STATE OF RHODE ISLAND



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April 5, 2023

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

RE: 2023 H 5330 - An Act Relating to Food and Drugs - Kratom Consumer Protection Act

Dear Chair Solomon:

BHDDH joins our colleagues at the Department of Health (RIDOH) in requesting the Committee not give favorable consideration of **H 5330**, which would 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. I would urge members of the Committee to not support passage of H 5330.

Mitragyna speciosa, commonly referred to as "kratom," is a tree whose leaves contain numerous active ingredients, including mitragynine and 7-a hydroxymitragynine, which are the primary substances producing its psychogenic effects.

The former federal HHS Assistant Secretary of Mental Health and Substance Use and former Medical Director at BHDDH, Elinore McCance-Katz, M.D., Ph.D., explained at the Substance Abuse and Mental Health Services Administration's Annual Prevention Day in 2019 that "the federal Food and Drug Administration (FDA) is concerned that kratom, which affects the same brain receptors as morphine, appears to have properties that expose users to the risks of addiction, abuse and dependence."

To date, there are no FDA-approved uses for kratom; the FDA has received reports regarding safety concerns, including reports related to life-threatening cardiac arrythmias resulting in hospitalization. Liver damage, seizures, including seizures in children accidentally exposed to these products, and neonatal abstinence syndrome experienced by infants whose mothers used kratom as well as other adverse events have been reported. A lawsuit is pending in the State of Georgia filed by the parents of a twenty-three-year-old who, according to the Georgia Bureau of Investigation, died from mitragynine intoxication in December of 2021.

Currently, there have been no rigorous studies which demonstrate the effectiveness or safety of mitgragyna speciosa (kratom) itself, or as a treatment intervention for any illness, including psychiatric or substance use disorders. The FDA has issued warning letters to companies selling kratom products regarding unproven medical claims related to opioid cessation, pain management, treatment of

depression, and other "medical" uses. The FDA has warned consumers not to use kratom because of these concerns.

The effects of kratom are dose-dependent; ranging from stimulant effects such as those produced by cocaine and amphetamines, to the sedative effects of opioids in larger doses. Kratom can produce cravings, compulsive use, anxiety, diaphoresis, diarrhea, tremor, and restlessness which mirror opioid withdrawal symptoms; and has been found in some circumstances to be contaminated with pathogens (e.g., salmonella) and heavy metals, which may seriously endanger the lives of the people who use it. As with other non-pharmaceutical products, there is the risk that kratom products may be contaminated with fentanyl, xylazine and/or other drugs.

Currently, there simply is insufficient medical evidence to indicate the purported benefits of authorizing the sale of kratom products outweigh the considerable risks; this is the metric used when evaluating any potential treatment option.

Thank you for the opportunity to comment on this legislation.

Sincerely,

Richard Charest, R. Ph., MBA 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