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Bill No 1101 – Scheduling of Mitragynine (Kratom)

House Judiciary Committee – 327B
9:30 AM - Monday – January 13th, 2025

Chairman Klemin, Members of the House Judiciary Committee, for the record I am Mark J. Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy. I appreciate the opportunity to be here to speak to you today.

Simply, House Bill 1101 looks to schedule the substance mitragynine which is better known as Kratom. Kratom is a naturally occurring substance which is sold and marketed as a nutritional supplement. Our current understanding is that this is most commonly sold in the state online or through non-medical professional retail locations like smoke shops. Chemically, Kratom contains psychoactive compounds that bind the opioid receptors in the brain and produce pharmacologic effects similar to other opioids like morphine or oxycodone.

Scheduling the substance is controversial, as you are going to experience and learn. The Drug Enforcement Administration has attempted to schedule Kratom and its compounds. That action was pulled back under the Obama administration in 2016. States also have been active on this drug with many states making it a scheduled drug. I have included a fact sheet, which is a couple years old, but does illustrate the history and approaches from states.

The Board has been monitoring this substance and has received concerns from pharmacists and other health care professionals. The reports center on addressing patients that may have developed an addiction related to Kratom and the tremendous difficulty of treating those addictions. While we have strongly considered adding Kratom in our recommended Controlled Substance bill this session, we believe a separate bill is the best vehicle for making this change so legislators and public have a focused bill for consideration. We commend the bill sponsor and advocates to bring this forward to have a very important and likely contentious discussion.

Given the true public health threats of this substance and risks for abuse, the Board certainly would recommend the movement to make this opioid like substance, Kratom, a scheduled substance in the state of North Dakota.

I have attached some references that may be helpful to the committee. I respect the difficulty of this decision and I would be more than happy to assist or address any questions you may have.

Kratom

WHAT IS KRATOM?

Kratom is a tropical tree native to Southeast Asia. Consumption of its leaves produces both stimulant effects (in low doses) and sedative effects (in high doses), and can lead to psychotic symptoms, and psychological and physiological dependence. Kratom leaves contain two major psychoactive ingredients (mitragynine and 7-hydroxymytragynine). These leaves are crushed and then smoked, brewed with tea, or placed into gel capsules. Kratom has a long history of use in Southeast Asia, where it is commonly known as thang, kakuam, thom, ketum, and biak. In the U.S., the abuse of kratom has increased markedly in recent years.

Kratom tree

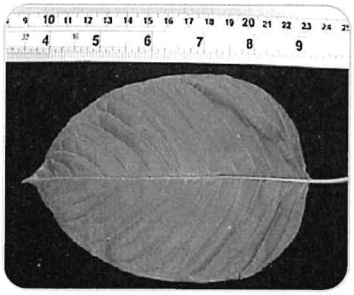
How is it abused?

Mostly abused by oral ingestion in the form of a tablet, capsule, or extract. Kratom leaves may also be dried or powdered and ingested as a tea, or the kratom leaf may be chewed.

What are the effects?

At low doses, kratom produces stimulant effects with users reporting increased alertness, physical energy, and talkativeness. At high doses, users experience sedative effects. Kratom consumption can lead to addiction.

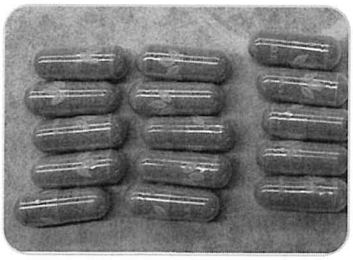
Several cases of psychosis resulting from use of kratom have been reported, where individuals addicted to kratom exhibited psychotic symptoms, including hallucinations, delusion, and confusion.



Leaf of kratom tree

What does it do to the body?

Kratom's effects on the body include nausea, itching, sweating, dry mouth, constipation, increased urination, tachycardia, vomiting, drowsiness, and loss of appetite. Users of kratom have also experienced anorexia, weight loss, insomnia, hepatotoxicity, seizure, and hallucinations.



Kratom capsules

What is its legal status?

Kratom is not controlled under the Controlled Substances Act; however, there may be some state regulations or prohibitions against the possession and use of kratom. The FDA has not approved Kratom for any medical use. In addition, DEA has listed kratom as a Drug and Chemical of Concern.

