

PINNEYASSOCIATES' SCIENTIFIC ABUSE POTENTIAL ASSESSMENT OF KRATOM FINDS EVIDENCE OF PUBLIC HEALTH BENEFIT AND LITTLE HARM

The DEA Withdraws Proposed Emergency Scheduling and Prohibition on Kratom, Allowing Consumers to Continue Lawful Use, Potential FDA Oversight, and Expanded Research

BETHESDA, MD (January 18, 2017) – Kratom leaves, from a South East Asian tree in the coffee family, are often used to prepare tea-like beverages and commercially manufactured products which are consumed by several million Americans annually to increase alertness, enhance well-being and occupational performance, and as a natural remedy for minor aches and pains. **PinneyAssociates'** review of the scientific evidence regarding kratom's effects is intended to assist FDA and DEA in determining the most appropriate regulatory approach within FDA authority to permit appropriate use, minimize unintended effects, encourage research, and contribute to the enhancement of public health.

DEA had proposed placing kratom in Schedule I (which includes drugs such as heroin and LSD), the most restrictive category of the Controlled Substances Act. In practical terms, this would have banned the sale of kratom and posed a major roadblock to research. The [American Kratom Association](#) petitioned the DEA to withdraw its proposal. **PinneyAssociates'** was then contracted to review the available information about kratom and develop an "8-factor analysis", the legal framework used to assess the abuse potential of substances, about kratom for submission to the FDA, DEA, and National Institute on Drug Abuse to inform the deliberations regarding regulation of kratom. See more about this in press coverage by [Wired](#), Forbes, and the [Washington Post](#).

One of the authors of the kratom 8-factor analysis was Dr. [Jack Henningfield](#), Vice President of Research, Health Policy and Abuse Liability, at **PinneyAssociates**, and Adjunct Professor of Behavioral Biology, The Johns Hopkins University School of Medicine. Dr. Henningfield commented, "It's important to understand that although kratom has some mild effects similar to opioids, its chemical make-up is different, and it appears overall much safer, with apparently relatively small effects on respiration. In fact, kratom's analgesic effects and impact on energy, combined with its favorable safety profile supports continued access by consumers to appropriately regulated kratom products while research on its uses continues." Furthermore, he said "surveys suggest that kratom products are used by many former opioid users as a natural remedy to help them abstain from opioids."

Dr. Henningfield concluded, “Our work on kratom is an example of how we help regulators and industry make scientifically informed decisions about the risks and benefits of pharmaceuticals and nutritional supplements. This is a key facet of the work we produce at the intersection of science and public health policy.” The kratom abuse potential assessment is an example of the comprehensive abuse potential assessments and CSA 8-factor assessments that **PinneyAssociates** scientists develop for pharmaceutical companies to submit to the FDA in support of CNS-acting products including opioids, ADHD stimulants, anti-epileptics, and sedative sleep aids.

About PinneyAssociates

PinneyAssociates is a pharmaceutical and consumer healthcare consulting company that helps clients to reduce their regulatory risk and enhance the commercial value of their life sciences products. **PinneyAssociates** consults with pharmaceutical companies that market a wide variety of prescription and over-the-counter medications. **PinneyAssociates’** experts have extensive expertise in abuse-deterrent drug formulation evaluation, abuse potential assessment, as well as pharmaceutical risk management, Rx-to-OTC switch, and tobacco harm reduction.

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