AMERICAN KRATOM ASSOCIATION

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KANSAS HOUSE COMMITTEE ON FEDERAL/STATE AFFAIRS
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Mr. Chairman, members of the Committee, my name is Pete Candland, and I am the Executive Director of the American Kratom Association, representing the more than 15 million kratom consumers in the United States. We thank you for this opportunity to be here in the Jayhawk state to address the proposed legislation, the Kansas Kratom Consumer Protection Act.

As a quick background, let me first start by telling you a little about kratom.

- The kratom trees grow in Southeast Asia and is a part of the coffee family.
- Kratom has been used safely for centuries in that area and is particularly popular with laborers and field workers who find its energy boosting and pain relief properties helps them get through long days of work in the fields.
- Kratom is not an opioid, and when you use a pure kratom product you do not experience the reinforcing euphoric high associated with classic opioids.
- Kratom does not impact your respiratory system as classic opioids do where an overdose results from a classic opioid user literally suffocating to death.
- Kratom is not addictive like classic opioids. You can, like caffeine in coffee, develop a dependency on kratom that has a similar withdrawal profile as caffeine– a headache, upset stomach, and maybe a runny nose – over a 4-5 day period.

The reason why we are here today is a simple one: The FDA is presently waging a decades-long war on natural plant-based products, and kratom is just the latest herb the FDA is targeting because this natural plant is being used by millions but is not a good candidate for review by the FDA as a new drug application. The NDA process typically involves a $3 billion investment and 10 years of review by the FDA.

In the mid-1990's, the FDA launched a similar attack on dietary supplements and vitamins with claims that these products were all unapproved drugs and there were significant number of adverse events and deaths resulting from the sale of these products. The FDA solution was to ban all dietary supplements and force consumers to use only FDA approved drugs to maintain their health and well-being.

At that time, the U.S. Congress intervened and stopped the broad regulatory overreach for literally hundreds of dietary supplement and vitamin products by passing the Dietary Supplement Health & Education Act that today provides regulations for the safe use of products accounting for $40 billion in sales to consumers.

Kratom got on the FDA's radar initially when consumers started reporting that they found it to be an effective alternative to FDA approved prescription pain relief opioids. In 2009, the FDA got what they wanted when reports out of Sweden revealed that 9 deaths in a 12-month period were caused by the consumption of a powdered kratom product sold on the Internet known as Krypton. It was later determined that these 9 individuals died of a lethal dose of O-desmethyltramadol, which was also found in Krypton.

That cluster of deaths in such a short time frame appropriately caught the attention of every public health official in the world, including the FDA. The FDA imposed an import alert on kratom and flooded the information pipeline with shrill warnings to state and local health officials, pharmacy boards, and drug task forces around the country that kratom was a dangerous substance that should be banned.

In a seven-year span between 2009 and 2016, six states enacted bans on kratom — Vermont, Alabama, Indiana, Wisconsin, Arkansas, and Rhode Island. The FDA regularly points to those states as evidence of how dangerous kratom is, **but** what is really surprising is that **only** six states enacted bans in the face of a full-throated disinformation campaign on kratom by the FDA with outrageously untrue claims about kratom being the cause of hundreds of deaths.

In August of 2016, with clear frustration that more states had not been seduced by their war on kratom, the FDA sent a recommendation to the Drug Enforcement Administration (DEA) to classify the two primary alkaloids of the kratom plant as Schedule I dangerous substances under the Controlled Substances Act (CSA), and used a section of the CSA reserved for the most dangerous street drugs to expedite the scheduling.

The DEA, following a procedural publication of the proposed kratom ban in the Federal Register, was flooded with an unprecedented number of citizen comments objecting to the FDA's false claims about the dangers of kratom. A bi-partisan group of 21 Democrats and 26 Republicans in the U.S. House of Representatives wrote to the DEA Administration objecting to the scheduling of kratom, and 23 members of the U.S. Senate also sent a letter — including Senator Bernie Sanders on one end of the political spectrum, and Senator Orrin Hatch on the other.

The DEA then took the unprecedented step of withdrawing its scheduling notice on October 13, 2016, the first time it had done so in 82 previous scheduling requests to remove dangerous drugs, and required the FDA to document its claims with a full scheduling recommendation — known as an 8-factor analysis that provides the specific scientific justification for banning any substance by December 1, 2016. The DEA then opened the issue for public comment while the FDA prepared its 8-factor analysis.

What happened next was astounding.

- 232,236 public comments were received in the next 48 days.
- 99.1% of those comments opposed the ban on kratom.
- Medical professionals, veterans, lawyers, construction workers, housewives, accountants, — people across the spectrum of life experiences and all kratom consumers — raised their voices opposing the FDA's disinformation campaign on kratom.

