

# Congress of the United States

Washington, DC 20515

September 26, 2016

The Honorable Shaun Donovan  
Director  
Office of Management and Budget  
725 17<sup>th</sup> Street, NW  
Washington, DC 20503

Dear Director Donovan:

We urge you to use your statutory authority to require the Drug Enforcement Agency (DEA) to delay their proposed regulatory action to temporarily place Mitragynine and 7-Hydroxymitragynine, more commonly known as kratom, into Schedule I of the Controlled Substances Act (CSA), until there is sufficient opportunity for public comment and Federal Agencies to work out discrepancies between them in terms of their understanding of the use of kratom.

The DEA published their notice of intent in the Federal Register on August 31, 2016, only 30 days before they plan to finalize this decision to place this substance in the most restrictive classification under CSA. The Agency did not provide any public comment process for this significant regulatory decision, which will restrict consumer choice and access to internationally recognized herbal product. We believe the Office of Information and Regulatory Affairs (OIRA), under your jurisdiction, must utilize its statutory authority to manage and oversee this specific regulatory action to ensure the DEA is not violating federal law.

In the Federal Register notice to temporarily place kratom as a Schedule 1 substance under the CSA, the DEA references that “available data and information for mitragynine and 7-hydroxymitragynine indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.” However, researchers at University of Massachusetts and the University of Mississippi received two National Institutes of Health (NIH) grants to investigate the use of kratom as a remedy for opioid withdrawal. This led the researchers to apply for a patent identifying the kratom extract, mitragynine, as a useful treatment for other addictive drugs besides opiate derivatives. The DEA’s decision to place kratom as a Schedule I substance will put a halt on federally funded research and innovation surrounding the treatment of individuals suffering from opioid and other addictions—a significant public health threat.

Due to the short time frame provided by the DEA’s decision, we urge your agency to immediately utilize your statutory authority and delay the process to place kratom in Schedule I until sufficient public comment is received and inconsistencies between Federal Agencies’ views of the product are addressed. We look forward to your timely response.

Sincerely,



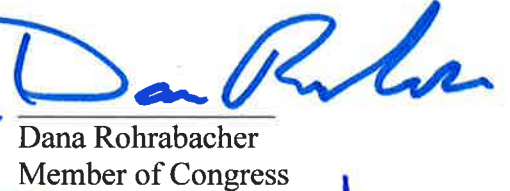
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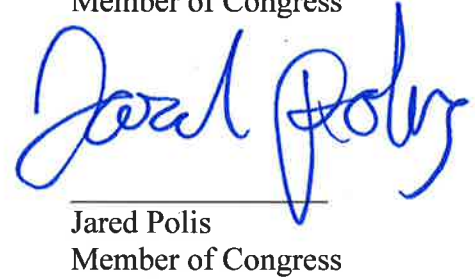
  
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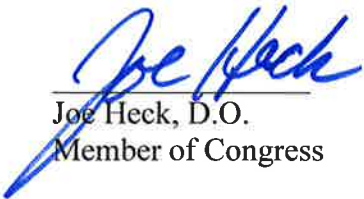
  
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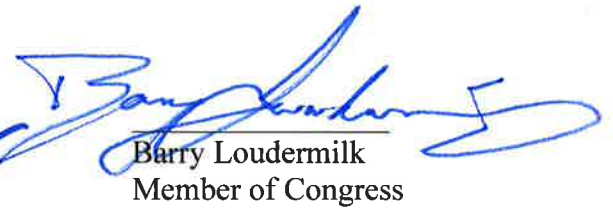
  
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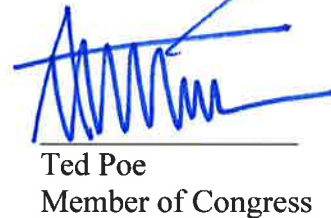
  
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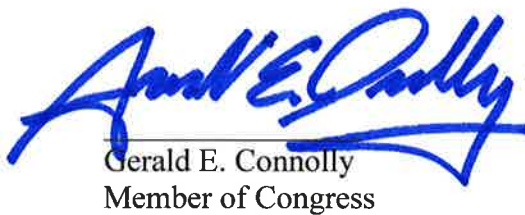
  
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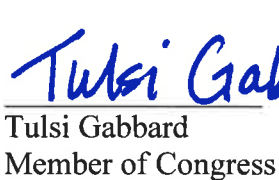
  
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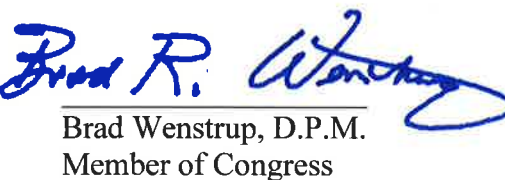
  
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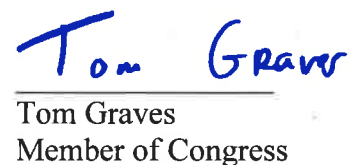
  
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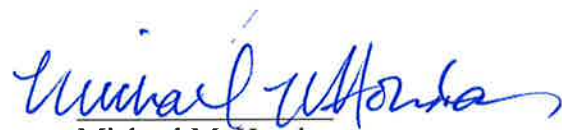
  
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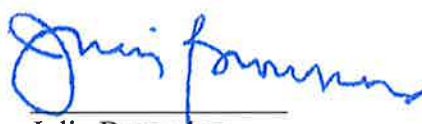
  
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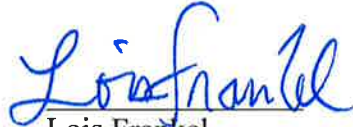
  
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