Additional Public Comment Workshop Agenda Item #15B

From: yhwh1133@everyactioncustom.com on behalf of Benjamin Gellman
To: Board Coordination
Subject: Oppose Mitragynine Scheduling
Date: Wednesday, April 22, 2026 1:44:58 AM

Dear Nevada BOP,

I am writing to respectfully oppose making mitragynine a controlled substance.

Kratom is the only substance that has ever improved my clinical depression and social anxiety disorder. Pharmaceuticals do not help.

Sincerely,
Benjamin Gellman

From: BRODIE PRIESTLEY
To: Board Coordination
Subject: Re: kratom ban
Date: Wednesday, April 22, 2026 12:03:29 PM

Yes please include this:

I really hope the board reconsiders their decision and Kratom has not hurt my life, it actually saved my life. It also helped save the life of my Father by helping him get away from his 22 year addiction to alcohol. An addiction that he was not able to break for 2 decades until he learned about Kratom. It literally saved his life and our family. For myself I would be deceased from either an opioid overdose or best case scenario living a miserable life if it was not for Kratom. Hearing the board talk about its deadly consequences I think missed what most people experience with Kratom. It has been safely used by my family, everyone I know and other people for decades. Like I said and I repeat it because it is so important. It did not destroy my life, it saved my life and my fathers.. in many more ways than just one. I can not say enough how much of a mistake it would be to get rid of this plant, especially today with opioid and fentanyl addiction being as prevalent as it is in this country. This law will hurt far more people than it would help. This plant helps so many people, I know the board does genuinely want to protect people and help people. This plant actually does that for many.

Best in Health,

Brodie Priestley
Owner
Peak Nutrition
Office: (775) 782-2244
Cell Phone: [redacted]

From:	Pharmacy Board
To:	Board Coordination
Subject:	Fw: Support for Schedule I Classification of Kratom + Supporting Materials
Date:	Thursday, April 23, 2026 8:48:55 AM
Attachments:	packet319.pdf lawpacket319.pdf Kratom extract lab results.pdf Outlook-thvitwcs.png

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Thank you.

Nevada State
Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
Office: 775-850-1440
Fax: 775-850-1444
Web Page: https://bop.nv.gov/

From: Jennifer Brandt [redacted]
Sent: Thursday, April 16, 2026 1:44 AM
To: Pharmacy Board <pharmacy@pharmacy.nv.gov>
Subject: Support for Schedule I Classification of Kratom + Supporting Materials

Dear Members of the Nevada State Board of Pharmacy,

I am writing to express my support for the classification of kratom (Mitragyna speciosa) as a Schedule I substance in Nevada and to provide the attached materials for your consideration.

The packets I am sharing are intended to support that position from a practical, enforcement-based perspective—not just a theoretical one.

They outline three key points:

1. Kratom meets the criteria used for scheduling
Federal findings consistently show that kratom:
- Acts on opioid receptors

- Produces opioid-like effects
- Is associated with dependence and withdrawal
- Has no accepted medical use in the United States

These are the same factors typically relied upon in Schedule I determinations.

2. Existing regulatory frameworks are not working
As outlined in the law packet (see page 3), kratom products already meet definitions of adulterated, misbranded, and unapproved drugs under state and federal law.
However, despite this, these products remain widely available in retail settings.

3. The issue is enforceability
The most important point is not whether authority exists—it is whether it can be applied.

As detailed in the enforcement section (page 5), there is:
- No field test for key compounds
- Dependence on LC-MS/MS testing
- Delays of days to weeks for results
- No practical way to verify compliance at the point of sale

This creates a system where standards exist on paper but cannot be enforced in real time.

Why Schedule I is the appropriate framework

Given that kratom:
- Has opioid-like pharmacology
- Has documented abuse potential
- Has no accepted medical use
- Cannot be effectively regulated or enforced at the retail level

Schedule I classification provides the only clear, enforceable structure.

Supporting lab data from current retail products

To show what is actually being sold today, I have included independent laboratory analyses of commonly available products.

These results demonstrate:
- Failure of recognized safety standards (USP <467>)
- Elevated ethanol levels beyond accepted limits
- Significant variability in product composition

Examples include:
– MIT45: ethanol 15,500 ppm (limit 5,000)
– Feel Free: ethanol 5,300 ppm (limit 5,000)
– OPMS Gold: 336,000 µg/g

These are products currently available to Nevada consumers, and they illustrate the broader issue: the market is inconsistent, difficult to verify, and not practically enforceable under

existing frameworks.

For these reasons, I strongly support scheduling kratom as a Schedule I substance in Nevada.

Thank you for your time and consideration.

Respectfully,
Jennifer Brandt, PharmD
Hospital Pharmacist

https://globalkratomcoalition.org/advocacy-buddy

Certificate of Analysis

ANALYZED BY:

Anresco Laboratories
1375 Van Dyke Avenue,
San Francisco, CA 94124
C8-0000052-LIC

CUSTOMER:

TestMyKratom.org
18117 Biscayne Blvd Suite #4220
Miami, FL 33160

SAMPLE INFORMATION

Sample No.: 1283841
Product Name: MIT45 Black Extra Strength liquid gel
Lot #: 2025-03

Date Collected: 03/04/2025
Date Received: 03/06/2025
Date Reported: 03/12/2025

TEST SUMMARY

Alkaloids: Tested
Overall: Fail
Residual Solvent Screen: Fail

Alkaloids

03/12/2025

Method: MF 12D030
Instrument: Liquid Chromatography Diode Array Detector (LC-DAD)
Limit of Quantitation Alkaloid Profile (LC-DAD) 0.1
Limit of Detection 0.04
Limit of Quantitation 0.1

Analyte	mg/g	%	mg/ml	mg/ package
7-OH Mitragynine	ND	ND	ND	ND
Mitragynine Pseudoindoxyl	ND	ND	ND	ND
Mitragynine	6.31	0.631	8.58	90.81
Paynantheine	0.24	0.024	0.32	3.39
Speciogynine	0.14	0.015	0.20	2.09
Speciociliatine	ND	ND	ND	ND
Total Alkaloids	6.69	0.669	9.10	96.29
Package Weight (g)	14.4			
g/ml Conversion Factor	1.3608			

