August 31, 2026

Written Testimony Submitted to the
North Dakota Legislative Ad Hoc Committee on Kratom Legislation
Special Session, September 2026

Re: House Bill 1628, Relating to the Regulation of Kratom Products

Members of the Committee,

My name is Dr. Heidi Sykora, DNP, Chief Scientific Officer of the International Plant and Herbal Alliance (IPHA), a 501(c)(3) nonprofit dedicated to science-based public education about botanical products. This testimony reviews the scientific evidence supporting House Bill 1628's regulatory approach to natural leaf kratom, along with a brief technical note on one definitional threshold in the bill.

Summary

- Natural leaf kratom and concentrated or synthetic 7-OH are pharmacologically distinct. This bill regulates the former and separately prohibits the latter, the same distinction DEA and HHS drew in their July 2026 scheduling actions.
- Federal regulators have reviewed kratom for potential scheduling twice and declined both times, most recently in 2018. NIH is now sponsoring a Phase 1 trial of purified mitragynine as a potential opioid use disorder treatment.
- Published seizure and mortality data do not support attributing those risks to natural leaf kratom specifically, as distinct from adulterated, concentrated, or synthetic products, which is precisely the distinction this bill's licensing, anti-adulteration, and labeling provisions are designed to address.
- One technical note: the bill's 7-OH threshold is defined by a different metric than the federal dry-weight standard, though it mirrors language FDA itself uses to describe natural leaf. Confirming the two metrics identify the same products may be worth a brief follow-up before the definition is finalized.

Where the Evidence Supports House Bill 1628

The Natural Leaf and Synthetic 7-OH Distinction

Precise terminology matters here, because much of the confusion in current policy debate stems from treating “kratom” as a brand name rather than a defined substance. Kratom is properly understood as the natural plant, Mitragyna speciosa, and any product derived from it that retains the plant's naturally occurring alkaloid profile and ratio, whether sold as powder, capsule, tea, or extract. Concentration alone does not change that designation: an extract that proportionally concentrates the plant's own alkaloid balance is still kratom.

Products in which 7-OH has been chemically elevated beyond the trace levels naturally present in the leaf are not kratom, regardless of how they are labeled or marketed. That elevation cannot occur through extraction of the plant material alone; it requires additional chemical processing to

convert mitragynine into 7-OH or to otherwise concentrate 7-OH disproportionately, which makes the resulting substance a distinct, semisynthetic compound rather than a form of the botanical. A recent peer-reviewed analysis describes these products in exactly these terms, characterizing high-7-OH items as misbranded as kratom rather than as a kratom product category,[5] and FDA's own public communications on this action describe 7-OH itself as an emerging opioid threat distinct from the plant.[4] The DEA's and HHS's July 2026 actions reflect the same underlying recognition: the scheduling notices target 7-OH above a specified threshold and its synthetic derivatives while stating explicitly that the action does not reach natural kratom leaf.[2, 3] In other words, the federal government's own most recent regulatory action treats concentrated 7-OH as the new, separately regulated substance it is, not as a form of kratom.

This distinction is not merely IPHA's framing; it now has a clear regulatory basis. The U.S. Drug Enforcement Administration's July 1, 2026 Notices of Intent target 7-OH above a specified threshold, along with three synthetic derivatives, while explicitly stating the action is not intended to reach botanical kratom leaf.[2, 6] House Bill 1628's approach, establishing age restriction, labeling, and regulatory oversight for natural leaf products while separately prohibiting synthetic alkaloids, reflects this same categorical distinction between the botanical and the chemically elevated compound.

Federal Scientific Review History

Kratom has never been placed in Schedule I at the federal level. Two separate federal reviews have considered it, and both concluded against control. In 2016, DEA issued notice of its intent to temporarily schedule kratom on an emergency basis, then withdrew that notice roughly six weeks later following public and congressional opposition, before any order took effect.[7] DEA then asked FDA to conduct a full scientific review. FDA's resulting recommendation to schedule, submitted to DEA in October 2017, was never acted on: HHS Assistant Secretary for Health Dr. Brett Giroir rescinded it in August 2018, concluding the evidence did not support Schedule I control and specifically warning that scheduling risked adverse public health consequences for the millions of people using kratom, including intractable pain, psychological distress, and increased risk of suicide, as well as transition to opioids for those managing opioid use disorder.[8] A subsequent independent review in 2021[9] and a World Health Organization expert review the same year[10] reached the same conclusion. The plain summary: federal regulators have looked at this question twice and said no twice.

It bears emphasis that the substance evaluated in the 2017 FDA recommendation and the 2018 rescission was 7-hydroxymitragynine as it occurs naturally in kratom leaf, present at trace concentrations, not the concentrated or chemically synthesized 7-OH found in the products DEA's July 2026 action targets.[9] Independent analytical work has found 7-OH typically present at roughly 0.01 to 0.04 percent by dry weight in natural leaf and powder, compared to levels that are only achievable through additional chemical processing in the concentrated products now at issue.[15, 16] This is the population of natural leaf products House Bill 1628 defines as kratom and regulates rather than prohibits.

