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Robert W. Patterson
Acting Administrator
Drug Enforcement Administration
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Dear Ms. Conway and Mr. Patterson:

It is our understanding that the Drug Enforcement Administration (DEA) has received a recommendation from the US Food and Drug Administration (FDA) to place mitragynine and 7-hydroxymitagynine, compounds found in the plant known as kratom, into Schedule I of the Controlled Substances Act (CSA). We believe strongly that the current body of credible research on the actual effects of kratom demonstrates that it is not dangerously addictive, nor is it similar to "narcotics like opioids" with respect to "addiction" and "death" as stated by the FDA in its November 14th Kratom Advisory. Equally important, four surveys indicate that kratom is presently serving as a lifeline away from strong, often dangerous opioids for many of the several million Americans who use kratom. A ban on kratom that would be imposed by CSA Scheduling would put them at risk of relapse to opioid use with the potential consequence of overdose death. Similar unintended consequences are to be expected in some who would be forced to use opioids to manage acute or chronic pain.

In the report issued on November 1, 2017 by the President's Commission on Combating Drug Addiction and the Opioid Crisis, where the Commission strongly supported research and development of alternatives to opioids for pain management, the powerful conclusion offered was that "[F]irst, individuals with acute or chronic pain must have access to non-opioid pain management options."[1] The available science is clear that kratom, although having effects on opioid receptors in the brain, is distinct from classical opioids (e.g. morphine, heroin, oxycodone, etc.) in its chemistry, biological effects, and origin (kratom is a tree in the coffee family, not the opium poppy family). Importantly, as commonly used in raw plant form, it does not appear to produce the highly addictive euphoria or lethal respiratory depressing effects of classical opioids.

It is our collective judgment that placing kratom into Schedule I will potentially increase the number of deaths of Americans caused by opioids because many people who have found kratom to be their lifeline away from strong opioids will be vulnerable to resumption of that opioid use, whether their prior opioid use was for relief of pain or due to opioid addiction. This opinion is supported by four national surveys conducted in the past two years, as well as decades of studies in the US and in Southeast Asia, where kratom has been used as a safer alternative to opioids for more than a century. Failure to evaluate this potential outcome of

[1] The President's Commission on Combating Drug Addiction and the Opioid Crisis, November 1, 2017, page 8.

any proposed scheduling of kratom would directly contradict the expressed purpose of the enactment of the CSA by the U.S. Congress, to protect the safety of consumers. Perversely, it is foreseeable that such an action may lead to the deaths of people and worsen the opioid crisis, not mitigate it.

In fact, publicly available research documents that kratom has a long history of acceptably safe consumer use, and, when used as an alternative pain management therapy, kratom provides a far more favorable safety profile for consumers compared to more dangerously addictive and potentially deadly classical opioid medications. Current scientific research suggests that kratom provides some pain relief activity on the pain centers in the brain without the dangerous and potentially deadly respiratory suppression induced by classical opioid medications. The federal government should be encouraging additional research into the potential benefits of kratom, as well as the possibility that extracts of kratom and/or new medicines that are similar to kratom's active ingredients might serve as breakthroughs in pain relieving medicines that are so desperately needed. However, this latter path will not be a rapid one, since the average time and cost of new drug development is more than 10 years and 2.5 billion dollars. Placing kratom into Schedule I of the CSA will also have a profound and pervasive chilling effect on this needed additional research.

Finally, it is our strongly held belief that the claims that kratom has caused the deaths of all or even most of the 36 individuals cited by the FDA in a November 14, 2017 Public Health Advisory on kratom cannot be supported by any reasonable scientific or medical standard. Unlike overdose deaths that are rightly attributed to classical opioids, which reliably cause respiratory depression and death at high doses, the fatalities that the FDA lists as having been associated with kratom include deaths with a wide variety of apparent causes in people suffering from various diseases and/or taking other substances that also likely contributed to their deaths. For example, it includes 9 fatalities in Sweden that resulted from an adulterated product that included the active substance of the prescription opioid tramadol (leading Swedish authorities to conclude that those deaths were caused by O-desmethyltramadol, not kratom). The assertion that a scheduling recommendation can be based on a claim of deaths "associated with kratom" rather than deaths "caused by kratom" is not, in our judgment, either scientifically valid nor the standard that was contemplated by the U.S. Congress for the scheduling of any substance under the CSA. Applying such a broad standard for scheduling substances would appear to be a significant overreach of the regulatory powers of the FDA and DEA beyond the currently established, rigorous, and clearly limited eight factors set forth in the CSA for scheduling of any substance.

The practical application of such a broad standard for scheduling would erode the foundational premise for the CSA that currently requires rigorous scientific standards to be applied to any analysis of a substance proposed for scheduling, and would open a Pandora's box of politically motivated scheduling decisions driven by arbitrary philosophical or partisan viewpoints without regard to any reliable scientific standards. We believe that any such public policy constitutes a clear abuse of the regulatory powers entrusted to the FDA and DEA under the CSA. Similarly, any actions taken by local or state governments to schedule or ban kratom at this time are

likewise misguided and could result in many people who use kratom for health and well-being to turn to opioids and potentially adulterated kratom products from the illicit market that would quickly replace the lawful market.

Rather than foster an illicit and dangerous kratom market, the FDA could protect the American public by appropriate regulation of kratom, as the FDA's Office of Dietary Supplements has been working toward. This could provide consumers and health professionals with the information to help guide safe use, and ensure that lawfully marketed products meet the same standards as other natural and dietary products relied upon by American consumers. The attached summary of regulatory principles from the American Kratom Association is an example of some of the regulatory actions that the FDA could take that would address concerns of the FDA and others, and serve to protect kratom consumers and public health.

We affirm our belief that the existing science on kratom does not justify its placement into Schedule I of the CSA, nor for kratom to be added to any local or state Controlled Substances list that would effectively remove it from consumer access. For reference, we have attached five recent peer-reviewed, published scientific articles addressing the addiction and safety profile for use of kratom by consumers supporting our position expressed herein. One of them is a major survey relevant to understanding the benefits and low risks of kratom use in America, as well as the risks of banning kratom (Grundmann, 2017). Another is an example of the sort of 8-factor analysis that is generally used by the FDA for Controlled Substances regulatory decision making (Henningfield et al. 2017). It relies on laboratory, clinical, and epidemiological studies including four national surveys of kratom use and other federal survey data and not the unvalidated computer model referenced by the FDA in its February 6th Advisory. These studies and other independent peer reviewed evaluations published in scientific and medical journals provide the profile of a substance that is largely used safely to the benefit of several million Americans (e.g., Kruegel and Grundmann, 2017; Swogger and Walsh, 2018).

We encourage you to support efforts to ensure continued lawful access to kratom, guide balanced regulation by the FDA, and facilitate research, thereby protecting and not harming public health.

Respectfully submitted,

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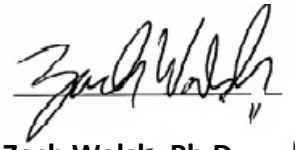

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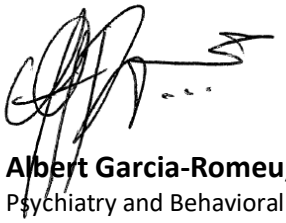

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