April 8, 2025

The Honorable Joseph Solomon Jr.
Chairman, House Corporations Committee
Rhode Island State House
Room 101
82 Smith Street
Providence, RI 02903

RE: H5565 - AN ACT RELATING TO FOOD AND DRUGS -- THE RHODE ISLAND KRATOM ACT

Dear Chairman Solomon and Honorable Members of the Committee,

I am submitting this testimony in regard to Bill H 5565, to seek amendments to improve the legislation based on the best scientific data to prevent any unintended consequences. I applaud the work the Rhode Island legislature has done thus far to consider the abundance of scientific literature related to mitragynine and kratom and the legislatures' efforts to regulate the botanical. In the past two years, eight states (Virginia, West Virginia, Florida, Louisiana, Georgia, Texas, Kentucky and Maryland) have enacted legislation in favor of the safe sale of kratom to consumers in the form of a Kratom Consumer Protection Acts (KCPA). We, as an organization, believe that effective state regulations help ensure that this botanical can safely be in the hands of consumers and effective legislation will keep bad market actors out.

Kratom or *Mitragyna speciosa* is a natural botanical in the same plant family as coffee. It is most often used as an energy boost and for mild mood enhancing effects. Its effects are relatively mild, like that of coffee and tea. Kratom has been used for centuries for a variety of therapeutic reasons, including improved mood, reduction in anxiety, increased energy, and for treatment of minor aches and pain. Kratom has traditionally been consumed in the form of steeped tea or by chewing on fresh leaves. In the U.S., kratom is typically available as a dietary supplement or beverage in numerous formats including crushed leaves, liquid "shots", or beverages.

Researchers from numerous academic institutes include Johns Hopkins University School of Medicine, Columbia University, University of Florida, and Ohio State University, are among the many scientists that have found that, kratom provides pain relief activity on the pain centers in the brain without the dangerous and potentially deadly respiratory suppression induced by classical opioid medications. Further, the U.S. Food and Drug Administration conducted their own clinical trial on kratom, the first leg of which was published in 2024, and showed kratom could be safely used and was effective and well tolerated in human populations.

While the FDA has made inflammatory statements about the safety of kratom in the past, the Agency recently acknowledged in federal court that it did not have evidence that kratom was dangerous[1] and that its prior statements regarding kratom were communicated through informal,

[1] See Ex. 30, Declaration of Andrew P. Young in Support of [Defendant] Guthery's Motion for Issuance of a Pretrial Subpoena Duces Tecum, *United States v. Nine2Five, LLC*, No. 3:23-cr-00179-TWR (S.D. Ca.) (filed Dec. 6, 2023) Dkts. 110-2, 110-6.

non-binding channels, were not made pursuant to any internal decision-making process and did not reflect the formal views of the Agency.[2]

FDA's recent statements in federal court are also consistent with its own actions related to products containing kratom. Such products are widely and openly sold in the United States and FDA's actions against them have historically been based on grounds unrelated to kratom. For example, FDA has taken action against kratom products containing undeclared food allergens (see, e.g., recall of Kula Can – Pina Colada + Kratom Seltzer), kratom products making drug claims (see, e.g., FDA warning letters to Cali Botanicals and Kratom NC), and kratom products potentially contaminated with Salmonella (see, e.g., recall of powdered kratom products by Triangle Pharmanaturals, etc.) These are the types of actions that FDA takes against other FDA-regulated dietary supplements.

FDA has always acknowledged that kratom is a botanical and, therefore, a dietary ingredient under the Dietary Supplement Health and Education Act of 1994. Given its long-established history of safe use, kratom can be used in both food (for example as its traditional form as a tea) or as a dietary ingredient in dietary supplements.

Kratom is not a controlled substance. In fact, the FDA was prohibited from making kratom a scheduled controlled substance in 2017 by Congress, Health and Human Services, and the National Institute on Drug Abuse. This was unprecedented action at the time with such action to prohibit the FDA's scheduling due to the therapeutic benefits of kratom. At the state level, while some states, such as Rhode Island, banned kratom in anticipation of the FDA acting, there have been no statewide bans of kratom since the FDA's failed attempt to do so.

Bans or outright prohibitions on kratom do not actually keep such prohibited products out of the marketplace. Product scheduling or bans do keep reputable, tested, properly labeled, and compliant products out of the market, though. Companies selling compliant products want to also comply with the law while gray market and illegal products continue to sell in defiance of any prohibition. A well-crafted regulatory regime with legislation that gives the state the tools to permit the sale of complaint products and remove illegal products is most effective for consumer safety.

In regard to H 5565, we feel that there are distinct differences from KCPAs that other states have enacted that raise some concern. While we do not recommend a wholesale replacement of H 5565, we would like to recommend certain changes to make the proposed Bill more effective. I respectfully submit the following recommendations:

(1) Section 21-28.12-3(a)(1) should be struck. Kratom in its traditional and arguably safest from when sold as a beverage such as a tea which is treated as a traditional food or beverage.

(2) Section 21-28.12-3(a)(3) should be struck. There are many safe 'psychoactive substances' that are used in dietary supplements. Caffeine, Sugar, kava etc. If not

[2] See Defendant's Memorandum in Support of their Motion to Dismiss, *Martian Sales, Inc. v. Food and Drug Administration, et al.*, case 1:24-cv-03031-RBW (DC) (filed on 12/23/24) Dkt 12-1.

struck, this Section should be restricted to such "…substances that are injurious to consumers."

(3) Section 21-28.12-3(a)(9) should be struck. The Poison Prevention Packaging Act of 1970 (16 C.F.R. 1700.15(b) and 16 C.F.R. 1700.200) itemizes specific substances subject to that Act and what packaging must be used. Neither dietary supplements in general, nor kratom products, are itemized therein and it would be impossible to comply with this Act. Further, many kratom products are single serving and there would be no consumer safety advantage to having such restrictive.

(4) Sections 21-28.12-3(a)(10)(ii) and (iii) should be struck. Both of these provisions are open to abuse by dangerous high concentrate 7-hydroxymitragynine product brands. The 1% provision in Section 21-28.12-3(a)(11) handles this issue effectively on its own.

(5) Section 21-28.12-3(a)(12)(v), the words "United States" should be struck. This disclaimer requirement should be harmonized with the federal requirement in 21 U.S.C. 343(r)(6)(C) and 21 CFR 101.93(b)–(d) that states: "This statement has not been evaluated by the Food and Drug Administration."

(6) Section 21-28.12-3(a)(12)(vii) should be struck. Section 21-28.12-3(a)(12)(vi) already requires the amount of mitragynine and 7-hydroxymitragynine per serving should be specified, which is consistent with product labeling practices.

(7) Section 21-28.12-4(b) should be replaced in its entirety to read "No person shall distribute kratom consumable products through displays accessible to the public without the assistance of a retailer's employee or agent other than in an establishment open only to persons 21 years of age or encased where other products accessible to persons 21 years of age are stored." This allows products to also be sold beside other similarly age-gated products.

Thank you for your time and consideration. I welcome the opportunity to discuss this matter further.

Kind Regards,

Andrew Kulpa