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Legal Sidebar

Kratom Regulation: Federal Status and State Approaches

November 28, 2023

Kratom, or *Mitragyna speciosa*, is a tree related to the coffee plant and is native to parts of Southeast Asia. Peoples indigenous to the tree's range have traditionally consumed the leaves of the tree for medicinal and other purposes. Users report both stimulant and sedative effects, believed to be caused by two compounds in the leaves, mitragynine and 7-hydroxymitragynine. Some commentators have raised safety concerns over kratom use, while others have suggested various beneficial uses. Additionally, some kratom products intended for sale in the United States have been found to contain dangerous contaminants, such as salmonella and heavy metals.

Kratom use in the United States has reportedly become more widespread in the past decade, and its regulatory status has been a matter of recent debate. This Sidebar begins by reviewing federal administrative actions relating to kratom before summarizing kratom-focused bills introduced in the current Congress. The Sidebar then describes the various approaches taken by 22 states that have regulated or banned kratom, which may be instructive as Congress considers action on kratom.

Executive Branch Actions

The Controlled Substances Act (CSA) creates the federal framework for regulating drugs and other substances deemed to pose a risk of abuse and dependence. The CSA divides controlled substances into five numbered lists, known as Schedules I-V, with Schedule I status imposing the most stringent restrictions. Congress may modify these schedules through legislation. Congress has also delegated authority to the Drug Enforcement Administration (DEA) to schedule, reschedule, or deschedule substances under the CSA through regulation.

In 2016, DEA published notice of its intent to place mitragynine and 7-hydroxymitragynine in Schedule I on an emergency basis, which would have criminalized possession of kratom and made distribution a felony. However, after receiving numerous comments from some Members of Congress, advocacy groups, and others, DEA withdrew that notice. DEA has listed kratom as a Drug and Chemical of Concern but to date has not exercised its authority to schedule kratom or its active compounds under the CSA.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, the Food and Drug Administration (FDA) may regulate drugs and dietary supplements sold in the United States. FDA has

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approved no drug products containing kratom, mitragynine, or 7-hydroxymitragynine. FDA has also taken the position that kratom is an unapproved new dietary ingredient and therefore may not be marketed in the United States as either a nutritional supplement or a food additive. FDA has issued a series of import alerts, most recently in July 2023, authorizing FDA personnel to seize imported kratom products from specified firms without physical inspection. FDA has also seized kratom products manufactured in the United States, including an April 2023 seizure of kratom products worth approximately $3 million from an Oklahoma company.

Congressional Proposals

In October 2023, Members introduced essentially identical bills in both the House and the Senate to "protect access to kratom." Members introduced similar bills in the House and the Senate in the 117th Congress. These bills would neither ban kratom nor impose new regulations on kratom. Instead, the bills would direct the Secretary of Health and Human Services (the Secretary) to gather information about kratom and would limit the Secretary's authority to impose regulations on kratom.

The bills would require the Secretary to hold at least one public hearing to discuss the safety of kratom products. That hearing would have to cover several specified topics, including any potential benefits of kratom usage and any adverse health impacts of a kratom ban. The bills would also require the Secretary to establish a task force to coordinate and report on federally funded kratom-related research. Before promulgating any new rule regulating kratom, the Secretary would have to follow procedures for formal rulemaking and to have public, in-person hearings.

The bills would prohibit the Secretary from:

- imposing requirements on kratom that are more restrictive than those for foods, dietary supplements, or dietary ingredients under the FD&C Act;
- requiring kratom to follow the notification requirements for new dietary ingredients;
- using certain specified grounds to treat kratom as an adulterated dietary supplement; or
- enforcing any import alert for kratom products absent evidence that the particular product is adulterated.

Each bill contains a nonpreemption provision, which would leave existing state laws—whether banning kratom or regulating it—in place.

State Regulation of Kratom

As Congress considers these bills or other action on kratom products, the experience of the states may be pertinent. States that have addressed the topic have taken two approaches: an outright ban on kratom or regulation of kratom sales or possession.

Kratom Bans

Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin currently ban mitragynine and hydroxymitragynine or 7-hydroxymitragynine (kratom's active alkaloids) under state-law analogues of the CSA. Legislators in Indiana, Rhode Island, Wisconsin, and Vermont have introduced bills to replace existing bans with regulations that would permit the sale of kratom products.