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Certificate of Analysis

Residual Solvent Screen — Fail

03/12/2025

Method: USP <467>

Analyte	LOD/LOQ (ppm)	Findings (ppm)	Limit (ppm)	Status
1,2-Dichloroethane	0.2/0.5	ND	5	Pass
Acetone	67/200	ND	5000	Pass
Acetonitrile	67/200	ND	410	Pass
Benzene	0.2/0.5	ND	2	Pass
n-Butane	67/200	ND	-	-
Chloroform	0.2/0.5	ND	60	Pass
Ethanol	67/200	15500.00	5000	Fail
Ethyl acetate	67/200	ND	5000	Pass
Ethyl ether	67/200	ND	5000	Pass
Ethylene oxide	0.2/0.5	ND	10	Pass
n-Heptane	67/200	ND	5000	Pass
n-Hexane	67/200	ND	290	Pass
Isopropyl alcohol	67/200	ND	5000	Pass
Methanol	67/200	ND	3000	Pass
Methylene chloride	0.2/0.5	ND	600	Pass
n-Pentane	67/200	ND	5000	Pass
Propane	67/200	ND	-	-
Toluene	67/200	ND	890	Pass
Total xylenes (ortho-, meta-, para-)	67/200	ND	2170	Pass
Trichloroethylene	0.2/0.5	ND	80	Pass

Comments Ethanol failure confirmed with dilution.

ND = None Detected
LOD = Limit of Detection
LOQ = Limit of Quantitation

Reported by

Vu Lam
Lab Co Director

March 12, 2025

Scan to verify

Certificate of Analysis

Customer Information

Client: TestMyKratom.org
Attention: test.my.kratom@gmail.com
Address: 18117 Biscayne Blvd, Suite #4220
Miami, FL 33160

Testing Facility

Lab: Cora Science, LLC
Address 8000 Anderson Square, STE 113
Austin, Texas 78757
Contact: info@corascience.com
(512) 856-5007

Sample Image(s)

Sample Information

Name: OPMS Gold liquid shot
Lot Number: 2025-03
Description: Liquid botanical extract
Condition: Good
Job ID: ISO03497
Sample ID: I09005
Received: 07MAR2025
Completed: 15MAR2025
Issued: 19MAR2025

Test Results

Mitragyna Alkaloids (UHPLC-DAD) **Method Code: T102** **Tested: 13MAR2025 | 2138**

PARAMETER	SPECIFICATION	RESULT	UNIT	LOQ	NOTES
Mitragynine	Report Results	116	mg/unit	0.067	N/A
7-Hydroxymitragynine	Report Results	0.244	mg/unit	0.067	N/A
Mitragynine Pseudoindoxyl	Report Results	0.234	mg/unit	0.067	N/A
Mitraciliatine	Report Results	1.82	mg/unit	0.067	N/A
Speciociliatine	Report Results	20.5	mg/unit	0.067	N/A
Speciogynine	Report Results	14.8	mg/unit	0.067	N/A
Paynantheine	Report Results	20.4	mg/unit	0.067	N/A
Corynoxine	Report Results	1.12	mg/unit	0.067	N/A
Isorhynchophylline	Report Results	0.381	mg/unit	0.067	N/A
Mitraphylline	Report Results	<LOQ	mg/unit	0.067	N/A
Total Mitragyna Alkaloids	Report Results	176	mg/unit	0.067	N/A

Mitragyna Alkaloids (UHPLC-DAD) **Method Code: T102** **Tested: 13MAR2025 | 2138**

PARAMETER	SPECIFICATION	RESULT	UNIT	LOQ	NOTES
Mitragynine	Report Results	1.06	w/w%	0.0006	N/A
7-Hydroxymitragynine	Report Results	0.002	w/w%	0.0006	N/A
Mitragynine Pseudoindoxyl	Report Results	0.002	w/w%	0.0006	N/A
Mitraciliatine	Report Results	0.017	w/w%	0.0006	N/A
Speciociliatine	Report Results	0.187	w/w%	0.0006	N/A
Speciogynine	Report Results	0.135	w/w%	0.0006	N/A
Paynantheine	Report Results	0.186	w/w%	0.0006	N/A
Corynoxine	Report Results	0.010	w/w%	0.0006	N/A
Isorhynchophylline	Report Results	0.003	w/w%	0.0006	N/A
Mitraphylline	Report Results	<LOQ	w/w%	0.0006	N/A
Total Alkaloids	Report Results	1.61	w/w%	0.0006	N/A

Residual Solvents: Class I (GC-MS) **Method Code: T201** **Tested: 13MAR2025 | 1110**

PARAMETER	SPECIFICATION	RESULT	UNIT	LOQ	NOTES
1,1-Dichloroethene	NMT 8	<LOQ	ug/g	0.40	PASS
1,1,1-Trichloroethane	NMT 1500	<LOQ	ug/g	75	PASS
Tetrachloromethane	NMT 4	<LOQ	ug/g	0.20	PASS
Benzene	NMT 2	<LOQ	ug/g	0.10	PASS
1,2-Dichloroethane	NMT 5	<LOQ	ug/g	0.25	PASS

Residual Solvents: Class II (GC-MS) **Method Code: T201** **Tested: 13MAR2025 | 1110**