When the December 1st DEA deadline tolled, the AKA submitted an authoritative 8-factor analysis authored by one of the world's experts on substance addiction and safety, Dr. Jack Henningfield of Johns Hopkins University and a 16-year veteran of the National Institutes on Drug Abuse (NIDA), recommending against scheduling of kratom.

The FDA failed to meet the deadline for justifying its case against kratom.

But they continued their incessant attacks in the media and their broad communications channels to state and local public health and law enforcement agencies making more and more outrageous claims about the risks of using kratom.

That all culminated on October 13, 2017 — one year after the deadline — with the FDA finally submitting an 8-factor analysis and claiming as many as 44 deaths caused by the use of kratom. They make these death claims to meet the criteria in the CSA that kratom must be dangerous to the public.

The FDA also alleges that kratom was an opioid because it binds to the mu-pain receptors in the brain, just as classic opioids do. The FDA made this false claim because the CSA requires a substance must have a deadly pharmacologic activity to be scheduled. The FDA claimed kratom acted just like classic opioids in suppressing the respiratory system.

Finally, the FDA claimed that kratom was highly-addictive just like heroin, morphine, and fentanyl the provided users with a reinforcing euphoric high that created an addiction profile that requires months of intensive rehabilitation for recovery. The CSA requires a substance have a high addiction liability to qualify for scheduling.

On each of these key criteria the FDA was wrong on the science and wrong on the policy.

When the NIDA researchers reviewed the claims of 44 deaths associated with kratom, they found all of those deaths were the result of polydrug use or dangerously adulterated kratom products — with only 1 unexplained death for which the FDA could not provide any blood work or autopsy report to support its allegation.

Additionally, the FDA claim that kratom has the same effects on consumers as classic opioids, independent scientists openly challenged that claim with numerous studies that showed kratom is only a partial agonist that does to have any measurable impact on the respiratory system as classic opioids do. When an overdose death occurs, it is because the user as literally suffocated from respiratory suppression that kratom does not cause.

Finally, the FDA's allegation that kratom has a high addiction liability required for scheduling was debunked by two animal studies funded by NIH and NIDA that found that kratom has no significant addiction liability and — more importantly — they found that the test animals actually experience a reduction in cravings for morphine, the reference drug used in the studies.

Overdose deaths, euphoric highs, and addiction are the signatures of adulterated kratom, and we want to eliminate those dangerous products from the marketplace.

That truly is why we are here today. To protect the freedom of Kansas citizens to make informed decisions on their health and well-being without the overreaching regulatory power the FDA is trying to seize.

The FDA wants kratom to be subject to its new drug application process. They want the same thing for homeopathic medicines, herbal remedies, and medical foods — all of which have been used safely by American consumers for decades.

Today, and we stand here, there is a significant disagreement about kratom on the federal level.

On one side of the disagreement, the FDA remains almost alone in its call for kratom to be scheduled.

Those lined up on the other side, includes NIDA who argues for more study on kratom and following a harm reduction policy to allow consumers to use pure kratom to manage acute and chronic pain as an alternative to highly addictive and potentially deadly opioid medications. NIDA has already funded more than $10 million in research studies, and more is in the research pipeline.

The DEA is also on the other side of FDA. DEA has the authority to schedule any dangerous substance that threatens the safety of the American people. When they receive a scheduling recommendation from the FDA, they typically issue a decision within 90 days to stop any safety risk that exists. The current recommendation from the FDA to schedule kratom has been before the DEA for more than 2 years that they have taken no action on scheduling kratom. If the FDA claim were true about deaths associated with kratom the DEA would have acted because it is their duty to do so.

The U.S. Congress is also opposed to the FDA scheduling recommendation on kratom. In its FY2020 budget bill that was passed a few weeks ago, there is a specific funding appropriated for new research on kratom; report language states that a Schedule I designation interferes with research; and the bill specifically cites the reports of kratom helping people reduce or stop the use of dangerously addictive and potentially deadly opioids.

Finally, the states are lining up against the FDA as well.

Four states in 2019 passed a similar version of the Kratom Consumer Protection Act that you are considering today, Utah, Georgia, Arizona, and Nevada.

This legislative session, the Kratom Consumer Protection Act has been or will be filed in Oregon, Idaho, Colorado, Missouri, Mississippi, Illinois, Wisconsin, Michigan, Ohio, Louisiana, Alabama, Florida, South Carolina, North Carolina, Virginia, Maryland, New York, Rhode Island, Pennsylvania, and Ohio.

NIDA, the U.S. Congress, DEA, and the states are all opposed to the FDA's policy on kratom.

I mentioned earlier that the FDA was "virtually" alone. They do have one ally siding with them, and that is the big pharmaceutical companies.

You may make whatever judgment you choose on why Big PhRMA is siding with the FDA against kratom.

The American Kratom Association asks the state of Kansas to stand up against overregulation by the FDA; stand up to the domination of the Big Pharma in the pain relief market; and stand with consumers

to have the freedom to make informed purchases of safe kratom products to manage their own health and well-being.