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### Senate Committee on Health Informational Hearing

### Kratom and 7-Hydroxymitragynine: Public Health Concerns and Regulatory Challenges February 18, 2026 – 1:30p.m.

#### Background

Kratom (*Mitragyna speciosa*) is a tropical plant native to Southeast Asia. Kratom leaves have traditionally been chewed or brewed into teas to treat fatigue, pain, diarrhea, fever, and opioid withdrawal. People typically use kratom by swallowing raw plant matter in capsule or powder form, by mixing kratom powder into food or drinks, brewing the leaves as tea, or taking liquid kratom extract. At low doses, kratom is a mild stimulant, but higher doses elicit sedative and analgesic responses due to substances in the plant that activate opioid receptors. Studies indicate that kratom can be habit-forming, and studies of regular kratom leaf tea drinkers described physical and psychological withdrawal symptoms in those who ceased use.<sup>1</sup> Over the past few years, some manufacturers have developed new, more potent products by extracting the primary alkaloid in the kratom plant, mitragynine, and converting it into more powerful substances, including 7-hydroxymitragynine (7-OH). The proliferation of kratom and products containing kratom derivatives, paired with a regulatory gray area and enforcement gaps, have made these products readily available to Californians. Despite being deemed unlawful by both the U.S. Food and Drug Administration (FDA) and the California Department of Public Health (CDPH), these products are widely available on the shelves of smoke and vape shops, gas stations, and convenience stores. This hearing is intended to examine what is known about the health effects of kratom's active alkaloids, their potential for abuse, and the challenges associated with regulating the labeling, marketing, and sale of these products.

#### Kratom's active alkaloids

Kratom leaves contain a blend of many biologically active alkaloids that contribute to its psychoactivity. The kratom plant itself has at least two different chemotypes currently grown within the U.S. Although these strains display variations in minor alkaloid profiles (which are also dependent on plant age, growing conditions, and processing methods), mitragynine is the most abundant alkaloid in all plants.

Mitragynine is a partial  $\mu$ -opioid receptor agonist that exhibits pain-blocking effects in animal studies, about 66 times less active than morphine.<sup>2,3</sup> Studies of mitragynine's reward and abuse potential are mixed; several animal studies of both whole kratom leaf extract and isolated mitragynine report a rewarding effect, while others do not.<sup>4-7</sup>

Animal studies suggest that the pain-blocking effects of mitragynine are primarily due to the metabolism of mitragynine into 7-OH in the liver and gut.<sup>8</sup> 7-OH comprises as much as 1.6% of the plant's alkaloid content, but is often undetectable in fresh kratom leaves.<sup>7</sup> Oxidation of mitragynine into 7-OH can be achieved through a variety of processes, including drying and processing of kratom leaves, metabolism of mitragynine in the liver and intestine, or chemical oxidation. Pharmacologically, 7-OH is much more potent than mitragynine. 7-OH has a 7- to 15-fold higher affinity<sup>3,9,10</sup> for  $\mu$ -opioid receptors than mitragynine, and a 4- to 40-fold increase in potency.<sup>2,3,8-10</sup> Pain-blocking tests in mice reveal that 7-OH is over 350 times more effective than mitragynine as an analgesic, superior even to morphine.<sup>3,10</sup> Behavioral studies in animals also suggest that 7-OH is a rewarding, habit-forming substance liable for abuse, similar to other opioids.<sup>4,6,7</sup> Given this pharmacological profile and potential for abuse, 7-OH has been declared a dangerous substance by the FDA. Proponents of 7-OH, however, argue that it can be a helpful harm-reduction substance because 7-OH's mechanism of action is less likely to cause respiratory depression than substances like fentanyl.<sup>4,11</sup>

7-OH itself can be converted into even more potent molecules like mitragynine pseudoinoxyl, a comparatively higher-affinity, higher-potency  $\mu$ -opioid receptor agonist,<sup>3</sup> or molecules developed by medicinal chemistry programs even more effective than 7-OH and morphine.<sup>12</sup> The most potent of these, MGM-16, is currently prohibitively expensive to synthesize, but MGM-15 has begun to emerge onto consumer markets, marketed alongside 7-OH as a kratom derivative.<sup>13-15</sup> Although animal studies of some of these molecules suggest potentially fewer side effects and lower addictive potential,<sup>3,12</sup> very little is currently known about the health effects of these molecules in humans.