PARAMETER	SPECIFICATION	RESULT	UNIT	LOQ	NOTES
Methanol	NMT 3000	<LOQ	ug/g	150	PASS
Acetonitrile	NMT 410	<LOQ	ug/g	21	PASS
Dichloromethane	NMT 600	<LOQ	ug/g	30	PASS
1,2-Dichloroethene, (E)	NMT 1870	<LOQ	ug/g	94	PASS
1,2-Dichloroethene, (Z)	NMT 1870	<LOQ	ug/g	94	PASS
Tetrahydrofuran	NMT 720	<LOQ	ug/g	36	PASS
Cyclohexane	NMT 3880	<LOQ	ug/g	194	PASS
Methylcyclohexane	NMT 1180	<LOQ	ug/g	59	PASS
1,4-Dioxane	NMT 380	<LOQ	ug/g	19	PASS
Toluene	NMT 890	<LOQ	ug/g	45	PASS
Chlorobenzene	NMT 360	<LOQ	ug/g	18.0	PASS
Ethylbenzene	NMT 2170	<LOQ	ug/g	109	PASS
o/p-Xylene	NMT 2170	<LOQ	ug/g	109	PASS
m-Xylene	NMT 2170	<LOQ	ug/g	109	PASS
Isopropylbenzene	NMT 70	<LOQ	ug/g	3.5	PASS
Hexane	NMT 290	<LOQ	ug/g	14.5	PASS
Nitromethane	NMT 50	<LOQ	ug/g	2.5	PASS
Chloroform	NMT 60	<LOQ	ug/g	3.0	PASS
1,2-Dimethoxyethane	NMT 100	<LOQ	ug/g	5.0	PASS
Trichloroethene	NMT 80	<LOQ	ug/g	4.0	PASS
Pyridine	NMT 200	<LOQ	ug/g	10.0	PASS
2-Hexanone	NMT 50	<LOQ	ug/g	2.5	PASS
Tetralin	NMT 100	<LOQ	ug/g	5.0	PASS

Residual Solvents: Class III (GC-MS) **Method Code: T201** **Tested: 13MAR2025 | 1110**

PARAMETER	SPECIFICATION	RESULT	UNIT	LOQ	NOTES
Pentane	NMT 5000	<LOQ	ug/g	250	PASS
Ethanol	NMT 5000	336000	ug/g	250	FAIL
Diethyl Ether	NMT 5000	<LOQ	ug/g	250	PASS
Acetone	NMT 5000	<LOQ	ug/g	250	PASS
Ethyl Formate	NMT 5000	<LOQ	ug/g	250	PASS
Isopropanol	NMT 5000	<LOQ	ug/g	250	PASS
Methyl Acetate	NMT 5000	<LOQ	ug/g	250	PASS
Methyl tert-Butyl Ether	NMT 5000	<LOQ	ug/g	250	PASS
1-Propanol	NMT 5000	<LOQ	ug/g	250	PASS
2-Butanone	NMT 5000	<LOQ	ug/g	250	PASS
Ethyl Acetate	NMT 5000	<LOQ	ug/g	250	PASS
2-Butanol	NMT 5000	<LOQ	ug/g	250	PASS
2-Methyl-1-Propanol	NMT 5000	<LOQ	ug/g	250	PASS
Isopropyl Acetate	NMT 5000	<LOQ	ug/g	250	PASS
Heptane	NMT 5000	<LOQ	ug/g	250	PASS
1-Butanol	NMT 5000	<LOQ	ug/g	250	PASS
Propyl Acetate	NMT 5000	<LOQ	ug/g	250	PASS
4-Methyl-2-Pentanone	NMT 5000	<LOQ	ug/g	250	PASS
Isoamyl Alcohol	NMT 5000	<LOQ	ug/g	250	PASS
Isobutyl Acetate	NMT 5000	<LOQ	ug/g	250	PASS
1-Pentanol	NMT 5000	<LOQ	ug/g	250	PASS
Butyl Acetate	NMT 5000	<LOQ	ug/g	250	PASS
Dimethylsulfoxide	NMT 5000	<LOQ	ug/g	250	PASS
Anisole	NMT 5000	<LOQ	ug/g	250	PASS

Adulterants (GC-MS/MS:1/2) **Method Code: T451** **Tested: 15MAR2025 | 0753**

PARAMETER	RESULT	UNIT	LOQ	NOTES
Meperidine	<LOQ	ug/g	0.05	PASS
cis-Tramadol	<LOQ	ug/g	0.05	PASS
Methadone	<LOQ	ug/g	0.05	PASS
Heroin	<LOQ	ug/g	0.05	PASS
Codeine	<LOQ	ug/g	0.05	PASS
Morphine	<LOQ	ug/g	0.05	PASS
Hydrocodone	<LOQ	ug/g	0.05	PASS
Hydromorphone	<LOQ	ug/g	0.05	PASS
Oxycodone	<LOQ	ug/g	0.05	PASS
Naltrexone	<LOQ	ug/g	0.05	PASS
Naloxone	<LOQ	ug/g	0.05	PASS
Oxymorphone	<LOQ	ug/g	0.05	PASS
Fentanyl	<LOQ	ug/g	0.05	PASS
Buprenorphine	<LOQ	ug/g	0.05	PASS
Tianeptine	<LOQ	ug/g	0.05	PASS

Adulterants (GC-MS/MS:2/2) **Method Code: T451** **Tested: 15MAR2025 | 0753**

PARAMETER	RESULT	UNIT	LOQ	NOTES
Amphetamine	<LOQ	ug/g	0.05	PASS
Phentermine	<LOQ	ug/g	0.05	PASS
Methamphetamine	<LOQ	ug/g	0.05	PASS
MDA	<LOQ	ug/g	0.05	PASS
MDMA	<LOQ	ug/g	0.05	PASS
MDEA	<LOQ	ug/g	0.05	PASS
Cocaine	<LOQ	ug/g	0.05	PASS
Amobarbital	<LOQ	ug/g	0.05	PASS
Butalbital	<LOQ	ug/g	0.05	PASS
Pentobarbital	<LOQ	ug/g	0.05	PASS
Phenobarbital	<LOQ	ug/g	0.05	PASS
Secobarbital	<LOQ	ug/g	0.05	PASS
Alprazolam	<LOQ	ug/g	0.05	PASS
Clonazepam	<LOQ	ug/g	0.05	PASS
Diazepam	<LOQ	ug/g	0.05	PASS
Flunitrazepam	<LOQ	ug/g	0.05	PASS
Lorazepam	<LOQ	ug/g	0.05	PASS
Oxazepam	<LOQ	ug/g	0.05	PASS
Nitrazepam	<LOQ	ug/g	0.05	PASS
Temazepam	<LOQ	ug/g	0.05	PASS

Additional Report Notes

T102 result, LOQ and unit converted from w/w% to mg/mL using a laboratory measured density of 1.121 g/mL.

