



Rhode Island Pharmacists Association
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[submitted electronically via: SLegislation@rilegislature.gov]

The Honorable Joseph Solomon, Jr.
Chair, House Committee on Corporations
State House
82 Smith Street Providence, RI
02903

RE: H7231 (Edwards) – KRATOM CONSUMER PROTECTION ACT

Dear Chair Solomon and members of the Committee:

We are writing as a neutral party to discuss concerns with the current version of Bill H7231, which would *“authorize and regulate the distribution of the product known as “kratom,” and would ban the adulteration of kratom with a dangerous non-kratom substance as to render the product injurious to a consumer. The act would require that any kratom product contain adequate labeling directions necessary for safe and effective use by consumers.”*

Since this bill is supported by the American Kratom Association (AKA), we want to acknowledge [AKA's support](#) of Resolution 515 by the American Medical Association (AMA) House of Delegates in 2023, **which we also support**. The [full text of the resolution is included below](#) with **our highlights**.

- 1. The safety and efficacy of kratom should be determined through research and clinical trials**, and subsequently evaluated by the relevant regulatory entities for its appropriateness for sale and **potential oversight via the Controlled Substances Act, before** it can be marketed, purchased, or prescribed.
2. Individuals who are currently using kratom for pain management or other conditions **should have access to appropriate medical care to manage their conditions and withdrawal symptoms**, if needed.
- 3. Individuals who are using kratom only for personal use should not face criminal consequences.**
- 4. Kratom should be regulated by the FDA**, and its safety and efficacy should be determined through clinical trials before it can be marketed or prescribed as a treatment for any condition

From a pharmacy practice perspective, we evaluate the use of kratom by its efficacy and safety, just like any other pharmacologically active substance. **In regard to efficacy, the FDA has not evaluated the efficacy of kratom, and does not regulate it.**

We have a few concerns regarding kratom's safety. The regulation of kratom, like every other substance, should ensure the safety of the consumers and patients, and there are currently no safety mechanisms written into Bill H7231. Such mechanisms are important as our safety concerns have been validated in multiple case reports:

- [Florida medical examiners have identified 587 deaths involving kratom since 2013, 46 of which were identified as kratom-only deaths \(not due to multiple substances\)](#)

Given the noted safety concerns, there have been **several instances of successful reversal of kratom overdose using naloxone**, an opioid antagonist used for opioid overdose.

Here are a selected few case reports describing such events:

- [A 38-year old woman with a positive urine sample of kratom and no other substances successfully reversed with naloxone](#)
- Similarly, [a woman in her 40s with urine toxicology negative for opioids or fentanyl successfully reversed with naloxone after large consumption of kratom](#)

We would be more compelled to support Bill H7231 **if the sale of over the counter (OTC) naloxone was required with each sale of kratom**. Since kratom has opioid-like effects, this will reduce the unintended harms of kratom use. This matches Rhode Island law and regulation that naloxone is co-prescribed with all higher dose opioids and opioids dispensed with benzodiazepines, since patients who take these medications as directed are at risk of overdose.

If rigorous, large, standardized, and randomized human clinical trials do not prove kratom's efficacy for the FDA, **we support safety studies to support kratom's regulation as a supplement under Federal Trade Commission's (FTC's) oversight.** Standardized, safe, and unadulterated kratom products could then be sold and monitored next to vitamins and other supplements.

Absent regulation by either the FDA or the FTC, **we would be willing to support a regulatory process like cannabis in Rhode Island,** which includes regulations for safe use through rigorous testing and **accountability that is sustainably funded.** We appreciate the inclusion of penalties in the bill, **but these are issued after potential patient harm.**

Instead, we advocate for changes to the bill including a **budget line item to establish a Kratom Control Commission,** for example, to assure safety and transparent labeling of products before they are sold to the public. As with supplements, OTC medications, and prescription drugs, this system should also have mechanisms for surveillance of safety after products are available and marketed.

Each of these regulatory structures, FDA, FTC, and cannabis, ensures **patient safety** through standardized dosing **verified through rigorous testing and clear labeling** so **consumers know not only how much kratom is in their products for therapeutic effects and to avoid unintentional overdose,** but also to **detect and prevent adulteration or contamination.**

Sincerely,



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CC:

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