

Chair Lipps, Vice Chair Holmes, Ranking Member Russo, and Members of the Committee, thank you for the opportunity to provide an update on the current state of kratom science, its place in public health, and the opioid epidemic, with implications for how to regulate kratom to minimize risks to kratom consumers while contributing to their health and wellbeing.

During the 1980s and 1990s I headed the Clinical Pharmacology laboratory of the National Institute on Drug Abuse (NIDA) and led research across a wide range of substances including opioids, cannabis, cocaine, and other drugs and contributed to drug scheduling assessments. I have published more than 450 papers.

I consult on pharmaceutical development and have contributed to the research and/or approval for most treatments approved for drug, alcohol and nicotine addiction since the 1980s and have advised NIDA, CDC, FDA, and the World Health Organization. I advise the American Kratom Association on science, regulation and public health. I do not promote, encourage, or advise on kratom use. I believe consumers would benefit by regulation as is emerging in Arizona, Georgia, Nevada, Oklahoma, and Utah, and ultimately by FDA.

## **Basic kratom facts:**

- Kratom is in the coffee family, not the opium poppy family it is not an opioid.
- It produces caffeine like stimulation and many consumers report using kratom to help maintain alertness, focus and productivity in the workplace – these are not typical uses of opioids.
- Kratom, like coffee, contains many alkaloids, most of which have little pharmacological or toxicological activity. Its primary alkaloid, common to most kratom products, is mitragynine. Mitragynine is not an opioid by nature, chemical structure, or overall profile of effects.
- Nature got it right. Kratom's primary active constituent, mitragynine and its metabolites, appears to
  account for most of the benefits reported by consumer and is of low respiratory depressant
  potential, whereas most other alkaloids are either biologically inactive or such low levels as to not
  contribute to kratom's effects or safety.
- Mitragynine mimics some of caffeine's alerting effects and also mimics some opioid effects like reducing pain and diarrhea, but with little of the signature powerful brain rewarding addictive effects and lethal respiratory depressing effects of heroin, fentanyl and opioids.
- Kratom does provide some of the pain relieving and constipating effects of opioids and can help relieve opioid withdrawal but it is not approved for this or any therapeutic use by FDA.
- It is possible to develop some dependence on kratom and this is reported by some heavy kratom users, however, such people report that it is generally far milder than opioid dependence and that unlike opioids, kratom helps them function in the workplace and home. It appears more likely to be used as an informal aid to opioid abstinence than for "abuse".
- Most deaths in which kratom use may have occurred have been determined to have been caused by other substances and factors and not by kratom itself.

 Rapidly emerging research supported by NIDA supports these conclusions. See Henningfield, Wang & Huestis. Kratom Abuse Potential 2021: An Updated Eight Factor Analysis. Frontiers in Pharmacology, 2022 at <u>https://www.frontiersin.org/articles/10.3389/fphar.2021.775073/abstract</u>

## Kratom by the numbers:

- There are an estimated 10-16 million kratom users in the U.S. Surveys indicate that the population of kratom users is adults aged 30-50 with lower rates of use among younger and older persons.
- These respondents report that they use kratom for health and well-being and that for them, kratom is either more effective, better tolerated with respect to side-effects, and/or more affordable than available pharmaceuticals. For many people, kratom is a path away from opioids, whether for managing pain or addiction, however, most people use kratom for other health-related reasons.
- The opioid crisis has hit Ohio hard with many of the more than 5000 drug overdose deaths in 2020 due to opioids and probably more in 2021.
- Kratom is an informal asset in addressing the opioid epidemic and it is helping people who find formal treatment ineffective, inaccessible, or unacceptable. I estimate Ohio's population of approximately 11.8 million likely includes approximately 300,000 adult kratom users of which surveys suggest that 20-30% or 60-90 thousand, are at reduced risk of opioid overdose due to their use of kratom in place of opioids. What former Assistant Secretary of Health, ADM Brett Giroir said about kratom at the national level applies to Ohio regarding Schedule 1 regulation: "… there is a significant risk of immediate adverse public health consequences for potentially millions of users if kratom or its components are included in Schedule I, such as… kratom users switching to highly lethal opioids … risking thousands of deaths from overdoses and infectious diseases associated with IV drug use…" (See formal US DHHS kratom scheduling rescission letter to the Drug Enforcement Administration (DEA) at

https://images.go02.informamarkets.com/Web/Informa02/%7b548e6d56-2ea4-4da4-9404-0348b56e9a88%7d\_dhillon-8.16.2018-response-letter-from-ash-radm-giroir.pdf.

## **Regulatory Update:**

- The 2017 FDA recommendation for DEA to place kratom in Schedule I of the Controlled Substances Act was formally withdrawn after investigation and consideration of more recent science by DHHS (see above link to the DHHS letter).
- In 2021, the World Health Organization Expert Committee on Drug Dependence conducted a review of kratom and included a hearing on whether kratom should be considered for international scheduling. It concluded "there is insufficient evidence to recommend a critical review of kratom [for controlled substance scheduling]." see:

https://www.unodc.org/documents/commissions/CND/CND\_Sessions/CND\_64Reconvened/ECN72 021\_CRP12\_V2108992.pdf

**Recommendation:** I believe Ohio's residents would be best served by efforts to ensure adult access to kratom with a regulatory framework to discourage inappropriate use (including use by young people) and to address kratom's main health risks which are related to impure and adulterated products.

I can provide scientific articles including recent peer-review publications as sources of these facts. I will be pleased to do whatever I can to provide science and regulatory perspective to help you find a path to protecting kratom consumers in Ohio, addressing the opioid epidemic, and minimizing unintended consequences of kratom availability.

Thank you for the opportunity to provide this information. I would be happy to answer questions.