Revision History

rev 00 - Initial release.

Abbreviations

ID: identification, **N/A:** not applicable, **LOQ:** limit of quantitation, **CFU:** colony forming units, **w/w%:** weight by weight percent, **mg:** milligrams, **g:** grams, **ug:** micrograms, **mL:** milliliters, **ND:** not detected, **<LOQ:** below limit of quantitation, **NMT:** no more than, **NLT:** no less than, **UHPLC:** ultra-high performance liquid chromatography, **GC:** gas chromatography, **DAD:** diode array detection/detector, **MS:** mass spectroscopy/spectrometer, **ICP:** inductively coupled plasma, **ISO:** International Organization for Standardization, **USP:** United States Pharmacopeia

Authorization

This report has been authorized for release from Cora Science by:

Signature: Tyler West

Name: Tyler West

Position: Laboratory Director

Department: Management

Date: 19MAR2025

Certificate of Analysis

ANALYZED BY:

Anresco Laboratories
1375 Van Dyke Avenue,
San Francisco, CA 94124
C8-0000052-LIC

CUSTOMER:

TestMyKratom.org
18117 Biscayne Blvd Suite #4220
Miami, FL 33160

SAMPLE INFORMATION

Sample No.: 1283842
Product Name: Feel Free liquid shot
Lot #: 2025-03

Date Collected: 03/04/2025
Date Received: 03/06/2025
Date Reported: 03/12/2025

TEST SUMMARY

Alkaloids: Tested
Overall: Fail
Residual Solvent Screen: Fail

Alkaloids

03/12/2025

Method: MF 12D030
Instrument: Liquid Chromatography Diode Array Detector (LC-DAD)
Limit of Quantitation Alkaloid Profile (LC-DAD) 0.1
Limit of Detection 0.04
Limit of Quantitation 0.1

Analyte	mg/g	%	mg/ml	mg/ package
7-OH Mitragynine	ND	ND	ND	ND
Mitragynine Pseudoindoxyl	ND	ND	ND	ND
Mitragynine	0.65	0.065	0.68	40.12
Paynantheine	0.14	0.014	0.15	8.86
Speciogynine	0.11	0.011	0.11	6.57
Speciociliatine	0.17	0.017	0.17	10.27
Total Alkaloids	1.06	0.106	1.11	65.82
Package Weight (g)	62.207			
g/ml Conversion Factor	1.0508			

anresco LABORATORIES since 1943

Certificate of Analysis

Residual Solvent Screen — Fail

03/12/2025

Method: USP <467>

Analyte	LOD/LOQ (ppm)	Findings (ppm)	Limit (ppm)	Status
1,2-Dichloroethane	0.2/0.5	ND	5	Pass
Acetone	67/200	ND	5000	Pass
Acetonitrile	67/200	ND	410	Pass
Benzene	0.2/0.5	ND	2	Pass
n-Butane	67/200	ND	-	-
Chloroform	0.2/0.5	ND	60	Pass
Ethanol	67/200	5300.00	5000	Fail
Ethyl acetate	67/200	ND	5000	Pass
Ethyl ether	67/200	ND	5000	Pass
Ethylene oxide	0.2/0.5	ND	10	Pass
n-Heptane	67/200	ND	5000	Pass
n-Hexane	67/200	ND	290	Pass
Isopropyl alcohol	67/200	ND	5000	Pass
Methanol	67/200	<LOQ	3000	Pass
Methylene chloride	0.2/0.5	ND	600	Pass
n-Pentane	67/200	ND	5000	Pass
Propane	67/200	ND	-	-
Toluene	67/200	ND	890	Pass
Total xylenes (ortho-, meta-, para-)	67/200	ND	2170	Pass
Trichloroethylene	0.2/0.5	ND	80	Pass

Comments Ethanol failure confirmed with retest.

ND = None Detected
LOD = Limit of Detection
LOQ = Limit of Quantitation

Reported by

Vu Lam
Lab Co Director

March 12, 2025

Scan to verify

KRATOM & THE LAW

SUPPLEMENTAL LEGISLATIVE PACKET

What federal agencies have already determined.
What state law already allows.
Why enforcement is currently failing.

Prepared for Policymakers
A consolidated review of federal findings, state legal authority, and real-world enforcement limitations related to kratom (Mitragyna speciosa)

Inside This Packet:

- Federal findings on safety, addiction, and opioid-like effects
- State FD&C authority to remove unlawful products
- Law enforcement limitations in testing and enforcement
- FDA import alerts and public health determinations
- Policy gaps impacting public safety

Core Question for Lawmakers:
If a substance meets the definition of an unsafe, unapproved drug and cannot be effectively enforced, why is it still being sold?

Prepared by:
Jennifer Brandt, PharmD
Hospital Pharmacist
www.antikratom.org

DEA Drug Evaluation Summary — October 2025

DEA Evaluation of Kratom (Mitragyna speciosa)

Federal analysis outlines kratom's risks, highlighting opioid-like effects, addiction potential, and increasing harm across communities nationwide.

FROM THE DEA FACT SHEET

NO ACCEPTED MEDICAL USE

- Kratom has no legitimate medical use in the United States

ADDICTION & WITHDRAWAL

- Kratom consumption can lead to addiction
- Documented withdrawal in chronic users

OPIOID-LIKE DRUG EFFECTS

- Act similar to morphine and reversed by naloxone

OVERDOSE & DEATH SIGNALS

- FDA data:
  - 1,486 cases (2008–2025)
  - 1,387 serious cases
  - 715 deaths involved

WIDESPREAD RECREATIONAL USE

- Increasing use as:
- Opioid substitute
- Self-treatment for withdrawal
- Marketed online as a legal psychoactive product
- Available as:
- Powder, capsules, extracts, resins

POLICY QUESTION FOR LAWMAKERS

Why is a substance that mimics opioids and is linked to addiction and deaths still sold without restriction?