### **Data on adverse events and fatalities**

Kratom use is rising in the U.S., especially among those who are seeking to self-medicate for chronic pain, mental health conditions, or opioid withdrawal.<sup>16-18</sup> Social media analyses from the National Drug Early Warning System identify increasing kratom and 7-OH product discussion, rising steadily from June 2024 to May 2025. As kratom products increase in popularity, so do reports of adverse events. National Poison Control data from 2010 to 2019 indicate sharp increases in kratom exposures, but the specific alkaloid profiles of the kratom products are often not reported.<sup>19-21</sup> An analysis of 935 single-substance kratom exposure cases reported between 2011 and 2018 found that most exposures occurred via oral ingestion—typically as tablets, capsules, or powder—with the most frequently reported adverse effects including agitation, rapid heartbeat, drowsiness, and vomiting. Although rare, severe adverse effects included seizures, withdrawal, hallucinations, respiratory depression, coma, and cardiac or respiratory arrest.<sup>21</sup> Older adults also saw sharp increases in exposure after 2016, with a higher proportion experiencing adverse effects than younger adults; more than two-thirds of the exposures reported to poison control among older adults required significant medical intervention.<sup>20</sup>

Although naturally present at nearly undetectable concentrations in kratom leaves, processing and isolation of 7-OH from kratom allows for even more potent products in the kratom market, often in the forms of chewable or dissolvable tablets, shots, gummies, drink mixes, vape pens, capsules, or syrups. Dissolvable or intranasal formats can increase absorption and circulation in the body, further complicating dosing for consumers.<sup>15,22</sup> An analysis of 53 human exposures to

7-OH in the National Poison Data System from February to April 2025 highlights that the majority of cases (37) were single-substance exposures. Of the single-substance exposures, 35% resulted in “moderate clinical outcomes,” a designation used by poison control centers that indicates pronounced, prolonged, or systemic issues that require treatment but are not life-threatening (i.e., acid-base disturbances, disorientation, isolated and brief seizures, treatable blood pressure changes, or acute liver injury). Notably, five of the single-substance exposure cases were children under 18 years of age.<sup>7</sup>

Reports of deaths resulting from kratom are rare, given that kratom alkaloids are not commonly screened for in toxicology panels, but seem to be rising. An international study of 156 deaths involving kratom revealed the vast majority of these deaths occurred in young white males with a history of drug use. Kratom was the sole substance implicated in 27 of these cases, with cause of death most often related to pulmonary or cerebral edema or cardiovascular complications. Polysubstance cases involving kratom were more common, particularly in combination with other opioids, benzodiazepines, and recreational stimulants.<sup>18</sup> A Centers for Disease Control and Prevention (CDC) report on overdose deaths from 2016–2017 identified kratom in 0.56% of deaths (152 total). Nearly 60% of these deaths were determined to be caused by kratom, including seven for which kratom was the only substance detected in postmortem toxicology reports.<sup>23</sup> Between 2023 and 2025, the Drug Enforcement Administration’s (DEA) Toxicology Testing program database identified a threefold increase in fatalities involving kratom or kratom derivatives compared to the three years prior.<sup>7</sup> In California, Los Angeles County identified six deaths attributable to 7-OH in 2025, often in conjunction with alcohol use, in otherwise healthy young adults.<sup>24</sup>

### **Federal and state regulatory status of kratom and 7-OH**

In 2016, the DEA published a notice of intent to temporarily place mitragynine and 7-OH into Schedule I of the Controlled Substances Act, alongside other substances with no accepted medical use and a high potential for abuse. This effort was withdrawn after the DEA received numerous public comments and a bipartisan Congressional letter that expressed concerns about overly hasty regulation.

According to the FDA, kratom is not lawfully marketed in the U.S. as a drug product, dietary supplement, or food additive in conventional food. No prescription or over-the-counter products containing kratom or its alkaloids are legally available on the U.S. market. The FDA considers kratom a “new dietary ingredient” because it was not marketed as a dietary ingredient in the U.S. prior to October 15, 1994. Because new dietary ingredients require evidence of safety before marketing, any products labeled as dietary supplements that contain kratom are not permitted. Accordingly, the FDA has issued import alerts for kratom and has seized kratom products marketed as dietary supplements.<sup>25,26</sup>

More recently, the FDA appears to have directed its enforcement efforts towards products supplemented with 7-OH. In 2025, the agency published a technical report on 7-OH, issued consumer warnings, sent warning letters to retailers, and conducted seizures of 7-OH-containing products. Last summer, the FDA formally recommended that the DEA move 7-OH to Schedule I,

with FDA Commissioner Dr. Marty Makary stating, “we’re not targeting the kratom leaf or ground up kratom, we are targeting the concentrated synthetic byproduct.”

### **Review of state laws on kratom across the nation**

According to a Legislative Analysis and Public Policy Association report, as of January 2026, 30 states and the District of Columbia regulate kratom or its components in some manner. In six states (Alabama, Arkansas, Indiana, Louisiana, Vermont, and Wisconsin), both mitragynine and 7-OH are controlled substances, effectively banning all kratom products. Connecticut is currently in the rulemaking process to also schedule both mitragynine and 7-OH. The remaining 23 states and the District of Columbia regulate the possession, sale, or manufacture of kratom products. Within these states, most restrict kratom sales to adults 21 years of age or older, although seven states restrict kratom sales to those over 18. The legality of 7-OH also varies in these states: while Ohio and Florida have scheduled 7-OH as a controlled substance, eleven states have banned the sale of products containing 7-OH at greater than 1%-2% of the product’s alkaloid content (Arizona, Colorado, Georgia, Kentucky, Maryland, Mississippi, Oklahoma, Rhode Island, South Dakota, Texas, and Utah) or which contain synthetic 7-OH (Nebraska, Tennessee, and South Carolina). Twenty states, including California, do not have laws regulating kratom.

