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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
MEDICAL EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
July 15, 2026

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.

AGENDA

8:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-5)

B. Approval of Minutes of June 17, 2026 (6-9)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition
1. Introduction: Rebekah S. Blumenfeld, Public Member (Succeeds: Lerma)
2. Recognition: Carmen Lerma, Public Member (Resigned: 6/11/2026)

E. Administrative Matters – Discussion and Consideration (10-11)
1. Department, Staff and Board Updates
2. **Election of Officers, Appointment of Liaisons and Alternates**
3. Board Members – Term Expiration Dates
   a. Blumenfeld, Rebekah S. – 7/1/2030
   b. Bond, Jr., Milton – 7/1/2027
   c. Chou, Clarence P. – 7/1/2027
   d. Clarke, Callisia N. – 7/1/2028
   e. Ferguson, Kris – 7/1/2029
   f. Gerlach, Diane M. – 7/1/2028
   g. Leuthner, Steven R. – 7/1/2027
   h. Majeed-Haqqi, Lubna – 7/1/2027
   i. Ruud, Emily – 7/1/2028
   j. Schmeling, Gregory J. – 7/1/2029
   k. Siebert, Derrick R. – 7/1/2029
   l. Yu, Emily S. – 7/1/2028
   m. Gribble, Robert – Chairperson of the Injured Patients and Families Compensation Fund Peer Review Council – Non-Voting Member
4. **Wis. Stat. § 15.085 (3)(b) – Affiliated Credentialing Boards' Biannual Meeting with the Medical Examining Board to Consider Matters of Joint Interest**

a. Physician Assistant Affiliated Credentialing Board – Jennifer Jarrett, Chairperson

F. Administrative Rule Matters – Discussion and Consideration (12-15)

1. Pending or Possible Rulemaking Projects
   a. Rule Projects Charts
   b. Affiliated Credentialing Board Rule Summaries
   c. Possible Rule Project on Continuing Education

G. Legislative and Policy Matters – Discussion and Consideration

H. Interdisciplinary Advisory Committee Liaison Report – Discussion and Consideration (16)

1. Ketamine Guidance Document Review

I. Credentialing Matters – Discussion and Consideration

J. Professional Assistance Procedure (PAP) Discussion of Expansion to Include Mental Health Disorders

K. Federation of State Medical Board (FSMB) Matters – Discussion and Consideration

L. Speaking, Travel, or Public Relation Requests, and Reports – Discussion and Consideration

M. Newsletter Matters – Discussion and Consideration

N. Controlled Substances Board Report – Discussion and Consideration (17-135)

1. Kratom Discussion

O. Interstate Medical Licensure Compact Commission (IMLCC) – Report from Wisconsin's Commissioners – Discussion and Consideration

P. Screening Panel Report

Q. Future Agenda Items

R. Discussion and Consideration of Items Added After Preparation of Agenda:

1. Introductions, Announcements and Recognition
2. Elections, Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison Appointments
3. Administrative Matters
4. Election of Officers
5. Appointment of Liaisons and Alternates
6. Delegation of Authorities
7. Education and Examination Matters
8. Credentialing Matters
9. Practice Matters
10. Public Health Emergencies
11. Legislative and Policy Matters
12. Administrative Rule Matters
13. Liaison Reports
14. Board Liaison Training and Appointment of Mentors
15. Informational Items

16. Division of Legal Services and Compliance (DLSC) Matters
17. Presentations of Petitions for Summary Suspension
18. Petitions for Designation of Hearing Examiner
19. Presentation of Stipulations, Final Decisions and Orders
20. Presentation of Proposed Final Decisions and Orders
21. Presentation of Interim Orders
22. Petitions for Re-Hearing
23. Petitions for Assessments
24. Petitions to Vacate Orders
25. Requests for Disciplinary Proceeding Presentations
26. Motions
27. Petitions
28. Appearances from Requests Received or Renewed
29. Speaking Engagements, Travel, or Public Relation Requests, and Reports

S. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (Wis. Stat. § 19.85(1)(a)); to consider licensure or certification of individuals (Wis. Stat. § 19.85(1)(b)); to consider closing disciplinary investigations with administrative warnings (Wis. Stat. §§ 19.85(1)(b), and 448.02(8)); to consider individual histories or disciplinary data (Wis. Stat. § 19.85(1)(f)); and to confer with legal counsel (Wis. Stat. § 19.85(1)(g)).

T. Deliberation on DLSC Matters

1. Monitoring Matters

a. Brandon Welsh – Reinstatement of Licensure **(136-246)**

2. Proposed Stipulations, Final Decisions and Orders

a. 23 MED 378 – Neil J. Brahmbhatt **(247-252)**
b. 23 MED 615 – Traci R. Fritz **(253-260)**
c. 24 MED 0275 – Nicholas D. McCord **(261-268)**
d. 25 MED 0297 – Timothy G. Novick **(269-279)**
e. 25 MED 0474 – Dustin M. Brown **(280-285)**

3. Complaints

a. 23 MED 615 – T.R.F. **(286-290)**
b. 24 MED 0337 – H.M.L. **(291-352)**
c. 25 MED 0279 – C.M.T. **(353-355)**

4. Case Closings

a. 24 MED 0207 – R.A.D. **(356-369)**
b. 25 MED 0142 – K.O.D. **(370-381)**
c. 25 MED 0163 – M.J.N. **(382-387)**
d. 25 MED 0356 – A.J.S. **(388-413)**
e. 25 MED 0505 – E.A.F. **(414-423)**
f. 26 MED 0066 – W.Y. **(424-431)**

U. Credentialing Matters

1. Full Board Review

a. J.C. – Visiting Physician (IA-961649) **(432-451)**
b. N.R. – Initial Application (IA-724158) **(452-594)**

2. Full Board Oral Exam

a. A.L. – Physician Application (IA-868757) **(595-632)**

V. Deliberation of Items Added After Preparation of the Agenda

1. Education and Examination Matters
2. Credentialing Matters
3. DLSC Matters
4. Monitoring Matters
5. Professional Assistance Procedure (PAP) Matters
6. Petitions for Summary Suspensions
7. Petitions for Designation of Hearing Examiner
8. Proposed Stipulations, Final Decisions and Order
9. Proposed Interim Orders
10. Administrative Warnings
11. Review of Administrative Warnings
12. Proposed Final Decisions and Orders
13. Matters Relating to Costs/Orders Fixing Costs
14. Complaints
15. Case Closings
16. Board Liaison Training
17. Petitions for Extension of Time
18. Petitions for Assessments and Evaluations
19. Petitions to Vacate Orders
20. Remedial Education Cases
21. Motions
22. Petitions for Re-Hearing
23. Appearances from Requests Received or Renewed

W. Open Cases

X. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

Y. Open Session Items Noticed Above Not Completed in the Initial Open Session

Z. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

AA. Delegation of Ratification of Examination Results and Ratification of Licenses and Certificates

ADJOURNMENT

ORAL INTERVIEWS OF CANDIDATES FOR LICENSURE

VIRTUAL/TELECONFERENCE

9:30 A.M. OR IMMEDIATELY FOLLOWING THE FULL BOARD MEETING

CLOSED SESSION – Reviewing Applications and Conducting Oral Interviews of **three (3)** (at time of agenda publication) Candidates for Licensure –**Dr. Gerlach and Dr. Leuthner**

NEXT MEETING: AUGUST 19, 2026

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
MEDICAL EXAMINING BOARD
MEETING MINUTES
JUNE 17, 2026

PRESENT: Milton Bond, Jr. (*arrived at 8:03 a.m.)*; Clarence Chou, M.D.; Kris Ferguson, M.D.; Diane Gerlach, D.O.; Sumeet Goel, D.O.; Steven Leuthner, M.D.; Lubna Majeed-Haqqi, M.D.; Gregory Schmeling, M.D.; Derrick Siebert, M.D.; Emily Yu, M.D.

ABSENT: Callisia Clarke, M.D.; Robert Gribble, M.D.; Emily Ruud

STAFF: Tom Ryan, Executive Director; Renee Parton, Assistant Deputy Chief Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Tracy Drinkwater, Board Administration Specialist; and other Department staff

CALL TO ORDER

Gregory Schmeling, Chairperson, called the meeting to order at 8:00 a.m. A quorum was confirmed with nine (9) members present.

ADOPTION OF AGENDA

Amendment to the Agenda

- *Replace "Dr. Clarke" with "Dr. Chou" for oral interviews*

MOTION: Diane Gerlach moved, seconded by Lubna Majeed-Haqqi, to adopt the Agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF MAY 20, 2026

MOTION: Diane Gerlach moved, seconded by Emily Yu, to approve the Minutes of May 20, 2026, as published. Motion carried unanimously.

Milton Bond, Jr. arrived at 8:03 a.m.

INTRODUCTIONS, ANNOUNCEMENTS AND RECOGNITION

Recognition – Sumeet K. Goel, D.O. , Doctor of Osteopathy Member (Resigns 7/1/2026)

MOTION: Milton Bond, Jr. moved, seconded by Emily Yu, to recognize and thank Sumeet K. Goel, D.O. for their years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

CLOSED SESSION

MOTION: Diane Gerlach moved, seconded by Milton Bond, Jr. to convene to Closed Session to deliberate on cases following hearing (Wis. Stat. § 19.85(1)(a)); to consider licensure or certification of individuals (Wis. Stat. § 19.85(1)(b)); to consider closing disciplinary investigations with administrative warnings (Wis. Stat. §§ 19.85(1)(b) and 448.02(8)); to

consider individual histories or disciplinary data (Wis. Stat. § 19.85(1)(f)); and to confer with legal counsel (Wis. Stat. § 19.85(1)(g)). Gregory Schmeling, Chairperson, read the language of the motion aloud for the record. The vote of each member was ascertained by voice vote. Roll Call Vote: Milton Bond, Jr.-yes; Clarence Chou-yes; Kris Ferguson-yes; Diane Gerlach-yes; Sumeet Goel-yes; Steven Leuthner-yes; Lubna Majeed-Haqqi-yes; Gregory Schmeling-yes; Derrick Siebert-yes; and Emily Yu-yes. Motion carried unanimously.

The Board convened into Closed Session at 8:13 a.m.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Proposed Stipulations, Final Decisions and Orders

MOTION: Lubna Majeed-Haqqi moved, seconded by Steven Leuthner, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings of the following cases:

1. 23 MED 345 – Paul P. Heideman
2. 24 MED 0196 – Timothy A. M. Deering
3. 25 MED 0199 – Abby N. Fredrickson
4. 25 MED 0286 – Yusuf Kasirye

Motion carried unanimously.

Complaints

23 MED 318 – E.E.S.

MOTION: Clarence Chou moved, seconded by Emily Yu, to find probable cause in DLSC Case Number 23 MED 318, to believe that E.E.S. has committed unprofessional conduct, and therefore, to issue the Complaint and hold a hearing on such conduct pursuant to Wis. Stat § 448.02(3)(b). Motion carried unanimously.

(Gregory Schmeling recused and left the room for deliberation and voting in the matter concerning E.E.S., DLSC Case Number 23 MED 318.)

Case Closings

MOTION: Sumeet Goel moved, seconded by Steven Leuthner, to close the following DLSC Cases for the reasons outlined below:

1. 24 MED 0408 – B.J.K. – No Violation
2. 25 MED 0513 – D.F.K. –Prosecutorial Discretion (P7)
3. 25 MED 0527 – M.C.L. – No Violation
4. 25 MED 0571 – S.J.S. – Prosecutorial Discretion (P2)

Motion carried unanimously.

25 MED 0033 – H.A.J.

MOTION: Steven Leuthner moved, seconded by Lubna Majeed-Haqqi, to table DLSC Case 25 MED 0033 against H.A.J.. Motion carried unanimously.

26 MED 0164 – J.T.J.

MOTION: Sumeet Goel moved, seconded by Steven Leuthner, to close DLSC Case 26 MED 0164 against J.T.J., for Prosecutorial Discretion (P7). Motion carried unanimously.

(Clarence Chou recused and left the room for deliberation and voting in the matter concerning J.T.J., DLSC Case Number 26 MED 0164.)

CREDENTIALING MATTERS

Full Board Review

I.K. – Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training (IA-900956)

MOTION: Lubna Majeed-Haqqi moved, seconded by Steven Leuthner, to approve the Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training of I.K. (IA-900956), once all requirements are met. Motion carried unanimously.

J.A. – Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training (IA-902244)

MOTION: Kris Ferguson moved, seconded by Emily Yu, to approve the Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training of J.A. (IA-902244), once all requirements are met. Motion carried unanimously.

N.N.J. – Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training (IA-910321)

MOTION: Sumeet Goel moved, seconded by Steven Leuthner, to approve the Waiver of 24 Months of ACGME/AOA Accredited Post-Graduate Training of N.N.J. (IA-910321), once all requirements are met. Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Sumeet Goel moved, seconded by Lubna Majeed-Haqqi, to reconvene to Open Session. Motion carried unanimously.

The Board reconvened to Open Session at 8:45 a.m.

VOTE ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Lubna Majeed-Haqqi moved, seconded by Diane Gerlach, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

(Be advised that any recusals or abstentions reflected in the closed session motions stand for the purposes of the affirmation vote.)

DELEGATION OF RATIFICATION OF EXAMINATION RESULTS AND RATIFICATION OF LICENSES AND CERTIFICATES

MOTION: Derrick Siebert moved, seconded by Sumeet Goel, to delegate ratification of examination results to DSPS staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

ADJOURNMENT

MOTION: Lubna Majeed-Haqqi moved, seconded by Sumeet Goel, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 8:48 a.m.

Medical Examining Board
2026 Officers & Liaisons

Election of Officers

2026 OFFICERS	
Chairperson	Gregory Schmeling
Vice Chairperson	~~Sumeet Goel~~
Secretary	Emily Yu

Appointment of Liaisons and Alternates

LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Callisia Clarke, Lubna Majeed-Haqqi, Emily Yu, Diane Gerlach, Kris Ferguson, Gregory Schmeling, Derrick Siebert, Steven Leuthner *Alternate:* Clarence Chou
Education and Examinations Liaison(s)	Continuing Education: Diane Gerlach *Alternate:* Clarence Chou Examinations: Gregory Schmeling *Alternate:* Clarence Chou
Monitoring Liaison(s)	Kris Ferguson *Alternate:* Clarence Chou
Professional Assistance Procedure (PAP) Liaison(s)	Kris Ferguson *Alternate:* Clarence Chou
Legislative Liaison(s)	Gregory Schmeling *Alternate:* Clarence Chou
Travel Authorization Liaison(s)	~~Sumeet Goel~~ *Alternate:* Diane Gerlach
Newsletter Liaison(s)	~~Sumeet Goel~~ *Alternate:* Gregory Schmeling
Website Liaison(s)	~~Sumeet Goel~~ *Alternate:* Milton Bond Jr
Opioid Abuse Report Liaison(s) per 440.035(2m)(c)	Kris Ferguson *Alternate:* Derrick Siebert
Prescription Drug Monitoring Program Liaison(s)	Kris Ferguson *Alternate:* Lubna Majeed-Haqqi
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g) (MED)	Lubna Majeed-Haqqi *Alternate:* Steven Leuthner

Medical Examining Board
2026 Officers & Liaisons

OTHER APPOINTMENTS	
Council on Anesthesiologist Assistants	Kris Ferguson
Interdisciplinary Advisory Committee	Gregory Schmeling *Alternate:* Emily Yu
Interstate Medical Licensure Compact Commission (IMLCC) Representatives	Clarence Chou, Tom Ryan *Alternate:* Gregory Schmeling

Updated 7/1/2026 td

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin, Administrative Rules Coordinator	**7/3/26** **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**

3) Name of Board, Committee, Council, Sections:

Medical Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
7/15/26	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Pending or Possible Rulemaking Projects** **a. Rule Projects Charts** **b. Affiliated Credentialing Board Rule Summaries**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete **Appearance Request** for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

Attachments:
Rule Project Charts
ACB Rule Summaries

(Board Rule projects can be Viewed Here if Needed: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx)

11) Authorization

Nilajah D. Hardin — 7/3/26

Signature of person making this request **Date**

Supervisor (if required) **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Medical Examining Board
Rule Projects (updated 7/3/26)

Clearinghouse Rule Number	Scope #	Scope Expiration	Code Chapter Affected	Relating clause	Current Stage	Next Step
25-048	099-24	03/23/2027	Med 1	Licensure Requirements	Drafting Final Rule and Legislative Report	Submission to Governor's Office for Approval, Notification to the Legislature, and for Publication
Not Assigned Yet	Not Assigned Yet	TBD	Med 3	Visting Physician License	Scope Statement Anticipated Publication for 7/9/26	Possible Preliminary Hearing Ordered by JCRAR
Not Assigned Yet	066-25	03/29/2028	Med 14	Renewal	Drafting Rule	Board Review and Approval of Preliminary Rule Draft
Not Assigned Yet	Not Assigned Yet	TBD	Med 20	Implementation of the Respiratory Care Interstate Compact	Scope Statement Anticipated Publication for 7/9/26	Possible Preliminary Hearing Ordered by JCRAR
25-070	025-25	10/14/2027	Med 21	Patient Health Care Records	Effective 7/1/26	N/A

Medical Examining Board
Affiliated Credentialing Board (ACB) Rule Projects

Clearinghouse Rule Number	Scope #	Scope Expiration	ACB Name	Code Chapter Affected	Relating clause	Current Stage	Next Step
Not Assigned Yet	Not Assigned Yet	TBD	Dietitians Affiliated Credentialing Board	DI 1 to 5	Implementation of the Dietitian Licensure Compact	Scope Statement Anticipated Publication on 7/9/26	JCRAR may order a Preliminary Public Hearing
Not Assigned Yet	Not Assigned Yet	TBD	Massage Therapy and Bodywork Therapy	MTBT 2 and 4	CPR Requirements	Scope Statement Published on 04/13/26	Scope Statement Implementation
Not Assigned Yet	009-25	02/17/2027	Massage Therapy and Bodywork Therapy	MTBT 3	Education	Drafting	Board Review of Preliminary Rule Draft at a Future Meeting
Not Assigned Yet	024-25	10/14/2027	Podiatry	Pod 1 and 9	Supervision of Physician Assistants	Drafting	Board Review of Preliminary Rule Draft at a Future Meeting
Not Assigned Yet	023-25	10/14/2027	Podiatry	Pod 1 and 10	Podiatrists and Telehealth	Public Hearing at 6/10/26 Meeting	Drafting Final Rule and Legislative Report

Affiliated Credentialing Board (ACB) Rule Summaries

Athletic Trainers: None

Dietitians:

- DI 1 to 5, Implementation of the Dietitian Licensure Compact
    - 2025 WI Act 20 outlines all compact requirements in the statute.
    - This rule project adds compact privilege as a license option to the rules.

Massage Therapy and Bodywork Therapy:

- MTBT 2 and 4, CPR Requirements
    - The ACB plans to review Chapter MTBT 2 and 4 to determine if updating requirements for CPR training is appropriate.
- MTBT 3, Relating to Education
    - The ACB plans to change the initial licensure requirement of 600 education hours to match the standard recommended by the Federation of State Massage Therapy Boards.
    - Other updates may be made to the chapter to align with current practice if needed

Occupational Therapists: None

Physician Assistant: None

Podiatry:

- Pod 1 and 9, Relating to Supervision of Physician Assistants
    - Due to 2021 WI Act 23, the ACB plans to create requirements for supervision of Physician Assistants by a Podiatrist.
- Pod 1 and 10, Relating to Podiatrists and Telehealth
    - The ACB created requirements on Telehealth for Podiatrists in line with 2021 WI Act 121.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Brad Wojciechowski, Executive Director	7/7/2026
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Medical Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
7/15/2026	☐ Yes ☒ No	Interdisciplinary Advisory Committee – Discussion and Consideration 1) Ketamine Guidance Document Review

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if applicable:
☒ Open Session ☐ Closed Session	☐ Yes <Appearance Name(s)> ☐ No	<Click Here to Add Case Advisor Name or N/A>

10) Describe the issue and action that should be addressed:

11) Authorization

7/7/2026

Signature of person making this request	Date
Supervisor (Only required for post agenda deadline items)	Date
Executive Director signature (Indicates approval for post agenda deadline items)	Date

Directions for including supporting documents:

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3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Dr. Schmeling, Board Chairperson		**2) Date when request submitted:** 07/03/2026 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Medical Examining Board			
4) Meeting Date: 07/15/2026	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Controlled Substances Board Report – Discussion and Consideration 1. Kratom Discussion	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☒ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: To discuss recent literature and state guidance on Kratom.			
11) Authorization  *Gregory Schmeling* — **Signature of person making this request**		*7/03/2026* — **Date**	
Supervisor (Only required for post agenda deadline items)		**Date**	
Executive Director signature (Indicates approval for post agenda deadline items)		**Date**	

Directions for including supporting documents:

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Classification of Mitragynine as a Schedule I Controlled Substance

Section 1: Summary

The Ohio Board of Pharmacy (Board), pursuant to section 3719.44 of the Ohio Revised Code, proposes the placement of mitragynine, the primary psychoactive alkaloid found in the Mitragyna speciosa plant, commonly known as kratom, into Schedule I.

Section 2: Background

Pursuant to section 3719.44 of the Ohio Revised Code, the Board may add or transfer a compound, mixture, preparation, or substance to Schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.

In making a determination to add an unscheduled compound, the Board is required to consider the following 8 criteria:

(1) The actual or relative potential for abuse;
(2) The scientific evidence of the pharmacological effect of the substance;
(3) The state of current scientific knowledge regarding the substance;
(4) The history and current pattern of abuse;
(5) The scope, duration, and significance of abuse;
(6) The risk to the public health;
(7) The potential of the substance to produce psychic or physiological dependence liability; and
(8) Whether the substance is an immediate precursor.

Section 3: Evaluating Mitragynine Under the 8-Factor Criteria

(1) The actual or relative potential for abuse.

Mitragynine is the primary psychoactive alkaloid found in the Mitragyna speciosa plant, commonly known as kratom. Mitragynine accounts for up to 66 percent of the alkaloid content in kratom.[i] Manufacturers of natural kratom products profess that minor alkaloids in natural kratom are undetectable.[ii] Kratom has a long history of traditional use in Southeast Asia with the use of its leaf or extracts typically ingested orally for the treatment of pain and to aid in the performance of agricultural labor.[iii] These effects have been attributed to mitragynine, which acts as a partial agonist at the human μ-opioid receptor.[iv] The effects of kratom in humans are dose-dependent, with small doses producing a 'cocaine-like' stimulation while larger amounts cause 'morphine-like' sedative-narcotic effects.[v]

Although mitragynine is the most abundant alkaloid in kratom and credited for its effects, the plant contains over 40 naturally occurring known alkaloids. One study examined the likely effects of 25 of those compounds. The study concluded that all the compounds share the most structural similarities with controlled opioid analgesics, such as morphine derivatives. Further analysis determined that 22 (including mitragynine) of the 25 compounds in kratom bind to μ-opioid receptors. The authors further noted:

> *The data from the PHASE model shows us that kratom compounds are predicted to affect the body just like opioids. Based on the scientific information in the literature and further supported by our computational modeling and the reports of its adverse effects in humans, we feel confident in calling compounds found in kratom, opioids.*[vi]

The FDA confirms that no marketer has sought to develop a drug that includes kratom in the US.[vii] Further, the World Health Organization verifies that kratom and its alkaloids have never been licensed for therapeutic use.[viii] Mitragynine has not been approved for medical use as a drug, nor is it generally recognized as safe by the FDA.[ix]

Kratom is illegal in 33 countries, including Malaysia where it is found naturally.[x] It is also banned in several states, including Alabama, Arkansas, Indiana, Vermont, Rhode Island, Louisiana, and Wisconsin.[xi] [xii] A new law in Connecticut, effective October 1, 2025, requires the state's Department of Consumer Protection (DCP) to designate kratom and 7-hydroxymitragynie as Schedule I controlled substances.[xiii] On December 10, 2025, Connecticut's DCP issued a notice of decision to move forward with the scheduling action.[xiv]

Kratom has also been identified as a Drug of Concern by the US Drug Enforcement Administration (DEA).[xv]

Despite its lack of approved use, kratom and its primary alkaloid, mitragynine, have been used to self-treat conditions such as chronic pain, fatigue, and psychiatric disorders (including substance use disorder and attention deficit hyperactivity disorder). For example, the Ohio Substance Abuse Monitoring Network reported about the availability of kratom in Ohio and its marketing towards individuals who are experiencing opioid use disorder. One respondent noted: "Advertisement for kratom [are] on Facebook…advertised as a way to get off of opiates, certain kinds of opiates; [Kratom] has similar withdrawal [symptoms as heroin]; Kratom mimics the effects of heroin…but the POs (parole officers) are aware of it now." A treatment provider also reported that people are using kratom for its purported health benefits such as the treatment of pain, noting, "you can go to the store and buy [kratom] now…because people look up positive things about it (health benefits). It's a pain reliever…it does give the effect of opiates or heroin…If someone has a little pain and they think it's healthy and natural [then they may try it]…."[xvi]

Still others begin using kratom for relaxation, euphoria, or to enhance performance.[xvii] The end result for many consumers of these products has been an inability to control their use—actual abuse. Below are comments submitted to the Ohio Board of Pharmacy by consumers of products whose manufacturers profess are natural, herbal, or kratom.