SOURCE

Drug Enforcement Administration (DEA)
Diversion Control Division
Drug & Chemical Evaluation Section
Kratom (Mitragyna speciosa), October 2025

Learn more at

www.antikratom.org

and

www.kratomregulatoryreview.org

Kratom Already Meets Definitions of Unlawful Products Under FD&C Law

How Kratom Is Evaluated Under Existing Law

WHAT ARE FD&C LAWS?

State FD&C laws mirror federal law and prohibit the sale of products that are:

- Adulterated (unsafe or contaminated)
- Misbranded (false or misleading claims)
- Unapproved drugs (marketed with drug-like effects without FDA approval)
- Harmful or deleterious

HOW KRATOM FITS THESE DEFINITIONS

Adulteration

Kratom has no established safe use and has been linked to contamination and safety concerns.

Misbranding

Often marketed with claims related to pain, mood, or withdrawal without approval

Unapproved Drugs

Acts on opioid receptors and produces drug-like effects without FDA approval

WHY THIS MATTERS UNDER STATE LAW

- FD&C laws already provide enforcement authority
- Products do not need scheduling to be removed from the market
- If a product meets these definitions, it may already be unlawful to sell
- States have independent authority to act regardless of federal scheduling

KEY QUESTION FOR POLICYMAKERS

If a product meets the definition of an unapproved drug and lacks proven safety, why is it still being sold?

Sources:
State FD&C Statutes (modeled after federal FD&C Act)
FDA determinations on kratom (adulteration & unapproved drug status)

Learn more at
www.antikratom.org

KRATOM PRODUCTS DETAINED AT U.S. BORDERS AS UNSAFE

Why the FDA issues import alerts

Import alerts allow the FDA to stop potentially unsafe or illegal products from entering the U.S. without waiting for full inspection, protecting public health quickly and efficiently.

WHAT IMPORT ALERT 54-15 DOES

- Allows detention without physical examination (DWPE) of kratom shipments
- Applies to dietary supplements and bulk ingredients containing kratom
- Targets products entering the U.S. from identified manufacturers and importers

What the FDA found

- Kratom does not have adequate evidence of safety as a dietary ingredient
- No history of safe use prior to 1994 required for dietary ingredients
- Products are considered adulterated under federal law

Reported Health Risks

- Respiratory depression and neurologic effects
- Hallucinations, agitation, and aggression
- Nausea, vomiting, and severe withdrawal symptoms
- Multi-organ toxicity concerns identified in scientific literature

WHAT THIS MEANS FOR POLICY

- **The FDA is already blocking kratom at the international level**
- **Products are flagged as unsafe before reaching U.S. consumers**
- **Yet similar products remain widely available in domestic retail markets**

If kratom products are stopped at the border as unsafe, they should not be freely sold inside the United States.

Sources
- U.S. Food and Drug Administration (FDA) — Import Alert 54-15 (2025)
- Federal Food, Drug, and Cosmetic Act — Adulteration (Section 402(f)(1)(B))
- FDA Public Health Assessment of Kratom Safety

Learn more at www.antikratom.org

Can your state troopers test kratom for synthetic 7-OH?

If not, how can they enforce it?

Enforcement Reality

No Field Test Exists

Troopers cannot detect 7-OH in roadside or retail inspections.

Requires Advanced Lab Equipment

Identification requires LC-MS/MS–specialized, costly, and limited.

Delayed Results

Testing takes days to weeks–not actionable in real time.

No Practical Retail Enforcement

Products remain on shelves while results are pending.

What This Means for Policy

- **Standards without enforcement create false safety assurances**
- **Law enforcement is asked to enforce what it cannot measure**
- **Burden shifts to under-resourced state labs**
- **Retailers operate unchecked in real time**

If it can't be tested in the field, it can't be effectively regulated

Sources
• U.S. Drug Enforcement Administration (DEA) — Drug Identification & Forensic Testing
• National Institute of Justice (NIJ) — Field Drug Testing Limitations
• Forensic Toxicology Literature — Mitragynine & 7-Hydroxymitragynine Analysis (LC-MS/MS)

Learn More at www.antikratom.org

Would you allow impaired driving without standards?

Kratom can impair judgment, sedation, and reaction time—yet remains largely unregulated.

Opioid-Level Warnings Exist

Prescription opioids clearly warn:
"Do not operate heavy machinery."
Kratom acts on the same receptors—but carries no consistent warning.

No Real Driving Standards

There is no roadside test for kratom impairment
No defined legal limit
No way for officers to assess real-time impairment

Limited Human Data

- Limited real-world driving safety data
- Small study sample sizes
- No established safe driving thresholds

What Drivers Need to Know

Kratom acts on opioid receptors
May cause sedation, slowed reaction, dizziness, and impaired focus
Same risks warned for opioid driving

Policy Gap

No standardized impairment threshold
No required warning labels
No consistent product strength
No enforcement tools for officers

No roadside test exists for kratom impairment

SOURCES
• U.S. FOOD AND DRUG ADMINISTRATION (FDA) — KRATOM PUBLIC HEALTH ADVISORIES
• FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)
• NATIONAL INSTITUTE ON DRUG ABUSE (NIDA) — KRATOM DRUGFACTS
• ZAMARIPPA ET AL. — EFFECTS OF KRATOM ON DRIVING AND PSYCHOMOTOR PERFORMANCE
• OPIOID PRESCRIBING INFORMATION

FOR MORE INFORMATION:

www.antikratom.org

2026

KRATOM: PUBLIC HEALTH RISK & REGULATORY GAP

This brief summarizes poison control data, federal findings, and emerging product risks relevant to state-level kratom policy decisions.

