



**Written Testimony of Jonathan Miller**  
**General Counsel, Holistic Alternative Recovery Trust (HART)**  
**On H 5565, Before the Rhode Island House Committee on Corporations**

Chairman Solomon and Honorable Members of the House Corporations Committee:

I am grateful for the opportunity to testify on H 5565, on behalf of the Holistic Alternative Recovery Trust or HART. HART is committed to identifying and promoting natural, plant-based recovery solutions as an alternative to opioid use.

The U.S. opioid crisis is the leading public health challenge of the new millennium. There are more than 200 opioid overdoses and poisonings every day—and drug overdose is now the number one cause of death for 18-45-year-olds. To address this unprecedented crisis, policymakers and public health officials need to identify new tools for the toolbox.

HART believes that 7-hydroxymitragynine (7-OH), a metabolite of mitragynine, the most abundant alkaloid found in kratom, could provide a new set of tools to combat opioid misuse and improve public health. Proper regulation of this substance would also expand access to safe options for managing stress and decreasing reliance on harmful, illicit substances, while also supporting the transition from dependence on these substances.

7-OH products marketed by HART members comply with FDA's adulteration standard for dietary supplements, in that they do not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or under ordinary conditions of use. Based on monitoring of consumer feedback and adverse event reports by HART members, there also do not appear to be safety signals with products currently on the market.

Unfortunately, there are current efforts in a number of state legislatures to ban 7-OH. 7-OH can be an invaluable harm reduction tool that should remain an option for the hundreds of thousands of consumers that rely on it. This was a key factor in HHS' decision to reject efforts to ban kratom and 7-OH, stating that, by contrast, "there is significant risk of immediate adverse public health consequences for potentially millions of users if kratom and its components" were controlled as Schedule 1 drugs.

Instead of banning the compound, HART strongly supports robust regulation and is pursuing legislation federally, and in the states, to mandate that all 7-OH products are manufactured safely, are marketed transparently, and are kept out of the hands of children.

H 5565 is mostly a very good bill, applying for kratom the kind of robust regulation that we strongly support. However, two poison pill sections in the bill would ban, not regulate 7-OH products.

### **Section 21-28.12-3 (5) (page 3, lines 19-20)**

This section of H 5565 would prohibit the use of “synthetized material” as defined broadly in the Act. We support a ban on “fully” synthetic products – products that were created entirely in a lab with no basis in nature, but the language in the bill goes much further to ban products that are born from a plant but that undergo some synthesis.

7- OH is not lab-made or fully synthetic—it is naturally-derived from kratom, the same plant that all other kratom and mitragynine products come from, and undergoes a simple, one-step oxidation process, similar to how **vitamin C** is stabilized for supplements. (Attached is a full list of popular products that use synthesis.) The same critics that dismiss 7-OH as synthetic accept chemically modified vitamins and botanical extracts without restriction. This double standard is being pushed by special interest groups to create a false sense of danger.

HART would therefore support amending lines 19-20 on page 3 as follows:

(5) A kratom product containing any **fully** synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other **fully** synthetically derived compounds of the kratom plant.

### **Section 21-28.12-3 (10) (page 4, lines 3-8)**

This section of H 5565 would prohibit the sale of kratom products that contain a concentration ratio that is “greater than 0.5 mg 7-hydroxymitragynine per gram, or greater than 1 mg 7-hydroxymitragynine per serving, or that contain more than one percent of 7- hydroxymitragynine by percentage of total kratom alkaloids.”

There is no scientific basis for imposing a 1% cap on 7-OH. This figure stems from the amount of 7-OH naturally found in the plant but has nothing to do with safety or efficacy. A percentage cap inevitably leads to unsafe product formulations, some of which are on the market today. Science shows that very high mitragynine kratom extracts can lead to unpredictable metabolic conversion into 7-OH inside the body, meaning a consumer could ingest far more 7-OH than intended—the very outcome regulators claim to be preventing.

The solution is to impose milligram caps on natural products – exactly as states are doing in the hemp and cannabis spaces. HART supports a level of 7-OH not to exceed 28 mg/serving. However, while we are regulating 7-OH, we should also pursue milligram limits for other products coming from the kratom plant.

We would therefore support amending lines 3-8 on page 4 as follows:

(10) A kratom product that contains a concentration ratio that is:

- (i) Greater than 150 mg of mitragynine per serving;
- (ii) Greater than 0.5 mg 7-hydroxymitragynine per gram; or
- (iii) Greater than 1 28 mg 7-hydroxymitragynine per serving.

~~(11) A kratom product that contains more than one percent of 7-hydroxymitragynine by percentage of total kratom alkaloids.~~

HART would fully support H 5565 with the milligram limits and ban on fully synthetic products that we have proposed above.

Thank you for your consideration.

## **EXAMPLES OF PRODUCTS THAT USE SYNTHESIS**

### **VITAMINS**

- Vitamin A
- Vitamin B1
- Vitamin B2
- Vitamin B3
- Vitamin B5
- Vitamin B6
- Vitamin B7
- Vitamin B9
- Vitamin B12
- Vitamin C
- Vitamin D2
- Vitamin D3
- Vitamin E
- Vitamin K3

### **BOTANICAL SUPPLEMENTS**

- Melatonin
- Quercetin
- Resveratrol
- L-Theanine
- Curcumin
- Beta-Carotene
- Epigallocatechin gallate (EGCG)
- Coenzyme Q10

### **FOOD ADDITIVES & SWEETENERS**

- Aspartame
- Splenda
- Saccharin
- MSG

### **FRAGRANCES & FLAVORS**

- Vanillin
- Limonene
- Musk
- Menthol