Evidence Supporting the Bill's Anti-Adulteration and Labeling Provisions

The published literature on kratom-related adverse events supports the product-safety approach House Bill 1628 takes through its anti-adulteration, anti-synthetic-alkaloid, and labeling provisions. A 2025 systematic review of published seizure case reports, covering only 20 individuals across all identified case reports and small case series published between 2008 and 2021, concluded the evidence was insufficient to establish that kratom causes seizures, citing the absence of a demonstrated dose-response relationship, incomplete toxicology, the baseline frequency of seizures in the general population, and the lack of an established biological mechanism.[11] That such a small number of cases accumulated over thirteen years, against a background of an estimated ten to sixteen million kratom users in the United States, is itself informative: it points to an infrequent, poorly characterized event rather than a recurring pattern tied to ordinary use.

The review's own toxicology data underscore how thin this evidence base is. Of the 20 patients, only one had a quantitative laboratory result confirming mitragynine exposure at the time of the seizure. The remaining 19 had no quantitative confirmation that kratom was involved at all: several had only qualitative urine screens that do not test for mitragynine specifically, and others had no toxicology performed. In other words, the great majority of the cases behind this finding rest on reported or suspected kratom use rather than laboratory-confirmed exposure, which is a meaningfully different, and much weaker, evidentiary basis for attributing the seizures to kratom.[11]

Where the product's source was documented, adulteration is a recurring confound rather than an incidental detail. In one dataset drawn from that review, eight of eleven patients who reported seizures had sourced their kratom from a local supplier, which the review's authors note may indicate adulteration or contamination rather than an effect of natural leaf itself.[11] This is precisely the distinction House Bill 1628's licensing, anti-adulteration, and labeling requirements are designed to address, in a way a blanket prohibition cannot, since prohibition removes the regulated marketplace that makes product-level quality control possible.

IPHA's own independent forensic case review series, which examines the full medical examiner and toxicology record in individual cases publicly attributed to kratom, has identified this same pattern of misattribution at the case level. In one case reviewed under this methodology, a seizure and subsequent cardiac arrest publicly attributed to kratom toxicity occurred in a decedent whose record showed severe hyponatremia, an electrolyte disturbance capable on its own of causing both a seizure and cardiac arrest. IPHA is glad to share this case-level analysis, without identifying information, with Committee counsel or member offices upon request.

Mortality data raise a parallel concern. A 2025 review of acute adverse event case reports found that toxicology panels identified confounding substances capable of causing or contributing to the reported effects in a large majority of deceased cases, a statistically significant difference compared to surviving cases, despite many of those adverse effects having been attributed to kratom alone in the original reporting.[12] That pattern, fatal outcomes involving concurrent substances or independently explanatory conditions rather than mitragynine in isolation, is consistent with what IPHA's broader forensic case review series has found across the cases it has examined, including the hyponatremia case described above.

Ongoing NIH Research

In June 2026, the National Institutes of Health announced that its Investigational New Drug application for purified mitragynine (MG001) had taken effect with FDA, clearing a Phase 1 trial, sponsored by the National Institute on Drug Abuse and developed with the University of Florida, evaluating mitragynine as a potential treatment for opioid use disorder. That trial is expected to begin enrollment around September 2026.[13]

An Investigational New Drug application cannot proceed to human dosing without a supporting basis for safety in humans. That basis rests in part on human dosing data that already exists: an FDA-funded single ascending dose pilot study of botanical kratom (Reissig, McCurdy, Sharma, and colleagues) tested doses of 1, 3, 8, 10, and 12 grams in healthy volunteers and reported no serious adverse events at any dose, including the highest.[14] The same regulatory system that requires demonstrated safety before permitting human trials has already reviewed human dosing data on natural kratom and found no basis for concern.

A Technical Note on the Bill's 7-OH Definition

House Bill 1628 defines kratom as leaf or food-grade solvent extract in which 7-hydroxymitragynine makes up less than two percent of the alkaloid fraction of the product. This is a different metric than the federal DEA and HHS threshold described above, which is set at 0.05 percent of the product by dry weight. The two percent alkaloid-fraction figure is not an unsupported departure from federal practice, however: FDA's own public materials describe natural kratom leaf the same way, stating that 7-OH is a naturally occurring alkaloid that comprises less than two percent of the total alkaloid content in natural kratom leaves, the same figure and the same metric House Bill 1628 uses in its definition.[17] The two metrics still measure different things: dry-weight percentage of the whole product versus percentage of the plant's total alkaloid content, and a product's overall alkaloid concentration, which varies by cultivar, growing region, and processing method, affects how the two figures relate to one another in any specific case.[15, 16] The Committee may still find it useful to confirm with testing data that the two percent alkaloid-fraction threshold and the federal dry-weight threshold identify the same population of products, but this is a request to confirm consistency between two federally referenced metrics, not a signal that the bill's definition lacks a basis.

Available for Scientific Consultation

IPHA maintains a standing library of case-level forensic review methodology, citation-supported regulatory briefings, and pharmacology reference material developed for legislative and public health audiences in multiple states. We would welcome the opportunity to make this material, including the analytical chemistry question raised above, available to Committee counsel or member offices as deliberations continue, and are glad to answer any scientific questions in the meantime.

Respectfully submitted,

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