- Pediatric exposures are increasing, with young children most affected
- Poison control data show frequent hospitalizations and serious outcomes
- Federal agencies identify safety concerns, dependence, and opioid-like activity

Kratom products are widely available despite documented toxicity and lack of established safety. State-level action may be necessary where federal regulatory pathways remain unresolved.

The following materials provide evidence to support informed policy decisions regarding kratom access and regulation.

Prepared by:
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Hospital Pharmacist

FDA: Kratom Not Proven Safe for Use

Kratom (Mitragyna speciosa) is not approved as a drug, dietary supplement, or food additive in the U.S.

KEY FDA DETERMINATIONS

Not FDA-Approved

No approved drug products containing kratom
Not lawfully marketed as a supplement or food

Opioid Receptor Activity

Mitragynine and 7-OH bind to mu-opioid receptors

Potential Adverse Effects

Sedation, respiratory depression, dependence, and withdrawal reported

Contamination Risks

FDA has identified products contaminated with Salmonella and heavy metals.

Kratom products are widely available in the U.S., but FDA has determined there is insufficient evidence to establish safety for use as a dietary ingredient.

FDA has warned consumers about serious risks, including liver toxicity, seizures, and substance use disorder.

Public Health Concerns

- **No standardized dosing or product consistency.**
- **Documented dependence and withdrawal**
- **Limited well-controlled human studies**
- **Active federal enforcement actions**

FDA: Kratom safety has not been established and remains a public health concern.

No FDA-approved uses. Safety not established.

For more information

www.antikratom.org

Sources U.S. Food and Drug Administration — Public Health Advisories on Kratom (2023–2025)

CDC & Kratom (Mitragynine)

How CDC tracks overdose data, toxicology, and public health signals

SURVEILLANCE & REPORTING

CDC publishes findings from poison centers and overdose data to identify trends and emerging risks

SUDORS SYSTEM

Collects standardized data from death certificates, medical examiners, and toxicology reports

PUBLIC HEALTH ROLE

Issues guidance for clinicians, coroners, and first responders on emerging substances

KEY CDC CLARIFICATIONS

CDC distinguishes between substances detected on toxicology and those involved in death

- "Detected" means present — it does not necessarily indicate causation
- SUDORS is designed for signal detection and prevention, not to determine cause alone

KRATOM IN CDC DATA

- Appears in overdose surveillance systems
- Frequently involves polysubstance exposure
- Commonly co-detected with opioids (e.g., fentanyl)
- Presence in overdose data signals public health risk —even in polysubstance cases

KRATOM DETECTED IN OVERDOSE DEATHS (2020–2024)

2020: 866
2021: 1,016
2022: 1,017
2023: 1,151
2024: 995

KRATOM DETECTED IN OVERDOSE DEATHS REPORTED TO CDC SURVEILLANCE SYSTEMS

Sources
CDC. SUDORS.
CDC/MMWR. Kratom exposures & overdose reports.

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POISON CONTROL DATA: KRATOM EXPOSURES LINKED TO SERIOUS OUTCOMES

What U.S. Poison Centers Report

- 8,555 kratom exposure cases reported to U.S. poison centers (2019–2023)
- Among single-substance cases, 57.6% resulted in moderate, major, or fatal outcomes
- 34.3% required hospital admission following exposure

Clinical Impact

- Poison control cases frequently require medical treatment
- Reported outcomes include overdose and withdrawal
- Documented effects include seizures and confusion

What This Means for Policy

- Kratom exposures are not rare or minor events
- A significant portion result in clinically serious outcomes
- Products are widely available despite documented toxicity and healthcare utilization

Poison control data show kratom exposures frequently result in serious outcomes and hospitalization.

Source

America's Poison Centers® National Poison Data System (NPDS) Annual Reports (2019–2024)

Learn more at www.antikratom.org

PEDIATRIC KRATOM EXPOSURES ARE INCREASING

Pediatric Kratom Exposures (NPDS, 2019–2024)

Reported pediatric exposures to U.S. poison centers, categorized by age group. Data derived from NPDS Annual Reports (Appendix B, Table 22A/22B).

Year	<5 yrs	6–12 yrs	13–19 yrs	Total Pediatric
2019	60	3	39	102
2020	63	5	35	103
2021	91	5	43	139
2022	67	3	37	107
2023	71	3	32	106
2024	107	6	37	150

Source: America's Poison Centers® NPDS Annual Reports, 2019–2024.

WHAT POISON CONTROL DATA SHOW

- 150 pediatric exposures in 2024 (highest on record)
- Children under 5 are the largest exposure group each year
- Total exposures increased from 102 (2019) → 150 (2024)

YOUNGEST CHILDREN ARE MOST AFFECTED

- <5 years accounts for the majority of exposures
- Increase in recent years is driven primarily by this age group
- Most cases involve unintentional exposure in the home

CLINICAL IMPACT

- Many cases require medical evaluation or treatment
- Reported effects include:
  - sedation
  - vomiting
  - respiratory and neurologic symptoms

INCREASING EXPOSURES REFLECT REAL-WORLD ACCESS TO KRATOM PRODUCTS.

Sources
- America's Poison Centers® — National Poison Data System (NPDS) Annual Reports, 2019–2024
- NPDS Appendix B, Tables 22A–22B (Pediatric Exposures by Age Group)

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FDA REVIEW: KRATOM NOT SHOWN TO BE SAFE AS A DIETARY SUPPLEMENT

Regulatory Determination (Most Important Findings)

- FDA could not conclude kratom is reasonably safe
- Insufficient evidence to rule out a "significant or unreasonable risk of illness or injury"
- Product may be legally considered adulterated under federal law
- Interstate sale of such products is prohibited under the FD&C Act

CRITICAL SCIENTIFIC FAILURES IDENTIFIED BY FDA

- Identity and composition could not be established
- FDA could not verify what the product actually contains
- Safety data inadequate to support use—even at proposed low doses (50 mg/day)
- Submitted evidence failed to demonstrate consumer safety

Regulatory Conclusion

Kratom failed to meet the federal safety standard for dietary supplements—FDA found the evidence insufficient to establish safety and determined such products may be *adulterated* and illegal to introduce into interstate commerce.

