

HB 236 Written Proponent Testimony of Senator Curt Bramble
Utah State Senate
Before The Ohio House Health Committee
January 25, 2022

Chairman Lipps and members of the Committee, thank you for the opportunity to submit this written testimony and provide my perspective on kratom, including why I believe it is important for every state to protect consumers of kratom products.

Three years ago, I had never heard of kratom. House Health Committee members may have been in that same position prior to seeing this legislation introduced in the Ohio General Assembly.

I did not know that kratom had become a very popular product in the United States with consumers who had found an alternative to coffee for that energy boost and increased focus, to help reduce anxiety, and even to find an alternative to dangerously addictive and otherwise potentially harmful opioids in the management of acute and chronic pain.

What I did know was that we are all experiencing a public health crisis in the United States with the number of people who struggle with addiction to products that they initially used to manage acute and chronic pain issues, often related to workplace or sports injuries they had suffered.

That was certainly true in my own family. My daughter and her high school sweetheart were both active athletes and both had their share of injuries, leading to treatments that included doctor-prescribed opioid medication. After their marriage, the addiction cycle continued, which took the predictable path of impacting their social interactions with family and friends, and ultimately lead to incarceration.

While my daughter was eventually able to break the shackles of those addictions, her husband could not. Divorce followed that shattered their family, and eventually her former husband died of an overdose and became one of those statistics we read about in the context of the drug overdose public health crisis we are experiencing in America today.

When I first learned about kratom, the thing that stood out was the potential it offered for those trapped in the cycle of addiction, to have a safer alternative than the very predictable outcomes of opioid use. I was fascinated by the scientific reports documenting that kratom, a natural plant grown in Southeast Asia, had been used for centuries safely and that it had more recently been found to be an effective alternative to prescription medications that have had such devastating negative effects on consumers.

I was stunned to learn of the position of the Food and Drug Administration in Washington DC because I've always had confidence in the FDA to be the protector of the American public's health.

Instead, what we have today is an FDA that is determined to expand their regulatory authority, much like they attempted to do with dietary supplements and vitamins in the early 1990s, by restricting kratom to a prescription medication available to the public only after the onerous new drug application process that typically takes up to 10 years and costs more than \$5 billion to gain approval.

If that position by the FDA were taken because kratom is a dangerous substance, then I would be fully on board. But that is not the truth.

The FDA has had a long-standing bias against all dietary supplement and botanical products, and they have abused their regulatory authority to impose unrealistic and unfair regulatory burdens that essentially ban consumers from having access to otherwise safe and effective products. That is the story of kratom.

To clear the field for some innovator to submit a chemically formulated kratom product as a new drug application, the FDA had to have the natural plant banned. The market for a chemically formulated drug would be suppressed if consumers could just buy the natural plant at a significantly reduced price.

Accordingly, in 2016, the FDA petitioned the Drug Enforcement Administration (DEA) to classify kratom's two primary alkaloids as Schedule I substances under the Controlled Substances Act. The DEA withdrew that recommendation and asked the FDA to provide more complete evidence to justify the scheduling.

In 2017, the FDA submitted its second scheduling recommendation, and the HHS Assistant Secretary of Health, Dr. Brett Giroir, withdrew that recommendation in a blistering rebuke of the disappointingly poor science and data provided by the FDA. Dr. Giroir cited the risk to millions of Americans who would be forced from kratom to extremely dangerous and potentially deadly opioids to manage acute and chronic pain.

The FDA then ramped up their attack on kratom by taking their anti-kratom recommendations to the international level when they sought a ban on kratom through the UN Commission on Narcotic Drugs. That recommendation was rejected by an 11-1 vote by the Expert Committee on Drug Dependence at the World Health Organization, which determined there is insufficient evidence to even justify a critical review of kratom, much less an international ban.

The failure of the FDA to appropriately regulate kratom has allowed unscrupulous vendors to fill the marketplace with adulterated kratom products, that often include controlled substances like fentanyl, heroin, and morphine. These vendors infuse adulterants into kratom products in order to increase sales – in short, to make money.

The natural kratom plant does not give any consumer the reinforcing euphoric high that is the signature effect of traditional opioids. When an unsuspecting kratom consumer purchases what they believe is a pure kratom product, and they experience that euphoric high that is derivative of the adulterant, they continue to buy that adulterated kratom product simply because it seems to have a stronger effect than they experienced with pure kratom products. In short, they are duped by the bad-actor kratom manufacturers.

The addiction profile for fentanyl, heroin, and morphine is well-established. The progression from an addiction to these controlled substances to abuse is equally well documented and the unfortunate outcome is often a drug overdose death. The most recent data from the Centers for Disease Control (CDC) shows that we had the highest number of drug overdose deaths in our nation's history in the most recent 12-month period (over 100,000 overdose deaths).

The scientific research documents that kratom also does not have any significant impact on the respiratory system of the consumer. Respiratory depression is the reason why drug overdose deaths occur. The research documents that kratom does not induce any significant addiction liability.

To be clear, kratom, like many other consumer substances, can result in a dependence that requires responsible use. Because the kratom plant is part of the coffee family, research shows that withdrawal from a kratom dependence is relatively mild and includes a period of about a week to 10 days of upset stomach, headache, and minor discomfort. That is vastly different than withdrawal from an opioid addiction, which often requires intervention with other powerful drugs and months or years of withdrawal treatment.

A Johns Hopkins University study of adult consumers who used kratom to wean off opioids reported that 87% experienced relief from withdrawal symptoms, and 35% were opioid free within a year. That is the kind of harm reduction outcome all of us desire.

That is why I was the sponsor of the Utah Kratom Consumer Protection Act, which was the first KCPA enacted. Since then, Georgia, Arizona, Nevada, and Oklahoma have enacted similar KCPA legislation. On January 5, 2022, the Wisconsin House State Affairs Committee voted 9-2 to repeal the ban on kratom there and replace it with the KCPA. Wisconsin was one of six states that had banned kratom because of the FDA's disinformation campaign between 2012 and 2016. There are over 20 other states that are currently considering KCPA legislation.

I can also tell you that my interest in kratom—resulting from the tragedy our own family experienced—led me to find out as much as I could about the plant, including traveling to Indonesia and the jungles of Borneo where kratom grows naturally. I have seen how this plant grows, how it is harvested, and the processes of grounding kratom leaves into powder for shipment. I have talked with local farmers and government officials in Indonesia about the challenges that they experience in shipping kratom to the US because of the interference from our FDA.

I am convinced that the only way to hold the FDA accountable is for states to provide protections for kratom consumers. I believe our first obligation in the states is to formulate good public policies that provide those consumer protections for our citizens. We cannot allow ourselves to be pawns for the FDA to pursue their own biased regulatory agenda that puts consumers at significant health risks.

The legislation that is before you today, like the legislation I sponsored in Utah, protects consumers. It is based on good science and aligns with the position of the National Institute on Drug Abuse, the report language passed by the United States Congress, the review of the Department of Health and Human Services, and the review by the Expert Committee on Drug Dependence at the WHO—all of which emphasize that kratom should not be banned, but appropriately regulated.

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