Regulation of Kratom in America

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 of these compounds have the ability to bind to μ-opioid receptors and produce a pharmacological response that is similar to those produced by other μ-opioid agonists, such as morphine.

Historically, kratom has been ingested since the 19th century. Farmers in Southeast Asia traditionally used kratom to boost their productivity and as a substitute for opium. When kratom is consumed in small doses it produces a mild stimulant effect; in moderate to high amounts, kratom produces opioid like effects, and at very high doses it produces a sedative effect.

The Use of Kratom in America

Kratom was first introduced in America after the Vietnam War by returning soldiers and those immigrating from Southeast Asia. However, it was not until this past decade that kratom use started to become mainstream. Currently, an estimated 5 million people in the United States use kratom. In the U.S., kratom is available for purchase online and in head shops, vaping establishments, gas stations, and corner stores. Kratom is relatively inexpensive, selling for nine to twenty dollars per ounce on the Internet. According to the Botanical Education Alliance, the kratom industry is worth $1.13 billion.

Typically sold as a bitter powder, kratom can be consumed by swallowing capsules or using the powder to make tea. Users claim that kratom eases the symptoms of opioid withdrawal as well as treats pain, increases energy, decreases anxiety, and enhances mood. Adult men are the most common users of kratom and the average user age is 31. As kratom use rose in the U.S., however, so did calls to poison control centers about kratom exposure. 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 great controversy. Federal regulators and kratom organizations are at odds about the potential dangers (or lack thereof) of kratom use and how kratom should be regulated. In addition to battles on the federal level, several states have banned, or are considering banning, kratom products.

Attempts at regulating kratom in the U.S.

In the mid-1990s, when smoke shops first began stocking kratom products, some store operators attempted to boost sales of kratom by adulterating the products with other drugs, like heroin and morphine. Eventually, the adverse events caused by adulterated kratom products prompted the U.S. Drug Enforcement Administration (DEA) to issue a product warning in 2005. In 2009, nine people died in Sweden over the course of a 12-month period after consuming a kratom product known as "Krypton." Subsequent testing showed that the Krypton at issue contained a toxic level of the opioid tramadol. The U.S. Food and Drug Administration (FDA) issued an import alert on kratom in 2012, which was additionally affirmed by import alerts in 2014 and 2016. As a result of these import alerts, the FDA seized more than 25,000 pounds of raw kratom, worth more than $5 million, in California during September 2014. In January 2016, the FDA seized around 90,000 bottles of dietary supplements containing kratom in Illinois, and in August 2016, the FDA seized more than 100 cases of products containing kratom in California.

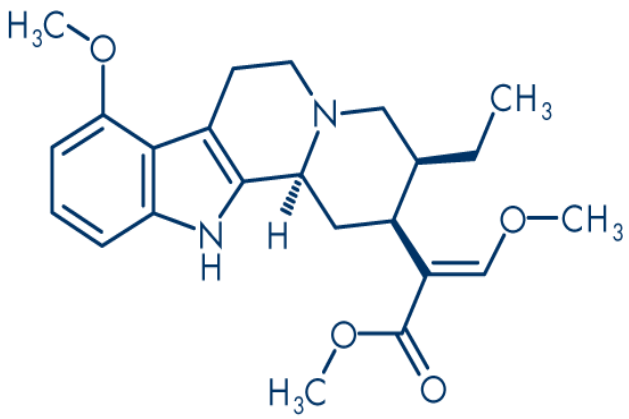
The DEA, on August 31, 2016, published a notice of intent to list kratom's two psychoactive compounds, mitragynine and 7-hydroxymitragynine, as Schedule I substances under the emergency scheduling provisions of the Controlled Substances Act. This decision outraged the kratom community. In September 2016, kratom organizations organized the "March for Kratom" at the White House and convinced more than 60 members of Congress on both sides of the aisle to sign a letter against the DEA's proposal.

As a result of the backlash, the DEA withdrew the scheduling notice on October 14, 2016, and instead, opened up a public comment period and directed the FDA to provide an "expedited 8-factor analysis" by December 1, 2016 to justify the scheduling of kratom. Over 23,000 comments were submitted and 99.1 percent of them opposed the ban. The FDA failed to submit the expedited 8-factor analysis to the DEA before the deadline, and the DEA, therefore, dropped the scheduling attempt.

