WHAT IS KRATOM?

Kratom is an herb that is derived from a leafy Southeast Asian tree, known formally as *Mitragyna speciosa*. The tree is native to a number of countries, including Indonesia, Malaysia, and Thailand and is a member of the coffee family. Kratom contains two psychoactive compounds, mitragynine and 7-hydroxymitragynine; both compounds bind to μ-opioid receptors in the brain and produce a pharmacological response that is similar to those produced by other μ-opioid agonists, such as morphine.

Historically, individuals began ingesting kratom in the 19th century. Farmers in Southeast Asia traditionally used kratom to boost their productivity and as a substitute for opium. When consumed in small doses, kratom produces a mild stimulant effect; in moderate to high amounts, kratom produces opioid like effects. At very high doses it acts like a sedative.

THE USE OF KRATOM IN AMERICA

Soldiers returning from the Vietnam war and immigrants from Southeast Asia introduced kratom to America. However, it was not until the past 15 years that kratom use started to become more mainstream. An estimated 11 to 15 million Americans consume kratom products regularly. In the U.S., kratom can be purchased online and in head shops, gas stations, and corner stores. Kratom is relatively inexpensive, selling for nine to 20 dollars per ounce on the internet. The kratom industry generated $1.3 billion in sales in 2019.

Typically sold as a bitter powder, individuals consume kratom by swallowing capsules or using the powder to make tea. In a survey of 2,798 kratom users conducted by researchers at Johns Hopkins University School of Medicine, individuals cited pain relief, treating anxiety and depression, and managing opioid dependance as reasons for using kratom. Of those who use kratom to manage opioid dependence, 87 percent reported relief from opioid withdrawal symptoms. As kratom’s use rose in the U.S., so did calls to poison control centers about kratom exposures. In 2011, poison control received 13 calls nationwide related to kratom exposure; in 2017, the number of calls skyrocketed to 682. With respect to adult kratom exposure cases occurring between 2011 to 2017, 32 percent of cases resulted in an admission to a healthcare facility, and 52 percent of cases resulted in a serious medical outcome, such as seizure, respiratory distress, or slow heartrate.

KRATOM REGULATION AT THE FEDERAL AND STATE LEVELS

Despite kratom’s mainstream presence for a relatively short period in the U.S., its use has managed to cause much controversy. Federal regulators and kratom organizations are at odds about the potential dangers (or lack thereof)
of kratom and how kratom should be regulated. In addition to battles on the federal level, several states banned, or considered banning, kratom products.

The federal government’s positions and actions toward kratom

In 2009, nine people died in Sweden over the course of a 12-month period after consuming a kratom product known as “Krypton.”7 Subsequent testing showed that the kratom product at issue contained a toxic level of the opioid tramadol.8 With the deaths in Sweden and the increase in kratom consumption in the U.S., the U.S. Food and Drug Administration (FDA) became concerned about the use of kratom due to the FDA’s limited knowledge about kratom’s safety and effect on consumers. In 2012, the FDA identified kratom on an “import alert” for unapproved drugs, which it subsequently affirmed by another import alert in 2014.9 As a result of these alerts, the FDA seized more than 25,000 pounds of raw kratom, worth more than $5 million, in California during September 2014.10 In January 2016, the FDA seized approximately 90,000 bottles of dietary supplements containing kratom in Illinois, and in August 2016, the FDA seized more than 100 cases of kratom products worth more than $150,000 in California.11 Most recently, in May 2021, U.S. Marshals, at the FDA’s request, seized more than 207,000 units of dietary supplements containing kratom valued at approximately $1.3 million.12

On August 31, 2016, the U.S. Drug Enforcement Agency (DEA), published a notice of intent to list kratom’s two psychoactive compounds, mitragynine and 7-hydroxymitragynine, as Schedule I controlled substances under the emergency scheduling provisions of the Controlled Substances Act.13 The kratom community was outraged by this decision. In September 2016, kratom organizations organized the “March for Kratom” at the White House and convinced 51 members of Congress on both sides of the aisle to sign a letter against the DEA’s proposal.14 Additionally, kratom supporters sent a petition containing more than 145,000 signatures to President Obama against the DEA’s proposal.15 As a result of the backlash, the DEA withdrew the scheduling notice on October 13, 2016, and instead, opened a public comment period to solicit comments regarding the scheduling of mitragynine and 7-hydroxymitragynine. It stated that it would receive a scientific and medical evaluation and scheduling recommendation from the FDA.16 Interested parties submitted over 23,000 comments, with 99.1 percent of them opposing the ban.17

