The Case for the Kratom Consumer Protection Act (KCPA)

AMERICAN KRATOM ASSOCIATION

AMERICAN KRATOM ASSOCIATION

Regulatory Status of Kratom in the United States

STATE	DATE OF BAN
WISCONSIN*	2014
INDIANA	2014
ARKANSAS*	2015
ALABAMA	2016
VERMONT	2016
RHODE ISLAND*	2017

* Under Review

STATE	KCPA
UTAH	2019
GEORGIA	2019
ARIZONA	2019
NEVADA	2019
OKLAHOMA	2020
OREGON	2022
COLORADO	2022

SHEDULING RECOMMENDATIONS	
FDA – Aug. 31, 2016	Withdrawn by DEA on Oct. 13, 2016
FDA – Nov. 17, 2017	Withdrawn by HHS on Aug. 16, 2018
UN Commission on Narcotic Drugs	Declined by Expert Committee on Drug Dependence on Dec. 1, 2021

AMERICAN KRATOM ASSOCIATION

State of Rhode Island

HOUSE OF REPRESENTATIVES

REPRESENTATIVE BRIAN PATRICK KENNEDY, *District 38*
Speaker Pro Tempore
Committee on Corporations
Committee on Rules
Committee on Innovation, Internet and Technology
Committee on State Government and Elections

November 1, 2022

Utpala Bandy, MD, MPH
Interim Director
Rhode Island Department of Health
3 Capitol Hill
Providence, Rhode Island 02908

Dear Dr. Bandy:

Representative Edwards and I have several recommendations flowing from our discussion that will inform our planning for the upcoming legislative session where we will propose a regulatory framework that will fill the gap to provide appropriate protections for consumers. We appreciated greatly the acknowledgment of the Department that emerging science confirms that kratom does not meet scheduling requirements in Rhode Island's P.L. 1974, ch. 183, §2; P.L. 1979, ch. 168, § 1.

AMERICAN KRATOM ASSOCIATION

REVIEWS OF KRATOM'S SAFETY AND ADDICTION LIABILITY

OCTOBER 13, 2016

DEA is withdrawing the August 31, 2016, notice of intent; and soliciting comments from the public regarding the scheduling of mitragynine and 7-hydroxymitragynine under the Controlled Substances Act.

U.S. Department of Health & Human Services

AUGUST 16, 2018, WITHDRAWAL OF KRATOM SCHEDULING RECOMMENDATION

Therefore, I conclude at the current time, available evidence does not support mitragynine and 7- hydroxymitragynine being controlled in Schedule I of the Controlled Substances Act.

Assistant Secretary of Health, Brett Giroir, MD

World Health Organization

December 1, 2021
Expert Committee on Drug Dependence (ECDD,

The Committee concluded that there is insufficient evidence to recommend a critical review of kratom.

AMERICAN KRATOM ASSOCIATION

STATEMENT BY 19 INTERNATIONALLY RECOGNIZED SCIENTISTS AND RESEARCHERS ON WHETHER KRATOM EVIDENCE AND DATA MERITS SCHEDULING

September 21, 2021

Conclusions and Recommendations

We conclude that there is a lack of sufficient scientifically sound evidence that kratom or its alkaloids pose imminent regional or global public health threats warranting scheduling.

Furthermore, the pharmacological profiles of kratom and its main alkaloid, MG, are not indicative of high abuse potential that supports scheduling.

We are concerned that scheduling kratom and/or any of its alkaloids carries serious unintended consequences that would foreseeably cause the emergence of an illicit kratom market that could not be regulated.

Surveys also support the foreseeable conclusion that many people who are taking kratom as an acceptable alternative to opioids and/or approach to self managing opioid and other addictions would return to use of those substances with their far greater risks of overdose and other adverse personal and societal risks.

We, therefore, do not recommend any international or national drug scheduling of kratom and/or its alkaloids.

AMERICAN KRATOM ASSOCIATION

U.S. Department of Health & Human Services

Xavier Becerra
Secretary of HHS

March 16, 2022, response to Congressional inquiry on kratom:

"To that end, HHS and its component agencies are working to address knowledge gaps through research."

"Many kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

AMERICAN KRATOM ASSOCIATION

8-Factor Analysis for Scheduling

Federal CSA: Section 201 (c), [21 U.S.C. § 811 (c)]

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter

Most states have adopted the federal standard for scheduling and codified those requirements in state statutes.

AMERICAN KRATOM ASSOCIATION

NIH National Institute on Drug Abuse
The Science of Drug Abuse & Addiction

Is Kratom Dangerously Addictive?

Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine

Scott E Hemby [1], Scot McIntosh [1], Francisco Leon [2], Stephen J Cutler [3], Christopher R McCurdy [2]

The present findings indicate that MG does not have abuse potential and reduces morphine intake, desired characteristics of candidate pharmacotherapies for opiate addiction and withdrawal . . .

Abuse liability of mitragynine assessed with a self-administration procedure in rats

Kai Yue [1], Theresa A Kopajtic [2], Jonathan L Katz [3]

These results suggest a limited abuse liability of mitragynine and potential for mitragynine treatment to specifically reduce opioid abuse . . .

AMERICAN KRATOM ASSOCIATION

FDA Claim: Deaths related to kratom exposure have been reported in the scientific literature beginning in 2009–2010, with a cluster of nine deaths in Sweden from use of the kratom product ‘‘Krypton’’ (*Federal Register Notice Aug. 31, 2016*).

J Anal Toxicol. 2011 May;35(4):242-7. doi: 10.1093/anatox/35.4.242.

Unintentional fatal intoxications with mitragynine and O-desmethyltramadol from the herbal blend Krypton

Robert Kronstrand [1], Markus Roman, Gunilla Thelander, Anders Eriksson

We believe that the **addition of the potent mu-receptor agonist O-desmethyltramadol to powdered leaves from kratom contributed to the unintentional death of the nine cases presented . . .**

Kratom

There have been multiple reports of deaths in people who had ingested kratom, but most have involved other substances. A 2019 paper analyzing data from the National Poison Data System found that between 2011-2017 there were 11 deaths associated with kratom exposure. Nine of the 11 deaths reported in this study involved kratom plus other drugs and medicines, such as diphenhydramine (an antihistamine), alcohol, caffeine, benzodiazepines, fentanyl, and cocaine. Two deaths were reported following exposure from kratom alone with no other reported substances.* In 2017, the FDA identified at least 44 deaths related to kratom, with at least one case investigated as possible use of pure kratom. **The FDA reports note that many of the kratom-associated deaths appeared to have resulted from adulterated products or taking kratom with other potent substances, including illicit drugs, opioids, benzodiazepines, alcohol, gabapentin, and over-the-counter medications, such as cough syrup. Also, there have been some reports of kratom packaged as dietary supplements or dietary ingredients that were laced with other compounds that caused deaths.** People should check with their health care providers about the safety of mixing kratom with other medicines.

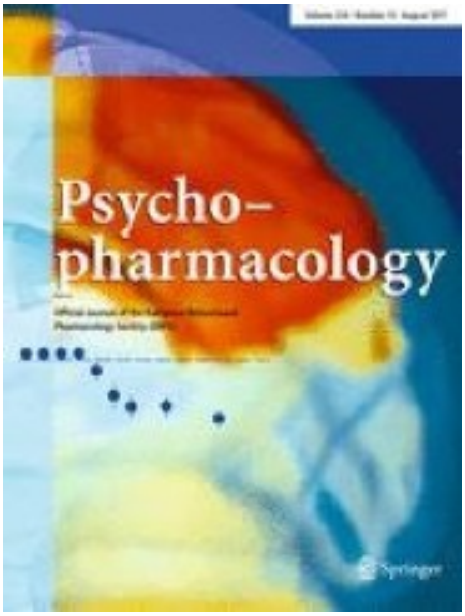
*(Post et al, 2019. Clinical Toxicology).

AMERICAN KRATOM ASSOCIATION

Christopher McCurdy, PhD
Leading scientist on kratom safety and addiction -- NIDA
University of Florida
University of Mississippi

"We know that very few deaths are attributable to a kratom product alone, and for those that are, there could be extreme circumstances, in terms of overdosing, or it could be adulterated with synthetic compounds," such as fentanyl derivatives or other novel psychoactive substances that are unknown or undetected."

NIH Record, June 24, 2022



Original Investigation | Open Access | Published: 29 October 2022

Respiratory effects of oral mitragynine and oxycodone in a rodent model

Jack E. Henningfield, Joseph V. Rodricks, Aaron M. Magnuson & Marilyn A. Huestis

Psychopharmacology (2022) | Cite this article

2 Altmetric | Metrics

Findings:

Oxycodone administration produced significant dose-related respiratory depressant effects and pronounced sedation with one death each at 60 and 150 mg/kg. Mitragynine did not yield significant dose-related respiratory depressant or life-threatening effects. Sedative-like effects, milder than produced by oxycodone, were evident at the highest mitragynine dose. Maximum oxycodone and mitragynine plasma concentrations were dose related.