The FDA's recent positions and actions toward kratom

In October 2017, the FDA renewed its interest in scheduling kratom's two psychoactive compounds and submitted an 8-factor analysis to the DEA. A month later, the FDA announced a public health advisory on kratom, asserting that kratom was associated with 36 deaths and has similar effects to and dangers of opioids. On February 6, 2018, the FDA issued a statement increasing the number of kratom-associated deaths to 44. The FDA statement noted 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 since February 2018, numerous kratom products contained extremely high amounts of salmonella, and 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 was forced to issue its first mandatory recall order against one kratom supplier who was uncooperative with the voluntary recall. The problems 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. Most recently, the FDA issued warning letters in June 2019 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 apparently also made claims "that kratom can protect you against cancer," and that it can treat, among other disorders, migraines, ADHD/ADD, depression, and arthritis.



The American Kratom Association's positions

Established in 2014, the American Kratom Association (AKA) is a Virginia-based nonprofit corporation that advocates on behalf of American kratom users. The AKA vehemently opposes any attempts 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 there have been no fatal overdoses associated with pure kratom. The organization alleges that none of the 44 deaths reported by the FDA display any cause that is consistent among all the cases or that can be specifically linked to the use of kratom. Moreover, 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.

Despite the AKA's disagreement 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 age restrictions on the procurement or the substance and child resistant packaging.

With kratom currently largely unregulated, the AKA developed a good manufacturing practices (GMP) standards 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 it must also complete independent audits annually to remain in the program.

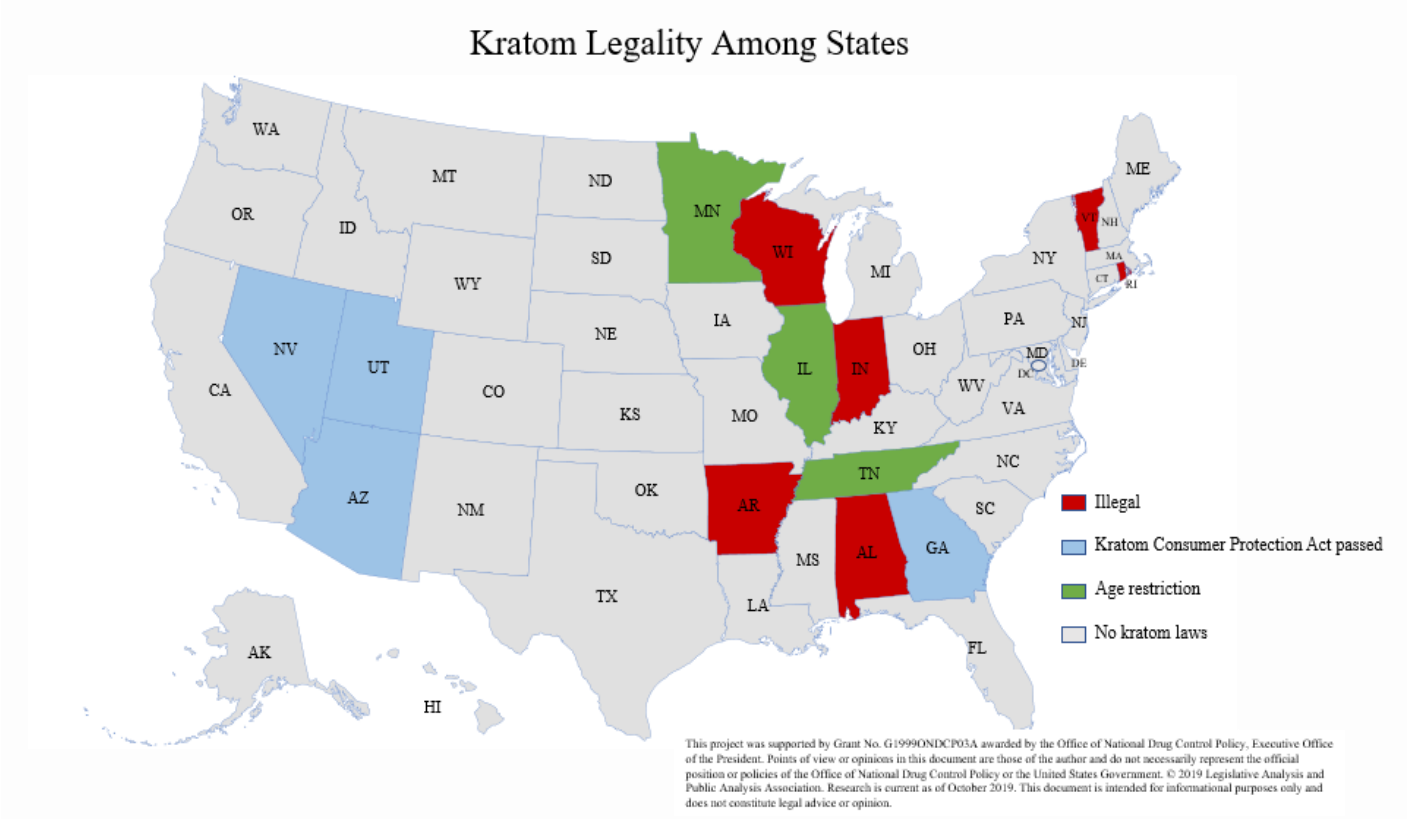
The AKA's GMP program also requires a $500 initial program registration fee and a $1,000 annual re-certification fee. In determining whether to accept a manufacturer into the GMP program, the AKA considers the presence of standard operating procedures; proper recordkeeping; an adverse event reporting system; truthful marketing practices; and the implementation of a compliance program. There are currently 12 AKA GMP qualified vendors and 16 vendors whose acceptance into the GMP program are pending.