- *Good morning. I understand the Ohio Board of Pharmacy is considering a ban on Kratom. I am in support of this ban. I have a family member that has become addicted to Feel Free made by Botanic Tonics. It was originally marketed as a kava drink and alcohol alternative. Come to find out the company is facing many lawsuits due to its false marketing. While they now say it includes kratom, it's too late for my family. The drink is extremely addictive and very strong. I don't believe that it is pure leaf kratom, there has to be more in this drink. It has created many issues for my family and severely negatively impacted my family's life. Please consider this ban. This drink is legal opioid and available at most gas stations. This drink is very addictive and dangerous. Please seriously consider the ban on kratom and more specifically Feel Free. Also, please reference the Reddit thread quitting feelfree, you will see all the people suffering from the dangerous and addictive qualities of this drink.*[xviii]

- *Hello, I am a married wife of a kratom addict. I married my husband 7 years ago after he was clean off drugs (pills, cocaine, weed) for 8 years. He relapsed after 4 years into our marriage and has been addicted to kratom since. He was offered a sample by a gas station attendant … stated "are you looking for energy, try this". Since then he takes up to 60 capsules a day lost 25 pounds and is in a constant state of irritability, speedy, highs, and super lows withdrawling ect. He tried detox once and relapse 2 days later. He says it's so hard to quit bc it's so easy to get and cheap. This garbage is horrible and I cannot believe kids can get a hold of this junk. I am pleading for your office to understand the severity of this "supplement". My soon to be ex-husband has now transitioned to the "7oh tabs" that are more potent and also easy to get apparently sold at smoke shops and cbd stores. I know it is the choice of the individual to pick up a substance and it's their responsibility to quit, but I worry about my kids (16 and 5) in their future if they stumble upon this gas station heroine. To whatever it's worth I just wanted to share my story.*[xix]

- *My husband is a recovering opioid addict. Recently, he was introduced to kratom tablets and began taking them without telling me. When I first noticed the physical changes—his pupils shrinking and his energy levels spiking—I honestly believed he had relapsed on opioids. It was terrifying and brought back painful memories of our past struggles. He has now been taking kratom daily for months. He repeatedly tells me he plans to stop, but I can see that he cannot. He is worried about withdrawal and continues to use it despite the harm it is causing to his health and to our family. To me, this feels like we are back at square one, only with a substance that is currently unregulated and readily available. This is not the first time we have faced this danger. About a year ago, my husband was using the "blue bottle Feel Free" drinks (also containing kratom). After months of daily use, he ended up hospitalized with dangerously high liver enzyme levels and signs of serious liver damage. It took a long recovery, and now we are living through a repeat situation with kratom tablets. I know kratom is sometimes marketed as a "safe alternative" or a supplement, but my family's experience shows otherwise. For people in recovery, it is not a harmless plant—it is another addictive drug that threatens to undo years of hard work and healing.*[xx]

- *Someone very close to me began using kratom thinking it was a safe, natural way to manage stress and pain with out opiates. Over time, I watched it take over their life. They became anxious, detached, angry, and sick when they tried to stop. It broke my*

heart to see how something so easy to buy could cause such deep harm — not only to them, but to everyone who loves them. He would pass out while alone with our 22month old, he has been hospitalized with heart problems from use. We both have missed work, it has damaged our relationship, careers, children, and every aspect of our lives.[xxi]

According to a recent news report, "many people who descended into kratom addiction say gas station products sucked them in. The 'Quitting Kratom' subreddit has 52,000 members and several posts a day from people documenting their journeys trying to quit kratom and 7-OH."[xxii] Medications approved by the FDA to treat opioid-use disorder have been used to treat individuals experiencing substance-use disorder associated with kratom. For example, a case report of a male in his 40s with a history of kratom use was successfully treated with buprenorphine/naloxone, which helped alleviate his withdrawal symptoms and allowed him to abstain from kratom.[xxiii] Other case examples have been cited throughout medical literature to support the use of buprenorphine/naloxone to treat kratom-use disorder.[xxiv] [xxv]

Another study conducted interviews with 395 kratom users and classified users into four distinct categories. Two classes included people using kratom for the self-treatment of chronic pain or substance use disorder and comprised approximately 52 percent of respondents. The other two classes, about 48 percent of respondents, reported using kratom to "get high." The study also notes that individuals who reported using kratom to "get high" and who had the highest probability of kratom-use disorder were more likely to characterize kratom as "habit-forming, addictive, problematic, and inconsistent in its effects."[xxvi]

(2) The scientific evidence of the pharmacological effect of the substance.

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) notes that kratom and its related compounds are selective and full agonists of the μ-opioid receptor. The effects of kratom in humans are dose-dependent, with small doses producing a 'cocaine-like' stimulation while larger amounts cause 'morphine-like' sedative-narcotic effects.[xxvii]

A review published in 2024 notes that "mitragynine intake may be beneficial according to previous scientific data that presents its characteristics in antinociception, anti-inflammation, antidepressant, stimulant activity, sedative activity, anxiolytic activity, cognitive effects, and management of opioid withdrawal, which might be used as natural

remedies for various illnesses." However, the authors noted that uncontrolled use of mitragynine may promote tolerance development and produce withdrawal symptoms upon abstinence."[xxviii]

One study conducted of kratom users in Malaysia found high rates of severe kratom dependence among regular users. More than half of regular users (those using for more than 6 months) reported severe kratom dependence, while 45% showed moderate kratom dependence. Physical withdrawal symptoms commonly experienced include muscle spasms and pain, sleeping difficulty, watery eyes/nose, hot flashes, fever, decreased appetite, and diarrhea. Psychological withdrawal symptoms commonly reported were restlessness, tension, anger, sadness, and nervousness. The study authors also noted that regular users who consumed 3 or more glasses of kratom per day had "higher odds of developing severe Kratom dependence, withdrawal symptoms, and inability to control Kratom craving."[xxix]

Medications approved by the FDA to treat opioid-use disorder have been used to treat individuals experiencing kratom-use disorder. Case examples have been cited throughout medical literature to support the use of buprenorphine/naloxone to treat kratom-use disorder.[xxx] [xxxi] There are also examples of treating kratom withdrawal symptoms with medications such as clonidine and hydroxyzine that are often used off-label to manage opioid withdrawal.[xxxii] [xxxiii] [xxxiv]

A case report of a male in his 40s with a history of kratom use was successfully treated with buprenorphine/naloxone, which helped alleviate his withdrawal symptoms and allowed him to abstain from kratom:

> *The patient was introduced to kratom 12 years ago by his brother for relaxation, stress relief, and as a substitute for oxycodone. He gradually increased his dose up to 40g of powder per day from an initial 6g/daily. He purchased kratom online and at a local gas station, and his weekly expenditure on the substance ranged from $100 to $600. Over time, he spent less time with family and friends, engaged in fewer recreational activities, and spent more time using kratom to relax at home. He realized that he was dependent on the substance when he experienced withdrawal symptoms such as diarrhea and anxiety when he skipped or reduced his use of the substance. He attempted to self-treat his addiction by decreasing his dose but experienced severe withdrawal symptoms, including stress, headaches, diarrhea, nausea, and dizziness. His inability to quit kratom*

prompted him to seek medical help from his primary care physician. This was his first time seeking help from a physician. The patient was provided with the opportunity to connect with substance abuse clinics and other self-help groups, but he preferred pharmacological treatment.[xxxv]

(3) The state of current scientific knowledge regarding the substance.

Little clinical dosing research exists for kratom and its primary alkaloid, mitragynine. Neither kratom nor mitragynine have progressed past Phase 1 clinical trials.[xxxvi] [xxxvii] "Despite the increasing availability of human in vitro and in vivo animal data, rigorous fundamental information about the pharmacokinetics of kratom alkaloids in humans remains limited."[xxxviii]

Of the sparse pharmacokinetic research available, one study of twelve enrolled subjects monitored plasma levels of mitragynine and one of its metabolites, 7-hydroxymitragynine (7-OH), at various doses. The study found that 7-OH in plasma increased in a dose proportional manner after subjects consumed mitragynine contained in botanical kratom. The study also concluded that 7-OH steady state is reached after seven days of continuous dosing.[xxxix]

An increasing amount of 7-OH in plasma that is proportional with an individual's dose of mitragynine is important for two reasons. First, as discussed under Factor 4 below, mitragynine found in consumer products today is often several times more potent than traditional leaf products. Second, 7-OH is approximately 10 times more potent than mitragynine.[xl] At just 10 times the potency of mitragynine, the effects and actual abuse of 7-OH prompted Food and Drug Administration (FDA) Commissioner Dr. Martin Makary to warn that it could be the next wave of the opioid crisis.[xli]

Mitragynine has not undergone randomized, placebo-controlled studies necessary to demonstrate efficacy for any condition while minimizing the significant risks associated with it.[xlii] "FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports."

Significantly, Phase I clinical studies explore the safety and tolerability of substances on 100 or fewer healthy adults.[xliv] Most drugs—nearly 70 percent—that undergo Phase 1 clinical trials succeed to Phase 2 clinical trials. It is not until Phase 2 that research on a substance's ability to treat a condition and its side effects are studied. This usually occurs with several hundred subjects who have the disease or condition in question. Approximately 33 percent of substances proceed to Phase 3 where efficacy is continued to be studied, and adverse effects are monitored on somewhere between several hundred to several thousand individuals with the disease or condition in question.[xlv]

(4) The history and current pattern of abuse.

Kratom has been used for centuries in Southeast Asia by laborers for its stimulant and analgesic effects.[xlvi] As previously discussed, kratom and its primary alkaloid, mitragynine, have been used to self-treat conditions such as chronic pain, fatigue, and psychiatric disorders (including substance use disorder and attention deficit hyperactivity disorder). Still others begin using kratom for relaxation, euphoria, or to enhance performance. [xlvii]

Despite a long history of use originating from Southeast Asia, the widespread commercialization of kratom and its primary alkaloid, mitragynine, is a recent development. Both products sold as vegetation and those labeled as ground vegetation have been found to contain several times the amount of mitragynine than actual kratom leaf material. [xlviii] Indeed, manufacturers of products marketed as "all-

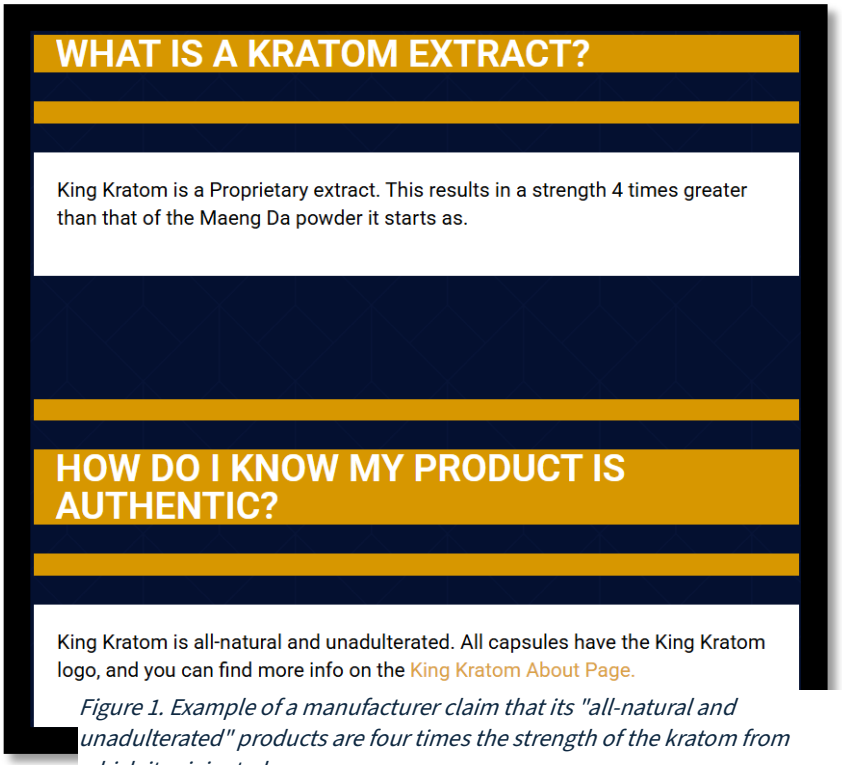


Figure 1. Example of a manufacturer claim that its "all-natural and unadulterated" products are four times the strength of the kratom from which it originated.

natural and unadulterated" acknowledge that extracts are several times greater than the plant from which they start (see Figure 1).[xlix] Postmortem toxicology findings from patients who used kratom had concentrations "higher than those reported in Thai individuals consuming traditional kratom tea without adverse effects."[l]

As kratom commercialization has grown, so too have the number of adverse events reported to poison control centers. From January 1 to July 31, 2025, poison control centers in the United States (US) received 1,690 reports of exposure cases involving kratom, a number that already surpasses the total for all of 2024.[li] Notably, adverse events associated with items that can be categorized as supplements are underreported. At least one source estimates the reporting rate for adverse events related to supplements to be approximately 2 percent.[lii] Reports of kratom exposure have been associated with opioid toxicities including seizures, agitation, and death.[liii]

The Ohio Substance Abuse Monitoring (OSAM) Network report from January 2025 found kratom use associated with opioid use, as the substance reportedly has similar effects, and kratom is reportedly advertised to help mitigate opioid withdrawal symptoms and stop opioid use. While its notoriety appears to be causing drug screening to expand, there is evidence that some individuals consumed kratom because it would not appear on drug screens. One testimonial provided, *"[a]dvertisements for kratom* [are] *on Facebook … advertised as a way to get off of opiates, certain kinds of opiates;* [Kratom] *has similar withdrawal* [symptoms as heroin]*; Kratom mimics the effects of heroin … but the POs (parole officers) are aware of it now."*[liv]

Access to mitragynine can be further abused when it is isolated from kratom leaves. It can then be synthetically transformed into 7-OH and other semi-synthetic opioids—some with significantly enhanced μ-opioid receptor activity. One such compound, MGM-15 (dihydro-7-hydroxy mitragynine), first described in 2014, is a highly potent semi-synthetic opioid that can be synthesized from 7-hydroxymitragynine in a single step. In September 2025, the presence of MGM-15 was confirmed in commercially available tablets.[lv] These compounds were legally available in Ohio until rule 4729:9-1-01.1 of the Ohio Administrative Code became effective on December 12, 2025.[lvi]

(5) The scope, duration, and significance of abuse.

Although there is apparent consensus that the number of Americans who use kratom is in the millions, the precise number of those who use it is more nebulous. The Substance Abuse and Mental Health Services Administration estimated that in 2021, 1.7 million Americans aged 12 and older used kratom.[lvii] More recently, Harvard Medical School estimated that between 2 and 15 million Americans may be using kratom.[lviii]

The Ohio Substance Abuse Monitoring (OSAM) Network report from January 2025 found kratom use associated with opioid use, as the substance reportedly has similar effects, and kratom is reportedly advertised to help mitigate opioid withdrawal symptoms and stop opioid use. They stated: *"[a]dvertisements for kratom* [are] *on Facebook … advertised as a way to get off of opiates, certain kinds of opiates;* [Kratom] *has similar withdrawal* [symptoms as heroin]*; Kratom mimics the effects of heroin … but the POs (parole officers) are aware of it now."*[lix]

One research group prioritized its study in part because, "[t]eas and powders made from the kratom . . . plant are gaining in popularity due to their opioid-like effects."[lx] A treatment provider in the Cleveland region spoke about the promoted health benefits of kratom, saying, *"[y]ou can go to the store and buy* [kratom] *now … because people look up positive things about it (health benefits). It's a pain reliever … it does give the effect of opiates or heroin…. If someone has a little pain and they think it's healthy and natural* [then they may try it]*…"*[lxi]

Reportedly, kratom is desirable to some because it is not always included on drug screens. Treatment providers observed, *"Kratom is still one of those things that's out there that's being abused, that's not being caught* [through drug screening]*; I spoke to our nurse practitioner, and in small doses* [kratom] *doesn't show up on the* [drug] *screen. It's because people are taking way high doses that are detectable* [on drug screens] *that are not good for you, you know, addiction wise; A lot of places don't test for it* [on drug screens]*. So, until we started testing for it, I didn't hear that much about it, but now our lab tests routinely include kratom."*[lxii]

Public comments serve as further evidence of the significance of kratom abuse in Ohio. As discussed in the analysis of Factor 1, the Board of Pharmacy received comments from several individuals regarding the impact of kratom use. Reported impacts include relapses by those

in recovery, significant weight loss, inability to cease use despite adverse impacts on personal relationships and finances, liver damage, and heart issues.

Finally, a reality of modern drug misuse is that an increasing number of individuals engage in polydrug use with little to no knowledge of contraindications. This is true of both illicit drugs and prescription medication. From 2019 to 2023, the amount of unintentional drug overdose deaths in Ohio that involved multiple drugs ranged from 58 to 69 percent.[lxiii] Given this context, it would be irresponsible to discount the risk of polydrug use.

Kratom is no different. "In parallel with the increase in popularity of kratom is an increase in kratom-associated overdose deaths when concomitantly used with other drugs."[lxiv] The impact of consuming kratom with other substances is described in two Reddit posts from those impacted by kratom misuse found in Appendix A. These posts warn that kratom consumption with common medications can cause heart issues and even death.

(6) The risk to the public health.

"FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports."[lxv]

In Ohio, a growing number of deaths associated with kratom have been reported, indicating that it is a risk to public health. From 2019 to 2024, the Ohio Department of Health reported at least 202 deaths in which kratom is listed as a cause of death (see Table 1).

Table 1. Number of Unintentional Drug Overdose Deaths Involving Kratom (Mitragynine), 2019 - 2024[lxvi]							
Year	Total No. of Overdose Deaths	No. of Deaths with Kratom Detected in Postmortem Toxicology	% of Total Overdose Deaths with Kratom Detected in Postmortem Toxicology	No. of Deaths with Kratom Listed as a Cause of Death	% of Deaths with Kratom Detected in Postmortem Toxicology where Kratom Was Listed as a Cause of Death	No. of Deaths with Kratom Detected in Postmortem Toxicology That Were Also Positive for Other Substances	% of Deaths with Kratom Detected in Postmortem Toxicology That Were Also Positive for Other Substances
2019	3,962	19	0.5%	15	78.9%	17	89.5%
2020	4,943	34	0.7%	29	85.3%	29	85.3%
2021	5,174	49	0.9%	37	75.5%	41	83.7%
2022	4,916	47	1.0%	40	85.1%	44	93.6%
2023	4,461	52	1.2%	37	71.2%	43	82.7%
2024*	3,015	54	1.8%	44	81.5%	43	79.6%
Total	**26,471**	**255**	**0.9%**	**202**	**79.2%**	**217**	**85.1%**

**Data for 2024 is not yet complete.*

Several forensic cases of opioid-like deaths with lung congestion and high postmortem mitragynine blood concentrations with no obvious alternative causes of death have now been reported.[lxvii] [lxviii] There is also a report of naloxone being successfully used to reverse kratom intoxication.[lxix] This evidence suggests that high enough doses of kratom alkaloids may cause opioid toxicity via the usual opioid-receptor pathways implicated in conventional opioid overdoses.[lxx]

In 2019, Utah developed a regulatory scheme that allowed continued access to kratom over-the-counter. Despite age restrictions and limited alkaloid access, overdose deaths related to kratom and treatment for kratom use disorder persisted. One emergency room physician reported patients sharing that they "had no idea it was just like a narcotic," and that his patients experience the same withdrawal symptoms as those withdrawing from narcotics.[lxxi] The Utah State Medical Examiner reported nearly 160 kratom-related deaths over a five-year period. While most of those overdoses involved polysubstance use, the state saw almost 50% as many kratom-only deaths in the most recent 12-month reporting period as Utah had seen since 2014.[lxxii] Consequently, the Utah legislature proposed to add all alkaloids from kratom and their analogs to the state's list of controlled substances in November 2025. The bill sponsor originally voted to regulate kratom in 2019 but now "sees kratom in all forms as a dangerous opioid masquerading as a supplement."[lxxiii]

There are also documented cases of kratom use by expecting mothers resulting in neonatal abstinence syndrome for newborns.[lxxiv] [lxxv] [lxxvi] [lxxvii] These cases are particularly concerning given that the promotion of kratom products as safe alternatives to opioids may well persuade expecting mothers to consume kratom products to avoid the adverse impacts of opioids on their unborn child. The concern is compounded by the tendency of consumers to believe that the legal status of a substance means that it is a safe alternative to a controlled substance.[lxxviii]

At least one manufacturer reinforces this notion with misleading statements like, "[f]eel better with the only kratom products studied in clinical trials," and "US Made in our FDA-registered space in Florida" (see Figure 2).[lxxix] The FDA is unequivocal in its warning against kratom use due to its adverse effects.[lxxx] "There are no FDA-approved drugs containing kratom."[lxxxi] According to the FDA, kratom and mitragynine are also unlawful "when added to conventional foods, as dietary supplements, [and] as ingredients in any FDA-approved drug."[lxxxii]

Figure 2. Claims made by a manufacturer of self-proclaimed "pure, unadulterated" kratom.

Evidence supports the position that the ingredients in kratom available to consumers are void of robust quality control. In 2019, FDA conducted laboratory testing on 30 different kratom products from a variety of sources. The analysis found "significant levels of lead and nickel at concentrations that exceed safe exposure for oral daily drug intake."[lxxxiii] A third-party analysis of kratom products also found samples that exceeded daily exposure limits for lead. The authors noted that "non-extract products (powders, capsules, tablets) generally contain greater concentrations of elemental impurities than extract products or the soda preparation."[lxxxiv]

In 2018, the CDC investigated a multistate outbreak of *Salmonella* infections linked to kratom. The agency reported that a total of 199 people were infected with outbreak strains of *Salmonella* across 41 states, including 7 individuals in Ohio. Of those 199, thirty-eight percent of those individuals were hospitalized. CDC investigators stated that "epidemiologic and laboratory evidence indicated that kratom was the likely source of this multistate outbreak."[lxxxv]

The presence of lead and other heavy metals may increase the risk of adverse health outcomes for regular kratom users.[lxxxvi] For example, a case report from Iowa found a patient with suspected Fanconi syndrome from cadmium toxicity due to heavy kratom use. The report found high levels of cadmium in both the patient's blood stream and kratom the patient consumed.[lxxxvii]

According to the World Health Organization, chronic kratom use has been associated with at least 92 cases of liver toxicity. They note that common presenting signs and symptoms include abdominal discomfort, jaundice, pruritus, and dark-colored urine. These typically start about 3 weeks after initiation of kratom use and resolve within one month of stopping kratom use.[lxxxviii]

Additionally, there are no age verification requirements to prevent the sale of kratom products to children. This raises serious concerns about the impact of these compounds on the developing brain. The 2021 National Survey on Drug Use estimates that at least 45,000 adolescents in the US (ages 12-17) used kratom in the past year. This presents public health risks to adolescents given studies showing "adolescent kratom exposure particularly mitragynine and LKD [lyophilised kratom decoction] may cause selective cognitive and behavioural deficits. The brain metabolite profiles further suggest that the altered metabolic pathway (i.e., arachidonic acid, pantothenate and CoA, and tryptophan) may underlie the kratom-induced cognitive and behavioural deficits. Together, these findings demonstrate that adolescents' brain is sensitive to the impact of early kratom exposure during this critical development period."[lxxxix]

(7) The potential of the substance to produce psychic or physiological dependence liability.

Cases of dependence to kratom have been documented for the last several decades.[xc] Mitragynine has agonist activity at μ-opioid receptors and may lead to dependence and addiction.[xci] Further, the European Union Drug Agency, FDA, DEA, Mayo Clinic, and others agree that individuals can develop a dependence to kratom.[xcii] According to the FDA, "[c]ases of kratom-related SUD have also been observed. In these cases, individuals met certain criteria for SUD, including using kratom for longer than intended, using more kratom than intended, having cravings for kratom, continuing to use kratom despite adverse consequences (either physically or in their personal life), increasing the amount of kratom used to produce the same effect (tolerance), and experiencing withdrawal symptoms when kratom use was stopped (physical dependence)."[xciii]

In-person interviews with convenience samples of long-term daily oral kratom users in Southeast Asia find up to three-quarters reporting withdrawal symptoms after cessation of use. Typical withdrawal symptoms include irritability, anxiety, depression, sleep disturbance, lacrimation, rhinorrhea, muscle and bone pain, muscle spasm, diarrhea, and decreased appetite. The likelihood and severity of withdrawal are positively associated with duration, frequency, and intensity of kratom use.[xciv]

Recent news reports also highlight the psychic or physiological dependence of kratom. For example, an Akron woman reported developing "a debilitating kratom addiction" after consuming a product containing the substance thinking it was a safe, "plant-based" drink. She ended up losing her house, marriage, and half of her body weight because of her exposure and subsequent addiction to this compound. The woman reports "her addiction would have taken her life too, had she not gone to rehab in 2024."[xcv]

Another news report demonstrates the danger of having these products readily accessible. An individual using a popular kratom-based drink available at local gas stations reported spending about $2,000 per month (consuming about 10 to 12 bottles per day). According to the report, he "…soon found that after the immediate euphoria from the shot, he would be hit with a cycle of unpleasant symptoms, including a runny nose and achy body." The individual closed down their business and had to seek in-patient treatment.[xcvi]

Finally, it is not unusual for kratom manufacturers themselves to acknowledge the risk of developing a dependence to kratom. One such acknowledgement provides, "[s]ensing the need to up your serving size or not feeling the expected results? A tolerance break might do the trick. Take 2–3 days off from kratom, then restart at a lower serving size" (see Figure 3).[xcvii]

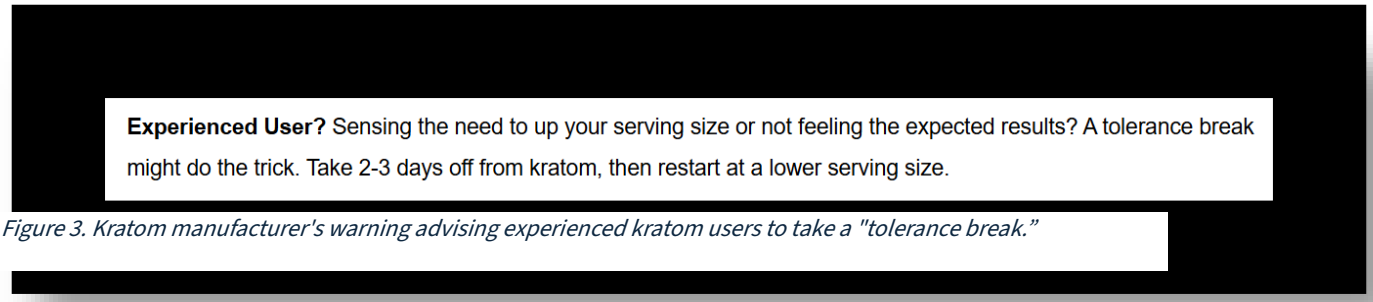


Figure 3. Kratom manufacturer's warning advising experienced kratom users to take a "tolerance break."

Despite warnings that kratom may be habit forming and should not be consumed every day, testimonials posted by kratom manufacturers encourage daily use for relief of discomfort, stating, "this is my favorite kind of kratom. . . It is the best for relieving daily discomfort in your mind or your body."[xcviii] Additional examples from a variety of manufacturers warning of the risk of addiction can be found in Appendix B.

(8) Whether the substance is an immediate precursor.

Mitragynine is a known precursor to mitragynine-related compounds, which are schedule I controlled substances in Ohio. According to the European Union Drug Agency, "[t]he chemical total syntheses reported for several kratom alkaloids are too complex to be used for economic production of any [of] these compounds. However, mitragynine can serve as a chemical precursor to the more potent 7-hydroxymitragynine."[xcix]

Mitragynine is highly likely to follow the same pattern seen with other drug classes like bath salts. Bath salts were created by modifying cathinones, a primary active ingredient found in a plant called khat.[c] As soon as one of those modifications was identified and scheduled, a new cathinone-like compound was developed to evade the law.

Looking to past illicit drug patterns, unexpected ways to synthesize mitragynine-related compounds will be established. At least one pathway would use mitragynine to make 7-OH and then MGM-15, the previously discussed potent opioid already identified in commercially

available tablets.[ci] Should unfettered access to mitragynine remain, we can anticipate the creation of additional potent novel compounds that are marketed to the general public, including children.

Section 4: Finding of the Board

Pursuant to section 3719.44 of the Ohio Revised Code, the Board may add or transfer a compound, mixture, preparation, or substance to Schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.