In October 2017, the FDA renewed its interest in scheduling kratom’s two psychoactive compounds and submitted an “eight-factor” analysis to the DEA.18 A month later, the FDA announced a public health advisory on kratom, asserting that kratom was associated with 36 deaths and has similar effects and dangers to other opioids.19

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8 Id.
10 Id.
11 Id.
On February 6, 2018, the FDA issued a statement increasing the number of kratom-associated deaths to 44. The FDA also announced through this statement that it developed a new technology, called the Public Health Assessment via Structural Evaluation (PHASE) model, that could “simulate, using 3-D computer technology, how the chemical constituents of a substance are structured at a molecular level, how they may behave inside the body, and how they can potentially affect the brain.” Based on the data obtained from the PHASE model, the FDA stated “[it felt] confident in calling [the] compounds found in kratom, opioids.”

In July 2018, the FDA concluded that numerous kratom products contained extremely high amounts of salmonella. According to the FDA, as of the end of May 2018, 199 cases of salmonellosis in 41 states were associated with kratom consumption. Due to the outbreak, multiple kratom products were voluntarily recalled, but the FDA issued a mandatory recall order against one kratom supplier who failed to cooperate with the voluntary recall. The trouble with kratom products continued in April 2019, when the FDA discovered 30 different kratom products that contained nickel and lead in amounts exceeding the safe exposure limit for oral daily drug intake. In June 2019, the FDA issued warning letters to two kratom marketers and distributors, Cali Botanicals and Kratom NC, “for illegally selling unapproved, misbranded kratom-containing drug products with unproven claims about their ability to treat or cure opioid addiction and withdrawal symptoms.” These companies also made claims “that kratom can protect you against cancer,” and that it can treat, among other disorders, migraines, ADHD/ADD, depression, and arthritis. In July 2022, the FDA, jointly with the Federal Trade Commission, issued similar warning letters to four companies selling unapproved kratom products for the treatment or cure of opioid use disorder and withdrawal symptoms.

The World Health Organization’s position on kratom

In July 2021, the World Health Organization (WHO) announced that it would conduct a pre-review of kratom while at its annual Expert Committee on Drug Dependence (ECDD) meeting. The ECDD is an independent, international group of 12 experts in the field of drugs and medicines tasked with reviewing the public health impact of psychoactive substances and making recommendations to the international community. The ECDD

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21 Id.
22 Id.
24 Id.
25 Id.
28 Id.
conducts a pre-review of a substance to determine whether current information justifies a critical review by the committee. A pre-review is only a preliminary analysis of a substance, and the findings do not determine whether the substance under review should be scheduled.

On July 23, 2021, the FDA put out a request for comments on the “abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use” of kratom and the other six substances set to be reviewed during the ECDD’s October 2021 meeting. The FDA planned to consider the comments in preparing a response from the U.S. to the WHO regarding the misuse and diversion potential of the substances up for review. The WHO then used the information provided by the U.S., as well as information from other countries, when considering whether to recommend a substance be subject to international restrictions. In addition to the public comments requested by the FDA, Senator Mike Lee (R-UT) and Representative Mark Pocan (D-WI) sent a letter to the Secretary of the U.S. Department of Health and Human Services and the U.S. Ambassador to the United Nations asking that the U.S. oppose any effort to add kratom to the list of internationally controlled substances. The letter stated that there is no conclusive evidence that would warrant the U.S. voting in favor of international scheduling of kratom and that more research is needed to better understand kratom’s safety profile.

In December 2021, the ECDD released a summary of its assessments, findings, and recommendations from the October 2021 meeting. In an 11-1 decision, the committee determined that there is insufficient evidence to recommend a critical review of kratom. The committee recommended that kratom instead continue to be under surveillance by the WHO Secretariat, which it has been since 2020.

