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.

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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.

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)

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)

www.antikratom.org

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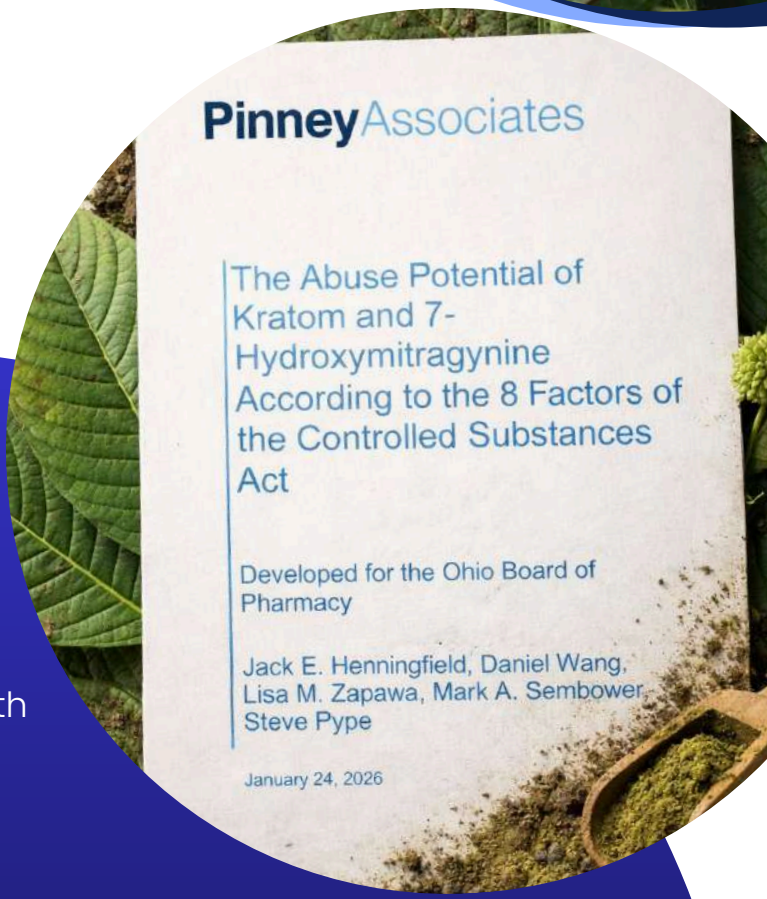
EIGHT-FACTOR ANALYSIS: INDUSTRY-FUNDED REVIEW USED IN REGULATORY DEBATES

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

Visit Our Website
www.antikratom.org

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.

www.antikratom.org

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