After a review of all available data, the Board finds mitragynine has a high potential for abuse, has no accepted medical use in treatment in this state, and that it lacks accepted safety for use in treatment under medical supervision.

Section 5: Resolution of the Board

Based on these findings, the Board hereby authorizes the filing of rule 4729:9-1-01.2 of the Administrative Code with the Common Sense Initiative and the Joint Committee on Agency Rule Review to classify as a schedule I opiate or opiate derivative any material, compound, mixture, or preparation that contains mitragynine.

Section 6: Proposed Rule

4729:9-1-01.2 – Mitragynine (NEW)

Notwithstanding any other provision of the Administrative Code, the following is classified as a schedule I controlled substance opiate or opiate derivative:

(A) Mitragynine ((αE,2S,3S,12bS)-3-ethyl-1,2,3,4,6,7,12,12b-octahydro-8-methoxy-α-(methoxymethylene)-indolo[2,3-a]quinolizine-2-acetic acid, methyl ester) and / or synthetic substances, derivatives, prodrugs, isomers, esters, ethers, salts, and salts of isomers with similar chemical structure.

Appendix A - Reddit Comments

Kratom had a toxic effect with the antidepressant and antipsychotic meds and killed my daughter

My 24 yo daughter died from mixing her regular prescribed psych meds with kratom. Her full autopsy listed the cause as poly drug toxicity and her prescribed meds were all in therapeutic levels.

The toxicology and full autopsy report confirmed what was in her system:

- Aripiprazole (antipsychotic)
- Lamotrigine (mood stabilizer)
- Venlafaxine (antidepressant)
- Mitragynine (the active compound in kratom)

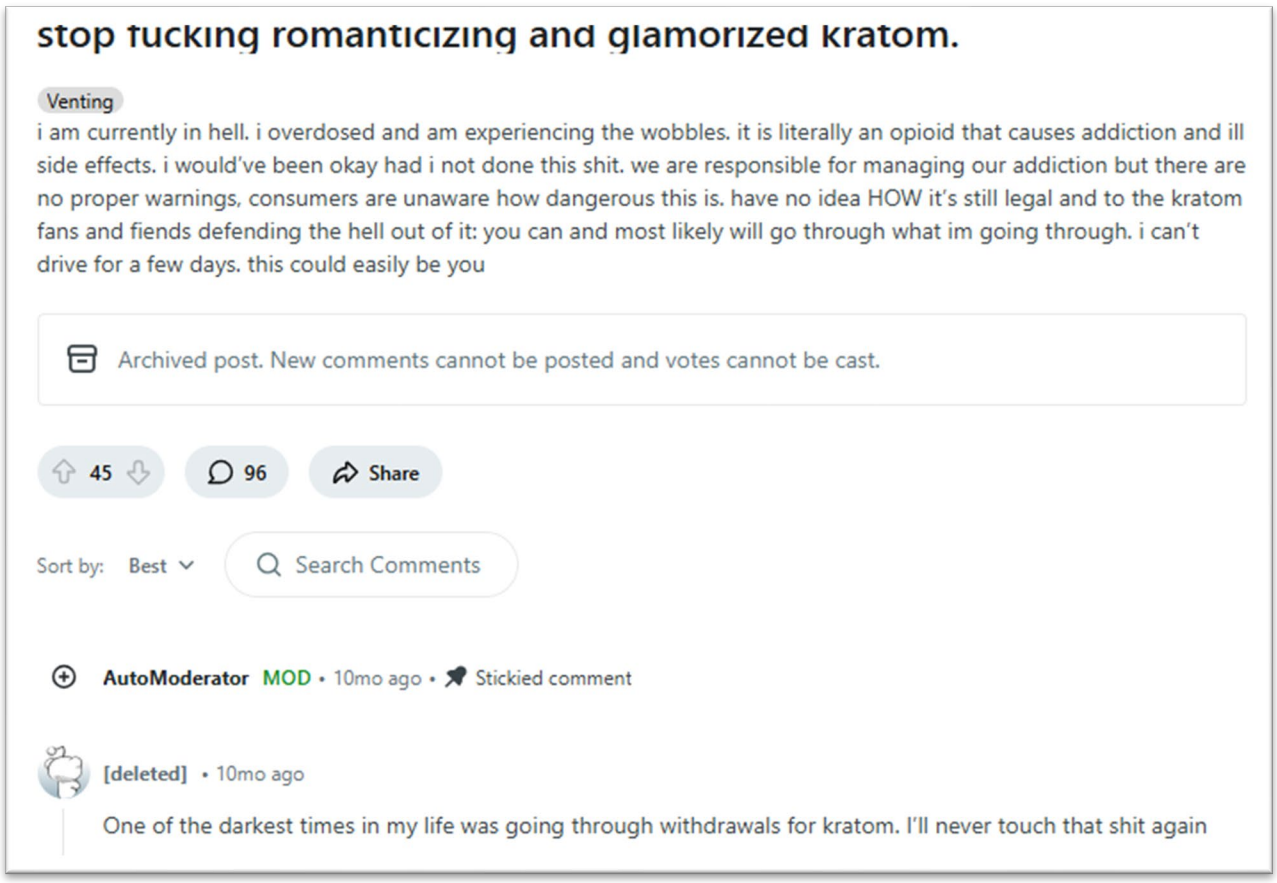
There was no warning on the kratom for interactions with other meds or the dangers. This stuff is sold in smoke shops and gas stations, over the counter and marketed as "natural" and "safe".

I was with her when she died. She was scared. She said she didn't want to die. She felt that something was wrong and her chest hurt. Her heart was beating so fast, then she had cardiac arrest and died right in front of me. CPR could not bring her back. The EMTs gave her narcan, it didn't help.

I've since learned that Kratom AMPLIFIES the toxicity of certain meds (psych meds specifically) and overwhelms the nervous system.

My daughter took what was prescribed to her, and she bought and took something she thought was safe, a supplement.

Kratom is NOT SAFE if you are taking other medications. Please share this information. I know she is not the only one this has happened to and if only there were warnings, it could have saved her life


stop fucking romanticizing and glamorized kratom.
Venting
i am currently in hell. i overdosed and am experiencing the wobbles. it is literally an opioid that causes addiction and ill side effects. i would've been okay had i not done this shit. we are responsible for managing our addiction but there are no proper warnings, consumers are unaware how dangerous this is. have no idea HOW it's still legal and to the kratom fans and fiends defending the hell out of it: you can and most likely will go through what im going through. i can't drive for a few days. this could easily be you
Archived post. New comments cannot be posted and votes cannot be cast.
45
96
Share
Sort by: Best
Search Comments
AutoModerator MOD • 10mo ago • Stickied comment
[deleted] • 10mo ago
One of the darkest times in my life was going through withdrawals for kratom. I'll never touch that shit again

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KRATOM WARNING: Do not mix with these medications (heart problems)

Let me preface this by saying I've mixed kratom with tramadol myself and had no problems, but that doesn't mean it's safe. Always air on the side of caution.

I recently found out that kratom is something called a QTc interval prolonger. QTc intervals are an EKG reading. If you mix QTc proloingers, it can potentially cause a heart arrhythmia reaction called torsades de pointes arrythmia. Many common medications and drugs including psych meds and tramadol are QTc interval prolongers.

I never heard any warnings about mixing kratom with these medications. This information is important and very very unknown.

If you want to know what medications can cause a torsades de pointes arrythmia, this is a good place to start (although they require registration which is free) https://crediblemeds.org/index.php/login/dlcheck

Click all the AVAILABLE TDP RISK CATEGORIES, set show entries to all,and sort by name or category. There are also usually pubmed articles if you look for them, that will tell you whether a medication is or isn't one.

here is my source for kratom causing this reaction https://www.ncbi.nlm.nih.gov/pubmed/25535742

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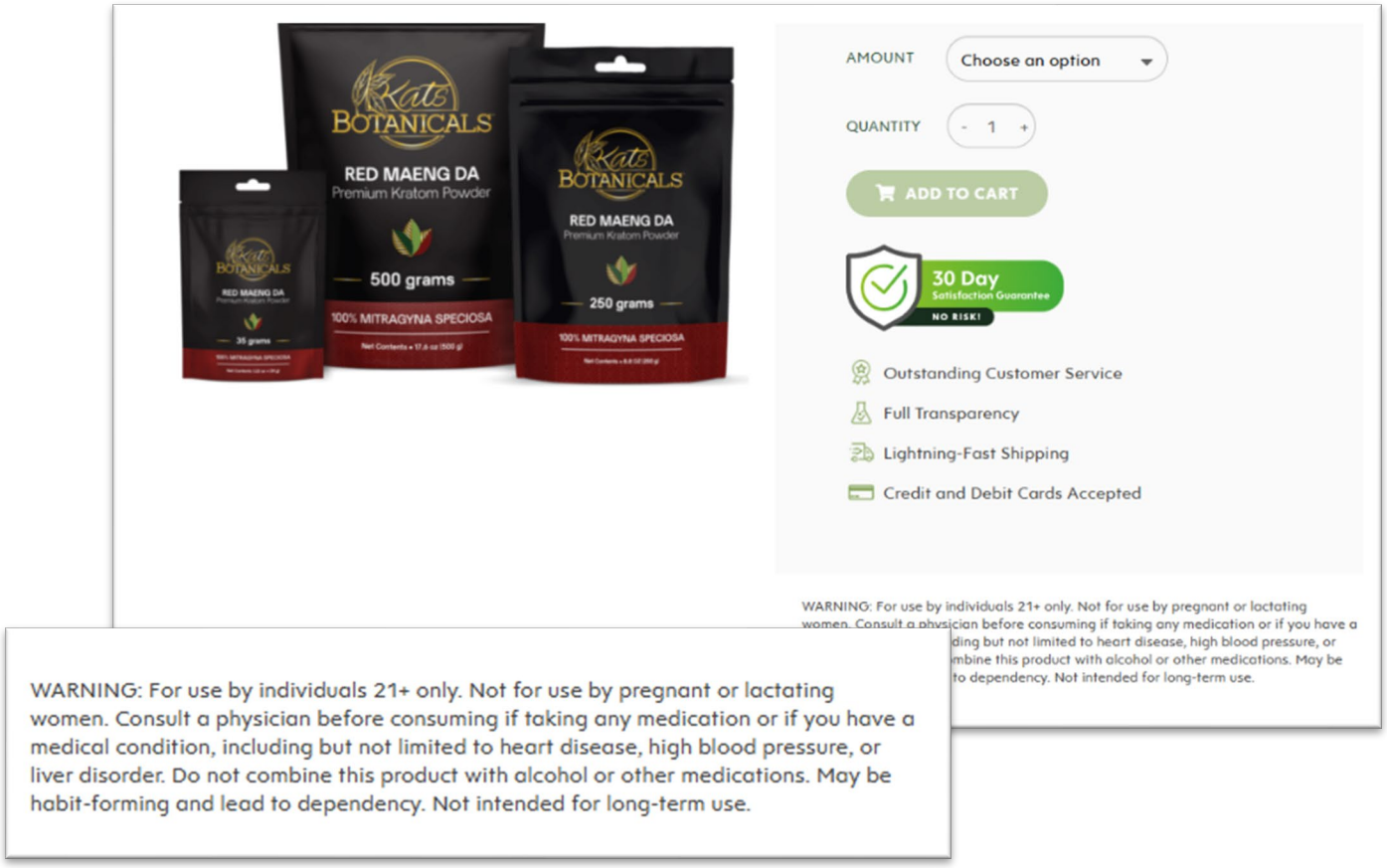
Appendix B – Product Labels & Examples



Source: ***https://katsbotanicals.com/product/red-maeng-da-kratom-powder*** ***(Last Accessed Jan 3, 2026)***

Source: ***https://amazingbotanicals.net/product/platinum-kratom-extract-tablets-80-ultra-purified-alkaloids/?srsltid=AfmBOopW-Igl9MBHQuhAoFJ_bvVLkeKiIgZoygOXYMvQH8N02PF3ZbAZ (Last Accessed Jan 3, 2026)***

23

ADULTS 21+ ONLY

KEEP OUT OF REACH OF CHILDREN

Supplement Facts

Serving Size: 1 fl oz (29.6 mL)
Servings Per Container: 2

	Amount Per Serving	%DV
Iron	0.4 mg	4%*
Kava root (extract)		
Total Kavalactones	260 mg	†
Leaf kratom (ground)		
Total Alkaloids	34 mg	†
Mitragynine	20 mg	†
7-hydroxymitragynine	<0.05 mg	†

* Percent Daily Value (DV) based on a 2,000 calorie diet.
† Daily Value (DV) not established.

Other ingredients: water, pineapple juice, natural flavors, stevia leaf, citric acid.

8 60003 64960 2

REV #007

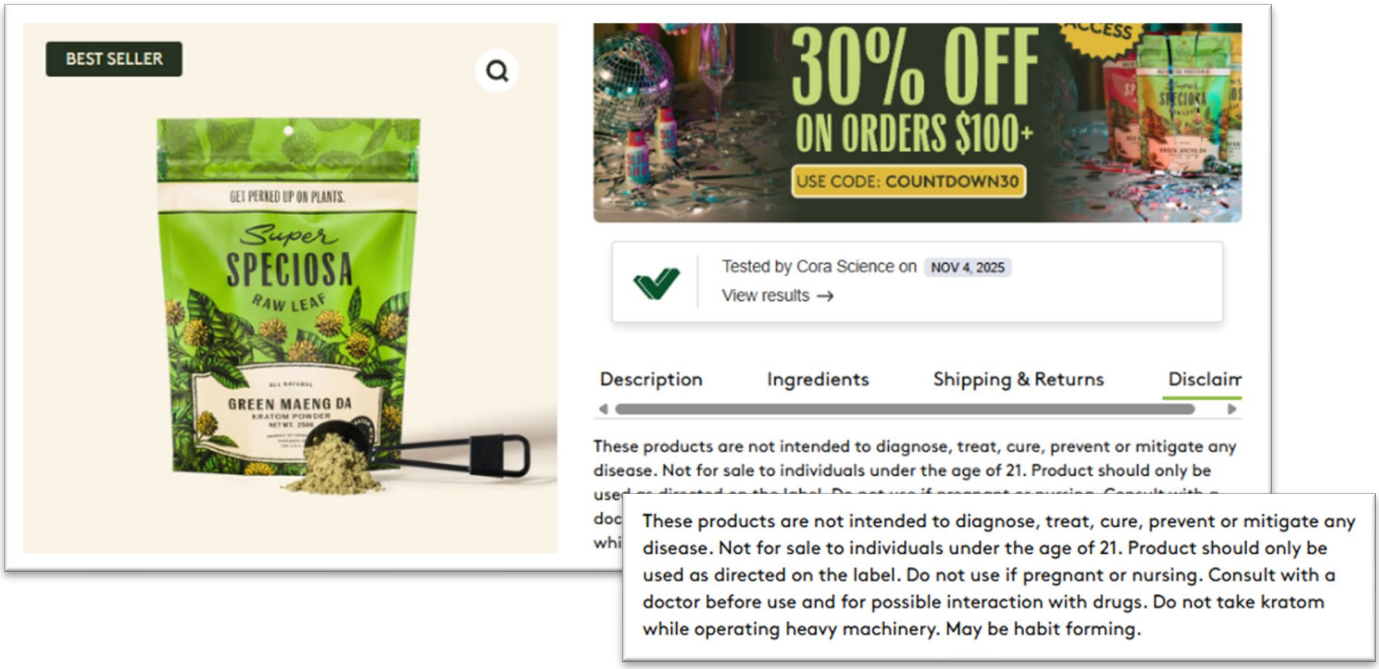
DIRECTIONS: ONLY TAKE 1 OZ (1/2 BOTTLE) BY MOUTH AT A TIME. DO NOT EXCEED 2 OZ (1 BOTTLE) IN A 24-HOUR PERIOD. SHAKE WELL. REFRIGERATE AFTER OPENING.

Warning: This product contains leaf kratom which, like caffeine and alcohol, may be habit-forming and harmful if consumed irresponsibly. Avoid if you have a history of substance abuse. When consumed as recommended, *feel free* CLASSIC has not been shown to cause any serious physical or social harm. **Caution:** Not for consumption by or sale to persons under the age of 21. May interact with certain medications—consult a licensed, qualified healthcare professional before use. Do not consume with excessive alcohol. **This product is not intended for those who are sensitive to the active ingredients or women who are pregnant, nursing, or trying to become pregnant.**

These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease or illness.

BOTANIC TONICS, LLC
13105 E. 61ST STREET, SUITE B • BROKEN ARROW, OK 74012

Source: ***https://botanictonics.com/products/feel-free-classic-tonic*** ***(Last Accessed Jan 3, 2026)***



Source: https://superspeciosa.com/products/green-maeng-da-kratom-powder?_ab=0&_fd=0&_sc=1&selling_plan=5215191261 ***(Last Accessed Jan 3, 2026)***

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Ohio Board of Pharmacy
Pharmacy.Ohio.gov
Mike DeWine, *Governor* Jim Tressel, *Lt. Governor* Steven W. Schierholt, *Executive Director*

Mitragynine Compounds – Comment Response Memo

Date: 6/8/2026

Comment Summary:

Comment Type	# Individual Comments (Local*)	# Individual Comments (Non-Resident)
0 – Blank / Sentiment Unclear	23	3
1 – Support Adoption of Rule	43	26
2 - Oppose - Corruption/Bigger Interests at Play	59	4
2 - Oppose - Criminalizing Non-Violent Offenders is Not a Good Use of Resources	1	1
2 - Oppose - For Calm/Focus/Energy	7	2
2 - Oppose - General Opposition, No Reasons Given	56	19
2 - Oppose - Losing Business	5	4
2 - Oppose - No Side Effects/Positive Health Benefits	22	19
2 - Oppose - Pushes People to Unregulated Alternatives	19	12
2 - Oppose - Questions the Science	65	19
2 - Oppose - Regulation Over Ban	139	57
2 - Oppose - Restless Leg Syndrome	2	1
2 - Oppose - Used to Treat Chronic Pain	394	182
2 - Oppose - Used to Treat Depression/Anxiety/Mental Health	53	23
2 - Oppose - Used to Treat Substance Use Disorder/Alcoholism	183	79
4 – Other	80	1
Total	**1,151**	**452**

**Local includes all Ohio-based IP addresses as well as those in IN, MI, WV, KY, and PA.*

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Organizations Providing Comment:

Blank / Sentiment Unclear	• Lefty's Tobacco Plus • Fumee • Clairsville tobacco and vape • Private company
Support	• Community Overdose Action Team • Northeast Ohio Opioid Consortium • NAMI Ohio • Kratom Danger Awareness, Inc • Ohio Prosecuting Attorneys Association • Prevention Action Alliance • Cuyahoga County ADAMHS Board • Wagar Hickman, LLC • Ohio Alliance of Recovery Providers • City of Troy (Mayor Oda) • Cleveland Clinic
Oppose	• American Kratom Association • Holistic Alternative Recovery Trust • HAVEN Access Inc. • Miracle Kratom, LLC • PDX Aromatics, LLC • Reason Foundation • Top Tree Herbs • Channel Zero Marketing • Krazy Daze • Pure Infinity Botanicals • Grand Rapids Botanicals • Oasis Farms • Lefty's Tobacco Plus • Roxbury Kava Bar • US Marketing Examiners LLC • Stella Maris is Cleveland (NOTE: Fraudulent Comment) • Sacred vortex house • Artisan Botanicals • Kratom Consumer Advisory Council • North Coast Kratom LLC • Advocates for Natural Wellness

	• The Wild Berry • Street 43-music • Mitra 9 Brands, LLC • Club13 • Euro Grocers, Cigars and Smoking Accessories • Sacred waters Kava bar Lakewood • Monkeys Smoke Shop • Herblux Botanicals • 3 Hearts LLC • Christopher's Organic Botanicals • International Plant & Herbal Alliance • Ohio TeaHouse, Inc • Sacred Vortex Teahouse & Kombuchery • Wild Berry Incense • JFL Energy • Spirit Apotheosis Botanicals & Findings • Life of kratom • Mitra9 • Botanaway Inc. • Kratom Consumer Advisory Council • Zeiger, Tigges & Little (On Behalf of Botanic Tonics)
Supports Regulation Over Ban	• Boulder Care via Drew Mossman

DRAFT Comment Response - Individual Responses:

Individual Comment	DRAFT Board Response
2 - Oppose - Corruption/Bigger Interests at Play • Accuses the Board of favoring FDA-approved medications over kratom. • Promoting a monopoly on FDA-approved treatments at the expense of natural plants products. • Focus on extracts while not interfering with access to natural kratom products.	• FDA approval of a drug means that data on the drug's effects have been reviewed by the agency, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population. • To date, kratom (regardless of natural leaf, extracts, or synthetic formulations) has not been approved via the FDA's formal approval process. • Furthermore, FDA has not recognized kratom as generally recognized as safe (GRAS), which means it cannot be added or sold as a food product. • Kratom is not authorized to be sold as a dietary supplement by the FDA. • Additionally, vendors selling kratom advise consumers to specifically engage the medical system stating: "Consult with a licensed healthcare provider before using this product for any reason to determine if this product is right for you. If so, ask your provider how to use it safely. You should also consult with a licensed healthcare provider about potential interactions or other possible complications before using this product."
2 - Oppose - Criminalizing Non-Violent Offenders is Not a Good Use of Resources • Divert police resources away from more substantial threats.	• As with other scheduling actions, police are not the only resources utilized for enforcement. For example, local health departments can also assist with enforcement actions.
2 - Oppose - For Calm/Focus/Energy	• While some kratom products proport to be "natural leaf kratom," there is a burgeoning market that is selling hyper-

• Users report natural kratom products help promote calm, focus, or provide energy throughout the day.	potent formulations of mitragynine that far exceed any FDA phase I dosing studies. For example, two capsules marketed as natural kratom contain more than 296 mg of mitragynine and 7 mg of 7-OH. • FDA has also issued warnings against these products citing "serious adverse health effects, including death."
2 - Oppose - General Opposition, No Reasons Given • Generally asked the Board not to ban kratom.	• The FDA continues to warn consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD).
2 - Oppose - Losing Business • Concern about lost business from kratom shops and bars selling kratom drinks.	• According to the Ohio Department of Agriculture, natural kratom is not permitted to be processed into, or marketed as, a food, drug, or dietary supplement (e.g., incorporated into a food or represented as any edible product.). • Kratom is not generally recognized as a safe ingredient in food, nor is it an approved drug or dietary supplement. For more information on ODA's guidance, click here. • Ohioans are also losing their livelihoods to kratom use disorder, as reported by commenters and from news reports. For example, one commenter wrote: "It took $25,000 to get my husband off of this drug just for him to relapse and easily go into our local gas station and grab liquid MIT only a month after returning home from a 38 day stay at OARC." • Other news reports highlight the impact of kratom access, specifically drinks that are marketed as alcohol alternatives with one physician noting that patients who use these products experience very intense opioid withdrawal necessitating the use of buprenorphine.