Tennessee enacted a ban on mitragynine and hydroxymitragynine in 2013. An opinion of the state's Office of the Attorney General, however, indicated that this ban extended only to synthetic versions of

those alkaloids, not to the kratom plant itself. Tennessee law, as amended, now regulates the sale of the kratom plant in its natural form but continues to ban synthetic kratom alkaloids.

Some local governments in other states have also adopted bans.

Kratom Regulations

As of the date of this Sidebar, sixteen states regulate the sale of kratom products in some fashion. Some states have adopted versions of a model law proposed by kratom advocacy groups, but these state laws are not uniform. Their differences arise in their handling of particular issues relating to kratom products, as described below.

Age restriction: Arizona, Georgia, Illinois, Minnesota, Nevada, Oklahoma, Texas, and Utah ban sales to persons under 18 years of age. Colorado, Florida, Louisiana, Oregon, South Dakota, Tennessee, Virginia, and West Virginia ban sales to persons under 21. Georgia, Illinois, Minnesota, South Dakota, Tennessee, and West Virginia also ban possession by underage persons. West Virginia imposes a separate requirement that websites and remote sellers employ an age-verification mechanism.

Marketing to children: Utah prohibits flavoring or packaging that appeals to children and requires child-safe packaging. West Virginia's recently adopted law requires the commissioner of agriculture to develop similar standards.

Adulteration and contamination: Arizona prohibits sale of a kratom product adulterated with a "nonkratom substance" that affects the quality or strength of the product "to such a degree as to render the kratom product injurious to a consumer." Nevada, Oklahoma, Texas, and Utah have similar prohibitions. Effective July 1, 2024, Colorado will prohibit sale of kratom products "adulterated with fentanyl" or other substances controlled under state law. Arizona, Oklahoma, Texas, and Utah separately prohibit sale of kratom products contaminated with dangerous or deleterious non-kratom substances.

Strength: Arizona, Oklahoma, Texas, and Utah prohibit sale of products in which 7-hydroxymitragynine is greater than 2% of the total alkaloid content.

Labeling: Nine of the sixteen states with laws regulating kratom sales require labels on kratom products, but the content required varies by state:

- **Directions for safe use:** Texas, Nevada, Georgia, and Oklahoma require that kratom products include labels with directions for safe or suggested use. Texas also requires a recommended serving size.
- **Warnings:** Utah and Virginia require that labels bear a warning that the product may be harmful; has not been evaluated by the FDA; and is not intended to diagnose, treat, cure, or prevent any disease. West Virginia requires the commissioner of agriculture to develop labeling standards, which must include warnings to keep the product out of reach of children and to consult a physician before use if pregnant or taking medication. Georgia and Oklahoma require a statement that sale or transfer to a person under 18 is prohibited, along with "[a]ny precautionary statements as to the safety and effectiveness" of the kratom product.
- **Manufacturer or distributor information:** Colorado (effective July 1, 2024), Georgia, and Oklahoma require that labels state the identity and address of the product's manufacturer or distributor.
- **Alkaloid content:** Arizona, Georgia, Oklahoma, and Utah require that labels state the amount of mitragynine and 7- hydroxymitragynine in the product.

- **Ingredients:** Colorado (effective July 1, 2024), Nevada, and Virginia require labels listing all ingredients. Georgia and Oklahoma require a list of ingredients that includes common names.
- **Factual basis:** Arizona and Utah require that labels indicate the "factual basis" underlying any representation that the product is a "kratom product," defined as a food or dietary ingredient containing part of the leaf of *Mitragyna speciosa*.

Testing and sampling: Oklahoma law requires kratom vendors to provide, upon request of the State Department of Health, test results from a "United States-based testing facility" confirming the items on the label. Oregon requires third-party testing for microbiological contaminants, pesticides, solvents, heavy metals, and mycotoxins. Utah requires a certificate of analysis from a certified third-party laboratory indicating the results of testing for alkaloid content and levels of pathogens and specified heavy metals. The state periodically tests kratom products to confirm those certificates of analysis and may test for pesticides, fentanyl derivatives, cannabinoids, cocaine, and benzodiazepines. West Virginia requires sampling and testing of kratom "to determine purity levels."

Registration and permitting: Oregon and Utah require kratom sellers to register with state agencies. West Virginia requires kratom sellers to obtain state permits.

