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

June 8th, 2018

Dear Acting Administrator Patterson,

The American Society for Pharmacology and Experimental Therapeutics (ASPET) opposes the proposal of the Drug Enforcement Administration to place mitragynine and 7-hydroxymitragynine—key constituents of the kratom tree—into Schedule 1 of the Controlled Substances Act.

ASPET is a 5,000-member scientific society whose members conduct essential basic and clinical pharmacological research and work for academia, government, large pharmaceutical companies, small biotech companies, and non-profit organizations. ASPET members work in a variety of different fields and their efforts help to develop new medicines and therapeutic agents to fight existing and emerging diseases.

Kratom is the common name for the tropical tree *Mitragyna speciosa* native to Southeast Asia and a relative of the coffee plant. A supplement is made from the leaves of the kratom tree by brewing them like a tea or crushing and mixing them with water. In the U.S., kratom is used by consumers to increase energy, manage pain, and fight depression.

Though structurally different from commonly used opioids, mitragynine and 7-hydroxymitragynine activate the same cell receptors but with apparently different downstream pharmacological consequences. Indeed, kratom is used by consumers to wean themselves from opioid addiction, and numerous scientific studies—including those funded by the National Institutes of Health—suggest the addiction potential for kratom to be substantially lower than that of commonly prescribed opioids.

Given the current scope of the opioid epidemic in the United States, ASPET believes it is necessary to consider all scientific research conducted on the use and safety of kratom to assess its potential to mitigate the effects of opioid abuse. Researchers at Columbia University have discovered that several compounds in the class of mitragynine, 7-hydroxymitragynine, and its analogs are effective pain relievers while inducing very limited respiratory depression in animals; an important point considering that respiratory failure is the key cause of death from opioid overdose. Further study may yield a major breakthrough that results in the development of a new, safer drug for pain.

Transforming Discoveries into Therapies

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A Schedule 1 classification for kratom will curtail the very much needed studies that will define the potential therapeutic usefulness and dangers of this widely abused agent, and will increase the regulatory burden on researchers significantly. The cost of licensing, the extended wait time to receive approval, the limitations on supply, the storage requirements, and the mandatory inspections all contribute to making research on any Schedule 1 drugs both arduous and expensive. A Schedule 1 classification will effectively foreclose research opportunities for all but the small number of investigators that possess a license. For a substance that has shown significant promise, but for which much more is needed to fully evaluate its safety and efficacy, this regulatory action would effectively eliminate an important avenue of research that has the potential to ameliorate the effects of the ongoing opioid crisis and possibly lead to more effective treatments of pain.

ASPET recommends that any scheduling action be delayed until input can be solicited from all relevant stakeholders, including the scientific community.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Schuetz". The signature is fluid and cursive, with the first name "John" being the most prominent.

John D. Schuetz, PhD
President, ASPET