2 - Oppose - No Side Effects/Positive Health Benefits • Kratom is harmless and safe in its unadulterated, natural form. • Some commenters stated they were natural kratom users for years without any adverse effects.	• FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports. • Current kratom products available today lack any regulation or quality standards. Therefore, there are no requirements that ensure kratom is sold in its unadulterated, natural form. • Furthermore, while some kratom products proport to be "natural leaf kratom," there is a burgeoning market that is selling hyper-potent formulations of mitragynine that far exceed any FDA phase I dosing studies. For example, two capsules marketed as natural kratom contain more than 296 mg of mitragynine and 7 mg of 7-OH. • FDA has also issued warnings against some of these products citing "serious adverse health effects, including death." ○ One specific product the FDA issued a warning over (O.P.M.S.® Black Liquid) comes with a warning label that reads: "Do not take more than 5 days per month." • There are also documented cases of individuals requiring buprenorphine and other treatments to address kratom-use disorder, prior to the development of newer synthetic formulations of mitragynine. • One commenter wrote to the Board: *"My husband's life was gambled with, for money. I understand that there will always be addicts, but you can't just walk into a gas station and ask for heroin or cocaine. The kids that I have watched grow up on my street are getting to age where they can go get this substance easily. It has to stop. We have to do better. Be better."*

	• Kratom has also been shown to block drug metabolizing enzymes in the lining of the intestine. This means that possible interactions with prescription drugs may occur that could patients at risk. • Courts around the country have also recognized the impact of kratom use disorder on the ability of individuals to care for children: o An Ohio court upheld termination of parental rights where the child's caregiver had a history of substance abuse, including the consumption of "Feel Free" kratom products and was unable to stop using kratom (*In re K.K.*, 2025-Ohio-8th District). o A West Virginia court upheld the termination of parental rights where a mother hid her chronic kratom use and second child was born with symptoms of drug withdrawal (*In re B.P.*, 2023, W. Va.). o A Washington State court upheld a finding of dependency based on abuse or neglect against mother who was a daily kratom user (*In re Dependency of V.W.,* 2023, Wash.*)* • A wrongful death and product liability lawsuit filed is currently pending in Franklin County (*Jennifer Young et al. v. Miracle Kratom, LLC - Case No. 26-CV-003473*).
2 - Oppose - Pushes People to Unregulated Alternatives • Banning the product would not eliminate use and drive people to riskier alternatives. • Not the same risk as FDA-approved	• Mitragynine products are already unregulated alternatives, as they are not subject to standardized testing, dosing, and other requirements. • Lack of its status as a regulated alternative is supported by the fact that vendors advise consumers to: "Consult with a licensed healthcare provider before using this product for any reason to determine if this product is right for you. If so, ask your provider how to use it safely. You should also

opioids, NSAIDs, or alcohol.	consult with a licensed healthcare provider about potential interactions or other possible complications before using this product." • Furthermore, while some kratom products proport to be "natural leaf kratom," there is a burgeoning market that is selling hyper-potent formulations of mitragynine that far exceed any FDA phase I dosing studies. For example, two capsules marketed as natural kratom contain more than 296 mg of mitragynine and 7 mg of 7-OH. • Kratom products are not without risk. Even manufacturers FDA has also issued warnings against some of these products citing "serious adverse health effects, including death." • A 2026 study found there were significantly fewer incidence rates of exposures, severe medical outcomes, healthcare evaluation and hospitalization related to kratom in states with a ban compared to any other regulatory status. The authors further noted "relative to ban states, all other regulatory categories combined were associated with higher incidence rates of poison center-reported exposure." (Comstock G, Gulotta AP, Rein LE, Feldman R. Association between state-level kratom regulations and poison center-reported severe medical outcomes and healthcare use: A United States national analysis. Addiction. 2026. https://doi-org.proxy.library.ohio.gov/10.1111/add.70416) • The unregulated nature of kratom already presents an inherent risk to the consumer. For example, an analysis of elemental impurities in kratom products found that regular ingestion of these products may expose consumers to levels of lead and other metals that exceed daily exposure limits. (Snow Caroti K, Joseph A, Sapowadia A, Michael White C. Elemental impurities (heavy metals) in kratom products: an assessment of published individual product analyses. Clin Toxicol (Phila). 2024 Oct;62(10):651-660. doi:

	10.1080/15563650.2024.2395552. Epub 2024 Sep 5. PMID: 39235176.) • Another example is an October 2025 recall of kratom products announced by the Ohio Department of Agriculture for products that could be potentially contaminated with *Salmonella*. • FDA has also issued warnings against kratom products citing "serious adverse health effects, including death." ○ One specific product the FDA issued a warning over (O.P.M.S.® Black Liquid) comes with a warning label that reads: "Do not take more than 5 days per month."
2 - Oppose - Questions the Science • Their eight-factor analysis is a conglomeration of information, much of which is one-sided and fails to fully and objectively evaluate all relevant data—including data supporting potential health and societal benefits resulting from properly-regulated use of natural leaf kratom	• As an initial matter, the commenter cites an article that he co-authored. This article states that "kratom has insufficient evidence to determine its efficacy and safety for pain management," and "there is insufficient evidence to determine kratom's relative value versus other methods including buprenorphine or methadone," to treat substance use disorder. Another societal risk identified in the same article is, "[b]ased on mitragynine plasma concentration data available from forensic analysis after fatalities, it is feasible that coadministration of kratom alkaloids at high doses can lead to significant adverse events due to its interaction with [enzymes] responsible for the metabolism of many clinically important drugs. McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142. Pursuant to section 3719.44 of the Ohio Revised Code, the Board of Pharmacy may add or transfer a compound, mixture, preparation, or substance to Schedule I when it appears that there is a high potential for abuse, that it has

	no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision. In its analysis, the Board cited a variety of evidence including kratom industry statements, those with lived experience using kratom—which extends to Ohioans interviewed by epidemiologists through the Ohio Department of Behavioral Health—data from public health repositories, and peer reviewed literature, among others. To date, mitragynine has not been approved for medical use as a drug, nor has it been generally recognized as safe by the FDA. Beginning on page 8 of its analysis, the Board discusses benefits many currently seek from kratom use. On page 12 of its analysis, the Board also examines the impacts of regulated use, stating "[i]n 2019, Utah developed a regulatory scheme that allowed continued access to kratom over-the-counter. Despite age restrictions and limited alkaloid access, overdose deaths related to kratom and treatment for kratom use disorder persisted."
• Their determination to schedule natural leaf kratom is at odds with the determination of the FDA, DEA, and WHO—without a reasoned explanation for the conflicting conclusion.	• Although the FDA recently recommended that the DEA schedule only 7-OH, the Board is unaware of a determination made by the DEA regarding that recommendation. Despite the FDA's recommendation to the DEA, on page 7 of its analysis, the Board discusses the FDA's continued warning to the public against the use of kratom stating, "[t]here are no FDA-approved kratom drug products or over-the-counter drugs containing kratom that are legally on the market in the U.S. FDA continues to warn consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD)." With respect to the suggestion that the Board's determination is at odds with the determination of the World Health Organization (WHO), section 3792.07 of the

	Revised Code expressly prohibits the state from enforcing or funding the implementation of "any health policy guideline, mandate, recommendation, or rule issued by the [WHO], including the prohibition of issuing a prescription for or dispensing of a drug."
• They rely on a modeling study for opioid binding, which is cited to the exclusion of other more substantial data, including in vitro and in vivo data that is substantially stronger.	• Commenter correctly states that in vivo studies are performed on animals. Commenter's own publications question the translatability of findings using rodent models to humans. Commenter, however, co-authored and cited a paper that calls the ability to rely on animal studies involving kratom into question. The paper specifically states that when kratom was studied on humans, "[7-OH] was not present in the kratom product administered to healthy volunteers but was quantifiable in plasma samples . . . Another metabolite, resulting from further metabolism of [7-OH] in human plasma is mitragynine pseudoindoxyl, which is a potent [mu]-opioid receptor agonist . . . and [kappa] and [delta] opioid receptor antagonist. Pre-clinical animal models indicate that there are species-specific differences in terms of bioavailability, metabolism, and pharmacological effects of the alkaloids." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142. With respect to reliance on the modeling study, page 2 of the Board's analysis contains two sentences and a quote dedicated to the PHASE study as part of the Board's analysis. The text characterizes the findings as "likely" and "predicted," and not as definitive. As part of its analysis, the Board also cited a variety of evidence including kratom industry statements, those with lived experience using kratom—which extends to Ohioans interviewed by epidemiologists through the Ohio Department of Behavioral Health—data from public health repositories, and peer reviewed literature, among others.

	Page 7 of the Board's analysis recognizes the growing body of in vivo studies stating that "[d]espite the increasing availability of human in vitro and in vivo animal data, rigorous fundamental information about the pharmacokinetics of kratom alkaloids in humans remains limited."
• They do not consider the proven and major pharmacological differences between natural leaf kratom and mitragynine versus prescription or illicit opioids.	• This rule proposes to schedule mitragynine and not natural leaf kratom (although the effect is that natural leaf kratom would be prohibited because it contains mitragynine). Pursuant to section 3719.44 of the Ohio Revised Code, the Board of Pharmacy may add or transfer a compound, mixture, preparation, or substance to Schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision. Pharmacological differences between mitragynine and / or leaf kratom is not a required element. In its analysis, the Board cited a variety of evidence including kratom industry statements, those with lived experience using kratom--which extends to Ohioans interviewed by epidemiologists through the Ohio Department of Behavioral Health--, data from public health repositories, and peer reviewed literature, among others. Commenter's own cited reference identifies abuse potential of kratom. Specifically, "kratom did produce a constellation of effects commonly associated with drugs of abuse such as increases in subject-rated measures of good effects, high, and feeling drunk." Reissig CJ, Setnik B, Milovan D, et al. A Pilot, Placebo Controlled, Dose Finding Pharmacodynamic and Pharmacokinetic Study of Orally Administered Botanical Kratom in Non-Dependent, Recreational Polydrug Users with Opioid Experience Under Fed Conditions. US FDA. 2025. Available at:

	https://www.rilegislature.gov/senators/SenateComDocs/Health%20and%20Human%20Services/S0792%20FDA%20Kratom%20Dose%20Finding%20Study.pdf In its analysis, the Board also took publicly available statements from the FDA into consideration. These include the following, which are cited in the Board's analysis: 1. The statement that there, “are no FDA-approved kratom drug products or over-the-counter drugs containing kratom that are legally on the market in the U.S. FDA continues to warn consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports.” 2. "Cases of kratom-related SUD have also been observed. In these cases, individuals met certain criteria for SUD, including using kratom for longer than intended, using more kratom than intended, having cravings for kratom, continuing to use kratom despite adverse consequences (either physically or in their personal life), increasing the amount of kratom used to produce the same effect (tolerance), and experiencing withdrawal symptoms when kratom use was stopped (physical dependence)."
• They assume that the alternative to natural leaf kratom use is for consumers to abstain from all substances, which the available evidence suggests is untrue.	• As discussed on page 5 of the Board’s analysis, the FDA has approved medications to treat opioid-use disorder. Unlike kratom, these are evidence-based therapies that allow individuals to live with substance use disorder without abstaining from all substances. This is consistent with the paper co-authored and cited by Commenter, which states "there is insufficient evidence to determine kratom's relative value versus other methods including buprenorphine or methadone," to treat substance use disorder. McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on

	the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142.
• Banned substances cannot be researched further to better understand the benefits and risks	• The assertion that a Schedule I controlled substance "cannot be researched further to better understand the benefits and risks," is incorrect. Psilocybin is a primary active ingredient in illicit mushrooms and is a Schedule I controlled substance—the same schedule in which the Board proposes to place mitragynine. A search of "psilocybin" as "other terms" on clinicaltrials.gov, identified 291 studies as of March 6, 2026. By contrast, the same search for "mitragynine" returned seven studies. This rule proposes to classify the primary alkaloid in kratom, mitragynine, as a schedule I controlled substance. As stated in the cited reference, that was co-authored by Commenter, the Board recognizes that "uncontrolled self-experimentation is becoming more problematic given the increased availability of kratom extracts, which are highly concentrated . . . Use of such products further increases the risk of overdose and toxicity from kratom alkaloids, particularly when they are mixed with other psychoactive substances." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142.
• To suggest that the available data equates the addictive and safety profile of natural leaf kratom with illicit opioids, cocaine, and methamphetamines is unfounded and contrary to scientific	• This proposed rule seeks to classify mitragynine as a schedule I controlled substance. Pursuant to section 3719.44 of the Ohio Revised Code, the Board of Pharmacy may add or transfer a compound, mixture, preparation, or substance to Schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.

evidence that other health organizations that counselled or decided against doing so.	In its analysis, the Board cited a variety of evidence including kratom industry statements, those with lived experience using kratom--which extends to Ohioans interviewed by epidemiologists through the Ohio Department of Behavioral Health--, data from public health repositories, and peer reviewed literature, among others. It is unclear to the Board where the commenter concluded that the addictive and safety profile of natural leaf kratom was equal to any illicit opioid (schedule I to V), cocaine, or to methamphetamine. Nonetheless, the volume of substances reported to the State Unintentional Drug Overdose Reporting System (SUDORS), can provide helpful context for substances people consume before a fatal overdose. SUDORS captures all drugs detected by postmortem toxicology, even those not ruled by a medical examiner or coroner as causing death. Detection in postmortem toxicology only indicates if a substance was present. It does not indicate if the substance contributed to the drug overdose death or if it was the only substance present. Multiple substances are frequently involved in drug overdose deaths. According to national data from SUDORS, in 2024, there were 995 unintentional and undetermined drug overdose deaths where kratom (mitragynine) was detected in postmortem toxicology among the 43 jurisdictions included on the Centers for Disease Control and Prevention (CDC) SUDORS Dashboard. The same jurisdictions reported 395 unintentional and undetermined drug overdose deaths where ketamine was detected in postmortem toxicology in 2024. Centers for Disease Control and Prevention. State Unintentional Drug Overdose Reporting System (SUDORS). Final Data. Atlanta, GA: US Department of Health and Human Services, CDC; [2026, March, 26]. Access at: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/sudors-dashboard-fatal-overdose-data.html

• The benign results of [the FDA's] tolerability study, even at high doses (study discussed in detail below) in this clinical trial, are now prompting the FDA to conduct an additional study which will further our understanding of this natural ingredient. The FDA is engaged in better understanding the natural leaf kratom and is not concerned about severe immediate negative health risks to the public from natural leaf kratom.	• Conclusions from the cited reference used to support these assertions do not describe the effects of kratom as "benign." Notably, conclusions from this reference are exclusive to one botanical product and not to mitragynine as a whole—this rule seeks to categorize mitragynine as a schedule I controlled substance. The following quotes are contained in the cited reference: 1. "Kratom produced pupillary constriction, a finding consistent with mu-opioid effects." The study does say that these effects were less than morphine and oxycodone. 2. "This was a pilot, proof-of concept study . . . the results might not be representative of drug effects associated with other kratom-containing products on the market." 3. "[K]ratom did produce a constellation of effects commonly associated with drugs of abuse such as increases in subject-rated measures of good effects, high, and feeling drunk." 4. "This study utilized encapsulated, ground kratom leaf powder. It is unknown how the results of this study may extend to other kratom preparations such as teas that are commonly used to ingest kratom and may result increased alkaloid dissolution and bioavailability." Reissig CJ, Setnik B, Milovan D, et al. A Pilot, Placebo Controlled, Dose Finding Pharmacodynamic and Pharmacokinetic Study of Orally Administered Botanical Kratom in Non-Dependent, Recreational Polydrug Users with Opioid Experience Under Fed Conditions. US FDA. 2025. Available at: https://www.rilegislature.gov/senators/SenateComDocs/Health%20and%20Human%20Services/S0792%20FDA%20Kratom%20Dose%20Finding%20Study.pdf Commenter is not an authorized FDA representative. In its analysis, the Board took publicly available statements from

	the FDA into consideration. These include the following, which are cited in the Board's analysis: 1. The statement that there, “are no FDA-approved kratom drug products or over-the-counter drugs containing kratom that are legally on the market in the U.S. FDA continues to warn consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports.” 2. "Cases of kratom-related SUD have also been observed. In these cases, individuals met certain criteria for SUD, including using kratom for longer than intended, using more kratom than intended, having cravings for kratom, continuing to use kratom despite adverse consequences (either physically or in their personal life), increasing the amount of kratom used to produce the same effect (tolerance), and experiencing withdrawal symptoms when kratom use was stopped (physical dependence)."
• Mitragynine does not cause reinforcing effects	• Commenter cites an article containing a co-authored statement providing "[s]urvey studies consistently highlight the potential for kratom dependence and withdrawal symptoms, with users reporting tolerance and physical dependence." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024; 17(2): 131–142.
• Mitragynine does not produce traditional opioid respiratory depression risks	• This proposed rule seeks to classify mitragynine as a Schedule I controlled substance. Pursuant to section 3719.44 of the Ohio Revised Code, the Board of Pharmacy may add or transfer a compound, mixture, preparation, or substance to Schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for

	use in treatment under medical supervision. Production of traditional opioid respiratory depression is not a required element for classification as a schedule I controlled substance. The Board does not question the findings from the rodent studies that Commenter cites. The Board is aware, however, that "[t]he discovery that [7-OH] is converted [into] mitragynine pseudoindoxyl in human but not rodent plasma not only is unexpected but also may significantly alter our conclusions about the translatability of mitragynine findings using rodent models to the human condition." Kamble SH, Leon F, King TI, Berthold EC, Lopera-Londono C, Raju KSR, Hampson AJ, Sharma A, Aver BA, McMahon LR, McCurdy CR. ACS Pharmacol. Transl. Sci. 2020, 3, 1063−1068. Moreover, Commenter's co-authored statement warns that "[k]ratom use has been linked to a range of adverse health effects, including gastrointestinal upset and nausea, altered mental status, agitation, central nervous system depression, tachycardia, liver toxicity, seizures, and death." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142.
• If the FDA's concluded that there is no clear signal of risk in humans and that the correct step to protect public health is to conduct additional studies (one of which is already being planned by the FDA), it is difficult to reconcile the Ohio	• The Board agrees with Commenter and the FDA that more studies for kratom are important. However, the Board also recognizes that based on current scientific evidence the FDA has provided that it: 1. Will continue to warn the public against medical use of kratom; 2. Concluded from available information, including scientific data, that kratom is a new dietary supplement for which there is inadequate information to provide

	Board of Pharmacy's asserted belief that there is currently evidence to schedule the product now due to its addictive potential	reasonable assurance that kratom does not present a significant or unreasonable risk of illness or injury; and 3. Determined that kratom, when added to food, is an unsafe food additive. Along with the statements above, the FDA refers to the clinical trial that it funded as "preliminary" and states that its results "need to be considered in relation to the many and varied kratom-related products available to consumers and other scientific research." US Food and Drug Administration. FDA and Kratom. https://www.fda.gov/news-events/public-health-focus/fda-and kratom. Accessed June 1, 2026. This rule proposes to schedule mitragynine and not natural leaf kratom (although the effect is that natural leaf kratom would be prohibited because it contains mitragynine). As discussed on page 7 of the Board's analysis, the above study "found that 7-OH in plasma increased in a dose proportional manner after subjects consumed mitragynine contained in botanical kratom . . . An increasing amount of 7-OH in plasma that is proportional with an individual's dose of mitragynine is important [because] . . . mitragynine found in consumer products today is often several times more potent than traditional leaf products." An article co-authored by Commenter reinforces associated risks recognizing that "evidence suggests that high enough doses of kratom alkaloids may cause opioid toxicity via the usual opioid-receptor pathways implicated in conventional opioid overdoses." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142.
•	In their Eight-Factor Analysis, The Ohio	• This reference from page 8 of the Board's analysis, is not specific to any clinical study. Instead, it describes the

Board of Pharmacy downplays these [phase 1] clinical trials for having only ~100 people. However, these placebo-controlled does finding clinical trials have the highest internal validity of all study types.	phases of FDA clinical approval. This context is significant for understanding why balancing the benefits and risks of a substance might be challenging with current data. Tests that balance risks against benefits in humans do not begin until phase 2 clinical trials. No phase 2 clinical trials for kratom have been completed. Therefore, the tests that determine whether the benefit of kratom to treat any condition outweighs the risk have not been completed. In the absence of those facts, it is unreasonable to expect the public to navigate the safe use of even natural kratom when manufacturers of those products acknowledge a risk of death. As discussed in the Board's analysis, the need for manufacturer warnings of death is bolstered by the FDA, forensic findings, and years of case reports. Nonetheless, the Commenter cites the FDA's own conclusions about the clinical study in which it was involved. One of those conclusions is that, "[t]he small sample size limits the interpretability and translatability of the data." Reissig CJ, Setnik B, Milovan D, et al. A Pilot, Placebo Controlled, Dose Finding Pharmacodynamic and Pharmacokinetic Study of Orally Administered Botanical Kratom in Non-Dependent, Recreational Polydrug Users with Opioid Experience Under Fed Conditions. US FDA. 2025. Available at: https://www.rilegislature.gov/senators/SenateComDocs/Health%20and%20Human%20Services/S0792%20FDA%20Kratom%20Dose%20Finding%20Study.pdf
• However, they do not even acknowledge the fact that a number of states have banned isolated, concentrated 7-OH	• Recognition of regulation as opposed to an outright ban can be found on page 12 of the Board's analysis. In 2019, Utah was the first state to ban 7-OH and to regulate natural kratom. The Board discusses Utah's regulatory scheme providing that "[d]espite age restrictions and limited alkaloid access, overdose deaths related to kratom and

products but have not banned natural leaf kratom products (as the FDA is recommending) and the other states that have simply regulated or not banned natural leaf kratom.	treatment for kratom use disorder persisted. One emergency room physician reported . . . that his patients experience the same withdrawal symptoms as those withdrawing from narcotics. The Utah State Medical Examiner reported nearly 160 kratom-related deaths over a five-year period. While most of those overdoses involved polysubstance use, the state saw almost 50% as many kratom-only deaths in the most recent 12-month reporting period as Utah had seen since 2014. Consequently, the Utah legislature proposed to add all alkaloids from kratom and their analogs to the state's list of controlled substances in November 2025. The bill sponsor originally voted to regulate kratom in 2019 but now 'sees kratom in all forms as a dangerous opioid masquerading as a supplement.'" Furthermore, efforts to create a regulated market via legislation have not been successful in Ohio. Bills to regulate kratom have been introduced every legislative session since 2018.
• Research, in fact, suggests that natural leaf kratom may be beneficial to those who are addicted to other substances.	• The current state of scientific research is void of data necessary to assess whether the benefits of natural kratom outweigh its risks in humans. Tests that balance risks against benefits do not begin until phase 2 clinical trials. No phase 2 clinical trials for kratom have been completed. Therefore, the tests that determine whether the benefit of kratom to treat any condition outweighs the risk have not been completed. In the absence of those facts, it is unreasonable to expect the public to navigate the safe use of even natural kratom when manufacturers of those products acknowledge a risk of adverse events, including possible death. As discussed in the Board's analysis, the need for manufacturer warnings of death is bolstered by the FDA, forensic findings, and years of case reports. The National Institutes of Health recently announced that the University of Florida has developed a purified formulation of mitragynine that has resulted in an IND application with the FDA. This will allow NIH scientists are

	planning to conduct the first randomized, double-blind, placebo-controlled study to assess the safety and tolerability of the mitragynine formulation in humans. This is consistent with the paper co-authored and cited by Commenter, which states "there is insufficient evidence to determine kratom's relative value versus other methods including buprenorphine or methadone," to treat substance use disorder. McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142.
• Natural Leaf Kratom May Better Allow People to Fulfill Societal Obligations	• Commenter's own co-authored statements do not support this the proposition that natural leaf kratom may better allow people to fulfill societal obligations. Indeed, his co-authored article warns that "[k]ratom use has been linked to a range of adverse health effects, including gastrointestinal upset and nausea, altered mental status, agitation, central nervous system depression, tachycardia, liver toxicity, seizures, and death." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142. Furthermore, this statement ignores the negative consequences that have impacted those individuals who have developed kratom-use disorder as a result of its widespread availability in gas stations and corner stores. For example, An Illinois man reported becoming addicted to Feel Free products. The man says he would down a two-ounce bottle of Feel Free 10 to 12 times a day—far surpassing the recommended dosage of one per day. At about $8 per bottle, the habit cost him about $2,000 a month; he bought so much that the local smoke shop where he was purchasing the bottles began giving him an employee discount. He lost 35 pounds; his eyes sunk into

	his head, and his skin took on a gray color. He became so dependent on the drink he had to close down the thrift store he owned and seek in-patient treatment.
• Most kratom deaths involved polysubstance use.	• This is the same argument made by Jack Henningfield (as a representative of Pinney and Associates) in his 2004 Congressional testimony on behalf of Purdue Pharma. OxyContin was a cause of death even in "the vast majority of deaths that were . . . in fact, polydrug abuse deaths, frequently involving alcohol." Henningfield JE. Investigative Hearing: To do No Harm: Strategies for Preventing Prescription Drug Abuse. Committee on Government Reform. Feb. 9, 2004. US Gov. Print. Ofc. In 2004, arguments like this were made to detract from the reality that oxycodone, by itself, has abuse potential and is demonstrated to be psychoactive. Regarding kratom, Henningfield's statements on behalf of the American Kratom Association are that deaths associated with kratom "included the co-administration of other drug substances. As a result, the actual cause of death is not clear." Independent evidence of kratom's abuse potential and psychoactive qualities are cited several times in above responses. Moreover, Commenter's own co-authored statement warns that "[k]ratom use has been linked to a range of adverse health effects, including gastrointestinal upset and nausea, altered mental status, agitation, central nervous system depression, tachycardia, liver toxicity, seizures, and death." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142. Polydrug use is specifically addressed on page 11 of the Board's resolution, providing "a reality of modern drug misuse is that an increasing number of individuals engage in polydrug use with little to no knowledge of contraindications. This is true of both illicit drugs and

	prescription medication. From 2019 to 2023, the amount of unintentional drug overdose deaths in Ohio that involved multiple drugs ranged from 58 to 69 percent. Given this context, it would be irresponsible to discount the risk of polydrug use." Additionally, kratom is known to interact with P-glycoprotein as well as cytochrome P450 enzymes 2D6 and 3A4, potentially increasing the risk of adverse outcomes when used concurrently with other substances. One study concluded, "given the common practice of polysubstance use among kratom users, its safety profile and potential role as a harm reduction agent remain questionable." (Comstock G, Gulotta AP, Rein LE, Feldman R. Association between state-level kratom regulations and poison center-reported severe medical outcomes and healthcare use: A United States national analysis. Addiction. 2026. https://doi-org.proxy.library.ohio.gov/10.1111/add.70416) This interaction is also recognized by makers of kratom products. A label on one product reads: *"Consult with a licensed healthcare provider about potential interactions or other possible complications you may experience before using this product.* ***During this consultation, be sure to request advice on enzyme inhibition, specifically related to CYP enzymes.*** *Do not use this product if you have a serious medical condition or use prescription medications. Do not use this product in combination with any medications including, without limitation, prescription or over-the-counter medications, vitamins, herbal supplements, antihistamines, recreational or other drugs, alcohol, nicotine, or any other substances, including any other Kratom products."*
• Clinical studies and population surveys indicate that kratom is generally well-	• In its analysis, the Board cited a variety of evidence including kratom industry statements, those with lived experience using kratom--which extends to Ohioans interviewed by epidemiologists through the Ohio Department of Behavioral Health--, data from public health

tolerated when used responsibly.	repositories, and peer reviewed literature, among others. These references repeatedly identify harms associated with kratom use. In addition, conclusions from a referenced clinical study cited by Commenter suggest the need for more research and include the following: 1. "Kratom produced pupillary constriction, a finding consistent with mu-opioid effects." The study does say that these effects were less than morphine and oxycodone. 2. "This was a pilot, proof-of concept study . . . the results might not be representative of drug effects associated with other kratom-containing products on the market." 3. "[K]ratom did produce a constellation of effects commonly associated with drugs of abuse such as increases in subject-rated measures of good effects, high, and feeling drunk." 4. "This study utilized encapsulated, ground kratom leaf powder. It is unknown how the results of this study may extend to other kratom preparations such as teas that are commonly used to ingest kratom and may result increased alkaloid dissolution and bioavailability." Reissig CJ, Setnik B, Milovan D, et al. A Pilot, Placebo Controlled, Dose Finding Pharmacodynamic and Pharmacokinetic Study of Orally Administered Botanical Kratom in Non-Dependent, Recreational Polydrug Users with Opioid Experience Under Fed Conditions. US FDA. 2025. Available at: https://www.rilegislature.gov/senators/SenateComDocs/Health%20and%20Human%20Services/S0792%20FDA%20Kratom%20Dose%20Finding%20Study.pdf • There are multiple mechanisms by which kratom can produce acute toxicity, including but not limited to

• There have been no single attributable deaths in history due to its consumption.	hepatotoxicity, risk for cardiac dysrhythmia and seizure risk. Although pre-clinical data suggest decreased risk for respiratory depression when compared with traditional opioids, cases of respiratory depression responsive to naloxone in patients without co-exposure to opioids has been reported. The assertion that no deaths have been attributable to kratom consumption is inconsistent with Commenter's own co-authored statements, FDA warnings and industry labels. Furthermore, national poison control data finds that there were at least 27 deaths related to single substance kratom exposures. (Comstock G, Gulotta AP, Rein LE, Feldman R. Association between state-level kratom regulations and poison center-reported severe medical outcomes and healthcare use: A United States national analysis. Addiction. 2026. https://doi-org.proxy.library.ohio.gov/10.1111/add.70416) Commenter's co-authored statements warn that "[k]ratom use has been linked to a range of adverse health effects, including . . . death." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142. The Board's analysis includes publicly available statements from the FDA, including that, "[i]n rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports." US Food and Drug Administration. FDA and Kratom. https://www.fda.gov/news-events/public-health-focus/fda-and kratom. Accessed June 1, 2026. Page 23 of the Board's resolution contains an industry label for a natural product stating, "[s]ome publications have suggested kratom may be associated with serious potential side effects, including but not limited to . . . death."

2 - Oppose - Regulation Over Ban • Regulate kratom to improve quality and safety. • Removes all nuance and treats natural leaf products the same as altered extracts, isolates, and chemically modified compounds. That approach ignores an important middle ground regulation rather than prohibition. • Support Ohio's Kratom Consumer Protection Act (KCPA).	• The Board does not have the statutory authority to develop an entire regulated market for kratom via administrative rule. • Kratom's lack of designation as a food product or drug at the federal or state level creates an unregulated grey market. • Efforts to create a regulated market via legislation have not been successful in Ohio.
2 - Oppose - Restless Leg Syndrome • Kratom helps treat RLS symptoms. • *"I know it is still the solution to my problem to this day as I recently forgot to bring it with me on vacation and the 1st night I did not sleep AT ALL. Literally took several hot showers in the hotel room and found a place the next day that sold it. Is it addicting? I'm sure it is."*	• Clinical practice guidelines to treat RLS from the American Academy of Sleep Medicine were recently updated in 2025. The guidelines include new treatments and testing requirements for RLS. • The guidelines do not recommend the use of kratom or any kratom-related products. • FDA reports of adverse events related to kratom-extracts include restless leg syndrome as a symptom.