### **Status of kratom regulation in California**

While there is no specific California statute on kratom, the Sherman Food, Drug, and Cosmetic Law (Sherman Law) regulates the manufacturing, processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration and enforcement of CDPH in accordance with the Federal Food, Drug, and Cosmetic Act. Given the FDA’s determination that kratom is not approved as a dietary ingredient, dietary supplement, or drug, the Sherman Law treats kratom-containing products as adulterated ingredients or supplements illegal to sell for consumption. In January, CDPH issued a memo to licensed tobacco retailers regarding a “Prohibition on the Sale of Kratom and 7-OH Products,” stating that the retail and online sale of kratom and 7-OH is illegal under HSC §110555 (adulterated food). This letter does not make a distinction between leaf kratom and 7-OH containing products.

CDPH’s Center for Environmental Health is responsible for enforcing the Sherman Law, including product testing and seizure, along with certain counties with delegated enforcement authority (Los Angeles, Orange, and San Bernardino). Additionally, the California Retail Food Code provides counties and other local environmental health departments with authority to enforce food laws, including preventing the sale of adulterated food. However, the Retail Food Code only applies to retail food facilities, leaving most local public health agencies without the authority to enforce prohibitions on the sale of specific ingredients at gas stations and other locations.

To address this limited enforcement capacity based on state law, several counties and cities have enacted local ordinances to regulate or prohibit the sale of kratom and 7-OH. Riverside County, Fresno County, and Orange County prohibit the sale and distribution of kratom products to those under 21, and additionally prohibit products that contain more than 2% 7-OH. The cities of Oceanside and Jurupa Valley prohibit the sale, distribution, and possession of all kratom products, and Newport Beach prohibits the sale and distribution of kratom leaf and synthetic

alkaloid products. The City of San Diego defines mitragynine and 7-OH as novel psychoactive drugs and has prohibited the sale, distribution, or possession of these products. A number of cities have indicated they are considering kratom regulation in some form.

### **Labeling and consumer safety concerns**

Due to the fact that the FDA does not recognize kratom products as drugs, supplements, or dietary ingredients, no specific testing or labeling is required, meaning that consumers may not be aware of the specific alkaloid blends or dosages contained in a given product. One study of 7-OH supplemented products found that 92% were advertised as kratom, potentially misleading consumers about the potency of the product, especially when combined with advertising that spotlighted general wellness claims rather than drug claims.<sup>22</sup> Another market analysis revealed that fewer than half of mitragynine pseudoindoxyl-containing kratom product descriptions mentioned an increased risk of intoxication, tolerance, dependence, withdrawal, or addiction.<sup>27</sup> A conflation of products containing kratom alkaloid extracts with botanical kratom has been highlighted as a safety concern by the FDA, and the agency has begun issuing warning letters to online retailers who sell 7-OH-supplemented products.

The FDA's recent enforcement actions against the marketing of 7-OH products may be contributing to a lack of clarity about the safety and intended use of various kratom preparations. Some online retailers of kratom products tout that their products are "not for human or animal consumption," while simultaneously being advertised as being "food-grade,"<sup>28</sup> providing mixed messages about how these products are meant to be used. Finally, the formats of some of these products (flavored syrups or shots, gummies, vape pens) are likely appealing to children. A market analysis of products containing mitragynine pseudoindoxyl found that 69% used child-appealing flavors or scents and 63% used bright colors in packaging or labeling.<sup>27</sup>

### **Legislative history**

AB 2365 (Haney of 2023) would have added kratom products to the Sherman Food, Drug, and Cosmetic Law. Kratom processors would be required to register their products with CDPH annually and would establish a fee that would be used to prescribe specified quantities of alkaloids and establish labeling and packaging requirements and annual laboratory certification of products. It would also prohibit the sale of kratom leaf or kratom-containing products to those under 21 years of age and in inhalable forms or forms attractive to children. AB 2365 was held in the Assembly.

SB 758 (Umberg of 2026), as amended on January 5, 2026, among other provisions, would have added products containing 7-OH, except as it naturally occurs in kratom, to Schedule I, making the sale or distribution of these products a misdemeanor. The 7-OH section was amended out of SB 758.

AB 1088 (Bains of 2025) requires persons to be 21 years of age to purchase a kratom product and prohibits selling a kratom product that is attractive to children. AB 1088 also prohibits the selling of products with a level of 7-OH that is greater than 2% of the total kratom alkaloids in the product. AB 1088 is pending in the Senate Health Committee.

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