

Congress of the United States
Washington, DC 20515

December 20, 2017

Dr. Scott Gottlieb
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20857

Dear Dr. Gottlieb:

We are writing today in regards to the U.S. Food & Drug Administration's (FDA) public health advisory on alleged risks associated with the use of kratom, a natural supplement made from the leaves of a tropical tree native to Southeast Asia and a relative of the coffee plant.

The beneficial potential, safety, and efficacy of kratom has been discussed, studied, clinically researched, and found to be as safe as coffee. In fact, there have been several studies funded by the National Institutes of Health, some of which are still ongoing. We have heard from many constituents who have used kratom to successfully end their dependence on dangerous opioids, and maintaining legal access to kratom is important for many Americans to maintain sobriety.

According to your press release, the Agency's two main concerns, which we consider insufficient for a warning or action, are the significant increase in calls to Poison Control Centers between 2010 to 2015, as well as thirty-six deaths the Agency believes to be associated with kratom.

Our letter considers and puts these concerns in perspective when compared to other commonly used substances like energy drinks, and presents sound scientific evidence that was submitted to the FDA, Drug Enforcement Agency (DEA), and Members of Congress in 2016 showing that kratom is safe and poses little to no health risk to Americans. This letter also discusses manufacturing practices and standards adopted by the kratom industry that would alleviate any compliance issues and ensure continued safe use for the millions of Americans that enjoy this celebrated plant.

In late 2016, the DEA brought up the same concerns that the FDA has now, but the DEA sought a much more aggressive approach by attempting to schedule kratom under the Controlled Substances Act through emergency procedures. This was the first time a natural substance was targeted in this fashion. U.S. Senator Orrin Hatch, along with eight other U.S. Senators and fifty-one U.S. Representatives, advised the DEA to consider consumers, researchers, health professionals, law enforcement officials, and other stakeholders to allow for a more comprehensive review. This opened a six-week public comment period that resulted in over 23,000 Americans submitting comments to the DEA, which favored keeping kratom legal, with only 113 people requesting a ban.

Regarding the FDA's concerns with the increase in calls to Poison Control Centers, the Agency is citing a July 2016 study by the Centers for Disease Control and Prevention (CDC) that states that there were less than thirty calls in 2010 and then 263 calls in 2015. To put this number in perspective, in 2014 alone, Poison Control Centers received over 4,000 calls regarding energy drink consumption and possible poisoning. Scientific research, expert testimony, and Poison Control Center data have shown that kratom is far less dangerous than energy drinks. The purpose of this information is not to encourage FDA to act on energy drinks, but rather to show by comparison that kratom is of less health risk than many popular consumer beverages.

Regarding the thirty-six deaths the FDA associates with kratom, the individuals died while taking prescription drugs and other substances in combination with kratom. This was of great concern to the State of Florida and was addressed by the Florida Department of Law Enforcement Commissioner Rick Swearingen with the Office of Statewide Intelligence in 2015. Their investigation concluded that, "A review of available law enforcement and laboratory sources in Florida demonstrates that kratom does not currently constitute a significant risk to the safety and welfare of Florida residents. According to the Florida Department of Health (DOH), no pervasive health issues have been attributed to the ingestion of kratom products in Florida."

This subject has also forced independent studies by esteemed scientists like Jack Henningfield, PhD of Pinney & Associates, one the world's leading experts on addiction and safety. Regarding kratom, he states, "This is a remarkable record of safety and low abuse risk for any substance used by millions of Americans"

In recent years, most responsible manufacturers have properly labeled their products and have followed Current Good Manufacturing Practices (CGMP) guidelines, regulatory standards which were created by your agency. Because some states restrict sales to minors, most company labels reflect this. We believe that if legal access to professionally-manufactured kratom were made difficult or illegal, instances of kratom laced with opioids or other dangerous compounds would likely become more common.

Given that numerous stakeholders, former opioid addicts, and scientific researchers vouch for kratom's safety and support its use, and responsible manufacturers of kratom products ensure that their products are properly labeled for adult-only consumption, we respectfully request that the FDA reconsider its stance and take a closer look at the facts and recent science regarding this plant.

Sincerely,



Dave Brat
Member of Congress



Jared Polis
Member of Congress



Jack Bergman
Member of Congress



Tulsi Gabbard
Member of Congress



Peter DeFazio
Member of Congress



Ro Khanna
Member of Congress



Colleen Hanabusa
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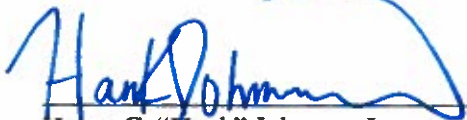
Barbara Lee
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Steve Cohen
Member of Congress



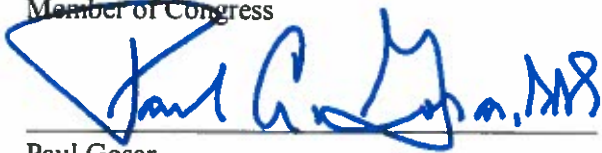
Robert C. "Bobby" Scott
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