2 - Oppose - Used to Treat Chronic Pain • The legality of kratom and its products help to ensure those who use it responsibly experience normal quality of life and relief due to otherwise debilitating conditions. • Research indicates these compounds act as partial agonists and demonstrate biased signaling, which may explain why kratom shows analgesic effects with a substantially lower risk of respiratory depression compared to full opioid agonists. • Kratom helps patients avoid taking opioids or allows them to reduce/eliminate opioid use. • Allow patients without health insurance to treat chronic pain.	• As with the treatment of other conditions, kratom has not been approved by the FDA to treat pain, nor has it been subject to robust clinical trials to demonstrate the risks outweigh any potential benefits. • There are no standardized dosing instructions for kratom products sold on the market today. Therefore, the management of chronic pain is difficult utilizing an unregulated product. • Kratom products are not without risk. The FDA continues to warn consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). • Those advocating for widespread availability of kratom products point to the need to treat pain outside of the medical system. However, kratom products are marketed with warnings to consult a healthcare professionals: vendors warn consumers to: "Consult with a licensed healthcare provider before using this product for any reason to determine if this product is right for you. If so, ask your provider how to use it safely. You should also consult with a licensed healthcare provider about potential interactions or other possible complications before using this product." • Kratom is often marketed as a safer alternative to prescription opioids. However, case reports and testimony show how the compound can lead to substance use disorder that mirrors opioid-use disorder, which may require the use of buprenorphine.
2 - Oppose - Used to Treat Depression/Anxiety/Mental Health • Kratom reportedly used to effectively	• As with the treatment of other conditions, kratom has not been approved by the FDA to treat mental health conditions, nor has it been subject to robust clinical trials to demonstrate the risks outweigh any potential benefits.

self-treat anxiety and depression. • Others reported it being used to treat ADHD. • Kratom is more cost effective than FDA-approved treatments. • Using kratom allows individuals to avoid the side-effects of prescription medications used to treat mental health conditions.	• A review of kratom case reports found that there was a significant association was found between kratom use and the worsening of psychotic and manic symptoms in individuals with psychiatric conditions. The authors note that their research "…highlights the possibility of worsening preexisting psychiatric conditions in the context of kratom use." (Bachu AK, Singal P, Griffin B, Harbaugh L, Prasad S, Jain L, Mohiuddin S, Papudesi BN, Nagi T, Youssef NA, Chopra A, Ahmed S. Kratom use and mental health: A systematic literature review and case example. J Addict Dis. 2024 Oct-Dec;42(4):301-312. doi: 10.1080/10550887.2023.2273192. Epub 2023 Nov 9. PMID: 37942896.) • A 2025 study found that people who use kratom exhibited higher odds of reporting past-year suicidal thoughts, plans, and attempts compared to people who never used kratom. (Sharron K, Diallo IB, Witmer AM, Nestadt PS. Kratom Use and Suicidal Thoughts and Behaviors in the United States. Subst Use Addctn J. 2025 Oct;46(4):972-980. doi: 10.1177/29767342251345229. Epub 2025 Jun 17. PMID: 40525319; PMCID: PMC12919396.) • A 2026 study of 169,408 individuals aged 12 and older found that 37.8% of those who reported prior kratom use experienced serious psychological distress. 24.4% of those who previously used kratom also reported major depression compared to just 7.8% who never used kratom. (McCabe, Sean Esteban PhD; Bogan, Ralph C. BA; Dickinson, Kara BS; McCabe, Vita V. MD, MHSA; Menke, Nathan B. MD, PhD; Schepis, Ty S. PhD. Kratom Use and Associations With Mental Health in the United States. Journal of Addiction Medicine ():10.1097/ADM.0000000000001701, May 13, 2026. | DOI: 10.1097/ADM.0000000000001701)
2 - Oppose - Used to Treat Substance Use Disorder/Alcoholism	• Newer injectable, long-acting formulations of buprenorphine are available to patients who may experience tooth decay resulting from buprenorphine administration.

• Buprenorphine has its own side effects that impact daily functioning such as tooth decay and gastrointestinal issues. • Kratom assisted with abstaining from alcohol, opioids, benzodiazepines, and cocaine. • Provides an alternative for individuals with opioid-use disorder. • Kratom is a safer, more well-tolerated alternative to existing treatments for opioid-use disorder. • Banning kratom will lead people to use other drugs such as heroin or fentanyl and could lead to increased overdose deaths.	• Kratom use disorder (KUD) symptoms include increased use, tolerance, withdrawal, unsuccessful quit attempts, and craving. • A 2024 review of kratom users (N=2061) found that 25.5% of participants reported KUD. (Hill, Katherine MPH; Grundmann, Oliver PhD; Smith, Kirsten E. PhD; Stanciu, Corneliu N. MD. Prevalence of Kratom Use Disorder Among Kratom Consumers. Journal of Addiction Medicine 18(3):p 306-312, 5/6 2024. | DOI: 10.1097/ADM.0000000000001290) • The assertion that kratom is somehow safer than FDA-approved medications to treat opioid-use disorder cannot be effectively established until kratom undergoes Phase 2 and 3 clinical trials. To date, no kratom product has proceeded to a Phase 2 clinical trial. The National Institutes of Health recently announced that the University of Florida has developed a purified formulation of mitragynine that has resulted in an IND application with the FDA. This will allow NIH scientists are planning to conduct the first randomized, double-blind, placebo-controlled study to assess the safety and tolerability of the mitragynine formulation in humans. • The Medical Director of Opioid Policy Research at Brandeis University recently noted that "with opioids, cycles of withdrawal followed by relief when a dose is taken can make a drug seem helpful, even when it is causing harm. That is why controlled studies, which can reliably distinguish true benefits from the relief of withdrawal symptoms, would be needed to prove that kratom's benefits outweigh its risks. But those studies have not been done." • Effective, evidence-based treatments already exist. This includes medications such as buprenorphine and methadone, which have been shown to reduce cravings, prevent withdrawal and lower the risk of overdose. These medications are usually coupled with psychosocial

	supports which have been shown to improve overall treatment outcomes compared to just the use of MOUD. (Liu C, Li Y. Psychosocial combined with methadone maintenance treatments versus methadone maintenance treatments alone for treatment of opioid use disorder: A meta-analysis. J Addict Dis. 2024 Apr-Jun;42(2):126-135. doi: 10.1080/10550887.2022.2158664. Epub 2023 Jan 6. PMID: 36607171.) • If kratom were helping reduce fentanyl overdose deaths, states that banned kratom might be expected to have a higher rate of fentanyl deaths. Kratom has been banned in several states for years. • For example, Wisconsin, which banned kratom in 2014, has a lower overdose death rate (19.8) than Ohio (27.2) in 2024.
4 – Other • Commenters identified a Board staff member who is an unpaid member of a non-profit focused on harm reduction. • Commenters incorrectly attributed this staff member as a Board member and questioned if there was a conflict of interest.	• The staff member in question follows the state's Secondary Employment Policy and serves in a voluntary capacity. Therefore, these comments are not germane to the Board's review of the proposed regulation.

Organization/Business Comments - *Addresses comments received in opposition to the rule and one comment supporting regulation.*

Ohio-Based Organizational/Business Comments

Organization	Comment	DRAFT Board Response
Boulder Care via Drew Mossman (Ohio)	Boulder recognizes that Kratom is easily available and poses health risks, including dependence. Discreet packaging and wide availability of Kratom downplay those risks and are deceiving to the consumer. Consumers deserve full transparency about products they may be purchasing. In that spirit, Boulder supports conspicuous labeling of the risks of Kratom and Kratom-related products, similar to warnings on nicotine and alcohol products. Further, restricting the purchase of these products to ages 18+ and keeping these products behind the counter may curb use by adolescents.	The Board does not have the statutory authority to develop an entire regulated market for kratom via administrative rule. Kratom's lack of designation as a food product or drug at the federal or state level creates an unregulated grey market. Efforts to create a regulated market via legislation have not been successful in Ohio.
Life of Kratom (Ohio)	I am owner of life of kratom. I have three stores in ohio. I don't	The Board recognizes that this commenter will no longer be able to sell products should the rule be adopted.

	think you guys understand how big of and impact this is going to make if you ban kratom powder. My stores do over $100000 a month in revenue. 40% of my business is 60 years old and older. I got into this business to help people get off pharmaceutical drugs. I was a nacar driver for many years and broke my neck in 2007. I was making over 2.5 million a year and had everything I wanted. I was put on pain pills and you know the rest of the story. I didn't know we had and opiate epidemic in this country. Heck I didn't even know what and addiction was. Doctor put me on them and said I would be on it the rest of my life. Kratom saved my life. I am a father husband and now a grandpa. I have built a huge business helping people with pain and so much more. Pain pills, heart medication, suboxan, methadone is killing tens of thousands every year. I don't see	Mitragynine has been listed as the cause of death in at least 202 in Ohio cases since 2019. Furthermore, a recent review of poison control center data reported single substance kratom deaths. Including individuals who were found in cardiac arrest and who suffered from seizures. (Comstock G, Gulotta AP, Rein LE, Feldman R. Association between state-level kratom regulations and poison center-reported severe medical outcomes and healthcare use: A United States national analysis. Addiction. 2026. https://doi-org.proxy.library.ohio.gov/10.1111/add.70416) Local news reports also highlight examples where kratom is listed as the cause of death, including a recent case in Ohio. Lack of any regulation at the state or federal level has led to the development and sale of hyper-potent extracts of kratom far exceeding what is found in nature. Nor are there any standard dosing schedules or maximum limits on what can be sold in Ohio. This places consumers who unknowingly purchase these products at risk, including children. This is especially important as the share of Americans ages 12 and older who said they had ever used kratom rose from 1.6% in 2021 to 1.9% in 2024. FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports.

	those getting banned. Alcohol kills hundreds of thousands of people. We are not running to ban it. The science has shown that kratom alone has kill not one person. Yes not one. There has always been something in there system and guess what that is? You got it pharmaceutical drugs. Anti depression medication and so much more. Kratom is saving millions of lives and helping people live a natural lifestyle without pharmaceutical drugs. There should be no one that should be able to take that away. I was all for banned of 7OH which was being marketed as kratom and the science proved it wasn't. I applaud you for that and I though by dewine seeing that and RFK said kratom powder was safe and the only thing that should be able to be sold. What you would do to this state if you ban it is cause alot of deaths and cause alot of people to go the other way. Bad	

	part is your just going to make people go outside of the state to buy it. That isn't very smart considering the amount of tax money you would be losing. I am always here to talk (330)350-1247. Lastly I don't think the board of pharmacy should be able to have anything to do with this. Of course they want this to go away. They want everyone on there drugs. It's about money! Not safety or about the people! Thank you for your time. Sincerely Jack Smith (CEO) Life of Kratom	
Spirit Apotheosis Botanicals & Findings (Ohio)	Kratom raw leaves and powder should remain legal in Ohio because it has a long history of safety and efficacy. We have been responsibly selling kratom since 2010 to documented adults, and have seen its benefit in people's lives. Our source in Indonesia provides all appropriate documentations declarations of it's purity. Responsible adults should be allowed responsible use	According to its website, the store sells a wide variety of products including: absinthe making kits, crystals, candles, incense, oils, and compounded herbal extracts claiming to address cholesterol health, heart health, and blood pressure support. The commenter has not indicated how the rule would specifically impact their business operations with respect to not being able to sell kratom.

	to manage whatever they feel this benefits.	
JFL Energy (Ohio)	While I can understand the confusion around Kratom.related products, the science is clear. The active ingredients in the Kratom leaf are perfectly safe for use to the public, while the synthetic form is problematic and potentially dangerous. This follow along with the FDA's recommendation from over the summer to the DEA to schedule synthetic forms and allowing products using natural leaf safe for public consumption. The public has spoken and like the effects these products provide. Also, pease consider the harm you will do to the entire business chain that a total ban would do. This would do serious harm to a $500MM industry affect all aspects of the growing, shipping, warehousing, manufacturing, distributing and retailing of this plant.	While the Board understands the concerns regarding lost revenue, JFL has not provided an economic impact of the rule on its total business operations. Regardless, the Board contends that Ohioans have been negatively impacted by the wide availability of kratom through the loss of lives, relationships, employment, and housing. As a reminder, the FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports.

	Thank you for reading and your consideration on this complicated issue. Joe Lardie Owner JFL Energy, LLC	
Wild Berry Incense (Ohio)	We have been a retailer of Kratom for many years. Our experience with those customers use Kratom for chronic pain issues. Many of them have been on Opioids and have suffered through the cycle of dependency. Most of our Kratom customers are veterans and the prescribed treatment at their hospital only leads to more dependency on opioids. It seems like big Pharma is the one that is pushing this restriction. The headlines about the harm created by Kratom is mostly related to additives that is mixed with Kratom. Please let people decide for themselves, whether this is right for them. Many of our customers consider this a godsend of treatment. Yesterday we had a customer come in and	A search for kratom on the Wild Berry Incense website finds that the store does not advertise the sale of kratom. Rather, it sells incense, burners, and other products. The commenter has failed to demonstrate the impact the rule would have on business operations.

	explain that his Doctor's protocall for his degenerative back pain was a prescriprion for 180 Oxycotin pills per month. 6 per day! He uses Kratomas a substitute for the opiods. 6 oxycotin per day would surely lead to addiction which he is trying to avoid. There may be some downside to Kratom use but for him the ;lthe releif is real and his abillity to work and have a fulfillling life has been tied to his Kratom use. Please, for harm reduction keep Kratom legal.	
Monkeys Smoke Shop (Ohio)	I am against this rule, I know more than several people that have had only positive outcomes from using kratom. Whether it's for pain management for cancer or back pain that opiods can't help manage, or for people trying to recover off heavy opiod usage.	A review of the Monkeys Smoke Shop website indicates the business sells a wide array of products. Including, bongs, delta-8 products, vapes, pipes, scales, etc. Kratom was not listed for sale.  The commenter has failed to demonstrate the impact the rule would have on overall business operations.

Ohio Kratom Bars (Sacred Waters Kava Bar Lakewood, Roxbury kava bar, Sacred Vortex Teahouse & Kombuchery, Ohio TeaHouse, Inc)	Several Ohio bars and tea houses that sell kratom teas and other items, stated the rule would negatively impact their business operations. The bars also feel that a ban would impact their clients would lose a type of medicine and potentially fall back into more dangerous alternatives.	Sale of kratom as a food product is already prohibited under ORC 3715. According to the Ohio Department of Agriculture, natural kratom is not permitted to be processed into, or marketed as, a food, drug, or dietary supplement (e.g., incorporated into a food or represented as any edible product.). Kratom is not generally recognized as a safe ingredient in food, nor is it an approved drug or dietary supplement. For more information on ODA's guidance, click here.
Business – Not Identified (Ohio)	The Kratom helps people in dealing with physical pain and is not known dangerous. It should be legal, people have more benefit from Kratom, many of our customers feel relief because of it. Just to help people don't banned it.	The commenter has not indicated how the rule would specifically impact their business operations with respect to not being able to sell kratom.
Advocates for Natural Wellness (Ohio)	As the Executive Director of Advocates for Natural Wellness, a nonprofit organization dedicated to promoting evidence-based use of natural botanicals for health and well-being, I am writing to express our strong support for the recognition and preservation of the	The Board does not have the statutory authority to develop an entire regulated market for kratom via administrative rule. Kratom's lack of designation as a food product or drug at the federal or state level creates an unregulated grey market. Efforts to create a regulated market via legislation have not been successful in Ohio. Furthermore, the Board remains concerned about the harm posed by the widespread availability of kratom and the lack of any consistent regulation of these

	natural benefits of kratom (Mitragyna speciosa). Our organization has long advocated for responsible access to plant-based remedies that have been used traditionally for centuries, and kratom stands as a prime example of nature's potential to support human health in a holistic manner. Kratom, a tropical evergreen tree native to Southeast Asia, has been utilized by indigenous communities for generations to enhance energy, alleviate discomfort, and promote mental clarity. Modern users report similar benefits, often turning to kratom as a natural alternative to synthetic pharmaceuticals for managing chronic pain, boosting mood, and aiding in relaxation without the harsh side effects commonly associated with conventional medications. Scientific	products (age restrictions, dose limits, etc.), as outlined in its 8-factor analysis and responses above. This places consumers who unknowingly purchase these products at risk, including children. This is especially important as the share of Americans ages 12 and older who said they had ever used kratom rose from 1.6% in 2021 to 1.9% in 2024.

	studies have begun to explore these properties, highlighting alkaloids like mitragynine and 7-hydroxymitragynine, which interact with the body's receptors in ways that may support pain relief and overall vitality. At Advocates for Natural Wellness, we believe in the importance of education, quality control, and regulation to ensure safe consumption. We support policies that protect consumers by mandating purity testing, accurate labeling, and age restrictions, while opposing blanket bans that deny individuals access to this beneficial plant. By fostering research and informed dialogue, we can harness kratom's natural advantages to improve quality of life for many, particularly those seeking non-opioid options in an era of widespread wellness challenges. We urge	

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	policymakers, health professionals, and the public to consider the growing body of anecdotal and emerging scientific evidence supporting kratom's role in natural health practices. Our organization is committed to collaborating with stakeholders to advance responsible use and protect this valuable resource. Thank you for your attention to this important matter. We welcome the opportunity to discuss how Advocates for Natural Wellness can contribute to informed decision-making on kratom and other natural botanicals. We support natural kratom	
Business – Not Identified (Ohio)	As a business and believer in Kratom products I see every day what a life-changing product this is. I've seen customers in paralyzing pain start living a better life after using kratom. I've seen people who couldn't work a standard shift be able to move and get around	The commenter has not identified the economic impact of the rule on their business. Regardless, the Board's rationale and reasoning for scheduling kratom have been outlined in previous responses above and in the 8-factor analysis reviewed and approved on January 6, 2026.

	like normal after using kratom. I could go on and on but simply put it can help the average person in ways nothing else could. There are some negative effects but the good outweighs the negative hands down. I myself am a very active person and on occasion get hurt or over do something where I'm hobbling around and kratom has helped me to keep on going. I understand the ban and issue with 7-o , but that is NOT Kratom or Mitragynine but a drug that was created. This bill is limiting and prosecuting Mitragynine with is the active in Kratom. True Kratom products have not hurt anyone, only bastardized products. There is no reason to go after an all-natural product that is bringing so much good into the world. Even High Mitragynine extracts may not be necessary, but they really don't hurt anyone. As in any industry there may be a few bad individual	

	products on the market that may need to be addressed but the industry as a whole is heroic and not the villain. The Villainous activity is trying to remove it.	
North Coast Kratom LLC (Ohio)	I am a small business owner in Ohio, operating a kratom shop that provides safe, natural, lab tested kratom to my community. I am also a combat veteran who served in Iraq, and I am writing to express my deep concern and outrage at the possibility of a natural kratom ban in Ohio. Our shop works closely with the American Kratom Association and only sources kratom from responsible suppliers who provide third-party lab testing, ensuring that our customers receive pure, natural kratom powder free from contaminants, adulterants, or dangerous additives. Every batch we sell is tested to the highest standards because we take our responsibility	The Board recognizes that this commenter will no longer be able to sell products should the rule be adopted. Given the lack of any laws requiring regulation and the totality of the evidence, as outlined in the 8-factor analysis and responses in this document, the Board contends kratom warrants control in Schedule I. It should also be noted that all branches of the U.S. armed forces prohibit service members from using kratom. The U.S. Coast Guard cites warnings that kratom can cause serious adverse effects. The U.S. Navy noted in a May 2026 fact sheet that kratom is being marketed around military bases and that service members are being targeted with products that "emphasize stress relief or energy enhancement."

	to our customers seriously. We follow the rules, pay our taxes, and operate with integrity. A state ban would destroy everything we have built. My shop employs hardworking people in my community. A ban would kill jobs, shutter my business, and put my family on the street. My children depend on me. They can't eat if I can't work. I am willing to pay high taxes and operate responsibly, yet I would be punished for providing a safe, natural product that millions of Americans rely on every day. This is not fair it is devastating. Listen to the people natural kratom safe Kratom is overwhelmingly safe when used responsibly. A federal ban will not stop people from using it; it will push them to the black market, where untested powders—often laced with fentanyl or other dangerous substances—endanger lives. By banning a safe, lab-tested product, the government would	

	increase public health risks, not reduce them. As a veteran, I understand sacrifice. I know what it means to fight for my country. Yet now, the law threatens to take away my ability to provide for my family, my employees, and my community—not because we are doing anything wrong, but because of fear and misinformation. This is not justice. This is not protection. I urge you to consider the human cost before supporting a federal kratom ban. Protect responsible small businesses, protect families, protect jobs, and protect Americans from unsafe, illicit alternatives. The responsible solution is regulation, testing standards, and education—not prohibition.	
Dr. Elena Ramirez, MD (Unable to locate Ohio Medical License in eLicense or in the ASAM	As a board-certified addiction specialist with over 15 years of experience treating substance use disorders in clinical settings, including opioid use disorder (OUD), I have	After confirming with the Medical Boad, it has been determined that this comment has been fabricated. As this comment is fraudulent, the Board will not be addressing the issues raised.

search directory)	witnessed the devastating impact of the ongoing opioid crisis. I've also seen firsthand how some individuals have found meaningful relief and recovery support through certain plant-based options when conventional treatments were inaccessible, insufficient, or not tolerated. I am writing to share a perspective grounded in patient reports, emerging observational data, and real-world clinical anecdotes: natural kratom referring to traditional, unadulterated leaf or minimally processed forms of Mitragyna speciosa, used responsibly in moderate doses appears to be saving lives for a significant number of people struggling with opioid dependence…. Sincerely, Dr. Elena Ramirez, MD, FASAM Addiction Medicine Specialist	
Lefty's Tobacco Plus	I think these products should be sold at our	This store primarily markets itself as a tobacco and vape shop. The commenter has not indicated how the rule

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(Ohio)	store with No restrictions they help people with pain and getting off bad drugs. Banning kratom would be incredibly disasterous not only for Ohio jobs, but Ohio citizens. Ohio citizens use kratom, a natural, proven safe product for countless reasons, and have done so for years if not decades. Despite the smear attempt of negative press in the last months, kratom is safe and should remain legal. Ohio has attempted to do this multiple times in the past, and received record response in support of keeping kratom legal. Waiting a couple of years and trying to ban it again when Ohio has already spoken seems disegnious and nefarious. Ohio has spoken time and time again. Keep kratom legal. Allow safe and legal access to this popular natural safe product.	would specifically impact their business operations with respect to not being able to sell kratom.

Krazy Daze (Ohio)	Banning kratom would have a detrimental effect on the public's well being. Many people who buy our kratom have a military and law enforcement background. Banning kratom would financially hurt us and the livelihoods of our employees. Thank you for your attention to this matter.	A review of the Krazy Daze website finds that it offers a wide array of products from vapes, tobacco, hookah, clothing, and body jewelry. The commenter has not indicated how the rule would specifically impact their business operations with respect to not being able to sell kratom.
Miracle Kratom, LLC (Ohio)	Over many years of lawful operation, our businesses have generated ongoing revenue for the State of Ohio. From 2019 through 2025, our Columbus location alone generated $260,273.46 in Ohio sales tax revenue. From 2021 through 2025, our Cleveland location generated an additional $52,298.12 in Ohio sales tax revenue. These figures do not include payroll taxes associated with our employees, commercial lease payments to Ohio property owners, or local spending with Ohio-based vendors and service providers.	This business would close should the rule go into effect. Regarding less regulatory restrictions considered, the Board does not have the authority to regulate a new industry. That authority is vested with the Ohio General Assembly. Since 2018, advocates have called for the regulation of kratom via the legislative pathway with no success. As outlined in the Board's 8-factor analysis and responses in this document, public health and safety concerns do not stop at 7-OH or other synthetic products. The assertion that a Schedule I controlled substance "cannot be researched further to better understand the benefits and risks," is incorrect. Psilocybin is a primary active ingredient in illicit mushrooms and is a Schedule I controlled substance—the same schedule in which the Board proposes to place mitragynine. A search of "psilocybin" as "other terms" on clinicaltrials.gov, identified 291 studies as of March 6, 2026. By contrast, the same search for "mitragynine" returned seven studies.