Conclusions

Consistent with mitragynine's pharmacology that includes partial μ-opioid receptor agonism with little recruitment of the respiratory depressant activating β-arrestin pathway, mitragynine produced no evidence of respiratory depression at doses many times higher than known to be taken by humans.

AMERICAN KRATOM ASSOCIATION

The College on Problems of Drug Dependence

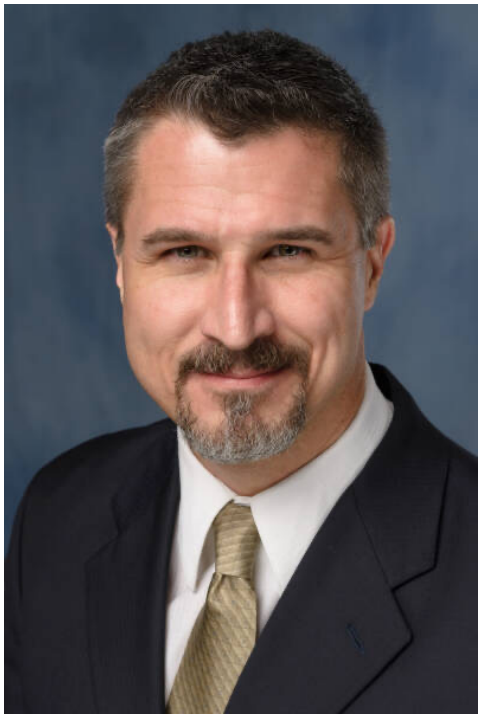
Presentation to the College of Drug Dependence, June 14, 2022

Phase I Study of the Safety, Tolerability & Pharmacokinetics of Three Kratom Formulations

- After 14 days of consumption of up to 29.6 mg daily mitragynine, neither COWS nor SOWS scores indicative of withdrawal effects
- No condition resulted in mean scores ≥1.5 on COWS or SOWS

AMERICAN KRATOM ASSOCIATION

NIH National Institute on Drug Abuse
The Science of Drug Abuse & Addiction



Jay McLaughlin, PhD
University of Florida

Kratom can treat withdrawal.

A five-year, $3.4 million grant from the National Institute on Drug Abuse

Scientists are now developing multifunctional (partial) agonists, which initially block drug-related reward effects, followed by longer-term mitigation of withdrawal symptoms

Mitragynine, and other alkaloids of kratom, seem to already have this type of multifunctionality. Not only do they activate opioid receptors, but they also work entirely different kind of receptor altogether called the α-adrenergic receptor, which is the target site of opioid withdrawal medication. This may explain why kratom alkaloids can substitute some of the effects of opioids and simultaneously treat withdrawal symptoms.

Published October 22, 2021

Albert Garcia-Romeu, PhD
Johns Hopkins University

"Kratom is used among white, middle-aged Americans for symptoms of pain, anxiety, depression, and opioid withdrawal. Although regular use was typical, kratom-related SUD and serious adverse effects were uncommon."

Among those treating opioid dependence:

- **87% reported relief from withdrawal symptoms**
- **35% were free from opioids >1 year**

NIH
National Institute on Drug Abuse
The Science of Drug Abuse & Addiction

Nora Volkow, PhD
NIDA Director

Congressional Testimony on May 25, 2022, on HHS Response to Drug Overdose Crisis.

". . . There's also interest in the community to test other products that may serve as harm reduction. For example, the use of kratom which is sold as tea and that contains a drug/molecule that has effects that are similar to a dose of buprenorphine [a safe and effective treatment for opiate use disorder] but could be utilized also for decreasing withdrawal or depression. . ."

AMERICAN KRATOM ASSOCIATION

Jack Henningfield, PhD
Leading scientist on kratom safety and addiction
Johns Hopkins University
Pinney Associates

"Kratom is not an opioid by plant origin, chemical structure, pharmacology, or law, or it would automatically be scheduled under the federal Controlled Substances Act (CSA)."

Letter to Rhode Island House Corporations Committee, April 4, 2022

FISCAL YEAR 2023 APPROPRIATIONS, Page 218”

“Kratom.—Combating Opioid Overdoses.—The Committee commends NIDA for funding studies on kratom based on promising results that unadulterated kratom may provide help for some Americans struggling with addictions, given its analgesic and less addictive properties as compared to opioids.”

