AMERICAN KRATOM ASSOCIATION

New Study Adds to Evidence of Low Abuse Potential of Kratom
Research Directly Contradicts FDA's Position that Kratom is a Morphine-Like Opioid

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SEPTEMBER 21, 2020, Washington D.C. – A new study by leading kratom researchers from the National Institute on Drug Abuse (NIDA)-funded kratom research program of the University of Florida found low abuse potential of mitragynine and 7-hydroxymitrgynine in a classic animal model. This research adds to the body of evidence that directly contradicts the FDA's claim that kratom is a morphine-like opioid.

The American Kratom Association (AKA) applauds this important new research that adds to the evidence that the FDA is wrong on its conclusions on kratom. "Kratom needs to be responsibly regulated to prevent dangerously adulterated counterfeit kratom products," commented Mac Haddow, Senior Fellow on Public Policy for the AKA. "The FDA has sufficient statutory authority to protect consumers, and this research proves once again the FDA has been wrong on characterizing kratom as having the same effects as classic opioids. The FDA must begin protecting consumers from adulterated kratom products rather than using adulterated products as the justification for a total ban just to expand their regulatory authority."

The study concluding that kratom's primary alkaloids did not produce rewarding brain effects was published in the peer-reviewed journal, *Drug and Alcohol Dependence* by Dr. Behnood-Rod and colleagues.[i] This animal study employed the well-established intracranial self-stimulation procedure (ICSS)[ii] that has been used for decades to document the rewarding effect of drug in male and female rats.

The authors conclusions included the following:

- "These initial findings indicate that mitragynine and 7-hydroxymitragynine are not rewarding in the ICSS procedure. The present results suggest that these kratom alkaloids do not have abuse potential."
- "These preliminary ICSS studies suggest that the kratom alkaloids are not rewarding, and high doses might be aversive."

In contrast to mitragynine and 7-hydroxymitragynine, they found, as shown in other studies "that the 10 mg/kg dose of morphine is rewarding", clearly differentiating these constituents from morphine.

This study is an important complement to other recent studies employing the drug self-administration procedure which show that mitragynine is of very low abuse potential.[iii] [iv] This is important because mitragynine is the alkaloid that is common to most marketed kratom products in the US and globally

and is believed to be the primary naturally occurring kratom constituent the provides the effects[v] [vi] that consumers report is the basis for their consuming kratom products.

The study also complements two other studies that employed well-established models for comparing substances to morphine with respect to physical dependence and withdrawal. Those studies found very low levels of withdrawal[vii] [viii] produced by mitragynine exposure as compared to morphine. This is consistent with surveys and field studies[ix] [x] [xi] suggesting that even in heavy long term users of kratom who might experience withdrawal from kratom when they stop using it, the effects are generally far less intense and more readily self-manageable than those produced by abstinence from morphine and other classic addicting opioids. In fact, these studies and other evidence also indicate that many people report using kratom to self-manage opioid addiction, craving, and withdrawal though this is not recognized as an approved safe and effective use by health authorities.[xii] [xiii]

Dr. Jack Henningfield, an internationally recognized expert in the assessment and regulation of substances with a potential for abuse and addiction who was not involved in the study, stated, "This new study provides important additional scientific evidence that kratom does not warrant regulation as morphine-like opioid (i.e., "narcotic"). Nor should kratom be described as opioid-like with respect to its abuse potential or addictiveness or safety profile based on this study and other research"[xiv] [xv] [xvi] Dr. Henningfield[xvii] has researched and contributed to the regulatory approaches for many substances and new drugs through his studies with the National Institute on Drug Abuse, Johns Hopkins University, and other research institutions, and provides consulting support through PinneyAssociates on drug regulation as well as kratom science, including advising to the American Kratom Association.

Dr. Henningfield further commented: "Abuse potential assessment and substance regulation is strongest when based on a broad range of types of laboratory studies and real world evidence to understand the pharmacological effects, safety and public health risks and benefits, as recommended in FDA's 2017 guidance: Assessment of the Abuse Potential of Drugs.[xviii] This was the approach by my colleagues and I in our analyses[xix] of kratom's abuse potential and our regulatory recommendations. It is exciting to see kratom research efforts increasing and using a broad range of techniques such as the animal self-administration, ICSS, and withdrawal models, and studies of potential therapeutic effects, as well as surveys of real world use and effects in the US and other countries such as by Malaysia's Center for Drug Research."[xx]

Relevance of COVID-19 and the Opioid Epidemic

Dr. Henningfield added: "The COVID-19 pandemic on top of the opioid overdose epidemic adds to the urgency of regulatory approaches to preserve access to kratom by consumers but with product standards to address safety concerns. Kratom was the lifeline away from opioids for many people before the COVID pandemic because for many people formal treatment programs and FDA approved treatment approaches were not accessible, effective or acceptable. The COVID pandemic has been associated with increased opioid overdose deaths and impaired access to formal addiction treatment programs."[xxi]

Utah State Senator Curt Bramble, the primary sponsor of the first state legislation to provide for responsible regulation to prevent adulterated kratom products, agreed: "Now is not the time to reduce access to kratom. Now is the time for other states and ideally the Federal government to follow

the lead of Utah and other states such as Arizona, Georgia, and Nevada: Begin to regulate kratom to ensure access to kratom products that meet high standards for purity, packaging, labeling and marketing, and are not adulterated with other substances including artificially elevated alkaloid levels."

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REFERENCED RESEARCH:

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