Synthetic alkaloids: Colorado, Florida, Illinois, Louisiana, Minnesota, Nevada, and South Dakota apply their laws regulating kratom sales to both natural and synthetic products. Arizona, Texas, Oklahoma, and Utah use definitions of "*kratom*" that do not include synthetic kratom alkaloids, but each state prohibits the sale of any kratom product adulterated with synthetic compounds. Tennessee prohibits the sale of kratom except "in its natural form." Virginia's kratom law applies to "extracts" of *Mitragyna speciosa*.

Local authority: Colorado and Louisiana explicitly allow localities to adopt stricter controls on kratom or to ban kratom completely but do not allow localities to permit sales to persons under 21 years of age. Florida's kratom law does not address localities, but at least one county bans the sale of kratom as a "designer drug."

Private right of action: Oklahoma and Utah permit individuals harmed by violations of their kratom laws to bring private civil actions for damages.

Tax: West Virginia law provides for a tax on kratom, the proceeds of which are split among an agricultural fees fund, an alcohol beverage control enforcement fund, and a substance abuse fund.

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LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

LAPPA

REGULATION OF KRATOM IN AMERICA: UPDATE

SEPTEMBER 2022

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.[1] 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.[2]

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.[3] Of those who use kratom to manage opioid dependence, 87 percent reported relief from opioid withdrawal symptoms.[4] 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.[5] 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.[6]

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)

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[1] "Policy Brief: What is Kratom?," American Kratom Association, last modified January 2021, https://assets.website-files.com/61858fcec654303987617512/619ddeac793d144d09fbc28a_aka-policy-brief-1---what-is-kratom-jan-2021.pdf.

[2] Paul Georgia, "The Human and Economic Impacts of the Kratom Industry in the United States," American Kratom Association, last modified September 24, 2021, https://drive.google.com/file/d/1ChyAKfdOrWzckau9kKwWti1F47D0WjUO/view.

[3] Albert Garcia-Romeu, et al., "Kratom (*Mitragyna speciosa*): User Demographics, Use Patterns, and Implications for the Opioid Epidemic," *Drug and Alcohol Dependance* 208 (March 2020), https://doi.org/10.1016/j.drugalcdep.2020.107849.

[4] *Id.*

[5] Sara Post, et al., "Kratom Exposures Reported to United States Poison Control Centers: 2011-2017," *Clinical Toxicology* 57, no. 10 (February 2019): 847-854, https://doi.org/10.1080/15563650.2019.1569236.

[6] *Id.*

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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[7] "Swedish Docs Identify Deadly Legal Drug," *The Local*, December 29, 2010, https://www.thelocal.se/20101229/31134/.
[8] *Id.*
[9] "FDA and Kratom," U.S. Food and Drug Administration, last modified April 27, 2022, https://www.fda.gov/news-events/public-health-focus/fda-and-kratom.
[10] *Id.*
[11] *Id.*
[12] "FDA Announces Seizure of Adulterated Dietary Supplements Containing Kratom," U.S. Food and Drug Administration, last modified October 29, 2021, https://www.fda.gov/news-events/press-announcements/fda-announces-seizure-adulterated-dietary-supplements-containing-kratom.
[13] "DEA Announces Intent to Schedule Kratom," Drug Enforcement Administration, last modified August 20, 2016, https://www.dea.gov/press-releases/2016/08/30/dea-announces-intent-schedule-kratom.
[14] Steven Nelson, "Dozens of Congressmen Ask DEA Not to Ban Kratom Next Week," *U.S. News*, September 23, 2016, https://www.usnews.com/news/articles/2016-09-23/45-congressmen-ask-dea-not-to-ban-kratom-next-week.
[15] "Please do not make Kratom a Schedule I Substance," We the People, last accessed August 17, 2022, https://petitions.obamawhitehouse.archives.gov/petition/please-do-not-make-kratom-schedule-i-substance/.
[16] Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-hydroxymitragynine into Schedule I, 81 Fed. Reg. 70,652 (Oct. 13, 2016).
[17] " Review Of DEA Kratom Public Comments Shows Strong Support Among Vets, Doctors, Cops And Seniors For Coffee-Like Herb," *PR Newswire*, February 2, 2017, https://www.prnewswire.com/news-releases/review-of-dea-kratom-public-comments-shows-strong-support-among-vets-doctors-cops-and-seniors-for-coffee-like-herb-300401575.html.
[18] "Leading Scientists Strongly Reject FDA 8-Factor Analysis Of Kratom, Call Upon The DEA And NIDA To Reexamine FDA Claims," *PR Newswire*, November 28, 2018, https://www.prnewswire.com/news-releases/leading-scientists-strongly-reject-fda-8-factor-analysis-of-kratom-call-upon-the-dea-and-nida-to-reexamine-fda-claims-300757232.html. The eight factors to be considered in permanently scheduling a substance as controlled are identified in 21 U.S.C. § 811(c).
[19] "Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom," U.S. Food and Drug Administration, last modified April 5, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-advisory-about-deadly-risks-associated-kratom.