AMERICAN KRATOM ASSOCIATION

American College of Neuropsychopharmacology

PERSPECTIVE
Addiction should be treated, not penalized

Nora Volkow, Director, National Institute on Drug Abuse
August 2021

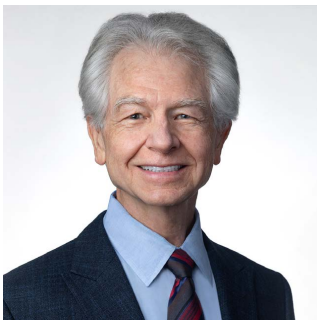
"Abundant data show that Black people and other communities of color have been disproportionately harmed by decades of addressing drug use as a crime rather than as a matter of public health."

Mitchell O, Caudy MS. Examining racial disparities in drug arrests. Justice Q. 2015;32:288–313.

AMERICAN KRATOM ASSOCIATION

Kratom Science Update: Evidence-Based Facts

October 2022



Jack Henningfield, PhD
Johns Hopkins University

Albert Garcia-Romeu, PhD
Johns Hopkins University

Marilyn Huestis, PhD
Huestis & Smith Toxicology

Oliver Grundmann, PhD
University of Florida

"**What is clearly needed is balanced regulation to ensure that kratom products purchased by consumers are pure and unadulterated, in other words meeting the same types of standards that apply to other food products, and even bottled water**. Steps toward such standards were taken in states that passed their own versions of kratom consumer protection act laws. Ultimately, the Food and Drug Administration (FDA) needs to develop national performance standards for kratom as it does for other products. Such standards will help ensure access to kratom products that are appropriately marketed and are without contaminants and adulterants that might pose safety risks."

AMERICAN KRATOM ASSOCIATION

The Solution: Kratom Consumer Protection Act (KCPA)

- **Recommendations for Rules on the sale of kratom products:**
  - No adulterated kratom products can be sold in Kansas
  - No synthetic kratom alkaloids
  - No kratom extract with residual solvents higher than allowed by USP 467 for food products
  - No kratom containing a 7-Hyroxymitragynine in the alkaloid fraction greater than 2% of the overall alkaloid composition of the product
  - No kratom product that is not labeled with ingredients and directions for use – and no illegal therapeutic claims
  - No sales to minors under that age of 18

AMERICAN KRATOM ASSOCIATION

SUPPORTING DOCUMENTS

DOCUMENT #1: Federal Register Notice from the DEA withdrawing kratom scheduling recommendation on Oct. 13, 2016:

https://www.dropbox.com/s/7af8wcsb1wcwqoo/TAB%201%20-%20DEA%20Withdrawal%20Oct%2013%202016.pdf?dl=0

DOCUMENT #2: HHS withdrawal letter on kratom scheduling recommendation on August 16, 2019:

https://www.dropbox.com/s/p1ek5ge88x1wtl5/TAB%202%20-%20HHS%20Rescission%20Letter%20Dr.%20Giroir%20Aug%2016%202018%20highlighted%20copy.pdf?dl=0

DOCUMENT #3: UN Commission on Narcotic Drugs Report from the Expert Committee on Drug Dependency on insufficient evidence to recommend scheduling of kratom – issued Dec. 1, 2021:

https://www.dropbox.com/s/e6keirbmbcxwt5d/TAB%203%20-%20Pages%20from%20ECDD%2044th%20Report.pdf?dl=0

DOCUMENT #4: Updated 8-Factor Analysis on Kratom, 2021

https://www.dropbox.com/s/jda9lq5yhx9ybeo/TAB%204%20-%208%20Factor%202021.pdf?dl=0

DOCUMENT #5: Kronstrand Study on Kratom Deaths in Sweden, 2011

https://www.dropbox.com/s/kknkcybmk33swy4/TAB%205%20-%20Kronstrand%20Sweden%20Adulterated%20Kratom.pdf?dl=0

DOCUMENT #6: Lydecker Study on Adulterated Kratom Products, 2016

https://www.dropbox.com/s/n24yc8e31iknry8/TAB%206%20-%20Lydecker%20Commerical%20Adulterated%20Kratom%202.pdf?dl=0

DOCUMENT #7: Acute Renal Insufficiency Study on Adulterated Kratom Products

https://www.dropbox.com/s/f897d18dmt1gd9w/TAB%207%20-%20AcuteRenalInsufficiencyAssociatedWithConsumptionofHydrocodone-andMorphine-AdulteratedKratom.pdf?dl=0

DOCUMENT #8: NIDA Statement on Deaths from Adulterated Kratom Products

https://www.dropbox.com/s/o88nd71hht2w11x/TAB%208-%20NIDA%20Statement%20on%20Kratom%20Adulterated%20Kratom%20Deaths.pdf?dl=0

