

June 10, 2025

The Honorable Caroline Menjivar, Chair Senate Health Committee California State Capitol Sacramento CA 95814

Dear Madam Chair,

On behalf of the Holistic Alternative Recovery Trust (HART), we urge the Senate Health Committee to **oppose AB 1088 (Bains) unless amended as proposed below.** HART supports the child protection provisions.

However, beyond those important protections, the bill would reduce consumer safety by establishing an incomplete and flawed regulatory structure for kratom and kratom-derived products. The bill establishes a monopoly for kratom/mitragynine products, ignoring the potential dangers with those products. Instead, it proposes a percentage cap on the kratom alkaloid, 7-hydroxymitragynine (7-OH), that would be a de facto ban on 7-OH, which is a far safer alternative to fentanyl and other opioids. Nothing demonstrates the glaring difference between 7-OH and kratom/mitragynine than the FDA's own Adverse Events Reporting System (FAERS), which reports 5 events for 7-OH in 2023-2025 versus 469 for kratom/mitragynine.

We propose that the bill be amended to

- Delete subdivision (d) in section 111224.85, which would cap 7-OH at 2% of the total kratom alkaloids in a product.
- Establish a working group in the Department of Public Health to monitor, investigate and assess clinical peer-reviewed research relative to kratom and 7-hydroxymitragynine (7-OH) and their effect on the human body in terms of both therapeutic benefits and adverse effects and to assess the efficacy of 7-OH in pain management, harm reduction and the alleviation of opioid addiction.

**Child protection.** We want to make it clear that HART supports the bulk of AB 1088 addressing child safety:

- Prohibit the sale of kratom products, including 7-OH, to consumers under the age of 21. HART originally asked the author to introduce this age-gating proposal.
- Prohibit advertising for kratom products, including 7-OH, which appeals to children.
- Impose child resistant packaging requirements like those that are required of cannabis products.

We respectfully urge your committee to consider that a bill must be thoughtfully and thoroughly crafted and implemented in order for child safety provisions to be efficacious.

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Clinical and laboratory research. 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 exploring the potential applications of 7-OH, the most abundant alkaloid found in kratom, could contribute to discussions on addressing opioid misuse and public health strategies. 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.

As to the current state of research, FDA states on its website today that it "recognizes that there is much that is not known scientifically about kratom...there are few published reports from well-designed scientific studies where kratom was administered to humans. <u>Additional investigation by researchers, including those in the academic community, drug companies, and government agencies, into the many safety issues and potential therapeutic uses of kratom would provide important public health information." [emphasis added]</u>

HART respectfully urges lawmakers to prioritize harm reduction as the key principle in promoting consumer health and safety. 7-OH is plant-derived from the kratom leaf, and early peer-reviewed clinical research is beginning to show promise in products for adults 21-and-over. We acknowledge that laboratory research about 7-OH is in its infancy, but it is rapidly evolving. This includes encouraging research on whether 7-OH has any adverse effects on the consumer. But with that in mind, we cannot ignore the fact that there have been 500 million doses of 7-OH since the middle of 2023 with no deaths attributed to it.

We urge policymakers to remember that first and foremost, public policy must be created to protect the consumer. Well-crafted harm reduction policies are based on research and take substantial time and attention to get right. New statutes intended to promote consumer health and safety related to 7-OH should first consider and cite clinical and laboratory research about the risks and benefits of these products.

We agree that a cap on 7-OH in any product may make sense from a consumer protection standpoint, and we are more than willing to have that discussion. However, as the recent debate over hemp products has amply demonstrated, a percentage cap is a fatally flawed measurement. Bad actor manufacturers who wish to create a high milligram 7-OH product can easily adhere to the percentage cap and add the corresponding amount of mitragynine, thereby releasing a potentially dangerous, but compliant, product out into the marketplace.

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**Industry fight.** It cannot be ignored that this issue was first brought to the Legislature last year because some kratom manufacturers seek to erase 7-OH manufacturers as competitors from the marketplace. Some supporters have cherry-picked data or funded statements by researchers that attempt to place 7-OH in a bad light. These same supporters have ignored the reality that kratom/mitragynine has its own potential dangers in order to prevail in this industry fight.

We have been forthright in our acknowledgement that research is in its early stages; what we have not done is cherry-pick data to suggest that research is conclusive about the benefits of 7-OH. We encourage the committee to let the research proceed and reserve judgment about the integrity and viability of 7-OH until the research has matured.

Finally. The US Department of Health and Human Services recommended that mitragynine and 7-OH, chemicals in kratom, not be scheduled at this time acknowledging that "(f)urther analysis and public input regarding kratom and its chemical components are needed." HHS declared further that "there is significant risk of immediate adverse public health consequences for potentially millions of users if kratom or its components are" scheduled. [emphasis added]

For these reasons, we respectfully encourage you to oppose AB 1088 in its current form. We further ask that the committee work with the author, the stakeholders, and other policymakers to strive for an effective proposal that protects children, avoids a massive new bureaucracy, prevents bad actors, and ensures that Californians who want nothing more than access to plant-based products that provide them some therapeutic relief are not unnecessarily deprived.

We thank you for your favorable consideration.

Sincerely,

Adam Israel President

cc: Members, Senate Health Committee

The Honorable Jasmeet Kaur Bains, MD