



RI Department of Health
Three Capitol Hill
Providence, RI 02908-5097

TTY: 771
www.health.ri.gov

April 5, 2023

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

RE: H 5330 -- An Act Relating to Food and Drugs -- Kratom Consumer Protection Act

Dear Chair Solomon:

Please accept this letter opposing H 5330, legislation which would regulate the distribution of the drug known as kratom to consumers by the Rhode Island Department of Health (RIDOH). Kratom is a drug with known active ingredients. 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 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 on the basis of scientific data and information demonstrating that the drug is safe and effective. There are no FDA-approved applications in effect currently for any kratom products.

There has been considerable ongoing dialogue about the safety and efficacy of kratom use by consumers. At this point, the data emerging from research is preliminary and/or animal data. Currently, 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 United States are generally dried plant material or other more concentrated forms, which are different than fresh harvested plant leaves. According to researchers at the University of Florida, who have been studying kratom for years, the products available in the US can be different in chemical makeup than forms of the plant harvested in Southeast Asia. Currently these researchers at University of Florida have NIH funding to investigate forms of kratom to evaluate pharmacological properties and evaluate for medical use. However, these results are years away. There is widespread agreement that more research is needed.

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 popular belief that kratom is safe because it is a “natural” substance is both misleading and untrue. There is currently no evidence of therapeutic effect from kratom in humans, but there is

evidence of harm. These harms include seizures, agitation, liver toxicity, and death. Other adverse outcomes include dependence, withdrawal from cessation of use, and cases of neonatal abstinence syndrome.

The medical literature has documented withdrawal symptoms occurring in individuals with chronic kratom use upon abrupt cessation of this substance. Kratom's active ingredients have been documented to have effects on the opioid receptors as well as serotonergic and adrenergic effects. Unfortunately, there are no concrete guidelines on management of kratom withdrawal or dependence. However, based on previous case reports and current case studies, the best approach seems to follow that of opioid withdrawal with symptomatic management. In addition, there is no evidence of how to handle long-term maintenance of sobriety. There is no scientific evidence that kratom is effective or safe as an alternative to FDA-approved medical treatment in attempts to control withdrawal symptoms and cravings caused by addiction to opioids.

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 use of these therapies. FDA-approved MOUD include methadone, buprenorphine, and naltrexone. Using products with unsubstantiated claims, such as kratom, may prevent those addicted to opioids 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 addiction, overdose, and death. In fact, patients receiving FDA-approved MOUD cut their risk of death in half, according to the federal Substance Abuse and Mental Health Services Administration.

There is currently no legitimate medical use for kratom. As our nation struggles with epidemic levels of opioid abuse, we should be doing everything possible to ensure that those suffering with addiction have access to FDA-approved medicines and appropriate treatment options; not unregulated substances bought and sold over the internet and/or as over-the-counter drug products.

Evidence exists that individuals taking mitragynine and 7-OH-mitragynine (two psychoactive alkaloids present in kratom with known effects at the mu opioid receptor) in amounts sufficient to create a hazard to their health or to the safety of other individuals or the community. Evidence also exists from epidemiological databases and the scientific literature that individuals are using kratom for abuse purposes. A leading kratom researcher recently noted during an NIH national webinar there are increasing reports of kratom abuse 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 figure out what alkaloids are responsible for what effects and dosing to effect.

There are statements on the Internet noting that "kratom is used by people for pain management, energy, even depression and anxiety that are common among Americans". It is claimed that "at

higher serving sizes, kratom has been found by many to be an effective pain reliever for acute and chronic pain, and to wean off highly-addictive and potentially deadly opioid medications.” It is further claimed that it is estimated that “about a third of kratom consumers use it to manage acute and chronic pain as an alternative to dangerous opioids or to reduce or wean off opioids entirely” and that kratom “research and consumer use experience have combined to affirm the value kratom offers as a harm reduction agent in the treatment of acute and chronic pain.”

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

- 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.

The statements are unproven claims about kratom’s ability to treat or cure opioid addiction and withdrawal symptoms. These sites also make claims about treating pain, as well as other medical conditions like depression, anxiety, and cancer.

Finally, the intent of H 5330 is to establish a new state regulatory structure within RIDOH for kratom. As with the proposed adult use marijuana program in Rhode Island, the structure that would be needed to properly regulate kratom in Rhode Island would have to include both a focus on, and funding to address, growth, processing, distribution, sales, and packaging to ensure consumer safety. Regulatory efforts must also put in safeguards to prevent companies from making false claims about the benefits of this drug.

In addition, substantial funding would be needed to address the treatment needs of Rhode Islanders who become addicted to this drug as well as funding for public health prevention, education, and surveillance that targets vulnerable populations including, but not limited to, pregnant women, youth, and individuals with substance use disorder. Currently, it cannot be said that kratom commercial products (even free from adulteration) would be safe for Rhode Islanders.

Salmonella and high levels of heavy metals have been found in kratom products being sold that put people using the drug at risk. Rhode Island cannot allow unscrupulous vendors to take advantage of consumers by selling products with unsubstantiated claims that they can treat opioid addiction or alleviate other medical conditions.

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

As seen with the adult-use marijuana program, a strong regulatory structure with adequately funded prevention, education, surveillance, and treatment components in place is tremendously costly. Given that H 5330 does not include the necessary funding to implement the necessary regulatory framework, RIDOH is not able to implement the provisions of the proposed legislation. 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. If you would like to schedule a meeting to discuss this topic further, please do not hesitate to reach out to RIDOH's legislative liaison, Neil Hytinen, by email, at neil.hytinen@health.ri.gov.

Sincerely,



Utpala Bandy, MD, MPH
Interim Director

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