**The American Kratom Association’s positions**

Established in 2014, the American Kratom Association (AKA) is a Virginia-based non-profit corporation that advocates on behalf of American kratom users. The AKA opposes the attempts by the FDA and the DEA to schedule kratom and strongly disagrees with the FDA’s assertions that kratom is a dangerous substance with a high potential for abuse. As opposed to opioids, the AKA asserts that the pattern of use and the abuse potential for kratom is similar to unscheduled substances, like caffeine. Additionally, the AKA claims that no fatal overdoses are associated with pure kratom. The organization alleges that none of the 44 deaths reported by the FDA

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32 44th Expert Committee on Drug Dependence: Substances for review, last accessed August 17, 2022, https://cdn.who.int/media/docs/default-source/2021-dha-docs/v2.annex1_final_44th-ecdd-list-of-substances.pdf?sfvrsn=83978385_1&download=true;--text=The%20purpose%20of%20a%20pre%20substance%20should%20change.
33 Id.
35 Id.
36 Id.
38 Id.
40 Id.
41 Id.
43 Id. at 583.
display any cause that is consistent among all the cases or that can be specifically linked to the use of kratom.\textsuperscript{44} Moreover, the AKA argues that the FDA did not take into consideration polydrug use, adulterated kratom, or underlying physical or mental health issues when determining whether the primary cause of death was due to kratom.\textsuperscript{45}

It is important to note that despite the AKA’s disagreements with the FDA, the AKA is not opposed to the regulation of kratom; rather, it is opposed to the FDA’s current suggestions. One of the AKA’s stated missions is to protect consumers from adulterated kratom products. With this mission in mind, the AKA supports FDA regulations that would ensure the safety and purity of kratom products and is open to the FDA development of labeling guidelines for kratom. Additionally, the AKA supports minimum age of procurement laws for kratom products and child resistant packaging.

With kratom currently largely unregulated, the AKA developed a good manufacturing practices (GMP) program to increase the safety of kratom products. In order for a manufacturer of kratom products to qualify for the program, and thus be listed as such on the AKA website, the manufacturer must commit to following strict manufacturing and processing requirements and be verified by a pre-approved, independent auditor. If the manufacturer qualifies for the GMP program, then they must also complete annual independent audits to remain in the program. The AKA’s GMP program also requires an initial program registration fee and an annual re-certification fee. The factors on which the AKA focuses when determining whether to accept a manufacturer into the GMP program include the presence of standard operating procedures; proper recordkeeping; an adverse event reporting system; truthful marketing practices; and the implementation of a compliance program. As of August 2022, there are 43 AKA GMP qualified vendors.\textsuperscript{46} In addition to the GMP program, the AKA supports a truth in labeling compliance program. This program is a form of self-regulation that encourages kratom consumers to report potential kratom product marketing violations to the AKA. The AKA will then submit these reports to the FDA, so that the FDA can investigate, and if necessary, take action against kratom vendors “who use impermissible health claims to mislead consumers about the actual benefits of using [an] otherwise safe food product.”

\textbf{Kratom laws on the state and local levels}

In addition to federal regulatory battles, some state and local governments have implemented regulatory controls on kratom. In six states (Alabama,\textsuperscript{47} Arkansas,\textsuperscript{48} Indiana,\textsuperscript{49} Rhode Island,\textsuperscript{50} Vermont,\textsuperscript{51} and Wisconsin\textsuperscript{52}) and the District of Columbia,\textsuperscript{53} kratom’s psychoactive components are controlled substances.\textsuperscript{54} A handful of cities and counties also ban kratom, including: San Diego, California; Sarasota County, Florida; and Denver, Colorado.\textsuperscript{55} To encourage states to stop short of enacting a total ban, the AKA developed model state legislation under which a dealer of kratom products may not legally prepare, distribute, or sell a kratom product that is adulterated or