	The Board's own language, public statements, and media coverage frequently fail to distinguish between natural kratom leaf products and high-potency 7-hydroxymitragynine products, which have significantly different potency and risk profiles. Regulatory concern appears to be focused on concentrated or synthetic derivatives, yet this rule targets mitragynine broadly, which would criminalize traditional kratom leaf products. Treating risks associated with semi-synthetic or highly concentrated derivatives as representative of all kratom products has increased confusion in both the public record and media coverage. Current evidence shows that the risks associated with highly concentrated or altered compounds are not the same as risks associated	Phase 1 clinical trials with mitragynine are using doses far below what is available on the market today. For example, the maximum dose in the study was 53.2 mg of mitragynine. An Ohioan can purchase one bottle of extract that contains 1,000 mg of mitragynine. Given the lack of any laws requiring regulation and the totality of the evidence – as outlined in the 8-factor analysis and this document – the Board contends that kratom warrants control in Schedule I.

	with kratom in its natural vegetative state. The proposed rule does not address this distinction. The rule also does not explain why less restrictive regulatory options were rejected, including age restrictions, product testing and labeling standards, alkaloid content limits, licensing requirements, or consumer protection frameworks adopted in other states. Jumping directly to Schedule I classification without addressing these alternatives reflects a failure to consider proportional regulation. House Bill 587or Senate Bill 299, would formalize the Board's emergency rule while allowing natural kratom products to be regulated within the state. Classifying mitragynine as Schedule I would also restrict research access and discourage scientific study, making	

	it more difficult to generate safety and efficacy data. This creates a circular outcome in which the absence of research is then used to justify continued prohibition.	
Zeiger, Tigges & Little (On Behalf of Botanic Tonics)	As explained and corroborated in the GKC comments, the applicable science and law favors the scheduling of concentrated kratom alkaloid isolates ("synthetics"), but not the scheduling of natural kratom leaf ("kratom leaf'). The former (the synthetics) are indistinguishable from opioids in their addictive potential and risk of injury. The latter (kratom leaf) have been proven in clinical trials not to present any significant or unreasonable risk of illness or injury, including the risk of severe addiction. BT has a direct and substantial interest in each of these proceedings. BT currently sells Feel Free	This commenter represents Feel Free Botanicals. Kratom products manufactured by Feel Free have been identified in various media reports as having serious adverse consequences for its users. Some examples include: A woman in Illinois who thought she was consuming a wellness tonic that is marketed as an alternative to alcohol. She reported that after a few months, she was consuming several bottles per day and could not control her cravings. She required a 5-week rehab stay. A woman in Michigan thought she was purchasing a natural botanical drink. Within her first three weeks of taking her first Feel Free, she found the product to be habit-forming, “causing her to rely on the foul-tasting tiny bottles of liquid to get through the day while struggling with postpartum depression.” A woman in Texas began using Feel Free when she got sober from alcohol in 2022. On heavier days, she says she would consume three to five bottles. An Illinois man reported becoming addicted to Feel Free products. The man says he would down a two-ounce bottle of Feel Free 10 to 12 times a day—far surpassing the recommended dosage of one per day. At about $8 per bottle, the habit cost him about $2,000 a month; he bought so much that the local smoke shop where he was purchasing the bottles began giving him an

	in Ohio through distributors. Its annual revenues from the sale of Feel Free exceed $5 million.	employee discount. He lost 35 pounds; his eyes sunk into his head, and his skin took on a gray color. He became so dependent on the drink he had to close down the thrift store he owned and seek in-patient treatment. There is also a reddit dedicating to quitting Feel Free kratom products. It has 12,000 weekly visitors and 1,400 weekly contributions. A recent post highlights the concerns about the product's ease of availability and the impact of Utah's recent ban on these products: *I have been violently addicted to feel free for 3 years. It has cost me my friendships, my finances, jobs, and almost my marriage. I have been to rehab twice and quit on my own multiple times only to fall back harder. For the last 6 months it's gotten so bad (15-20 bottles a day) but I can honestly say yesterday I drank my last one. It wasnt a choice, I've never been able to successfully CHOOSE to quit, but my state officially banned them as of today. I knew it was coming and as the deadline approached a lot of stores ran out because they wouldn't resupply and risk all the dead inventory. It feels like a MASSIVE burden off my shoulders.* Feel Free was also the subject of a class action lawsuit. Botanic Tonics paid $8.75 million to settle a class-action lawsuit involving allegations that Feel Free's labeling didn't make clear just how much kratom is in each bottle and had failed to alert consumers to the dangers of taking the substance in large quantities. Given the lack of any laws requiring regulation, ease of access to a product that activates at the brain's opioid receptors, and the totality of the evidence – as outlined in the 8-factor analysis and this document – the Board contends that kratom warrants control in Schedule I.

Channel Zero Marketing (Ohio)	I am a small business owner operating in Ohio and employ 4 people. The proposed scheduling of kratom as a Schedule I substance would cause immediate and severe economic harm to my business. Kratom represents approximately 100% of my lawful revenue, and this rule would result in unsellable inventory, loss of income, and potential layoffs. I urge the Board to consider less restrictive regulatory alternatives. Your last presenter talked about following the 6 other states that have banned kratom, but she failed to speak about the 14 states that adopted KCPA regulations, rather than an outright ban that would devastate Ohio businesses and employees.	The Board recognizes that this business will no longer operate if 100% of its lawful revenue is derived from the sale of kratom or products containing kratom. Regarding less regulatory restrictions considered, the Board does not have the authority to regulate a new industry. That authority is vested with the Ohio General Assembly. Since 2018, advocates have called for the regulation of kratom via the legislative pathway with no success. Given the lack of any laws requiring regulation, ease of access, and the totality of the evidence – as outlined in the 8-factor analysis and this document – the Board contends that kratom warrants control in Schedule I.
American Kratom Association (Virginia)	The most comprehensive and authoritative evaluation of kratom under the Controlled	Please be advised that Jack Henningfield's CV includes paid consulting for both the American Kratom Association and Purdue Pharma. In many cases, Henningfield's arguments in favor of regulating kratom

	Substances Act framework is the 8-Factor Analysis prepared and submitted to the Ohio Board of Pharmacy by Dr. Jack Henningfield, one of the nation's foremost experts on abuse liability and drug scheduling. That analysis directly addresses the same statutory factors the Board purports to apply, yet reaches conclusions that are diametrically opposed to the Board's proposed action. Critically, Henningfield's analysis makes a clear and consistent distinction between mitragynine, the primary naturally occurring alkaloid in kratom leaf, and 7-hydroxymitragynine, a metabolite that is present only in trace amounts in natural leaf but appears in vastly elevated chemically manipulated concentrations in certain manufactured products.	mirror prior testimony in favor of less strict regulation of Oxycontin. These statements include the following: 1. Minimizing the addictive nature of OxyContin – "The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare." 2. Warnings that limiting access will drive people to more serious drugs – "The challenge to reducing diversion, abuse, and addiction is to respond appropriately to the 'drug of the day' without simply shifting abusers to other drugs, which in some cases may be even more risky." 3. Inducing fear of harm to those suffering from SUD if access is limited – "If you took the extreme action to ban the top prescription opioids . . . you would disrupt the lives of the many patients with pain whose well-being depends upon those drugs." 4. Continued access serves the greater good by treating the untreated – "It is important that in our zeal to reduce abuse and diversion, we do not forget that we have a significant problem of under treatment of pain and its attendant suffering, in part due to fears surrounding the use of opioid analgesics." Henningfield JE. Investigative Hearing: To do No Harm: Strategies for Preventing Prescription Drug Abuse. Committee on Government Reform. Feb. 9, 2004. US Gov. Print. Ofc. The Board is unaware of any registered clinical studies on kratom alkaloids other than mitragynine. One of the few clinical studies on mitragynine is discussed on page 7 of the Board's analysis. That study "found that 7-OH in plasma increased in a dose proportional manner after subjects consumed mitragynine contained in botanical kratom . . . An increasing amount of 7-OH in plasma that

	In sum, the Ohio Board of Pharmacy's proposal cannot be reconciled with the Henningfield 8-Factor analysis, the prevailing scientific consensus, or the history of federal review. The Board has failed to demonstrate that mitragynine has a high potential for abuse, lacks accepted use in a manner relevant to non-drug products, or poses an imminent hazard to public health. What the evidence does support is a targeted regulatory response focused on concentrated and synthetic 7-hydroxymitragynine products, not the emergency scheduling of natural kratom leaf alkaloids. Proceeding with this rule would repeat mistakes already identified and rejected at the federal level, with foreseeable and adverse consequences for public health.	is proportional with an individual's dose of mitragynine is important [because] . . . mitragynine found in consumer products today is often several times more potent than traditional leaf products." The associated risks are clear as "evidence suggests that high enough doses of kratom alkaloids may cause opioid toxicity via the usual opioid-receptor pathways implicated in conventional opioid overdoses." McCurdy CR, Sharma A, Smith KE, Veltri CA, Weiss ST, White CM, Grundmann O. An update on the clinical pharmacology of kratom: uses, abuse potential and future considerations. Expert Rev Clin Pharmacol. 2024 ; 17(2): 131–142. Even consumption of products that are GMP certified by the American Kratom Association have been reported to result in deaths. In July 2024, the FDA issued a notice to consumers not to consume OPMS black liquid kratom due to an individual's death. The FDA went on to explain that "[t]his is one of many reports of serious adverse events individuals have reported after consuming OPMS Black Liquid Kratom. Other reported adverse health effects include withdrawal symptoms, addiction, digestive issues, restless leg syndrome, skin problems, aggressive behavior, increased anxiety, lack of energy, and inability to focus." The notice goes on to say, "the FDA has not approved any prescription or over-the-county drug products containing kratom or associated compounds, mitragynine and the more potent metabolite, 7-OH mitragynine. Furthermore, the FDA has serious safety concerns with the use of kratom in dietary supplements and conventional foods." Notably, OPMS kratom is prominent on the American Kratom Association's GMP certified webpage because "[a]ll O.P.M.S. products are 100 percent natural and never adulterated."

		OPMS also acknowledges the risk their products pose via extensive warning labels on their products: ***Warning:*** *This is a kratom extract, NOT raw leaf. The mitragynine and other alkaloid content in this product are multiple times greater than that of raw kratom leaf, resulting in an increased potency with this extract product. Treat accordingly and proceed with enhanced caution. Using Mitragyna Speciosa can be dangerous. As with all Kratom products, do not use this product without first consulting your licensed healthcare professional. There have been reports of adverse health effects associated with using Kratom products. Some publications have suggested Kratom may be associated with serious potential side effects including seizures, liver damage, withdrawal, addiction, abuse, and death. Please review all advisories and commentary from the website of the United States Food and Drug Administration for concerns about Kratom products. Do not take any other Kratom product or any medications, vitamins, herbal supplements, antihistamine, recreational or other drugs, alcohol, nicotine, or any other substances within 24 hours before or after taking this product. Do not use this product or any other Kratom product on consecutive days. Mixing Mitragyna Speciosa extracts with medications, vitamins, herbal supplements, antihistamines, recreational or other drugs, alcohol, nicotine, or any other Kratom product (whether an extract or not), or any other substance may result in adverse drug interactions and can be highly dangerous. Do not use this product in combination with medications, vitamins, herbal supplements, antihistamine, recreational or other drugs, alcohol, nicotine, or any other substances, including other Kratom products. Do not use this product or any other Kratom product if you are pregnant, plan to become pregnant, or while breastfeeding. Do not take this product if you have any blood disorder, liver or kidney disorder, high blood pressure, heart disease, central nervous system disorder,*

		or any other medical condition. Do not use this product while operating motor vehicles or heavy machinery. Contact your healthcare provider immediately or seek emergency care if you experience any adverse effects. Neither this product nor any Kratom product, alone or in combination with other Kratom products, is intended for daily use. By using this product, you acknowledge and agree that you have read all directions, warnings and disclaimers, and that you have agreed to the Terms and Conditions. By using this product, you accept full responsibility for the use, or misuse of the product, including but not limited to any adverse events or health complications that may arise from its use or misuse. Manufacturers and distributors assume no responsibility or liability for the use or misuse of this product. *Do not take any other kratom product or any medications, vitamins, nicotine, herbal supplements, drugs, or any other substances within 24 hours before and after taking this product. Do not take Kratom Extract unless you have taken non-extract kratom multiple times in the past with no adverse effects. Do not use this product for multiple days consecutively, which includes this product and combined with other kratom products. Mixing Mitragyna Speciosa extracts with medications, vitamins, nicotine, herbal supplements, drugs, or with any other kratom product, extract or non-extract, or with any other substance, may result in drug interaction and can be highly dangerous. Do not use this product in combination with medications, vitamins, herbal supplements, drugs, alcohol, nicotine, or any other substances, including other kratom products. Do not use if you are pregnant, plan to become pregnant, or while breastfeeding. Do not take this product if you have any type of blood disorder, liver or kidney disorder, high blood pressure, heart disease, central nervous system disorder, or any other medical condition. Do not use this product while operating motor vehicles or heavy machinery. Contact your healthcare provider immediately or seek*

		emergency care if you experience any adverse effects. Not intended for daily use, this includes this product and in combination with other kratom products. With respect to the merits of a regulatory scheme, that discussion can be found on page 12 of the Board's. Here the Board examines the impacts of regulated use, stating "[i]n 2019, Utah developed a regulatory scheme that allowed continued access to kratom over-the-counter. Despite age restrictions and limited alkaloid access, overdose deaths related to kratom and treatment for kratom use disorder persisted." A recently published study reviewed reports of kratom exposure to the National Poison Data System from 2010 to 2023. The study compared rates of exposure and adverse health effects in states with no kratom regulation, those with age limits and label requirements (KCPA), those with local regulation and those with statewide bans. From 2019 to 2023, the rate of exposures, severe outcomes, hospitalizations and exposures resulting in healthcare use was higher in states with KCPA than in states with complete bans [see Figure 1 on next page). Comstock G, Gulotta AP, Rein LE, Feldman R. Association between state-level kratom regulations and poison center-reported severe medical outcomes and healthcare use: A United States national analysis. *Addiction*. 2026. https://doi-org.proxy.library.ohio.gov/10.1111/add.70416

Non-Resident-Based Organizational/Business Comments

Organization	Comment	DRAFT Board Response
Botanaway Inc. (Virginia)	Natural form Kratom and compliant extracts of it MAIN alkaloids are a wonderful harm reduction tool and benefit countless people of all types. Targeting and manipulating minor constituents of the plant is the problem. This problem also exists in other botanical industries, and especially the hemp industry. Ohio should look at targeting synthetic derivatives and not a natural form.	This commenter resides out of state and has not indicated a business impact related to the rule.
Mitra9 (Utah)	Hello, My company sells Kratom products in the US as a Dietary Supplement. This bill if it was to pass would directly impact us as a company and my employment. From a quality assurance side, our products are considered to be the highest purity of kratom. The main concern of the public would be towards 7-OH, and our product consistently tests at "Not Detected" for 7-OH at a testing level of one-hundred-thousandth of a percent. Our product is the safest on the market and our consumers rely on us for it. Passing this bill would hurt the economy in Ohio, and instead I urge Ohio to visit similar states that limit the amount of 7-OH using science backed resources. Trevor	Mitra9 advertises its products as such: "Whether you're replacing a second coffee, looking for an alcohol alternative, or just want something different in your rotation, this functional seltzer fits without overcomplicating things. The experience stays steady, without the peaks and crashes that come with more aggressive options." Mitra9 sells products containing 70 mg of the active ingredient in kratom. This exceeds the maximum dose administered during a Phase I clinical trial often cited by the kratom industry (53.2 mg). Additionally, unlike some of its competitors, its products contain no warnings or general age restrictions on the product. This does not allow the consumer to even make an informed decision about ingesting a partial opioid agonist.

		This is further compounded by the fact that some of these products are sold in concentrates where a consumer believes the standard dose is one bottle when the recommended dose is half. Given the lack of any laws requiring regulation, ease of access, and the totality of the evidence – as outlined in the 8-factor analysis and this document – the Board contends that kratom warrants control in Schedule I.
International Plant & Herbal Alliance (Utah)	I am a pain patient who has consumed kratom for 9 years. It has been life changing! I can participate in life again when before I was unable to function much. There are thousands like me in Ohio who depend on kratom for pain control or for harm reduction as they transition or step away from illicit drugs or abused opioids. Pain patients are being abandoned. We have very little access to prescribed pain medication. If a viable alternative like kratom is banned, the effects will be devastating. There will be suicides due to pain. I guarantee it. Those who continue to take kratom by purchasing out of state lines will be felons. Why would you want your most vulnerable to be criminals just for controlling their pain? This is crazy. The answer is good regulations! Schedule 7-OH and other synthetics. Take these products off shelves due to no science and no safety data. Please leave pure, whole-leaf natural kratom legal and accessible to your citizens. Pass the Kratom Consumer Protection Act and strictly enforce it. There is a right way to	This individual resides in Utah and therefore is not impacted by the adoption of this rule. It should be noted that Utah recently developed strict regulations on the sale of kratom products. This includes removing products from gas stations, requiring age verification, and products regulated by the Utah Department of Agriculture and Food.

	do this! Please DO NOT abandon those that truly need kratom for pain relief. DO NOT value the lives of those who choose to abuse substances over the lives of those who responsibly consume a product. Please DO NOT create criminals by taking away a lifeline. Thank you!	
Christopher's Organic Botanicals (New Jersey)	Public Comment: Business and Consumer Impact of a Natural Kratom To Whom It May Concern, I am writing on behalf of Christopher's Organic Botanicals, a small, family-owned online business that sells natural, plain-leaf kratom products directly to adults across the United States, including customers in Ohio. We are submitting this comment in response to the encouragement for impacted businesses—manufacturers, distributors, and retailers—to assess how a proposed ban on natural kratom would affect operations, customers, and commerce. A ban on natural, plain-leaf kratom in Ohio would have a direct and measurable negative impact on our business. We currently serve Ohio customers who legally purchase whole-leaf kratom tea and traditional extracts made from the leaf. Ohio represents an active and consistent portion of our customer base. A prohibition would immediately cut off lawful sales to those customers, resulting in lost revenue, disrupted inventory planning, increased compliance costs, and operational strain for a small business operating on tight margins. In addition to our customer base, this issue is personal for our family. My son is an Ohio resident and a member of the National Guard, and like many Ohioans, he and others in his community value access to lawful, responsibly produced botanical	This business would experience a reduction in sales because their products would no longer be permitted to be shipped into Ohio. The Board has outlined the various reasons for why it believes kratom meets the standards in ORC 3719. to warrant placement of kratom into Schedule I in its 8-factor analysis and in this supporting document. It should also be noted that all branches of the U.S. armed forces prohibit service members from using kratom. The U.S. Coast Guard cites warnings that kratom can cause serious adverse effects. The U.S. Navy noted in a May 2026 fact sheet that kratom is being marketed around military bases and that service members are being targeted with products that "emphasize stress relief or energy enhancement."

	products. Policies that eliminate access to traditional, natural products have real downstream effects on families, service members, and working adults who are trying to maintain stability in their daily lives. More importantly, such a ban would significantly affect our Ohio customers. Many of them rely on natural, unadulterated kratom leaf products as part of their daily routines to maintain stability, productivity, and quality of life. These are not synthetic products, isolated alkaloids, or high-potency formulations. They are traditionally prepared leaf products that customers have chosen specifically because they are simple, tested, and consistent. From direct customer communication, we know that if access to natural kratom is removed, many Ohio consumers will be forced into difficult choices: • Turning to unregulated or illicit markets • Traveling out of state to obtain products • Switching to alternatives that may carry greater risk or cost This outcome would harm consumers while providing no clear public safety benefit. Our company supports reasonable, targeted regulation—including age restrictions, labeling requirements, product testing, and clear distinctions between natural kratom leaf and synthetic or chemically altered substances. We do not support blanket bans that eliminate access to traditional plant products while failing to address the real sources of concern in the marketplace. A prohibition on natural kratom would not only damage small businesses like ours, but would also remove lawful access for informed adult consumers who depend on plain-leaf kratom products to manage their	

	daily lives responsibly. We respectfully urge Ohio decision-makers to consider the economic harm, consumer disruption, and unintended consequences of a natural kratom ban, and to pursue regulatory approaches that protect public health without eliminating legitimate businesses and traditional botanical products. Thank you for the opportunity to submit this comment and for considering the real-world impact on both businesses and consumers. Sincerely, Christopher Deaney Owner & Operator Christopher's Organic Botanicals Salem County, New Jersey customerservice@christophersorganicbotanicals.com 609-202-6880 856-581-1265	
Herblux Botanicals (Colorado)	My name is Luke Klepec and I am a founder of Herblux Botanicals, a small kratom distribution and online retail company that was founded in Cincinnati, Ohio in 2018. I am a Xavier University alumni and I built Herblux Botanicals out of my basement apartment in Cincinnati, OH with my business partners while driving for Uber on the side after graduating from Xavier. I received a degree in criminal justice, with my sight set on going into law enforcement. I completed an internship at a police department in my hometown of Bloomington, IL. My father had a 38 year career in law enforcement and my mother is a therapist. My family and I have both seen the harm that addiction has caused on individuals and society both personally and professionally. I decided to shift my focus to entrepreneurship, and after I discovered kratom and saw not only the potential, but the existing positive effect that kratom could have on society, I knew that it would be a	Sale of kratom as a food product is already prohibited under ORC 3715. According to the Ohio Department of Agriculture, natural kratom is not permitted to be processed into, or marketed as, a food, drug, or dietary supplement (e.g., incorporated into a food or represented as any edible product.). Kratom is not generally recognized as a safe ingredient in food, not is it an approved drug or dietary supplement. For more information on ODA's guidance, click here. This commenter resides out of state and has not indicated a business impact related to the rule.

	lifesaving tool for many. That is why I started a kratom company. Kratom has provided a solution to many Ohioan's substance abuse problems, which is has been a national epidemic for far too long. I have since moved to Golden, Colorado, and started a kava bar that serves kratom teas with my business partners in 2023. It's called Golden Kava Lounge. We employ 6 full-time workers, and provide a sustainable, livable wage for these employees, despite a shrinking job market due to AI and automation taking over so many jobs. Amidst a nationwide loneliness epidemic, where younger generations are getting married later, buying houses later, and turning away from alcohol, as alcohol sales are down $830B in the last 4 years, many Ohioans and Americans alike lack a sense of community. My bar has become a vibrant community where memories are made, relationships are formed, and lives are drastically changed for the better. We have been a safe haven for those recovering from hard drugs and alcohol. We provide an alternative mellow, fun, and safe experience, offering community, creating jobs, and generating tax revenue. We host pool tournaments, open mic nights, and chess tournaments, like a coffee shop vibe during the day, and a more socially stimulating nightlife-like environment at night, all supported by kratom as a product. Ohio has some kava bars, like Big Run Kava Bar in Athens, Ohio, whom Herblux Botanicals has supplied kratom to before. I plan to open many more kava bars that serve kratom throughout the country, and Ohio is a state that needs more. The success of kava bars	

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	that serve kratom can infinitely stimulate the economy and build community. Kratom, in its natural form, is safe. I have tested every batch of kratom that I've imported with third party labs and have closely analyzed all of the studies regarding kratom's risk. Hyper-potent extracts are the problem. If you must regulate in consideration of public safety, you must focus on hyper-potent extracts like 7-Hydroxymitragynine, not the natural kratom leaf, a safe, mildly uplifting tea and social stimulant that does not debilitate and acts as a safer alternative to alcohol. Kratom is community, connection, safety, recovery, and a booming industry that can create many jobs and generate millions in tax revenue while AI and automation takes them away. Ohio cannot afford to ban kratom.	
Euro Grocers, Cigars and Smoking Accessories (California)	Must keep kratom n Mitragynine n not ban it. Very helpful to customers. I'm n retired pharmacist.	This commenter resides out of state and has not indicated a business impact related to the rule.
Club13 (Florida)	We have been serving customer in Ohio for the past 27 years, who use natural Kratom products to better their lives We respectfully ask that you use reference FDA, NIDA, & NIH published studies proving the safety of natural Kratom products before recommending turn your neighbors into criminals. Thank you	This commenter does operate an online store where it appears Ohioans are able to purchase products. However, their comment does not indicate the level of lost revenue that would result from the adoption of this rule. It should be noted that this producer sells products containing 1,000 MG of kratom's active ingredient. This far exceeds any dosing administered

		during Phase I clinical trials conducted with kratom (53.2 mg).
Mitra 9 Brands, LLC (Colorado)	I support science-based regulation that protects consumer safety without unintentionally eliminating lawful, compliant kratom products. Overly restrictive limits could effectively criminalize kratom rather than regulate it, pushing consumers toward unregulated alternatives. I encourage the Board to base any thresholds on current scientific evidence, distinguish between compliant and illicit products, and consider alignment with established Kratom Consumer Protection Act (KCPA) standards used in other states. Thoughtful regulation can protect public health while preserving responsible adult access. Thank you for your consideration.	The Board does not have the statutory authority to develop an entire regulated market for kratom via administrative rule. Kratom's lack of designation as a food product or drug at the federal or state level creates an unregulated grey market. Efforts to create a regulated market via legislation have not been successful in Ohio. Furthermore, the Board remains concerned about the harm posed by the widespread availability of kratom and the lack of any consistent regulation of these products (age restrictions, dose limits, etc.), as outlined in its 8-factor analysis and responses above. This places consumers who unknowingly purchase these products at risk, including children. This is especially important as the share of Americans ages 12 and older who said they had ever used kratom rose from 1.6% in 2021 to 1.9% in 2024.
street 43-music (New York)	Looking at your Banning proposal and trying to classify Kratom as a schedule 1 Narcotic. Is irresponsible and it is wrong. Reasons stated in section 6, are without merit, and reason. Other than false information given by others with their own agenda. I personally have been using Kratom products	This commenter resides out of state and has not indicated a business impact related to the rule.

	purchased from a certified AKA vendor. I've been using Kratom for over 10 years, I am in excellent health, I don't use any other drugs and I don't drink. These other drugs and alcohol which are readily available to people. Those are the ones that you need to put your energy in Banning. Kratom "natural " kratom used regularly and responsibly is as safe as coffee. As a veteran I use for anxiety, depression and pain relief. Just like Ativan and or Tylenol or ibuprofen. Which I never take, and all which have more side effects than Kratom.	
Business – Not Identified (Virginia)	This is an incredibly inappropriate and traumatic experience to see and experience the Ohio government ban kratom. The negative impact of the ban would really be damaging to my business and myself as a person. It's really important that the government can be reasonable and look at all the evidence and the reality of the situation regarding the kratom plant in its raw form. I believe the plant has been undoubtedly a very positive thing and its legality is absolutely essential.	This commenter resides out of state and has not indicated a business impact related to the rule.
Artisan Botanicals (Oklahoma)	Kratom and 7oh are both incredible tools for the modern day challenges we are met with in society. leaf kratom specifically is an invaluable boon to our communities, family and friends and there should be a legal over the counter and retail friendly market that is regulated with oversight. it has saved millions and millions of souls and will continue to do so. proper education is VITAL. as one of the main people who spearheaded and got the oklahoma kratom consumer protection act passed, separate from the american kratom association. from a consumer and a business owner who wants	This commenter resides out of state and has not indicated a business impact related to the rule.

	the best for the people, and therefor the country. thank you for your time and concern in reading this, if you actually do.	
US Marketing Examiners LLC (Florida)	As an American citizen by birth, I prefer to have the freedom to use the herbs and natural nutrients that science has found our body needs either for growth and maintenance of our health -- or, in the case of herbs -- have been shown safe and useful over centuries of use by local populations for various purposes. As a kratom consumer for 13+ years, kratom has served me well in this regard and the 100 million dollars of National Institutes of Drug Abuse research studies also confirm this plant has little inherent addictive potential, unlike many legal substances like alcohol and pharmaceutical opioids. For this reason, it is disturbing that there are financially biased industries that want to ban this herb's responsible use on the questionable grounds that it may cause deaths and/or addiction. After more than 13 years of daily use in moderation because this plant serves so well to curb my blood sugar spikes, without spending any money for pharmaceutical meds, this plant seems to be a God-sent gift that shouldn't be denied to people because the medical/pharmaceutical industry finds they are losing money, or the alcohol industry is not selling as much booze. The most egregious conflict of financial interest is when trial attorneys advertise for clients that they are looking for clients who will presumably share in the settlements of lawsuits on kratom vendors if the client can expect to be paid for testifying that they become "helplessly addicted" to this herb.	This commenter resides out of state and has not indicated a business impact related to the rule.

