

**PRESERVE CONSUMER ACCESS AND SCIENTIFIC RESEARCH INTO INNOVATIVE
TREATMENTS FOR OPIOID ADDICTION AND PREVENT DRUG ENFORCEMENT
AGENCY OVERREACH**

***Join Reps. Mark Pocan and Frank LoBiondo in Urging the Drug Enforcement Agency to Utilize All
Available Scientific Evidence When Making Final Scheduling Decisions on Kratom***

Dear Colleague:

I invite you to join us in sending a bipartisan letter to the Drug Enforcement Agency to encourage them to employ all the available scientific information on kratom before making any final decisions on the scheduling of this natural product under the Controlled Substances Act (CSA).

Last year, the DEA attempted to expedite scheduling of kratom as a Schedule I substance without any public comment or input. A group of 50 bipartisan Members of Congress urged them to halt the expedited process to ensure that the public and scientists were able to provide comment and input before this significant decision was made. Ultimately, the DEA heard Congress' concerns and pulled the expedited schedule.

Now, the DEA has used the formal process to analyze whether kratom should be on listed under the Controlled Substances Act (CSA). Kratom is not an opioid, it is a natural supplement made from the leaves of a tropical tree native to Southeast Asia and a relative of the coffee plant. Kratom leaves are often brewed like a tea, or crushed and mixed with water. In the U.S., kratom has been used as an herbal supplement by consumers for managing their personal health and well-being. Numerous scientific studies, including studies funded by the NIH, have shown the addiction potential for kratom is substantially lower than that of "narcotic-like opioids" and it does not produce the deadly respiratory depressant effects that is the primary cause of opioid overdose deaths.^{1 2}

As our country continues to deal with the damage and pain the opioid crisis is causing our communities, it is important to consider all scientific research that has been conducted on the use and safety of kratom. To date, the FDA public health advisory of kratom encouraged the public to "conduct the research that will help us better understand kratom's risk and benefit profile."³ However, should the DEA schedule kratom through the CSA, it will greatly reduce the public's ability to conduct this important research. We remain concerned that any scheduling of kratom would likely "create a substantial illicit market" where consumers would be put at significant safety risks, or drive consumers to the dangerously addictive and potentially deadly use of opioids.

Please join us in this effort to ensure the DEA takes into all available scientific evidence regarding the safety and efficacy of kratom. We need to continue to conduct research and find innovative treatments for individuals suffering from opioid and other addictions—a significant public health threat. If you have questions or would like to sign on to the letters, please contact Leslie Zelenko in Rep. Mark Pocan's office at 202-225-2906 or Eric Arndt in Rep. Frank LoBiondo's office at 202-225-6572.

Sincerely,

Mark Pocan

Frank A. LoBiondo

¹ Kruegel AC and Grundmann O. The medicinal chemistry and neuropharmacology of kratom: A preliminary discussion of a promising medicinal plant and analysis of its potential for abuse. *Neuropharmacology*. 2017 Aug 19.

² Kruegel AC, Gassaway MM, Kapoor A, Váradi A, Majumdar S, Filizola M, Javitch JA, Sames D. Synthetic and receptor signaling explorations of the mitragyna alkaloids: Mitragynine as an atypical molecular framework for opioid receptor modulators. *J Am Chem Soc*. 2016 Jun 1;138(21):6754-64.

³ Federal Drug Administration. "Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom" November 14, 2017.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584970.htm>

The Honorable Robert Patterson
Administrator (Acting)
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrisette Drive
Springfield, VA 22152

December X, 2017

Dear Acting Administrator Patterson:

Recent reports indicate the Federal Drug Administration (FDA) has sent over their Eight Factor Analysis (8FA) of mitragynine and 7-Hydroxymitragynine, more commonly known as kratom. As you review the analysis, we urge you to take all the available scientific information on kratom into consideration before making any final decisions on the scheduling of kratom under the Controlled Substances Act (CSA).

