EXHIBIT H2

INTERIM STUDY PROPOSAL 2023-004

State of Arkansas
94th General Assembly
Regular Session, 2023

A Bill

JMB/JMB
SENATE BILL

By: Senators J. Boyd, G. Leding, Irvin
By: Representative Eubanks

Filed with: Senate Committee on Public Health, Welfare, and Labor pursuant to A.C.A. §10-3-217.

For An Act To Be Entitled

AN ACT TO ESTABLISH THE ARKANSAS KRATOM CONSUMER PROTECTION ACT; TO REMOVE MITRAGYNINE AND 7-HYDROXYMITRAGYNINE, ALSO KNOWN AS KRATOM, FROM THE CONTROLLED SUBSTANCES LIST IN ARKANSAS; AND FOR OTHER PURPOSES.

Subtitle

TO ESTABLISH THE ARKANSAS KRATOM CONSUMER PROTECTION ACT; AND TO REMOVE MITRAGYNINE AND 7-HYDROXYMITRAGYNINE, ALSO KNOWN AS KRATOM, FROM THE CONTROLLED SUBSTANCES LIST IN ARKANSAS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 20, Chapter 56, is amended to add an additional subchapter to read as follows:

Subchapter 4 — Arkansas Kratom Consumer Protection Act

20-56-401. Title.

This subchapter shall be known and may be cited as the "Arkansas Kratom Consumer Protection Act".

20-56-402. Legislative Findings.

The General Assembly finds that:

(1) On February 1, 2016, the Department of Health added mitragynine and 7-hydroxymitragynine, which are two (2) constituent compounds of the kratom plant, as Schedule I substances;

(2) The department justified this action on the basis that mitragynine and 7-hydroxymitragynine exhibit opioid-like activity when consumed, and included kratom as a Schedule I substance since it has no approved medical use by the United States Food and Drug Administration;

(3)(A) The United States Food and Drug Administration had encouraged every state to ban kratom on the premise that it would be scheduled by the United States Drug Enforcement Administration as a controlled substance in 2016, and that Alabama, Wisconsin, Indiana, and Vermont had already classified kratom as a Schedule I substance.

(B) Rhode Island also banned kratom in 2017 based on information provided by the United State Food and Drug Administration;

(4) Since 2016, the United States Drug Enforcement Administration withdrew the United States Food and Drug Administration's scheduling recommendation for kratom on October 13, 2016, citing insufficient evidence to meet the requirements for classifying mitragynine and 7-hydroxymitragynine as Schedule I substances;

(5) On August 16, 2018, the Assistant Secretary of Health at the United States Department of Health and Human Services withdrew the United State Food and Drug Administration's second scheduling recommendation for mitragynine and 7-hydroxymitragynine as Schedule I substances citing "disappointingly poor evidence and data and a failure to consider overall public health";

(6) On December 1, 2021, the Expert Committee on Drug Dependence at the United Nations Commission on Narcotic Drugs rejected the recommendation for international scheduling of mitragynine and 7-hydroxymitragynine citing insufficient evidence to support that action;

(7) On February 21, 2023, the Indiana House of Representatives, on a vote of 53-40, passed a repeal of the kratom ban and replacing it with the Kratom Consumer Protection Act;

(8)(A) On March 1, 2023, the Vermont Department of Health accepted a petition by the American Kratom Association to remove the kratom ban.

(B) Upon completion of the planned rule making of the Vermont Department of Health, the number of banned states is reduced to five (5) states;

(9) On March 10, 2023, the Wisconsin Controlled Substances Board passed a motion affirming to the State Legislature that kratom does not meet the statutorily mandated eight factors established by the Controlled Substances Act for scheduling despite their view kratom should not be removed from scheduling until more research is available;

(10) The Rhode Island Legislature is proceeding with the Kratom Consumer Protection Act after the Interim Director of the Department of Health acknowledged kratom does not meet the criteria for scheduling;

(11)(A) At this time, seven (7) states, including Utah, Georgia, Arizona, Nevada, Oregon, Colorado, and Oklahoma, have passed the Kratom Consumer Protection Act between 2019 and 2022.

(B) Two (2) additional states have passed the Kratom Consumer Protection Act during the current 2023 legislative session and they are now awaiting the Governor's signature in Virginia and West Virginia.

(12) On March 16, 2022, United States Department of Health and Human Services Secretary Becerra, in a letter to Senator Mike Lee and Representative Mark Pocan, acknowledged "knowledge gaps" on kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances";

(13) On December 29, 2022, President Joe Biden signed the FY23 Omnibus with kratom report language commending the National Institute on Drug Abuse for funding studies on kratom that "may provide help for some Americans struggling with addictions, given its analgesic and less addictive properties as compared to opioids";

(14)(A) Data from the Department of Health shows that fatal opioid overdoses have been on the rise in recent years.