\begin{itemize}
\item \textsuperscript{44} Jane Babin, “FDA Fails to Follow the Sciences on Kratom,” \textit{American Kratom Association}, August 2018, 13, \url{https://docs.wixstatic.com/ugd/9ba5da_54f08e1805c34c108ad7199481507d88.pdf}.
\item \textsuperscript{45} Id.
\item \textsuperscript{46} “AKA’s GMP Qualified Vendors,” \textit{American Kratom Association}, last accessed August 18, 2022, \url{https://www.americkratom.org/gmp-qualified-vendors}.
\item \textsuperscript{47} \textit{ALA. CODE} § 20-2-23 (West 2022).
\item \textsuperscript{48} \textit{ARK. ADMIN. CODE} § 007.07.2 (West 2021).
\item \textsuperscript{49} \textit{IND. CODE. ANN.} § 35-48-2-4 (West 2022) (mitragynine and 7-hydroxymitragynine are included in the definition of “synthetic drug.” (Ind. Code Ann. § 35-31.5-2-321 (West 2022). All synthetic drugs are Schedule I controlled substances).
\item \textsuperscript{50} Rhode Island Dept. of Health, Notice of Designation of Controlled Substance (May 31, 2017), \url{https://docs.wixstatic.com/ugd/9ba5da_9836aee2b9f04a30b55fe480fe3c6f4.pdf}.
\item \textsuperscript{51} \textit{12-VT. CODE R.} § 23:7.0 (West 2022).
\item \textsuperscript{52} \textit{WIS. STAT. ANN.} § 961.14 (West 2022).
\item \textsuperscript{53} The legal status of kratom in the District of Columbia (D.C.) appears unclear. Please see LAPPAs’s Kratom: Summary of State Laws, available \url{here}, for more information.
\item \textsuperscript{54} In Vermont, kratom’s components are “regulated drugs,” making them generally illegal except as specifically allowed.
\item \textsuperscript{55} For more information on the legality of kratom in states and local jurisdictions, please refer to LAPPAs’s 50-state review of kratom laws, available at \url{https://legislativeanalysis.org/kratom-summary-of-state-laws/}.
\end{itemize}
contaminated with a dangerous non-kratom substance. Additionally, kratom products may not be legally sold without labels containing the amount of mitragynine and 7-hydroxymitragynine contained in the product. The model law also bans the sale of kratom products to individuals under the age of 18 and proposes that violations of the above provisions would result in a misdemeanor.

Several state laws contain similarities to the AKA’s model law. In 12 states, the possession, sale, manufacture, and distribution of kratom products is regulated. Of these 12 states, seven of them (Arizona, Colorado, Georgia, Nevada, Oklahoma, Tennessee, and Utah) also have requirements for kratom product labels, such as requiring a list of the product’s ingredients and stating the amount of mitragynine and 7-hydroxymitragynine contained in the product. In the other five states (Illinois, Louisiana, Minnesota, Oregon, and South Dakota), there are no product labeling requirements. In all 12 states where the possession, distribution, sale, or manufacture of kratom products is regulated, the regulation contains age restrictions. In eight states (Arizona, Georgia, Illinois, Louisiana, Minnesota, Nevada, Oklahoma, and Utah), kratom products are restricted to individuals over the age of 18. In the other four states (Colorado, Oregon, South Dakota, and Tennessee), the age restriction is age 21 and older. See the map below for a visual representation of state laws.

During 2021 and 2022, 28 states introduced legislation related to kratom. Of those 28 states, 21 states introduced legislation to regulate the possession, distribution, sale, or manufacture of kratom products in some fashion. Two states (Louisiana and West Virginia) introduced legislation to make kratom’s components Schedule I controlled substances. Five states (Kentucky, Mississippi, New Jersey, Pennsylvania, and Washington) introduced dueling pieces of legislation—that is, state legislators introduced at least one bill to make kratom components Schedule I controlled substances and at least one bill to regulate the possession, distribution, sale, or manufacture of kratom products. The conflictive nature of the proposed legislation underscores the controversies involving kratom and differing perspectives of its use and safety.

CONCLUSION

The differing perspectives on the efficacy and safety of kratom use has resulted in a complex regulatory landscape. While federal agencies and kratom consumer advocacy groups continue to argue over the best way to regulate kratom and protect public health, states and local governments have begun to regulate kratom in some fashion. As the popularity of kratom products increases, states continue to introduce kratom related legislation ranging from making kratom a controlled substance to establishing labeling requirements for kratom manufacturers and distributors. The controversies around kratom will likely continue until scientists can provide consumers and policymakers with more information about kratom’s pharmacological effects.
RESOURCES


ABOUT LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces timely model laws and policies that can be used by national, state, and local public health, public safety, and substance use disorder practitioners who want the latest comprehensive information on law and policy as well as up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to fact sheets. Examples of topics on which LAPPA has assisted stakeholders include law enforcement/community engagement, naloxone laws, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

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