	There seem to be many large industries that are challenged by this inexpensive herb and they are trying to take this useful plant away from many people whom no longer can get prescriptions for FDA-approved opioids -- people with a legitimate need, some that only kratom has found to work so well. Finally, our U.S. Food and Drug Administration has done some human testing on kratom and -- though their Website still doesn't fully reflect their findings, they have admitted they are not focused on scheduling the natural plant kratom, Rather, they have recommended that the DEA do Emergency Scheduling of the sem-synthetic molecule 7-OH, which is plainly being unlawfully marketed, thus confusing many lawmakers that this is "kratom", which it plainly is NOT. As a citizen of this great and beautiful nation, I would hope that I won't need to dodge Ohio and a handful of other banned states and small communities that would be happy to put me in jail because I have found a natural plant that eases the discomforts of turning 77 years old. (Ironic, isn't it that in many states -- with a doctor's permission -- I could be driving your highways high as can be on cannabis and not be arrested, but no so, with possession of kratom, which is nothing like weed or opioids.) Please study this plant carefully and don't ban this gentle pain neutralizer.	
Grand Rapids Botanicals (Michigan)	As a business owner and advocate for kratom, we have been open for 6 years here in Michigan. I have seen many customers coming into our store and dealing with all types of addictions and looking for something that would help them to get off of	This commenter resides out of state and has not indicated a business impact related to the rule.

	very harmful drugs, alcohol or dealing with pain or suffering from anxiety and depression. And now to this day, I see them come in with a smile on their face and back to work and living their life again. Kratom has helped in so many ways to turn their lives around and feel normal again. These people are so grateful for kratom and it changing their lives. I speak for myself and many others when I say please don't ban kratom! It does help people and changes lives. The Kratom leaf is such a better all natural alternative than opioids or harmful drugs on the streets. Kratom Saves Lives.	
Pure Infinity Botanicals (Florida)	WOW! Yes, I'm in the business, yes this is my livelihood, BUT this is such an important plant for so many people. We are the only company with the care to create a youtube channel for the purpose of educating. I'd be honored if you took a look at our content to see what we are about. We love Ohioans and we love kratom, and we know that this will hurt a lot of people. It's not just an issue of regulation, it's an issue of compassion. Please share some compassion for your constituents.	This commenter does operate an online store where it appears Ohioans are able to purchase products. However, their comment does not indicate the level of lost revenue that would result from the adoption of this rule. It should be noted that this producer sells products containing 600 MG of kratom's active ingredient. This far exceeds any dosing administered during Phase I clinical trials conducted with kratom. Furthermore, they advertise these high dose products as a method to quit synthetic formulations of kratom such as 7-OH.
HAVEN Access Inc. (Tennessee)	Schedule I placement requires findings that a substance has a high potential for abuse, no	The commenter has not provided data or evidence to indicate how the Board's assessment fails to prove the requirements of ORC 3719.41.

	accepted medical utility, and a lack of accepted safety even under medical supervision. The proposed rules do not demonstrate these findings using real-world, population-level evidence. Instead, they rely on speculative, indirect, or incomplete reasoning while disregarding the lived experiences of individuals who utilize kratom-derived products and the consequences of abruptly eliminating lawful access.	It is also notable that this organization supports full legalization of synthetic formulations of kratom (7-OH, MGM, MP), that are full opioid agonists that are more potent than morphine and which are currently classified as Schedule I controlled substances under OAC 4729:9-1-01.1.
Holistic Alternative Recovery Trust (Florida)	HART supports sensible regulation for all natural therapeutics derived from *mitragyna speciosa* or "kratom," including mitragynine and 7-hydroxymitragynine (7-OH). This work will take time. Furthermore, it must necessarily disregard political exigencies, allowing for rigorous, methodical public health research and feedback from stakeholders including the scientific community, medical experts, and public and consumer perspectives. And, it should endeavor to balance the ideals of protecting children and the public while also protecting access for the hundreds of thousands of Ohio consumers who rely on kratom and its alkaloids to manage pain and overcome addiction. No category is inherently risk-free. Physical dependence, withdrawal symptoms, and adverse effects can occur across all categories, particularly with high doses, frequent use, or riskier routes of administration such as	This commenter resides out of state and has not indicated a business impact related to the rule.

	drinks. Importantly, however, no categories are associated with death when consumed in isolation.	
Kratom Consumer Advisory Council	The FDA looked at four markers that could suggest future addictive potential, feeling high/euphoric, feeling drunk, drug liking, and desire to take it again. These factors were not elevated above placebo levels for normal consumption doses of 1-3 g. There were some qualitative increases at the 8 to 12 g doses, but the FDA did not identify these as being concerning and merely recommended additional study. What the FDA study clearly identified was dose related increases in gastrointestinal adverse events like nausea and vomiting. This effect, bolstered by the leaf vegetal matter, is a built-in hedge against binging the product and one that prescription and illicit opioids do not have. They also inexplicably discount or ignore the fact that the vast majority of countries in the world are following the World Health Organization's position that natural leaf kratom does not meet the criteria for scheduling/banning. All these quality control issues can be dealt with through a Kratom Consumer Protection Act that is meaningfully enforced. The KCAC has many best practices that can support the Ohio Board of Pharmacy in reducing the risk of unwanted adulteration without banning a substance that many people believe has given them back the ability to function and reduced risks associated with	The commenter seems to be citing a single phase 1 clinical trial as proof that the compound is safe and effective. No phase 2 clinical trials for kratom have been completed. Therefore, the tests that determine whether the benefit of kratom to treat any condition outweighs the risk have not been completed. Furthermore, the phase 1 clinical trial used vegetative kratom. This does not replicate the available products that are sold in gas stations and vape stores, which include hyper potent extracts with mitragynine concentrations significantly higher than what is naturally occurring. For example, one kratom company produces an extract that contains 1000 MG of mitragynine in a 2 oz bottle. On the labeling, the product states that there are 50 servings per bottle (which each serving size being a small squeeze). In the absence of those facts, it is unreasonable to expect the public to navigate the safe use of even natural kratom when manufacturers of those products acknowledge a risk of death.

	illicit opioid use like respiratory depression and blood borne diseases. Those adverse gastrointestinal effects, and users' desire to avoid them, provide an additional barrier to the overuse of natural leaf kratom that does not exist as to other, enhanced mitragynine-containing products. As such, there is a great need for vulnerable people to use an accessible and affordable option if the alternative is continued use of illicit opioid products. In a public health scenario where FDA approved options are inaccessible or have failed many people, the decision to try natural leaf kratom instead of continuing illicit opioids could be positive. The KCAC knows that natural kratom use is not risk free and public health protections are needed. We have numerous position statements on how to regulate natural leaf kratom products to reduce public health risks without denying vulnerable people access to the products.	As discussed in the Board's 8-factor analysis, the need for manufacturer warnings of death is bolstered by the FDA, forensic findings, and years of case reports. With respect to the suggestion that the Board's determination is at odds with the determination of the World Health Organization (WHO), section 3792.07 of the Revised Code expressly prohibits the state from enforcing or funding the implementation of "any health policy guideline, mandate, recommendation, or rule issued by the [WHO], including the prohibition of issuing a prescription for or dispensing of a drug."
Top Tree Herbs (Colorado)	We also want to address the proposal's "bath salts/cathinone" analogy. It is true that novel analogs can proliferate. But the core driver of that "cat-and-mouse" market is prohibition or looming prohibition of a known product class. When a natural product remains legal under clear, enforceable guardrails, there is less economic incentive to create unknown, riskier substitutes. Each new analog is, by definition, less characterized and therefore more likely to create unexpected toxicity or harm.	The Board does not have the statutory authority to develop an entire regulated market for kratom via administrative rule. Kratom's lack of designation as a food product or drug at the federal or state level creates an unregulated grey market. Efforts to create a regulated market via legislation have not been successful in Ohio.

	A sweeping Schedule I action could unintentionally accelerate the very dynamic the Board is trying to prevent by pushing consumers into illicit markets and increasing the rewards for clandestine chemistry. A more effective harm-reduction strategy is a consumer-protection regulatory framework designed to optimize personal freedom and public health. Kratom has a long history of traditional use as a tea/infusion, and modern tea bags are one practical way to keep use closer to that model. A peer-reviewed study led by Dr. Oliver Grundmann (Correlations of kratom tea bag preparations and reported pharmacological effects, 2023) found that tea infusion from tea bags yields substantially lower mitragynine than exhaustive methanolic extraction and concluded that traditional tea infusions "provide a potentially safer formulation compared to more concentrated products."	
Reason Foundation (Washington, DC)	The board itself acknowledges that many users consume kratom to self-treat pain, fatigue, and even opioid withdrawal. However, because there is “no FDA-approved medical use,” the board classifies this "self-treatment" as abuse. Testimonials indicate some users see kratom as a way to reduce or end abuse of opioids. One of the direst consequences of a total ban, which makes even personal possession of such products illegal, would be the criminalization of many consumers attempting to treat pain without pharmaceutical opioids. Drug use is first and	The commenter notes that the Board did not engage in any graduated regulatory options regarding kratom. The Board does not have the statutory authority to develop an entire regulated market for kratom via administrative rule. Kratom’s lack of designation as a food product or drug at the federal or state level creates an unregulated grey market. Efforts to create a regulated

	foremost a public health issue, and criminalization of individual possession and use is not an appropriate response. In addition to self-reported benefits, emerging evidence supports the therapeutic potential of kratom, including Phase 1 clinical trials and extensive observational data, demonstrating plausible therapeutic value for pain, mood disorders, and opioid cessation and withdrawal symptoms with an acceptable safety profile. The board ultimately conflates harms from contaminated, adulterated, or polydrug kratom products with harms from mitragynine itself. Outlawing products will do little to address contaminated or adulterated products. The board explicitly considered no graduated regulatory options (licensing, product standards, age limits, or potency caps) even though such options exist and are in use in other states.	market via legislation have not been successful in Ohio.
PDX Aromatics, LLC (Oregon)	For these reasons, we oppose a blanket ban on natural kratom, while supporting targeted prohibitions on 7-hydroxymitragynine (7-OH) and other synthesized or chemically altered compounds. At the same time, banning natural kratom leaf and non-synthetic alkaloid extracts would remove access to products that many adults use responsibly, while failing to address the root causes of safety concerns. Experience in other states has shown that prohibition does not eliminate demand; it	A review of poison control data from 2010-2023 found that there were significantly fewer incidence rates of exposures, severe medical outcomes, healthcare evaluation and hospitalization in states with a ban compared to any other regulatory status. (Comstock G, Gulotta AP, Rein LE, Feldman R. Association between state-level kratom regulations and poison center-reported severe medical outcomes and healthcare use: A United States national analysis. Addiction. 2026. https://doi-

	instead drives consumers to unregulated or illicit markets where quality controls are nonexistent.	org.proxy.library.ohio.gov/10.1111/add.70416)

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RESEARCH REPORT

ADDICTION SSA

Association between state-level kratom regulations and poison center-reported severe medical outcomes and healthcare use: A United States national analysis

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Abstract

Background and aims: Kratom use in the United States (US) has increased. Kratom is not federally scheduled; regulation is heterogenous and determined at the state level. Strategies include no regulation, bans and kratom consumer protection acts (KCPA) such as age limits, product purity or labeling requirements. Public health data informing these policies remain limited. This study aimed to compare rates of poison center (PC) reported kratom exposures, including those associated with severe medical outcomes and healthcare use, across US states with differing regulatory frameworks, and to characterize national trends in kratom exposures over time.

Design: Retrospective observational study of kratom exposures reported to the National Poison Data System from 2010 to 2023.

Setting: All 50 US states and the District of Columbia.

Participants: A total of 8919 kratom-related exposures were reported to PCs during the study period, including 5452 single-substance exposures (61%). Most cases involved adult males (69%), aged ≥18 years (8133; 91%).

Measurements: States were classified by kratom regulatory status into four categories: unrestricted (no regulations), KCPA, local restrictions (KCPA in 1 or more county, but no state regulation) or banned (retail sale illegal). The primary outcome was the incidence of severe medical outcomes defined as exposures coded by America's Poison Centers criteria as major effect (life-threatening or resulting in significant residual disability) or death. Secondary outcomes included rates of exposure, hospitalization and healthcare use (defined as hospital admission or evaluation in an emergency department, urgent care or primary care).

Findings: Kratom exposures increased from 19 cases in 2010 to 1242 cases in 2023 [incidence rate ratio (IRR) = 69.0 compared with 2010; 95% confidence interval (CI) = 39.6–120; $P < 0.001$]. Severe medical outcomes increased from zero cases in 2010 to 158 cases in 2023; 2012 was the first year in which a severe outcome was reported (2023 IRR = 56.9 vs 2012; 95% CI = 14.7–221; $P < 0.001$). Overall, 13% of kratom exposures resulted in a severe medical outcome. Compared with states where kratom was banned, statistically significantly higher rates of exposures (IRR = 2.49; 95% CI = 1.89–3.28), severe medical outcomes (IRR = 3.19; 95% CI = 1.78–5.70), healthcare use (IRR = 2.44; 95% CI = 1.66–3.60) and hospitalization (IRR = 2.45; 95% CI = 1.81–3.30,

$P < 0.001$) occurred (all $P < 0.001$). No statistically significant differences were identified between other regulatory categories.

Conclusion: Kratom exposures and severe medical outcomes reported to United States poison centers are increasing nationally, though states with bans in place have experienced less pronounced increases.

KEYWORDS
drug policy, harm reduction, Kratom, Mitragynine, opioids, poison center, substance use

INTRODUCTION

Kratom (*Mitragyna speciosa*), a Southeast Asian plant containing psychoactive alkaloids mitragynine and 7-hydroxymitragynine, has been used in traditional medicine for centuries, but has proliferated globally over the past two decades [1, 2]. Its psychoactive effects vary with dose, ranging from stimulant-like at low doses to opioid-like at higher doses [3, 4]. Common uses include managing chronic pain, depression, anxiety or opioid withdrawal, although robust evidence is lacking [5, 6].

Increased use has led to rising adverse health effects and healthcare utilization. From 2014 to 2024, 7333 emergency department or hospital visits related to kratom exposure were reported to United States (US) poison centers, with reported exposures increasing each year for the past decade [7]. Although poison center data are not population incidence data, this trend is concerning. More than half of these exposures reported adverse effects. Adverse effects from use can be mild, but also include severe symptoms such as cardiac dysrhythmias, seizures, respiratory depression and death, as well as dependence and withdrawal with chronic use [8, 9]. Although there are risks from use, advocacy groups highlight its potential as a harm reduction tool for opioid withdrawal and use in treatment of conditions such as chronic pain.

Kratom is not scheduled under the Controlled Substances Act (CSA), and the US Food and Drug Administration does not currently recognize it as a lawfully marketed food or dietary supplement, leaving a gap in federal regulation. As a result, regulatory oversight is determined at the state level. State specific regulatory strategies range from a state-wide ban, making it an illegal substance, to being completely unrestricted [10]. Other strategies include state-level Kratom Consumer Protection Acts (KCPA), which aim to reduce harm through measures such as age restrictions and labeling requirements [11]. Many states are considering legislation changes regarding kratom regulation, but research to support the public health impact of such policies is lacking and calls for research to inform regulation have been made [11].

Importance

Kratom use in the United States continues to rise, and legislatures across the country are actively debating the optimal way to regulate its use. There is an urgent public health need for evidence to inform this discussion in a way that promotes safety surrounding kratom use.

Specific aims

The aims of this study include:

1. compare total kratom exposures reported to US poison centers within each state regulatory status;
2. compare rates of severe medical outcomes associated with kratom exposures reported to US poison centers within each state regulatory status;
3. compare rates of kratom exposures resulting in hospitalization within each state regulatory status;
4. compare rates of kratom exposures using healthcare (evaluation at an urgent care, primary care provider, or emergency department or hospitalization) within each state regulatory status; and
5. characterize annual trends, demographic characteristics and clinical characteristics of fatal of kratom-associated exposures reported to US poison centers.

METHODS

Study design and setting

This was a retrospective observational study of kratom exposures reported to the National Poison Data System (NPDS) from 2010 to 2023. The NPDS is a US poisoning data warehouse maintained by America's Poison Center (APC) composed of poisoning exposures reported to the 55 US poison centers, populated with case data in near-real time.

Selection of participants

The NPDS was queried using the APC generic code for kratom from 2010 to 2023. Individuals of all ages were included. Both single and multiple substance exposures were included. Cases coded as 'confirmed non-exposure', representing inquiries regarding suspected kratom exposure that were ultimately determined not to have occurred, were excluded. Cases were categorized by the state from

which the call originated. Reported exposures may represent unique individuals or multiple distinct exposures involving the same individual.

Outcomes

United States poison centers are managed by trained healthcare professionals who assist in managing exposed patients and document the medical care and outcome in a standardized format. Captured data reflect the information provided by the caller at the time of the call. Accuracy of all reported information cannot be verified. Coding standardization is determined by APC. Outcomes of cases are coded as 'no effect', 'minor', 'moderate', 'major' or 'death' according to NPDS medical outcome criteria. Specific medical outcome criteria are available in appendix F of the APC Annual Report [12]. As per NPDS, 'no effect' is when a patient developed no symptoms as a result of exposure. 'Minor effects' refer to symptoms that are minimal with no residual disability (skin irritation, drowsiness and mild gastrointestinal symptoms). 'Moderate effects' are signs or symptoms that are more pronounced, prolonged or of a more systemic nature than minor symptoms, with no residual disability (e.g. fever, disorientation and tachycardia). 'Major effects' are life-threatening or result in residual disability or disfigurement (e.g. coma, hemodynamic collapse, respiratory or cardiac arrest, stroke or status epilepticus). 'Death' is coded when the patient died as a result of or as a direct complication of the exposure or if the exposure was a contributing factor.

The primary outcome was the incidence of severe medical outcomes, defined as cases coded by APC as a major effect or death, within each regulatory status category. A composite outcome was used because deaths alone were infrequently reported and were anticipated to occur at too low a frequency to allow reliable independent analysis, and major effects represent substantial morbidity that regulatory frameworks aim to prevent. Secondary outcomes included incidence of total kratom exposures, kratom exposures resulting in reported healthcare utilization (evaluation by an urgent care, primary care provider, emergency department or hospitalization) and kratom exposures resulting in hospitalization reported to poison centers, stratified by state regulatory status. This was chosen to help identify the total healthcare burden of kratom exposures within each regulatory status. Hospitalization and healthcare utilization categories are not mutually exclusive, as hospitalization represents a subgroup of healthcare utilization. For analysis, any kratom exposure (single substance of polysubstance) that resulted in a poison center contact, healthcare utilization, hospitalization or severe medical outcome was included.

Additional objectives

To aid in characterizing effects associated with kratom toxicity and their possible public health impact, single substance fatalities where kratom was identified as the causative substance, were reported. Fatality narratives for single substance deaths were also analyzed for themes. Information on poison center death causation assessment and documentation is available in Data S1. Themes from deaths with polysubstance exposures were not reported because the death may have been related to a separate substance.

Predictors and covariates of exposure

Outcome predictors were compared across state regulatory classifications. Regulatory status was determined through internet search for each state and the word 'kratom', followed by review of relevant state administrative codes and a summary report from the Legislative Analysis and Public Policy Association (LAPPA) describing kratom laws in all US states [13]. Search was performed by two independent reviewers (G.C. and A.G.). Discrepancies were arbitrated by a third reviewer (R.F.) and a Cohen's κ coefficient is reported for inter-reviewer reliability. States were categorized based on the legislation in effect for at least 50% of the calendar year (i.e. legislation had to be in effect by 1 July to be assigned that category for the year).

Because LAPPA does not provide details regarding timing of the passage of local legislation, local news publications and municipal code were accessed for additional detail. Sources used for the generation of each state legislative category are provided in Data S2. States were grouped by their kratom regulatory status separately for each year into the following four categories: unrestricted, KCPA, local restrictions or banned (Figure 1). States were classified as banned if kratom was listed as a Schedule I substance or if state law explicitly prohibited the sale of kratom. States were classified as having a KCPA if they had age-based sales restrictions, marketing restrictions or quality control requirements regulating product purity and strength. States were classified as having local restrictions if one or more counties or municipalities restricted kratom, but no state-wide regulation was in place. States were classified as unrestricted if no kratom-related regulations existed at either the state or local level.

Analysis and ethical considerations

The number of annual exposures per state was modeled using mixed effects quasi-Poisson regression. The model included year and the state's kratom regulatory status as fixed categorical predictor variables. States were grouped by their kratom regulatory status separately for each year into the following four categories: unrestricted, KCPA, local restrictions if non–state-wide regulation existed or fully banned. The model included an offset term for the log of the state population as reported by census data to account for population size within each group and a state-specific random intercept to account for repeated measures within states.

Exponentiated regression coefficients, interpretable as incidence rate ratios (IRRs), were reported with 95% CI. *Post hoc* comparisons

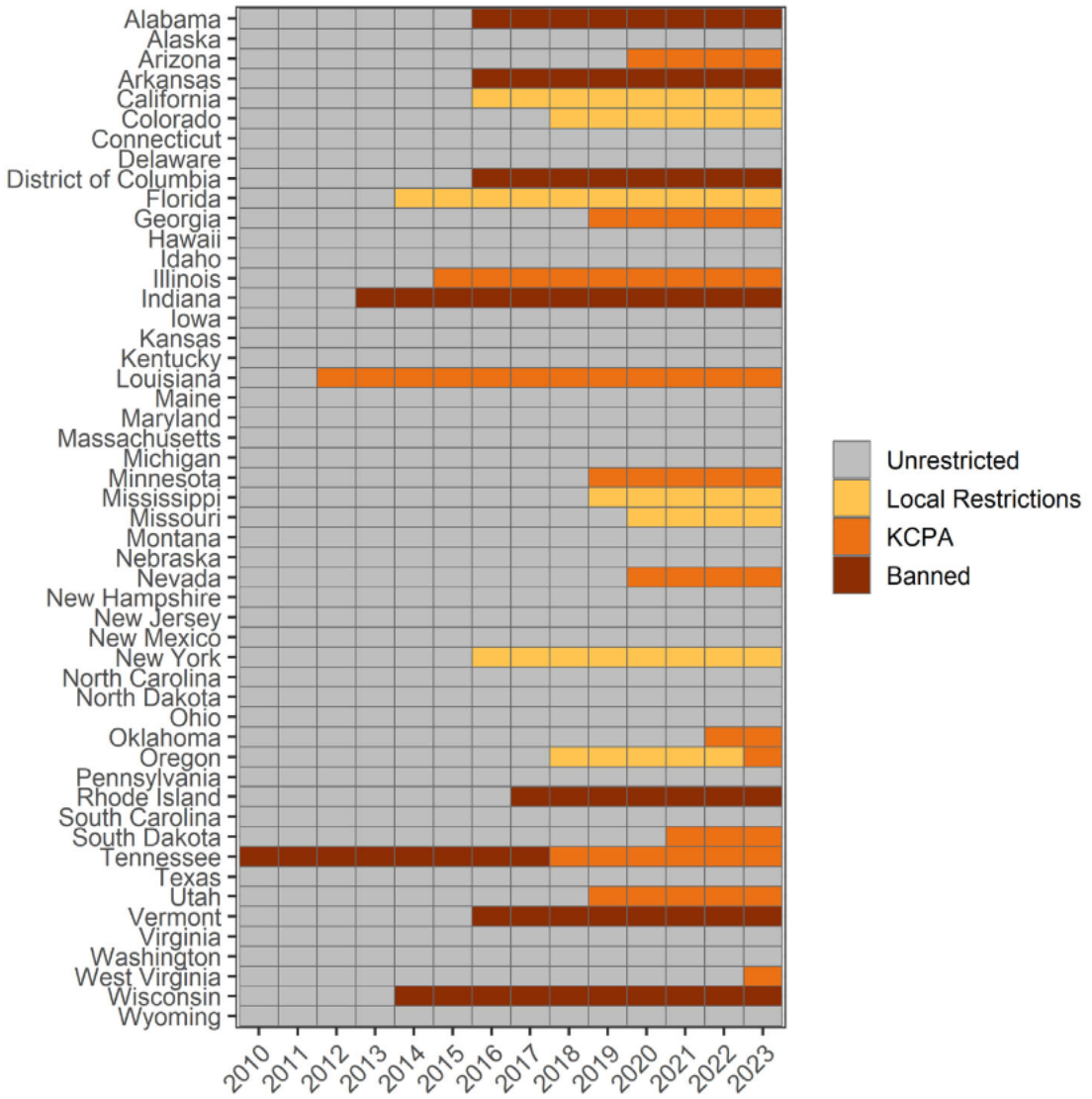


FIGURE 1 Swimmer's plot depicting regulatory status for each state and year.

KCPA= Kratom Consumer Protection Act

were performed to compare rates (averaged over the entire study period) across all pairs of legislative groups, to compare fully banned states with all other jurisdictions, and to assess whether results changed when states or territories with unclear classification status were reclassified [e.g. Disctrict of Columbia (DC)]. a Bonferroni correction was applied to all pairwise comparisons to adjust for multiple testing. Regression results were visualized using a line plot of estimated marginal mean rates over time for each legislative group. The Poisson regression analysis was repeated for the following outcomes: annual exposures resulting in severe outcomes, exposures resulting in hospitalization and exposures resulting in healthcare assessment or hospitalization.

All statistical analyses were performed using R version 4.3.1 (R Foundation for Statistical Computing, http://www.R-project.org). All tests were two-sided and $P < 0.05$ was considered statistically significant.

Our study protocol was reviewed and judged as non-human subject research by our institutional review board. This manuscript was written in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline for reporting observational studies [14]. The research question and analysis plan were not pre-registered on a publicly available platform and results should be considered exploratory.

RESULTS

Characteristics of study subjects

Demographic data is available in Table 1. Of 8919 total exposures, 8411 had an exact age reported, of which the median was 31 years, (IQR = 24–40 years, range = 1 day–100 years), and the majority of cases were male. Pediatric exposures were uncommon with 91% of exposures occurring in adults 18 years and older. States were separated into four categories each year for analysis of annual kratom regulatory status (Figure 1). Inter-rater reliability was excellent ($\kappa = 0.81$).

Outcomes by state regulatory status

There was a 65.4-fold increase in kratom-related poison center cases during the study, from 19 cases in 2010 to 1242 cases in 2023 (IRR = 69.0 vs. 2010, 95% CI = 39.6–120, $P < 0.001$). An increase in annual case volume was seen in states of each regulatory category, although the degree of rise differed between regulatory categories (Figure 2). Likewise, incidence of healthcare evaluation, hospitalization and severe medical outcomes associated with kratom rose during the study period, although trends varied by regulatory status. Description

TABLE 1 Patient demographics and characteristics of exposure.