On February 6, 2018, the FDA issued a statement increasing the number of kratom-associated deaths to 44.[20] 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."[21] Based on the data obtained from the PHASE model, the FDA stated "[it felt] confident in calling [the] compounds found in kratom, opioids."[22]

In July 2018, the FDA concluded that numerous kratom products contained extremely high amounts of salmonella.[23] According to the FDA, as of the end of May 2018, 199 cases of salmonellosis in 41 states were associated with kratom consumption.[24] 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.[25] 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.[26] 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."[27] 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.[28] 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.[29]

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.[30] 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.[31] The ECDD

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[20] "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," U.S. Food and Drug Administration, last modified April 5, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-scientific-evidence-presence-opioid-compounds.
[21] *Id.*
[22] *Id.*
[23] "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," U.S. Food and Drug Administration, last modified July 2, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-fda-deputy-commissioner-foods-and-veterinary.
[24] *Id.*
[25] *Id.*
[26] "Laboratory analysis of kratom products for heavy metals," U.S. Food and Drug Administration, last modified April 3, 2019, https://www.fda.gov/news-events/public-health-focus/laboratory-analysis-kratom-products-heavy-metals.
[27] "FDA issues warnings to companies selling illegal, unapproved kratom drug products marketed for opioid cessation, pain treatment and other medical uses," U.S. Food and Drug Administration, last modified June 25, 2019, https://www.fda.gov/news-events/press-announcements/fda-issues-warnings-companies-selling-illegal-unapproved-kratom-drug-products-marketed-opioid.
[28] *Id.*
[29] "FDA Roundup: July 5, 2022," U.S. Food and Drug Administration, last modified July 5, 2022, https://www.fda.gov/news-events/press-announcements/fda-roundup-july-5-2022.
[30] "Five New Psychoactive Substances to be Considered for International Control by 44th ECDD Meeting," United Nations Office on Drugs and Crime, last accessed August 17, 2022, https://www.unodc.org/LSS/Announcement/Details/601d676a-ec14-48df-8333-f167d7997baf.
[31] "Expert Committee on Drug Dependence: About Us," World Health Organization, last accessed August 17, 2022, https://www.who.int/groups/who-expert-committee-on-drug-dependence/about.

conducts a pre-review of a substance to determine whether current information justifies a critical review by the committee.[32] 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.[33]

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.[34] 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.[35] 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.[36] 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.[37] 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.[38]

In December 2021, the ECDD released a summary of its assessments, findings, and recommendations from the October 2021 meeting.[39] In an 11-1 decision, the committee determined that there is insufficient evidence to recommend a critical review of kratom.[40] The committee recommended that kratom instead continue to be under surveillance by the WHO Secretariat, which it has been since 2020.[41]

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.[42] Additionally, the AKA claims that no fatal overdoses are associated with pure kratom.[43] The organization alleges that none of the 44 deaths reported by the FDA

