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March 14, 2024

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

RE: H 7231 – An Act Relating to Food and Drugs –Kratom Consumer Protection Act

Dear Chair Solomon:

Please accept this letter opposing H 7231, legislation that would authorize and regulate the distribution of the product known as kratom in Rhode Island.

H 7231 also defines a "kratom product" to mean "a dietary ingredient, dietary supplement, botanical supplement, or containing any part of the leaf of the plant Mitragyna speciosa or an extract of it; is manufactured as a powder, capsule, pill, beverage, or other edible form and all kratom products are dietary ingredients, dietary supplements, or botanical supplements" and a "kratom extract" to mean "a dietary ingredient, dietary supplement, botanical supplement or containing any part of the leaf of the plant Mitragyna speciosa that has been extracted and concentrated to provide more standardized dosing". H 7231 defines "food" to mean "a dietary ingredient, dietary supplement, botanical supplement, or beverage for human consumption. This act shall take effect on January 1, 2025.

Currently in Rhode Island, kratom is a substance that is illegal to possess or sell. Kratom products are not generally recognized as safe and effective at this time and, therefore, these products are "new drugs" under section 201(p) of the *FD&C Act*, 21 U.S.C. 321(p). New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the US Food and Drug Administration (FDA), as described in sections 301(d) and 505(a) of the *FD&C Act*, 21 U.S.C. 355(a). FDA approves a new drug based on scientific data and information demonstrating that the drug is safe and effective. There are no FDA approved kratom products. On FDA's website, the FDA states that kratom is not lawfully marketed in the US as a drug product, a dietary supplement, or a food additive in conventional food because there is inadequate information to provide reasonable assurance that kratom ingredients do not present a significant risk of illness or injury.

A considerable dialogue about the safety and efficacy of kratom use by consumers is ongoing. The data emerging from research is preliminary and/or only contains use on animal data. The scientific community is still learning about the more than 40 alkaloids present in the kratom plant and its wide range of pharmacologic activity, including opioid, serotonergic, and adrenergic effects. Further, the kratom products sold in the US are generally dried plant material or highly concentrated forms, which are different than fresh harvested plant leaves. A significant concern exists about adverse interactions between kratom and common medications. For example, the National Institute of Health (NIH) recently funded Auburn University researchers to study how kratom may interfere with HIV medications, leading to decreased efficacy and increased toxicity. Furthermore, the *Tampa Bay Times* and academic researchers have recently documented hundreds of kratom-associated overdose deaths.

According to kratom researchers, the products available in the US can differ in chemical makeup compared to forms of the plant harvested in Southeast Asia. Currently, researchers have NIH funding to investigate forms of kratom to evaluate pharmacological properties and evaluate for medical use. However, these results are years away and the need for more research is widely agreed upon

FDA has issued an RFP [grants.nih.gov] for further study of kratom for abuse potential, which is in parallel to ongoing research at the National Institute on Drug Abuse (NIDA). To date, clinical evaluations of the potential for misuse have not been performed. This research proposal describes a human abuse potential (HAP) study of botanical kratom. The HAP study will help researchers, scientists, individuals using or considering the use of kratom, and the broader public health community because it will generate important findings related to the safety profile of kratom.

Kratom remains a substance of concern to many in the public health and substance use disorder treatment communities. At this time, the FDA is actively evaluating all available scientific information on this issue and continues to warn consumers not to use any products labeled as containing kratom or its psychoactive compounds, mitragynine and 7-hydroxymitragynine.

The belief that kratom is safe because it is a natural substance is both misleading and untrue. Documented harms include seizures, agitation, liver toxicity, and death. In 2023, a study was published that kratom is associated with disproportionate reports of life-threatening ventricular arrhythmia in North America. Other adverse outcomes include dependence, withdrawal after cessation of use, and cases of neonatal abstinence syndrome. There are multiple case reports that document that treatment with buprenorphine was needed to control kratom withdrawal symptoms.

Rhode Island has worked diligently to make safe and effective Medications for Opioid Use Disorder (MOUD) available to those who suffer from opioid use disorder and to reduce the stigma that is sometimes associated with the use of these therapies. FDA-approved MOUDs include methadone, buprenorphine, and naltrexone. Using products with unsubstantiated claims, such as kratom, may prevent those with opioid use disorder from seeking treatments that have been demonstrated to be safe and effective. Reliance on products with unsubstantiated claims may delay their path to recovery and put them at greater risk of overdose and death. Patients receiving FDA-approved MOUDs cut their risk of death in half, according to the federal Substance Abuse and Mental Health Services Administration. As our nation struggles with epidemic levels of opioid misuse, Rhode Island should be doing everything possible to ensure that those suffering from addiction have access to FDA-approved medicines and appropriate treatment options.

Evidence exists that individuals taking mitragynine and 7-OH-mitragynine (two psychoactive alkaloids present in kratom with known effects at the mu-opioid receptor) are taking them in amounts sufficient to create a hazard to their health. Evidence also exists from epidemiological databases and the scientific literature that kratom has potential risk for misuse and addiction. A leading kratom researcher noted during an NIH national webinar there are increasing reports of kratom misuse among younger generations in Southeast Asia, including polysubstance use.

The stimulant and opioid effects of kratom have been well documented. Although a clear dose-response relationship has not been established, preliminary data suggest that lower doses of kratom produce stimulant-like effects and higher doses produce sedative effects. However, researchers are still trying to determine what alkaloids are responsible for what effects and dosing to effect.

A quick review of the internet demonstrates that there are sellers of kratom who make medical claims, with no evidence that, among other things, kratom:

- Drives away obesity;
- Helps with opiate withdrawal symptoms;
- Helps treat anxiety and depression;
- Helps with poor sleep patterns;
- Serves as an anti-inflammatory; and
- Promotes heart health.

One frequently mentioned website states that "naturally occurring kratom is a safe herbal supplement that behaves as a partial mu-opioid receptor agonist and is used for pain management, energy, even depression and anxiety that are common among Americans." Such statements are unproven claims about kratom's ability to treat or cure opioid use disorder and treat withdrawal symptoms. These sites also make claims about treating pain, as well as other medical conditions like depression, anxiety, and cancer.

The current evidence regarding side effects and potential for adverse consequences associated with kratom use are sufficient to conclude it should not be available for consumer use in Rhode Island The marketing and sale of unapproved products for treatment of opioid use disorder is a potentially significant public health concern. Rhode Island needs to protect consumers from products that, without approval from the FDA, claim to diagnose, mitigate, prevent, treat, or cure opioid addiction.

It is for these reasons that RIDOH is opposed to this legislation. As always, RIDOH is open to reviewing additional evidence-based information on this drug. Please do not hesitate to email RIDOH's legislative liaison, Neil Hytinen, at neil.hytinen@health.ri.gov if you have any questions.

Sincerely,

Utpala Bandy, MD, MPH
Interim Director

CC: The Honorable Members of the House Committee on Corporations
The Honorable John G. Edwards
Nicole McCarty, Chief Legal Counsel to the Speaker of the House
Lynne Urbani, Director of House Policy