Learn More at antikratom.org

Source: U.S. Food and Drug Administration — NDI Review (Johnson Foods, Jan 4, 2023)

FDA STUDY: LIMITED DATA ON BOTANICAL KRATOM — NOT REPRESENTATIVE OF MARKET PRODUCTS

Data based on FDA pilot clinical study (2024)

A small controlled study does not reflect the products sold in gas stations and vape shops.

WHAT THE STUDY FOUND

- No serious adverse events
- Conducted in 40 healthy recreational drug users
- Used single-source botanical kratom with no 7-hydroxymitragynine (7-OH)

CRITICAL LIMITATIONS (FDA STUDY ITSELF ACKNOWLEDGES)

- Small sample size
- Controlled setting
- Did not evaluate typical retail products

THE STUDY RAISES CONCERNS

Kratom produced effects such as "high" and "feeling drunk" and showed opioid-like pharmacological activity.

7-hydroxymitragynine (7-OH) was detectable after dosing despite not being present in the administered product.

LEARN MORE

Source - U.S. Food and Drug Administration Pilot Single Ascending Dose Study of Botanical Kratom (2024)

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HUMAN DATA: KRATOM PRODUCES OPIOID-LIKE EFFECT

Results from three dose studies in humans

ACTS LIKE AN OPIOID

- Binds to the same receptors as opioids
- Converts in the body to a stronger active compound
- Produces opioid-like pharmacologic effects in humans

STAYS IN THE BODY

- Drug levels increase as doses increase
- Remains in the body for days—not hours
- Builds up with repeated use

REAL SIDE EFFECTS IN HUMANS

- Nausea, dizziness, and sedation reported
- Side effects increase with higher doses
- Liver enzyme changes observed in trials

WHAT THIS MEANS FOR POLICY

Kratom shows opioid-like effects in humans
Builds up in the body with repeated use
Produces real, dose-related side effects
These are the same criteria used to justify controlled substance scheduling.

WHAT THIS LOOKS LIKE IN PRACTICE

- Use leads to measurable drug exposure in the body
- Effects increase as dose increases
- Repeated use results in ongoing presence in the bloodstream
- Side effects are documented in controlled human trials

SOURCES:
HUESTIS ET AL. (2024, 2026) HUMAN CLINICAL STUDIES
FDA-REGISTERED CLINICAL TRIAL DATA

For more information, visit
www.antikratom.org

KRATOM CAN BE ABUSED AND CONTRIBUTE TO DEATH EVEN IF IT IS NOT THE ONLY SUBSTANCE INVOLVED.

KRATOM ABUSE DOES NOT REQUIRE A SINGLE CAUSE OF DEATH

Focusing only on "sole cause of death" ignores how drug-related harm is actually measured and can underestimate real public health risk.

WHAT "DRUG ABUSE" MEANS

- Use of a substance in a way that leads to harm or risk
- Includes misuse, dependence, and non-medical use
- Defined by effects on health and behavior—not just cause of death

HOW KRATOM DEATHS ARE EVALUATED

- Deaths often involve multiple substances
- Medical examiners report all contributing substances
- A drug can contribute to death without being the sole cause

WHY "SOLE CAUSE" IS THE WRONG STANDARD

- Most overdose deaths involve polysubstance use
- Public health systems track presence and contribution, not exclusivity
- Requiring a single cause would exclude most drug-related deaths

Kratom harm is measured by contribution—not exclusivity.

Based on federal public health definitions of substance use and overdose reporting.

Sources
- National Institute on Drug Abuse (NIDA) — Substance Use and Addiction Definitions
- Centers for Disease Control and Prevention (CDC) — Overdose Surveillance (SUDORS)
- U.S. Food and Drug Administration (FDA) — Adverse Event Reporting System (FAERS)

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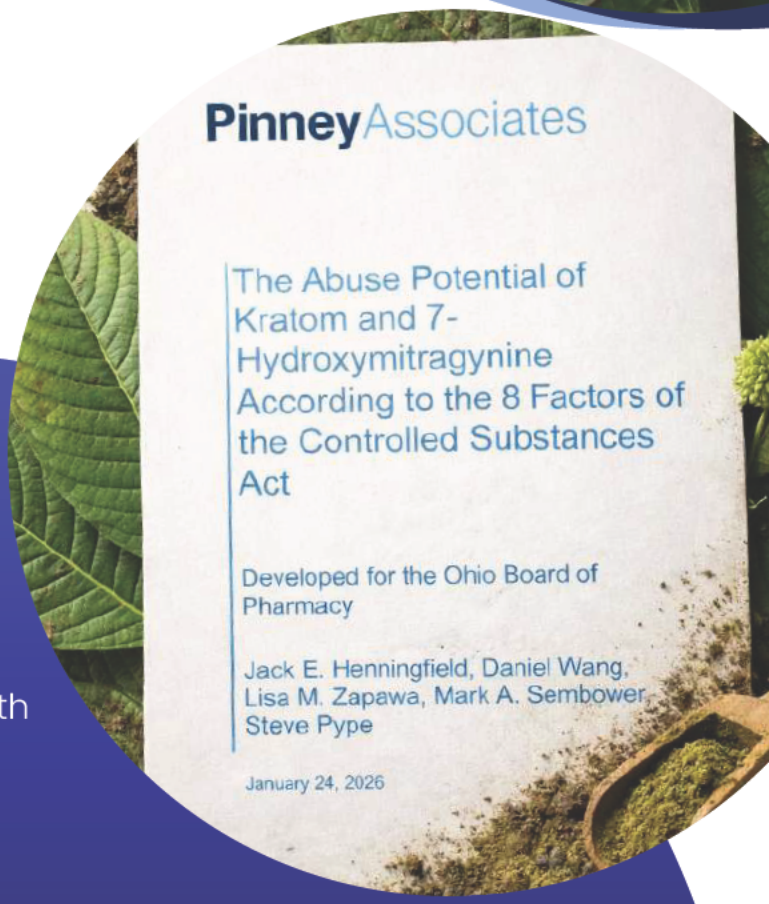
EIGHT-FACTOR ANALYSIS: INDUSTRY-FUNDED REVIEW USED IN REGULATORY DEBATES