	Legislative status				
Characteristic	**Overall *n* = 8919[a]**	**Unrestricted *n* = 4974[a]**	**Local restrictions *n* = 2134[a]**	**KCPA *n* = 1559[a]**	**Banned *n* = 252[a]**
Age, years					
<12	490 (5.5)	259 (5.2)	123 (5.8)	97 (6.2)	11 (4.4)
13–17	205 (2.3)	115 (2.3)	45 (2.1)	41 (2.6)	4 (1.6)
>18	8113 (91)	4537 (91)	1942 (91)	1404 (90)	230 (91)
Unknown age	111 (1.2)	63 (1.3)	24 (1.1)	17 (1.1)	7 (2.8)
Gender					
Female	2736 (31)	1524 (31)	663 (31)	472 (30)	77 (31)
Male	6149 (69)	3425 (69)	1465 (69)	1084 (70)	175 (69)
Unknown	34 (0.4)	25 (0.5)	6 (0.3)	3 (0.2)	0 (0)
Exposure type					
Single substance	5452 (61)	2992 (60)	1419 (66)	880 (56)	161 (64)
Multiple substance	3467 (39)	1982 (40)	715 (34)	679 (44)	91 (36)
Reason					
Intentional—abuse/misuse	5502 (62)	3140 (63)	1292 (61)	905 (58)	165 (65)
Intentional—suspected suicide	1174 (13)	620 (12)	256 (12)	263 (17)	35 (14)
Intentional—unknown	552 (6.2)	313 (6.3)	115 (5.4)	102 (6.5)	22 (8.7)
Other	40 (0.4)	21 (0.4)	13 (0.6)	6 (0.4)	0 (0)
Unintentional	1256 (14)	650 (13)	380 (18)	204 (13)	22 (8.7)
Unknown reason	395 (4.4)	230 (4.6)	78 (3.7)	79 (5.1)	8 (3.2)

Abbreviation: KCPA, Kratom Consumer Protection Act.
[a]*n* (%).

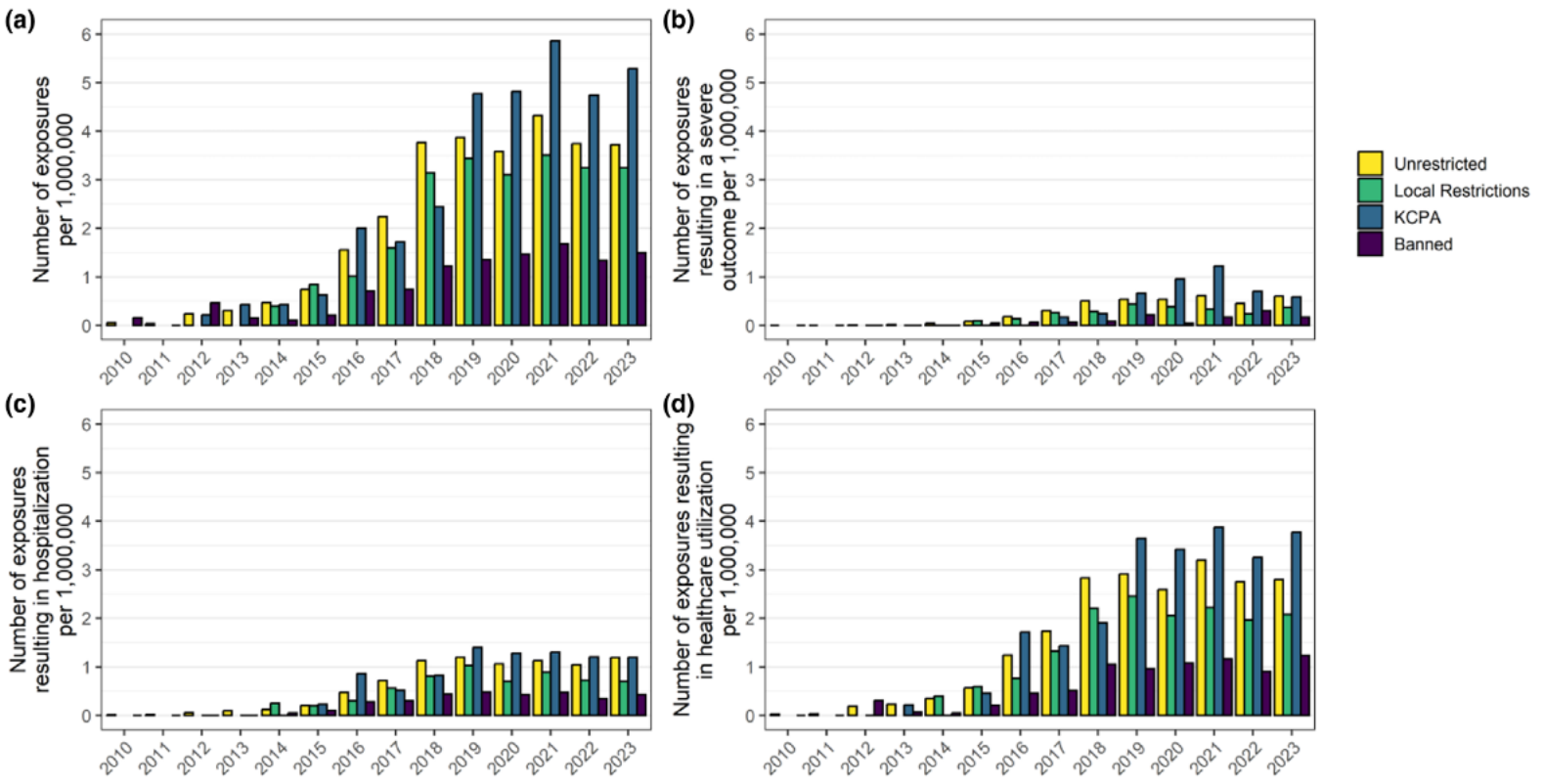
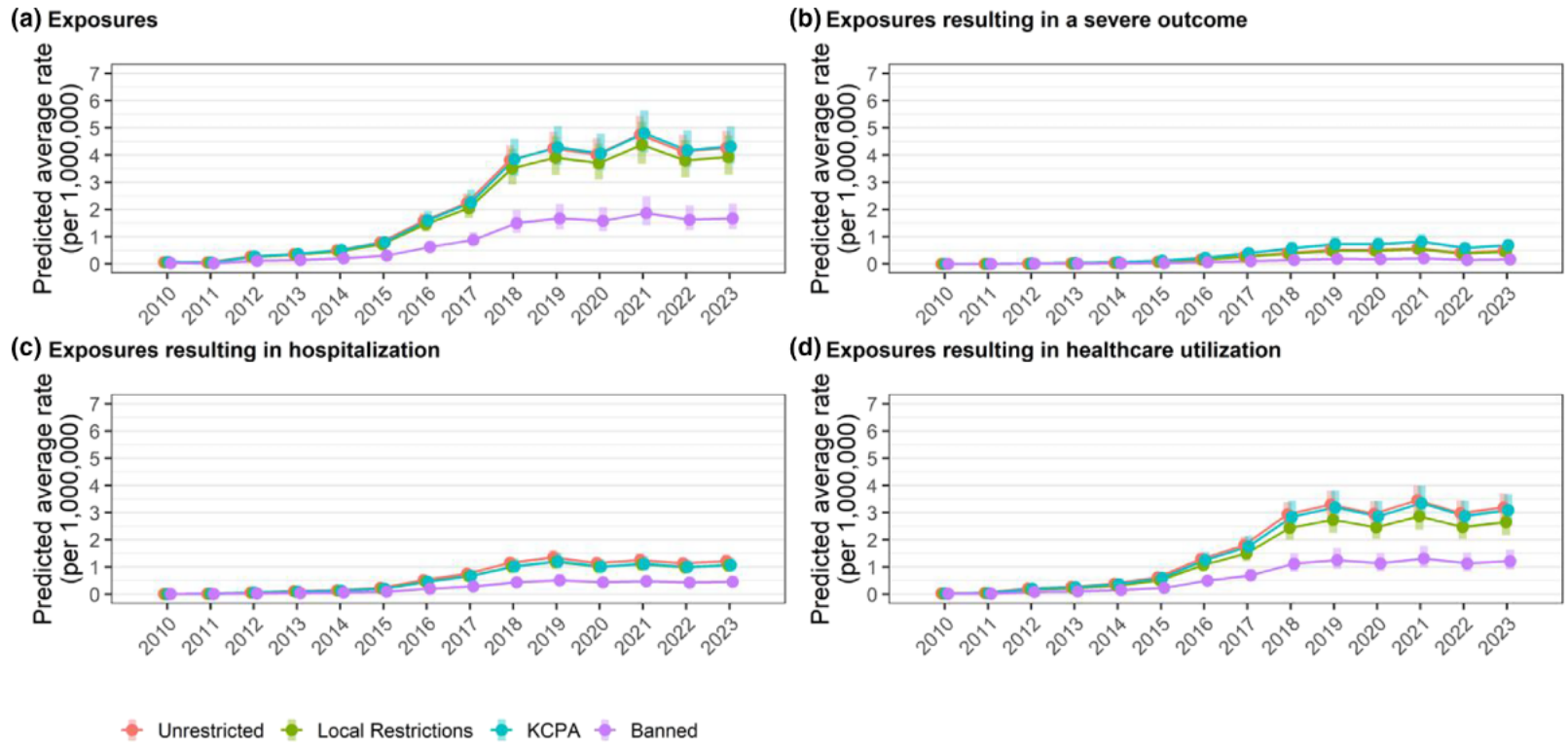


FIGURE 2 Bar chart of (a) annual kratom exposures reported to poison centers, (b) exposure with severe outcomes, (c) exposure with hospitalizations and (d) exposures with healthcare utilization per legislative group.



KCPA= Kratom Consumer Protection Act

FIGURE 3 Estimated marginal mean number (a) annual kratom exposures reported to poison centers, (b) exposure with severe outcomes, (c) exposure with hospitalizations and (d) exposures with healthcare utilization per legislative group modeled using quasi-Poisson regression with an offset for state population.

of patient outcomes and helthcare utilization by regulatory status are available in Table 2. Pairwise contrasts, including 95% CI and *P* values, for the estimated IRRs of each outcome by state regulatory status are presented in Table 3.

There were significantly fewer incidence rates of exposures, severe medical outcomes, healthcare evaluation and hospitalization in states with a ban compared to any other regulatory status (Figure 3, Table 3). Relative to ban states, all other regulatory categories combined were associated with higher incidence rates of poison center-reported exposure (IRR = 2.49, 95% CI = 1.89–3.28), severe outcomes (IRR = 3.19, 95% CI = 1.78–5.70), healthcare evaluation (IRR = 2.44, 95% CI = 1.66–3.60) and hospitalization (IRR = 2.45, 95% CI = 1.81–3.30; all $P < 0.001$). States with no kratom regulation (unrestricted) also demonstrated higher incidence rates of healthcare utilization compared with states with at least local restrictions in place (IRR = 1.20, 95% CI = 1.02–1.42), although this difference did not reach statistical significance ($P = 0.168$). No significant differences were observed between other regulatory categories (KCPA vs. local restriction; KCPA vs. unrestricted). Pairwise comparisons between regulatory classifications, reported as IRRs for each outcome, and each year, are available in Data S3.

Patient outcomes

The majority of kratom exposures (72.5%) received evaluation in healthcare settings (Table 2). Hospitalization occurred in 3035 cases (34%). Of those requiring hospital admission, 1353 (44.5%) were admitted to critical care units. Comparatively fewer single-substance kratom exposures required healthcare evaluation, hospitalization or critical care admission.

Among all kratom exposures, there were 174 deaths (2%), and 27 were reported among single substance kratom exposures (0.5%) (Table 2). Two deaths occurred in adolescent patients, both were polysubstance exposures. No deaths in children 12 years or younger were reported. Severe medical outcomes, defined as either death or major effects, were documented more frequently in polysubstance exposures (13%) as compared to single substances exposures (8.7%).

In the 490 kratom exposures in children less than or equal to 12 years, 163 (33%) were evaluated in a healthcare facility, 32 (6.5%) were admitted to a hospital and 11 (2.2%) were admitted to critical care units. Two (0.4%) children 12 years and younger experienced major medical effects, and there were no deaths. In one, a 2-day-old male experienced tremor, tachycardia, bradycardia and hyperventilation. In the other, a 22-month-old male experienced agitation and major central nervous system depression.

Of the single substance kratom deaths, six cases were adjudicated as 'probably' or 'undoubtedly responsible,' five involved males younger than 30 years of age. These individuals were found in cardiac arrest or were found unresponsive and subsequently developed cardiac arrest, all with a documented history of kratom use or recent ingestion. Care was withdrawn within days because of severe anoxic brain injury. No clear prodromal symptoms were described in four of the five cases. In one case, a kratom user experienced a seizure during

TABLE 2 Description of patient outcomes and characterization of healthcare utilization.

Characteristic	Legislative status				
	Overall *n* = 8919[a]	Unrestricted *n* = 4974r[a]	Local restrictions *n* = 2134[a]	KCPA *n* = 1559[a]	Banned *n* = 252[a]
Health care utilization					
Critical care	1353 (15.2)	810 (16.3)	285 (13.4)	207 (13.3)	51 (20.2)
Non-critical care	1141 (12.8)	657 (13.2)	259 (12.1)	196 (12.6)	29 (11.5)
Psychiatric facility	541 (6.1)	308 (6.2)	89 (4.2)	131 (8.4)	13 (5.2)
Treated/evaluated and released	3432 (38.5)	1956 (39.3)	805 (37.7)	580 (37.2)	91 (36.1)
Patient lost to follow-up or left AMA	936 (10.5)	461 (9.3)	276 (12.9)	166 (10.6)	33 (13.1)
Patient refused referral or did not arrive	309 (3.5)	175 (3.5)	76 (3.6)	46 (3.0)	12 (4.8)
No healthcare evaluation was reported or recommended	1207 (13.5)	607 (12.2)	344 (16.1)	233 (14.9)	23 (9.1)
Clinical outcome					
Death	174 (2.0)	74 (1.5)	21 (1.0)	76 (4.9)	3 (1.2)
Major effect	979 (11)	589 (12)	212 (9.9)	153 (9.8)	25 (9.9)
Moderate effect	3325 (37)	2022 (41)	665 (31)	536 (34)	102 (40)
Minor effect	1838 (21)	922 (19)	476 (22)	381 (24)	59 (23)
No effect	607 (6.8)	336 (6.8)	127 (6.0)	128 (8.2)	16 (6.3)
Not followed, minimal effects	721 (8.1)	383 (7.7)	237 (11)	85 (5.5)	16 (6.3)
Not followed, judged as nontoxic	28 (0.3)	9 (0.2)	15 (0.7)	4 (0.3)	0 (0)
Unable to follow, judged as a potentially toxic	1005 (11)	496 (10.0)	324 (15)	161 (10)	24 (9.5)
Unrelated effect	242 (2.7)	143 (2.9)	57 (2.7)	35 (2.2)	7 (2.8)
Subgroup of single substance exposures					
Characteristic	**Legislative status**				
	n = 5452[a]	*n* = 2992[a]	*n* = 1419[a]	*n* = 880[a]	*n* = 161[a]
Health care utilization					
Critical care	559 (10.3)	332 (11.1)	130 (9.2)	78 (8.9)	19 (11.8)
Noncritical care	560 (10.3)	312 (10.4)	142 (10.0)	95 (10.8)	11 (6.8)
Psychiatric facility	194 (3.6)	109 (3.6)	33 (2.3)	44 (5.0)	8 (5.0)
Treated/evaluated and released	2315 (42.5)	1307 (43.7)	576 (40.6)	363 (41.3)	69 (42.9)
Patient lost to follow-up or left AMA	674 (12.4)	318 (10.6)	213 (15.0)	118 (13.4)	25 (15.5)
Patient refused referral or did not arrive	234 (4.3)	130 (4.3)	63 (4.4)	34 (3.9)	7 (4.3)
No healthcare evaluation was reported or recommended	916 (16.8)	484 (16.2)	262 (18.5)	148 (16.8)	22 (13.7)
Clinical outcome					
Death	27 (0.5)	15 (0.5)	4 (0.3)	7 (0.8)	1 (0.6)
Major effect	446 (8.2)	256 (8.6)	107 (7.5)	70 (8.0)	13 (8.1)
Moderate effect	1,820 (33)	1,075 (36)	422 (30)	264 (30)	59 (37)
Minor effect	1,185 (22)	601 (20)	313 (22)	231 (26)	40 (25)
No effect	440 (8.1)	264 (8.8)	80 (5.6)	82 (9.3)	14 (8.7)
Not followed, minimal effects	569 (10)	306 (10)	179 (13)	72 (8.2)	12 (7.5)
Not followed, judged as nontoxic	24 (0.4)	8 (0.3)	12 (0.8)	4 (0.5)	0 (0)
Unable to follow, judged as a potentially toxic	751 (14)	364 (12)	252 (18)	119 (14)	16 (9.9)
Unrelated effect	190 (3.5)	103 (3.4)	50 (3.5)	31 (3.5)	6 (3.7)

Abbreviations: AMA, Against Medical Advice; KCPA, Kratom Consumer Protection Act.
[a]*n* (%).

TABLE 3 *Post-hoc* contrasts from each quasi-Poisson regression model, comparing all pairs of state regulatory statuses.

	Incidence rate ratio [95% CI] for outcome			
	Exposure	Exposures resulting in a severe outcome	Exposures resulting in hospitalization	Exposures resulting in healthcare assessment or hospitalization
Unrestricted vs. banned	**2.548 [1.929–3.366] *P* < 0.001**	**2.890 [1.614–5.176] *P* = 0.002**	**2.659 [1.800–3.927] *P* < 0.001**	**2.629 [1.947–3.548] *P* < 0.001**
Local restrictions vs. banned	**2.347 [1.731–3.182] *P* < 0.001**	**2.711 [1.415–5.196] *P* = 0.016**	**2.334 [1.511–3.606] *P* < 0.001**	**2.183 [1.571–3.033] *P* < 0.001**
KCPA vs. banned	**2.574 [1.927–3.439] *P* < 0.001**	**4.130 [2.239–7.620] *P* < 0.001**	**2.344 [1.552–3.540] *P* < 0.001**	**2.546 [1.863–3.481] *P* < 0.001**
KCPA, local restrictions, or unrestricted vs. banned	**2.488 [1.885–3.282] *P* < 0.001**	**3.187 [1.783–5.695] *P* < 0.001**	**2.441 [1.655–3.602] *P* < 0.001**	**2.445 [1.813–3.296] *P* < 0.001**
Unrestricted vs. local restrictions	1.085 [0.933–1.263] *P* = 1.000	1.066 [0.738–1.539] *P* = 1.000	1.139 [0.901–1.441] *P* = 1.000	**1.204 [1.020–1.421] *P* = 0.168**
Unrestricted vs. KCPA	0.990 [0.869–1.127] *P* = 1.000	0.700 [0.527–0.929] *P* = 0.082	1.134 [0.927–1.389] *P* = 1.000	1.032 [0.895–1.191] *P* = 1.000
Local restrictions vs. KCPA	0.912 [0.766–1.086] *P* = 1.000	0.656 [0.438–0.985] *P* = 0.251	0.996 [0.755–1.313] *P* = 1.000	0.857 [0.707–1.039] *P* = 0.698

Notes: The exponentiated regression estimates (interpreted as incidence rate ratios) are presented with 95% CI. *P*-values were adjusted using a Bonferroni correction for each regression model. Comparisons between all regulatory classes for each year and outcome can be found in Data S3. Bolded values represent those with 95% CI of incidence rate ratio > 1.
Abbreviation: KCPA, Kratom Consumer Protection Act.

intercourse, prompting emergency medical services, who subsequently found the patient in cardiac arrest. The sixth case involved a woman in her 50s who became unresponsive following kratom ingestion. She aspirated and required intubation, with subsequent concern for secondary sepsis. She developed hypotension and multi-system organ failure and died 3 days later. Confirmatory mitragynine concentrations were obtained in two of the six cases to corroborate kratom exposure.

DISCUSSION

Our study demonstrates a significant increase in kratom exposures reported to US poison centers over the past decade, consistent with previously published trends. [15] Alongside this rise, incidence rates of reported severe clinical effects and subsequent healthcare utilization have also increased. Although some exposures may have no adverse effects, severe effects such as seizure, coma and cardiac arrest are reported in this study. Nearly one in seven cases reported to a poison center with a single-substance kratom exposures were admitted to a hospital, and one in 16 were admitted to a critical care unit, highlighting the potential severity of kratom toxicity.

Although severe medical outcomes were common, it is important to recognize that prior studies have shown kratom is frequently used in combination with other psychoactive substances. For example, Olsen *et al*. [16] reported that among 152 decedents who tested positive for mitragynine *post-mortem*, only seven had no other psychoactive substances detected, and fentanyl was the most frequently listed cause of death [16]. More recent cases, however, have documented and increasing number of fatalities attributed to kratom use alone [17].

There are multiple mechanisms by which kratom can produce acute toxicity, including but not limited to hepatotoxicity, risk for cardiac dysrhythmia and seizure risk [18–20]. Although pre-clinical data suggest decreased risk for respiratory depression when compared with traditional opioids, cases of respiratory depression responsive to naloxone in patients without co-exposure to opioids has been reported [21]. Additionally, kratom is known to interact with P-glycoprotein as well as cytochrome P450 enzymes 2D6 and 3A4, potentially increasing the risk of adverse outcomes when used concurrently with other substances [17, 22]. Given the common practice of polysubstance use among kratom users, its safety profile and potential role as a harm reduction agent remain questionable.

As states continue to evaluate kratom legislation, our findings suggest that regulatory approaches short of an outright ban were not associated with lower rates of exposure, healthcare utilization or severe outcomes when compared to unrestricted states. In contrast, rates were consistently lower in states with kratom ban in place. These findings are consistent with prior studies showing lower incidence of kratom use in states with bans and no corresponding reduction in states with KCPA legislation [23].

Several hypotheses may explain these patterns. Availability of kratom is widespread among states without bans, irrespective of the presence of regulation [24]. Bans may reduce the availability of kratom in retail settings and its visibility through advertising, potentially decreasing both access and awareness. Although these findings do not establish causality, they raise important questions about the effectiveness of consumer protection-focused legislative framework.

The broader public health implications of kratom bans, including substance abuse patterns or management of withdrawal, are unclear. Legislators must navigate these questions without access to high-

quality evidence to inform decisions. Additionally, a portion of the limited literature available to inform decision-making has been published by groups with industry affiliations [4, 11]. There is an urgent need for larger, methodologically rigorous investigation independent of special group interest to better characterize benefits and risks of kratom access.

Kratom regulatory responsibility fell to states in 2016 following the withdrawal of a 2016 Drug Enforcement Agency (DEA) proposal to schedule mitragynine and 7-hydroxymitragynine [25]. At present, no federal approval or oversight mechanism exists, despite the DEA listing kratom as a drug of concern [26]. The US Food and Drug Administration kratom website as of 2025 states that it is not safe or lawful as a dietary supplement or food additive, and it cannot be legally added to dietary supplements or conventional foods [11, 26]. The resulting heterogeneity of state regulation has resulted in a rapidly evolving and inconsistent regulatory landscape.

State lawmakers continue to debate and explore legislation. Since the beginning of 2023, five of the six states with kratom bans have introduced or are considering KCPA legislation. Rhode Island passed a bill to implement a KCPA through both chambers of state congress, although it was ultimately vetoed. Florida passed a KPCA in 2023, Maryland in 2024, with Nebraska and South Carolina passing regulatory legislation in 2025 [13]. Debates continue in statehouses elsewhere, with South Dakota, Connecticut, Hawaii, Illinois, Missouri and New York exploring regulatory frameworks or legislation, which would classify kratom as a controlled substance [13].

Our findings highlight the need for high-quality data to continue to inform this ongoing policy debate. Future research should continue to rigorously evaluate public health outcomes associated with different regulatory frameworks to support evidence-based legislative and public health decisions.

Limitations

These findings are subject to important limitations. First is the inherent limitation of retrospective reviews because of potential for confounding. We, therefore, emphasize that any relationships between incidence rates and state regulatory status should be viewed as association rather than a causal link. Because polysubstance exposures were included, adverse outcomes and healthcare utilization may not be attributable solely to kratom. Toxicity from co-ingested substances may have been the primary driver, with kratom functioning as a contributing or non-relevant exposure.

We assessed the impact of KCPAs as a heterogeneous group of interventions. It is possible that specific regulatory components within this bundle exerted meaningful effects that were not detected because they were grouped with less effective measures. Accurately characterizing the legal and regulatory status of kratom across US states is inherently challenging because of variability in statutory language, administrative codes and the evolving nature of state and local regulations. As a result, some degree of state-level misclassification cannot be entirely excluded.

Certain jurisdictions, such as the District of Columbia, were particularly difficult to classify because of conflicting statutory and regulatory interpretations regarding the scheduling of kratom and its alkaloids [13]. However, given our findings, any misclassification would most likely bias results toward a type II error. For example, classifying jurisdictions with conflicting legislation as having a ban would tend to inflate exposure counts in 'banned' states, thereby attenuating observed effects. *Post hoc* sensitivity analyses were performed for jurisdictions such as the District of Columbia, and results were unchanged by reclassification. Finally, the sources and methods used for regulatory classification are fully described, allowing the analysis to be replicated or reclassified as appropriate.

Another important limitation is the inherent nature of poison center data, which rely on passive reporting. Poison centers depend on information provided by callers and are unable to independently confirm the specific substances reported. Laboratory confirmation of kratom exposure in clinical practice is exceedingly rare, consequently, most cases are evaluated and managed based on patient report. Additionally, because poison center data are encounter-based rather than patient-based, individuals may contribute more than one exposure, and the inability to reliably link repeat encounters precluded adjustment for within-person correlation.

Finally, poison center data is not representative of population incidence data. However, prior analyses suggest these data reflect similar trends observed in larger national databases, albeit on a smaller scale. For instance, the 2022 APC annual report demonstrated that rates of fentanyl exposures with serious outcomes rose at the same rate as Centers for Disease Control and Prevention None. Wide-ranging ONline Data for Epidemiologic Research (CDC WONDER) fentanyl fatality data [27].

No single database is likely able to capture the public health impacts related to kratom. Poison center data have the advantage of including cases from individuals who did not seek healthcare, but are limited by passive reporting nature and cannot log an exposure if not contacted. In contrast, healthcare aggregate data depend on proper coding and accurate identification of kratom as a contributing health issue. Under-reporting is a concern no matter the data source, as mitragynine testing is not routine. Notably, under-reporting may be further exacerbated in states with kratom bans, where individuals may be reluctant to contact poison centers or seek medical care because of fear of potential legal consequences.

CONCLUSION

Our study highlights the increasing public health concerns associated with kratom, evidenced by a significant rise in poison center-reported exposures and severe medical outcomes over the past decade. States with bans experienced a lower incidence of severe kratom-related medical outcomes and healthcare utilization. Conversely, states with consumer protections acts designed to promote safety experienced similar rates of severe outcomes as states with no regulation at all. These findings may help inform legislators of the possible health

effects of widespread kratom availability, but do not assess unintended consequence of kratom not being available.

AUTHOR CONTRIBUTIONS

Grant Comstock: Conceptualization; investigation; writing—original draft; methodology; writing—review and editing. **Anthony P. Gulotta:** Investigation; data curation; writing—original draft; project administration; validation. **Lisa E. Rein:** Formal analysis; software. **Ryan Feldman:** Conceptualization; investigation; writing—original draft; methodology; writing—review and editing; project administration; data curation.

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DECLARATION OF INTERESTS

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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