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DEA Scheduling Actions on Kratom

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On August 30, 2016, the Drug Enforcement Administration (DEA) announced its intent to temporarily place into Schedule I of the Controlled Substances Act (CSA) the "active materials" in the kratom plant. The DEA's notice of intent initiated an expedited temporary scheduling action and provided the 30-day notice required by 21 U.S.C. §811(h) of the CSA. However, on October 12, in response to public concern over the scheduling action and the public request for the DEA to consider public comments, the DEA withdrew its notice of intent to temporarily place kratom into Schedule I. The DEA is soliciting public comments until December 1, 2016. Additionally, the DEA has requested that the Food and Drug Administration (FDA) expedite its scientific and medical evaluation and scheduling recommendation for kratom.

Scheduling under the CSA

The CSA established five schedules under which substances may be classified. Schedule I is the most restrictive—substances in Schedule I have no accepted medical use and a high potential for abuse. There are designated procedures under which the scheduling of substances normally occurs.

Authority to Schedule

The Attorney General (through the DEA and in consultation with the Department of Health and Human Services) may place substances into schedules under the CSA based upon eight factors: actual or relative potential for abuse; known scientific evidence of pharmacological effects; current scientific knowledge of the substance; history and current pattern of abuse; scope, duration, and significance of abuse; risk to public health; psychic or physiological dependence liability; and whether the substance is an immediate precursor of an already-scheduled substance.

Congress may also add a substance to a schedule through legislation.

Authority to Temporarily/Emergency Schedule

In 1984, Congress gave the Attorney General the authority to temporarily place a substance into Schedule I of the CSA to "avoid imminent hazards to public safety." To do so, the Attorney General (through the DEA) must consider the drug's history and current pattern of abuse; scope, duration, and significance of abuse; and risk to public health. This emergency scheduling authority may be used to place substances into Schedule I only.

What is Kratom?

Kratom is a plant indigenous to parts of Southeast Asia; its leaves contain opioid compounds that produce psychoactive effects when ingested. Some people consume kratom leaves for purported medicinal purposes including self-treatment for pain or opioid withdrawal. Although kratom has commonly been sold as a dietary supplement, the American Kratom Association, an advocacy group, describes kratom as a "natural analgesic which has been used for hundreds of years to safely alleviate pain, combat fatigue and help with the effects of anxiety and depression." Arguably, the safety and health benefits of kratom have not been scientifically confirmed. Additionally, the National Institute of Drug Abuse has said kratom *may* cause dependence.

Why Did the DEA Want to Emergency Schedule Kratom?

In its notice of intent to emergency schedule kratom, the DEA stated that temporary control of mitragynine and 7-hydroxymitragynine (the two main active substances in kratom) in Schedule I "is necessary to avoid an imminent hazard to public safety." It cited data from U.S. poison centers from January 2010 through December 2015. During this six-year period, poison centers received 660 calls related to kratom. The DEA also pointed out that the identity, purity, and quantity of kratom products are uncertain and inconsistent. Further, in its notice of intent the DEA cited rising domestic and international concern over kratom, pointing out that six states (Alabama, Arkansas, Indiana, Tennessee, Vermont, and Wisconsin), the District of Columbia, and 15 countries have banned it.

Kratom is widely available in gas station stores and head shops, and on the Internet. Manufacturers and distributors have not been subject to more stringent federal regulation because it commonly has been marketed as a dietary supplement, and product labels do not claim medicinal value—some even state "not for human consumption." Since kratom is *not* scheduled under the CSA, the DEA does not have the authority to control this substance, but other federal agencies have taken action on it. Over the past few years, the FDA issued import alerts and requested the seizure of kratom products—its position is that kratom is an unapproved and misbranded drug under the Federal Food, Drug, and Cosmetic Act.

Implications of and Public Concern Regarding Scheduling

The scheduling of a substance has implications for the would-be violators of the CSA, and for the federal criminal justice system as a whole. Penalties for illicit manufacturing and possession as well as trafficking of controlled substances range from fines to life in prison, depending on a number of factors pursuant to the crime. Factors considered in federal sentencing include, but are not limited to, the amount of drugs involved in the crime, the number of offenders, the type and schedule of the drug, the number of prior offenses, and aggravating factors (e.g., death, weapons involved in the crime). As of August 2016, of the 191,963 federal inmates for whom offense data are known, 83,982 (46.4%) are serving sentences for federal drug offenses. It is unknown whether or how the relative number of drug-specific offenders may change if the DEA were to schedule kratom.

Placement on Schedule I would change the availability of kratom. It would no longer be legally available for consumption, and its lawful use would be restricted to highly regulated research. The DEA is proceeding with scheduling consideration, but not emergency scheduling. It may schedule kratom on Schedules I-V or decide not to schedule the substance.

Current Status of Kratom

As of October 13, 2016, kratom is *not* a controlled substance under the CSA. Absent any potential violations under the Federal Food, Drug, and Cosmetic Act or potential violations under relevant state laws, it remains a legal substance under federal law.