DOCUMENT #9: NIH Record – Dr. Christopher McCurdy Statement on Kratom

https://www.dropbox.com/s/5pwvnam98lqnhrr/TAB%209%20-%20NIH-Record-2022-06-24.pdf?dl=0

DOCUMENT #10: Testimony of Dr. Marilyn Huestis on kratom fatality data before the Expert Committee on Drug Dependence at the UN Commission on Narcotic Drugs:

https://www.dropbox.com/s/kcntpvu5uzpixl3/TAB%2010%20-%20Huestis%20Testimony%20to%20the%20Expert%20Committee%20on%20Drug%20Dependence%20on%20kratom.pdf?dl=0

DOCUMENT #11: CPDD Presentation on Kratom Safety

https://www.dropbox.com/scl/fi/be9j2xvb6rb4m6mns41m3/TAB-11-Huestis-Mitragynine-CPDD-Late-BreakingNews-29May22.pptx?dl=0&rlkey=0kjt7pm59nt30cvawqbqmiagi

DOCUMENT #12: Hemby et. al study on the Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine:

https://www.dropbox.com/s/9c0sprrx4cxhml8/TAB%2012%20-%20%20HembyKratomAddictionnBiology2018.pdf?dl=0

DOCUMENT #13: Yue et. al study on the Abuse liability of mitragynine [kratom] assessed with a self-administration procedure in rats:

https://www.dropbox.com/s/op8ypoyaj03bioy/TAB%2013-%20%20Yue_-_Abuse_Liability_of_mitragynine.pdf?dl=0

DOCUMENT # 14: Dr. McLaughlin on Kratom Treating Withdrawal

https://www.dropbox.com/s/m6sejxihmxxfuvz/TAB%2014%20-%20Dr.%20McLaughlin%20on%20Kratom%20Treating%20Withdrawal.pdf?dl=0

DOCUMENTS #15A and 15: Johns Hopkins University study on adult kratom users:

https://www.dropbox.com/s/4q7rltrqlw9jmrd/TAB%2015A%20-%20%20Garcia%20Study%20Infographic%20copy%202.jpeg?dl=0

https://www.dropbox.com/s/4p6e1sks1mnvjl1/TB%2015%20-%20Garcia%20Drug%20and%20Alcohol%20Dependence%20kratom%20study%20Feb%203%202020%20.pdf?dl=0

DOCUMENT #16: HHS Secretary Becerra's Response on Status of Kratom

https://www.dropbox.com/s/zl67mhh8jpoxp70/TAB%2016-%20HHS%20Secretary%20Kratom%20Response.pdf?dl=0

DOCUMENT #17: NIDA Director Volkow Congressional Testimony on Kratom

https://www.dropbox.com/s/twcfbzvzl28082o/TAB%2017%20-%20NIDA%20Director%20Volkow%20Testimony.pdf?dl=0

DOCUMENT #18: Henningfield & Huestis Letter to RI House Corporations Committee

https://www.dropbox.com/s/7hb7gmptf2mfu5n/TAB%2018%20-%20Henningfield%20and%20Huestis%20Letter%20to%20RI%20Corporations%20Committeee%20Apr%204%202022.pdf?dl=0

DOCUMENT #19: Letter from AMA President on June 11, 2022, confirming the withdrawal of the resolution to ban kratom at the federal level:

https://www.dropbox.com/s/hrgv1veihbozyk0/TAB%2019%20-%20AMA%20President%20Response%20on%20kratom%20ban%20resolution%20June2022%20copy.pdf?dl=0

DOCUMENT #20: Labor HHS Appropriations Report Language on kratom in the FY23 federal budget:

https://www.dropbox.com/s/9gk1kq1g6eicgnc/TAB%2020%20-%20FY%202023%20Labor%20HHS%20Report%20Language%20on%20kratom.pdf?dl=0

DOCUMENT #21: Kratom Science Update

https://www.dropbox.com/s/2d9m3w8xernomz4/TAB%2021%20-%20%20Kratom%20Science%20Update%20OCT%202022.pdf?dl=0

DOCUMENT #22: Proposed KCPA Legislation in Mississippi

https://www.dropbox.com/s/r39jb9ddskvqjob/KCPA%20Mississippi.pdf?dl=0

DOCUMENT #23: Supporting Documents
https://www.dropbox.com/scl/fi/l773nlptpu7elmj8lwrq5/TAB-23-Supporting-Documents.docx?dl=0&rlkey=3z4ugm0yh4jwkqjrvxml976cd