June 25, 2021

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



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

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RE: H 5909 A - AN ACT RELATING TO FOOD AND DRUGS -- KRATOM CONSUMER PROTECTION ACT

Dear Chairman Solomon:

I am writing in reference to H 5909 A, legislation which would regulate the distribution of the drug known as Kratom, a drug of concern for its stimulant and sedative effects, to consumers by the Rhode Island Department of Health (RIDOH). Please know that, currently, RIDOH supports a continued ban on this substance in Rhode Island. Kratom is a drug with known active ingredients.

There has been considerable ongoing controversy over the safety and efficacy of kratom use by consumers. Although some studies suggest that there may be value in exploring Kratom as an alternative strategy to treat pain, more studies are necessary to further explore this possibility. RIDOH also remains concerned about potential drug interactions that may occur when Kratom is consumed concurrently with opiates or other drugs.

Kratom remains a substance of concern to many in the public health and addiction treatment communities. The popular belief that Kratom is safe because it is a "natural" substance is both misleading and untrue. Most studies indicate that Kratom's potential benefits are largely offset by its side effects and safety issues. Kratom poses a substantial risk for dependence and does cause withdrawal symptoms for those who become dependent. There are case reports of pregnant mothers who used Kratom and who gave birth to newborns presenting with signs of Neonatal Abstinence Syndrome (NAS) like that for opioids. In addition, the safety and side-effect profile of Kratom are not well studied.

Epidemiological studies have seen an increased number of individuals presenting with various symptoms emerging upon abrupt cessation of this substance. Kratom's active ingredients have been declared opioid analogues. 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 herbal 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 Medication Assisted Treatments (MAT) available to those who suffer from opioid use disorder and to reduce the stigma that is sometimes associated with use of these therapies. 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 MAT 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. Kratom and its active ingredients clearly have opioid and stimulant properties and can be dangerous. 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.

Finally, H 5909 A would establish a new state regulatory structure within RIDOH for Kratom. As with the proposed adult use marijuana proposals being debated 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. In addition, 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 and surveillance that targets vulnerable populations including, but not limited to, pregnant women, youth, and individuals with substance use disorder.

As seen with the adult use marijuana proposals, a strong regulatory structure with adequately funded prevention, surveillance, and treatment components in place is tremendously costly. Given that H 5909 A does not include the necessary funding to implement the necessary regulatory framework, RIDOH would not be 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 topic. 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,

Nicole Alexander-Scott, MD, MPH

Director

CC: The Honorable Members of the House Committee on Corporations

The Honorable Brian Patrick Kennedy

Nicole McCarty, Esquire, Chief Legal Counsel to the Speaker of the House