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[32] 44th Expert Committee on Drug Dependance: 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,a%20substance%20should%20be%20changed.
[33] *Id.*
[34] International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; . . . Kratom (mitragynine, 7-hydroxymitragynine). . . Request for Comments, 86 Fed. Reg. 39,038 (July 23, 2021).
[35] *Id.*
[36] *Id.*
[37] Letter from Sen. Michael Lee and Rep. Mark Pocan, to Linda Thomas-Greenfield, U.S. Ambassador to the U.N., and Xavier Becerra, Sec'y of the Dep't of Health and Hum. Serv. (Oct. 19, 2021), available at https://s3.documentcloud.org/documents/21093913/lee-pocan-191021-kratom-letter-to-unhhs.pdf.
[38] *Id.*
[39] Expert Comm. on Drug Dependance, Summary of Assessments, Findings, and Recommendations of the 44th ECDD (2021), available at https://cdn.who.int/media/docs/default-source/controlled-substances/44ecdd_unsg_annex1.pdf.
[40] *Id.*
[41] *Id.*
[42] Jack E. Henningfield, et al., "The Abuse Potential of Kratom According the 8 Factors of the Controlled Substances Act: Implications for Regulation and Research," *Psychopharmacology* 235 (December 2017): 573-589, 575, https://doi.org/10.1007/s00213-017-4813-4.
[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.[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.[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.[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."

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,[47] Arkansas,[48] Indiana,[49] Rhode Island,[50] Vermont,[51] and Wisconsin[52]) and the District of Columbia,[53] kratom's psychoactive components are controlled substances.[54] A handful of cities and counties also ban kratom, including: San Diego, California; Sarasota County, Florida; and Denver, Colorado.[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

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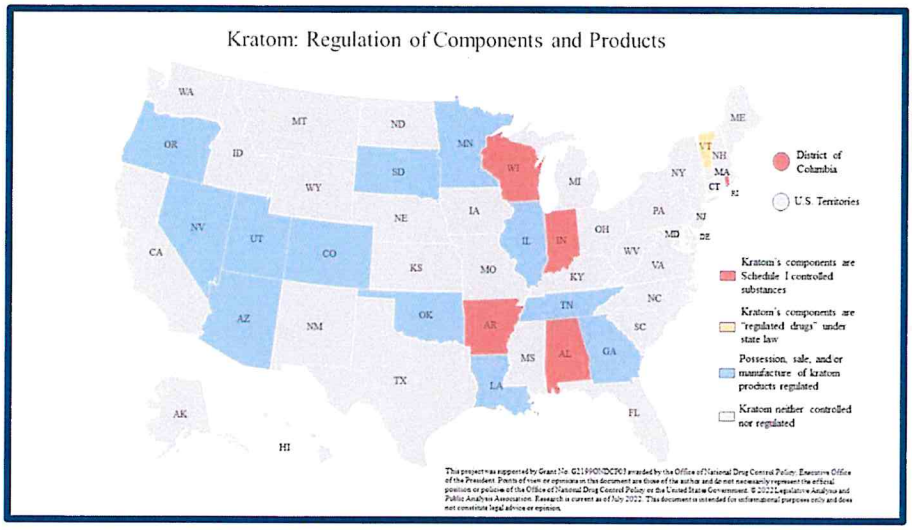
[44] Jane Babin, "FDA Fails to Follow the Sciences on Kratom," *American Kratom Association*, August 2018, 13, https://docs.wixstatic.com/ugd/9ba5da_54f08e1805c34c108ad7199481507d88.pdf.
[45] *Id.*
[46] "AKA's GMP Qualified Vendors," American Kratom Association, last accessed August 18, 2022, https://www.americankratom.org/gmp-qualified-vendors.
[47] ALA. CODE § 20-2-23 (West 2022).
[48] ARK. ADMIN. CODE § 007.07.2 (West 2021).
[49] 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).
[50] Rhode Island Dept. of Health, Notice of Designation of Controlled Substance (May 31, 2017), https://docs.wixstatic.com/ugd/9ba5da_9836aee2b9f04a30b55fe480fe3c6ff4.pdf.
[51] 12-5 VT. CODE R. § 23:7.0 (West 2022).
[52] WIS. STAT. ANN. § 961.14 (West 2022).
[53] The legal status of kratom in the District of Columbia (D.C.) appears unclear. Please see LAPPA's Kratom: Summary of State Laws, available here, for more information.
[54] In Vermont, kratom's components are "regulated drugs," making them generally illegal except as specifically allowed. VT. STAT. ANN. tit. 18, § 4205 (West 2022). In the remaining jurisdictions, kratom components are Schedule I controlled substances.
[55] For more information on the legality of kratom in states and local jurisdictions, please refer to LAPPA's 50-state review of kratom laws, available at https://legislativeanalysis.org/kratom-summary-of-state-laws/.

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-hydroxymirtragynine 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.

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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.

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