Kratom laws on the state and local levels

Some state and local governments have implemented regulatory controls on kratom. Six states place kratom's psychoactive compounds in Schedule I of their respective controlled substance schedules, effectively banning the sale or possession of kratom: Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin. In Washington D.C., it appears that 7-hydroxymitragynine was temporarily placed in D.C.'s list of Schedule I drugs and then removed, although the regulatory text is less than clear. In addition to the six states noted above, a handful of cities and counties have banned the product, including: San Diego, California; Sarasota County, Florida; and Denver, Colorado.

In an attempt to encourage states to stop short of enacting a total ban, the AKA developed model state legislation, known as the Kratom Consumer Protection Act. Under the model, a dealer of kratom products may not legally prepare, distribute, or sell a kratom product that is adulterated or 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. It also bans the sale of kratom products to individuals under the age of 18. The model proposes that violations of the above provisions would result in "a misdemeanor punishable by imprisonment for not more than 90 days or a fine of not more than $500.00, or both."

Currently, four states have passed the Kratom Consumer Protection Act (or something similar to it), all in 2019: Arizona, Georgia, Nevada, and Utah. There are also three states who have not passed the Kratom Consumer Protection Act but have established age restrictions for kratom products: Tennessee (21), Minnesota (18), and Illinois (18). According to its website, the AKA continues to lobby for the passage of the Kratom Consumer Protection Act in other states, including states where the use of kratom is illegal.



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Resources

1) Laurie McGinley and Katie Zezima, "Kratom is hailed as a natural pain remedy, assailed as an addictive killer. The U.S. wants to treat it like heroin," *Washington Post*, February 10, 2018

2) Ike Swetlitz, "HHS recommended that DEA make kratom a Schedule I drug, like LSD or heroin," *Stat*, November 9, 2018

3) Jacqueline Stenson, "What is kratom? The popular herbal supplement has caught flak from the FDA," *NBC News*, October 16, 2019

4) Joey Garrison, "Poison reports related to herbal drug kratom soar, new study says," *USA Today*, February 24, 2019

5) "Kratom Fact Sheet," *American Kratom Association*, January 2019

6) Megan Jula, "Kratom users say it's a miracle drug. The feds say it's dangerous.," *Mother Jones*, May 30, 2018

7) "FDA and Kratom," *Food and Drug Administration*, last modified September 11, 2019

8) Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom," *Food and Drug Administration*, November 14, 2017

9) Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse," *Food and Drug Administration*, February 6

10) "Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner for Foods and Veterinary Medicine Stephen Ostroff, M.D., on the ongoing risk of salmonella in kratom products," *Food and Drug Administration*, July 2, 2018

11) "Laboratory analysis of kratom products for heavy metals," *Food and Drug Administration*, last modified April 3, 2019

12) "FDA issues warnings to companies selling illegal, unapproved kratom drug products marketed for opioid cessation, pain treatment and other medical uses," *Food and Drug Administration*, June 25, 2019

13) "Legal," *American Kratom Association*, accessed October 21, 2019

14) Jack E. Henningfield, Reginald V. Fant, Daniel W. Wang, "The abuse potential of kratom according the 8 factors of the controlled substances act: implications for regulation and research," *Psychopharmacology*, 235 (December 2017): 575

15) Jane Babin, "FDA Fails to Follow the Sciences on Kratom," *American Kratom Association*, August 2018, 13

16) "Statement of Principles," *American Kratom Association*, accessed on October 21, 2019

17) "AKA Good Manufacturing Practice (GMP) Standards Program," *American Kratom Association*, accessed October 21, 2019

18) "State-by-state Kratom Developments," *American Kratom Association*, accessed October 21, 2019

19) "Rhode Island Schedules Kratom," *Speciosa*, accessed October 21, 2019

20) "Is kratom legal where I live?," *Kraken Kratom*, January 15, 2019

21) "AKA Advocacy Toolkit," *American Kratom Association*, accessed October 21, 2019

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