007/s40122-020-00151-x. Epub 2020 Jan 28. PMID: 31994019; PMCID: PMC7203303; <https://pmc.ncbi.nlm.nih.gov/articles/PMC7203303/>
4. US Food & Drug Administration, "FDA and Kratom," content current as of July 29, 2025, accessed on August 28, 2025; <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>
5. Anderer S. What to Know About 7-OH, the New Vape Shop Hazard. JAMA. Published online August 22, 2025. doi:10.1001/jama.2025.13592; https://jamanetwork.com/journals/jama/fullarticle/2838093?utm_medium=email&utm_source=postup_jn&utm_campaign=article_alert-jama&utm_content=olf-tfl
6. US Food & Drug Administration, News Release (July 29, 2025), "FDA Takes Steps to Restrict 7-OH Opioid Products Threatening American Consumers;" <https://www.fda.gov/news-events/press-announcements/fda-takes-steps-restrict-7-oh-opioid-products-threatening-american-consumers>
7. Food and Drug Administration (July 29, 2025), "Preventing The Next Wave of the Opioid Epidemic: What You Need to Know About 7-OH;" <https://www.fda.gov/media/187900/download>
8. Oweremohle, S. (Jul 30, 2025), CNN, "Federal officials push to restrict kratom-derived opioid 7-OH;" <https://www.cnn.com/2025/07/29/health/kratom-derived-opioid-7-oh>
9. Legislative Analysis and Public Policy Association, (Oct 2019) "Regulation of Kratom in America;" <https://legislativeanalysis.org/wp-content/uploads/2019/10/Kratom-Fact-Sheet-1.pdf>
10. Devitt, S. (Aug 12, 2025), America's Poison Centers, "Health Advisory: Serious Illnesses Associated with 7-OH Use;" <https://poisoncenters.org/news-alerts/13531044>
11. National Drug Early Warning System (May 30, 2025), "NDEWS Special Report EMS Encounters for kratom/7-OH-related overdoses (nonfatal or fatal) in the US, January 1, 2023 – April 30, 2025;" [NDEWS Weekly Briefing Issue 233 – This Week's Focus: Kratom and Mitragynine-Derived Substances](https://www.ndews.gov/weekly-briefing-issue-233)
12. Iowa Senate Bill SF 367 (Feb 19, 2025); <https://fastdemocracy.com/bill-search/ia/2025-2026/bills/IAB00021117/>
13. Kansas House Bill 2230 (Feb 4, 2025); https://kslegislature.gov/li/b2025_26/measures/hb2230/
14. Missouri House Bill 1037 (Jan 23, 2025); <https://house.mo.gov/Bill.aspx?bill=HB1037&year=2025&code=R#:~:text=All%20Bills,H%201631%20%2D%201632>
15. Nebraska LB 230 (Jan 14, 2025); https://nebraskalegislature.gov/bills/view_bill.php?DocumentID=59264
16. North Dakota HB 1566; <https://ndlegis.gov/assembly/69-2025/regular/bill-overview/bo1566.html>
17. South Dakota HB 1056; <https://mylrc.sdlegislature.gov/api/Documents/276177.pdf>
18. Ahmed S, Tran QV, McLean M. The Great Imitator: A Case of Accidental Kratom Overdose. Cureus. 2023 Aug 8;15(8):e43144. doi: 10.7759/cureus.43144. PMID: 37560054; PMCID: PMC10408695; <https://pmc.ncbi.nlm.nih.gov/articles/PMC10408695/>