As you are aware, the CSA sets specific and intentionally restrictive standards for scheduling of substances in Schedule I, including conclusive scientific and legally defensible proof that the substance has (1) a high abuse potential; and (2) there is a lack of accepted safety for use of the drug or other substance under medical supervision.

Kratom is not an opioid, it is a natural supplement made from the leaves of a tropical tree native to Southeast Asia and a relative of the coffee plant. Kratom leaves are often brewed like a tea, or crushed and mixed with water. In the U.S., kratom has been used as an herbal supplement by consumers for managing their personal health and well-being. Numerous scientific studies, including studies funded by the NIH, have shown the addiction potential for kratom is substantially lower than that of “narcotic-like opioids” and it does not produce the deadly respiratory depressant effects that is the primary cause of opioid overdose deaths.^{4 5}

We additionally ask that you fully review the 8FA on kratom authored by a leading independent authority on addiction and safety of substances, Jack E. Henningfield, that was submitted to the DEA in conjunction with a previous review of kratom.⁶ The conclusions of Dr. Henningfield’s 8FA, that mirrored the CSA requirements both the FDA and DEA should use in scheduling recommendations, document that “placement of kratom in the CSA is not warranted from a public health perspective, and is likely to cause public health problems that do not currently exist.”

Equally important, Dr. Henningfield’s research directly contradicts claims being made about deaths allegedly caused by kratom; that kratom is dangerously addictive; and that kratom has the same opioid-like effects in depressing the respiratory system. The fact that kratom may be mixed or blended with other toxic doses of prescription drugs or other illegal substances is not an appropriate basis for scheduling

⁴ Kruegel AC and Grundmann O. The medicinal chemistry and neuropharmacology of kratom: A preliminary discussion of a promising medicinal plant and analysis of its potential for abuse. *Neuropharmacology*. 2017 Aug 19.

⁵ Kruegel AC, Gassaway MM, Kapoor A, Váradi A, Majumdar S, Filizola M, Javitch JA, Sames D. Synthetic and receptor signaling explorations of the mitragyna alkaloids: Mitragynine as an atypical molecular framework for opioid receptor modulators. *J Am Chem Soc*. 2016 Jun 1;138(21):6754-64.

⁶ Pinney Associates (Henningfield JE and Fant RV, principal authors) (2016) Assessment of Kratom under the CSA Eight Factors and Scheduling Recommendation. In Hogan Lovells US LLP Comment on FR Doc #2016-24659. <https://www.regulations.gov/document?D=DEA-2016-0015-23186> or <http://www.pinneyassociates.com/our-work/>

under the statute. The FDA and DEA have sufficient statutory authority to interdict such illegal compounding, and we support the aggressive use of these powers to interdict those responsible for such adulteration and contamination of kratom products.

As our country continues to deal with the damage and pain the opioid crisis is causing our communities, it is important to consider all scientific research that has been conducted on the use and safety of kratom. To date, the FDA public health advisory of kratom encouraged the public to “conduct the research that will help us better understand kratom’s risk and benefit profile.”⁷ However, should the DEA schedule kratom through the CSA, it will greatly reduce the public’s ability to conduct this important research. We remain concerned that any scheduling of kratom would likely “create a substantial illicit market” where consumers would be put at significant safety risks, or drive consumers to the dangerously addictive and potentially deadly use of opioids.

The DEA has a limited amount of resources, and we feel taxpayer dollars should be prioritized to prevent the sale of illegal substances like heroin and fentanyl. These substances are causing the deaths of up to 90 Americans each day. Resources must be focused on preventing access to these most dangerous substances. The Food and Drug Administration (FDA) has the authority to create a balanced regulatory scheme for kratom, as a dietary supplement, to ensure consumer safety and quality.

Again, we strongly encourage the DEA to use all available scientific evidence on kratom when making a final decision about whether to place the plant on the CSA list or not. We look forward to your timely response.

Sincerely,

⁷ Federal Drug Administration. “Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom” November 14, 2017.
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584970.htm>