(B) In 2021, the Department of Health reported there were six hundred twenty-eight (628) drug overdose deaths in Arkansas; and

(15)(A) On May 17, 2022, the Director of the National Institute on Drug Abuse, Dr. Nora Volkow, testified regarding the drug overdose crisis at a hearing of the United States Senate Subcommittee on Labor, Health and Human Services.

(B) When asked about overdose prevention strategies, Dr. Volkow stated: “There’s also interest in the community to test other products that may serve as harm reduction. For example, the use of kratom, which is sold as tea and that contains a drug molecule that has effects that are similar to a dose of buprenorphine but could be utilized also for decreasing withdrawal or depression.”

20-56-403. Definitions.

As used in this subchapter:

(1) "Food" means a food, food product, food ingredient, dietary ingredient, dietary supplement, or beverage for human consumption;

(2)(A) "Kratom product" means a food product or dietary ingredient containing any part of the leaf of the plant mitragyna speciosa or an extract of the plant mitragyna speciosa.

(B) A "kratom product" may be manufactured as a powder, capsule, pill, beverage, extract, or other edible form;

(3) “Kratom extract” means a food product or dietary ingredient containing any part of the leaf of the plant mitragyna speciosa that has been extracted in order to provide more standardized dosing;

(4) "Processor" means a person that sells, prepares, manufactures, distributes, or maintains kratom products, or advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products; and

(5) “Retailer” means any person that sells, distributes, advertises, represents, or holds itself out as selling or maintaining kratom products.

20-56-404. Kratom product limitations.

A processor shall not prepare, distribute, sell, or expose for sale any of the following:

(1) A kratom product that:

(A)(i) Is adulterated with a dangerous non-kratom substance.

(ii) A kratom product is adulterated with a dangerous non-kratom substance if the kratom product is mixed or packed with a non-kratom substance and that substance affects the quality or strength of

the kratom product to such a degree as to render the kratom product injurious to a consumer;

(B)(i) Is contaminated with a dangerous non-kratom substance.

(ii) A kratom product is contaminated with a dangerous non-kratom substance if the kratom product contains a poisonous or otherwise deleterious non-kratom ingredient, including without limitation the substances listed in the state's controlled substances list;

(C) Contains:

(i) A level of 7-hydroxymitragynine in the alkaloid fraction that is greater than one percent (1%) of the overall alkaloid composition of the product; or

(ii) Any synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant;

(2) A kratom extract that contains levels of residual solvents higher than is allowed in the U.S. Pharmacopeia Chapter 467; or

(3) A kratom product or kratom extract that does not provide adequate labeling directions necessary for safe use by consumers, including a recommended serving size, the recommended number of servings per day, and the number of servings in the package that is sold.

20-56-405. Age limits.

A processor shall not distribute, sell, or expose for sale a kratom product to an individual under eighteen (18) years of age.

20-56-406. Processor registration.

(a)(1) A processor shall register annually with the Department of Agriculture any kratom product intended to be offered for sale to an end consumer that is in an approved kratom delivery form and pay a fee that is adjusted annually to cover all administrative costs for processing and administering the registrations.

(2) The registration shall include a certificate of analysis from a certified independent third-party laboratory showing compliance with the requirements for kratom products in this subchapter.

(b)(1) Upon receipt of a credible violation report of non-compliance with this subchapter on a kratom product offered for sale, the Department of Agriculture shall require the processor to produce an updated and current certificate of analysis in a reasonable time frame from a certified independent third-party laboratory showing compliance with the requirements of this subchapter for safe kratom products.

(2) If the processor does not provide the certificate of analysis in the specified time frame, the registration for that product shall be revoked.

(c)(1) Upon receipt of any adverse event related to a registered kratom product, the processor shall be required to submit a copy via certified mail to the department of their adverse event report that is required to be submitted to the United States Food and Drug Administration under Section 761 of the Federal Food Drug & Cosmetic Act.

(2) The department may revoke the kratom product's registration for any documented failure to report an adverse event to the department.

(d)(1) If the department has a reasonable basis to require an independent third-party test of a registered kratom product by a laboratory of the department's choice, the processor shall be required to submit payment for the test within a reasonable time frame.

(2) If the processor does not tender payment to the department within a set time period upon receipt of the invoice for the testing, the department shall revoke the registration for that product.

20-56-407. Violations.

(a)(1) A processor that violates this subchapter is subject to an administrative fine of not more than five hundred dollars ($500) for the first offense and not more than one thousand dollars ($1,000) for a second or subsequent offense.

(2) Upon the request of a person to whom an administrative fine is issued, the Secretary of the Department of Agriculture shall conduct a hearing in accordance with the Arkansas Administrative Procedure Act, § 25-15-201 et seq.

(b) A retailer does not violate this subchapter if it is shown by a preponderance of the evidence that the retailer relied in good faith upon the

representations of a manufacturer, processor, packer, or distributor of food represented to be a kratom product.

Referred by Senator J. Boyd
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