What the Analysis Is

- **CSA eight-factor analysis for drug scheduling**
- **Commissioned by industry to oppose scheduling**
- **Submitted to federal agencies in review**



WHAT IT CONCLUDES

- Claims kratom has lower abuse potential than traditional opioids
- Argues there is no imminent public health risk
- Recommends continued access rather than scheduling

CRITICAL CONCERNS

- Relies heavily on literature review and selected data interpretation
- Downplays dependence, withdrawal, and opioid receptor activity
- Does not reflect real-world products, extracts, or evolving market potency

WHY THIS MATTERS FOR POLICY

- Eight-factor analyses can influence DEA scheduling decisions
- Selective interpretation may delay regulatory action
- Legislators may receive conclusions without full context of limitations

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SOURCE: PINNEY ASSOCIATES / HENNINGFIELD EIGHT-FACTOR ANALYSIS SUBMITTED IN REGULATORY PROCEEDINGS REVIEWED PUBLICATIONS AND REGULATORY SUBMISSIONS

PINNEY ASSOCIATES REGULATORY STRATEGY & RISK MANAGEMENT CONSULTING

REGULATORY INFLUENCE IN ACTION

WHO IS SHAPING KRATOM POLICY?

Industry-funded analyses can directly influence scheduling decisions

WHAT THEY DO

Advises industry on regulatory strategy and abuse potential. Produces analyses used in federal and state decision-making.

In its kratom analysis submitted to regulators, the firm reached the following conclusions:

- Found lower abuse potential compared to opioids
- Minimized concerns around dependence and withdrawal
- Opposed scheduling in regulatory submissions

OPIOID POLICY POSITIONING

- Defended REMS programs despite rising overdose deaths
- Argued opioid safety programs are misunderstood—not failures
- Shifted focus to illicit drugs and system limitations

VAPING AS "HARM REDUCTION"

- Supported e-cigarettes as alternatives to smoking
- Framed nicotine delivery as lower-risk strategy
- Influenced regulatory conversations on tobacco policy

OVER-THE-COUNTER BIRTH CONTROL (O-PILL)

- Supported approval of first OTC oral contraceptive (Opill)
- Advanced self-selection model without clinician oversight
- Helped shape regulatory pathway for non-prescription access

Should industry-funded analysis determine public health policy?

Based on publicly available regulatory submissions and published analyses.

For more information, visit www.antikratom.org

NEW KRATOM-DERIVED PRODUCTS ARE EMERGING

Meet Oxonol!

A new pathway emerging around 7-hydroxymitragynine restrictions

Quick Relief you can count on.

FACTOR 8 OF THE CONTROLLED SUBSTANCE ACT

Factor 8 of the Controlled Substances Act evaluates whether a substance is an immediate precursor to a controlled drug or closely mimics its pharmacologic effects, allowing regulators to identify risks early and act before widespread harm occurs.

This framework exists to address substances that mimic controlled drugs.

SIMILAR PATTERNS WERE SEEN WITH SUBSTANCES LIKE 'SPICE' AND SYNTHETIC DRUGS BEFORE WIDESPREAD PUBLIC HARM WAS RECOGNIZED

Source
· Ohio Board of Pharmacy — Eight-Factor Analysis of Kratom (Mitragynine and 7-Hydroxymitragynine) under the Controlled Substances Act

Why it works

- Not labeled as 7-OH
- Derived from kratom alkaloids through processing
- Marketed using vague "proprietary blends"
- Designed to mimic or replace restricted compounds

This will continue unless action is taken

Learn more at www.antikratom.org

Widely available in the retail market

KRATOM PRODUCTS SOLD TODAY

Powders and Capsules

- Variable alkaloid content across batches
- Effects can accumulate with repeated dosing
- Difficult to measure consistent intake

Drinks & Seltzer

- Rapid absorption may intensify effects
- Flavored formulations can mask potency
- Easy to consume multiple servings quickly

Extracts

- Concentrated alkaloids increase potency
- Small amounts can produce strong effects
- Often lack clear strength standardization
- Can be produced from raw powder into higher-potency products

7-hydroxymitragynine (7-OH)

- Highly potent active alkaloid
- Direct activity at opioid receptors
- **Made from extracting mitragynine from kratom and using an chemical reaction.**
- Sold as tablets, usually in packs of four. Most clearly identified with “7” on package

Products with opioid-active compounds are being sold in variable forms

Sources
- U.S. Food and Drug Administration (FDA) – Public Health Advisories on Kratom
- National Institute on Drug Abuse (NIDA) – Kratom DrugFacts
- Centers for Disease Control and Prevention (CDC) – Toxicology and Overdose Data

Learn More at www.antikratom.org

KRATOM REMAINS WIDELY AVAILABLE DESPITE DOCUMENTED RISKS

Federal agencies have identified safety concerns, yet high-potency kratom products continue to be sold in retail settings without consistent oversight.

WHAT THE DATA SHOW

- Pediatric exposures are increasing, with young children most affected
- Poison control data show hospitalizations and serious outcomes
- Kratom is detected in overdose deaths and acts on opioid receptors
- FDA determined kratom has not been shown to be safe for use

WHAT THIS MEANS

- These are not rare or isolated events
- Products with opioid-like activity remain easily accessible
- Current retail availability does not reflect documented risk
- Delayed action allows continued expansion of higher-potency products

Kratom harm is documented. Access remains widespread. Regulatory gaps persist.

WHY STATE ACTION MATTERS

- **States can act where federal pathways are unresolved**
- **Retail access can be aligned with known risk**
- **Early action can prevent further normalization of higher-potency products**

The question is no longer whether risk exists—

but whether current access reflects that risk.

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Sources: FDA, CDC, NIDA, America's Poison Centers