Pinney Associates

August 21, 2026

North Dakota Legislature
Kratom Working Group

RE: Summary of oral comments and supporting documents

Dear Madam Chair, Senator Michelle Axtman, and Members of the Kratom Working Group

Thank you for the opportunity to comment in person August 12. This follow-up summarizes several points from my oral comments, including responses to questions from the Working Group. The opinions expressed orally and in this document are my own and do not necessarily represent the views of Pinney Associates, Johns Hopkins University, or any organizations for which I consult. For disclosure, through Pinney Associates, I advise the American Kratom Association on kratom science and regulatory matters, serve as an expert in kratom-related litigation, and advise developers of potential kratom-based new medicines, new dietary ingredients, and related regulatory filings. I also advise on the development, regulation, and potential Controlled Substances Act scheduling for new medicines for a broad range of medical conditions including pain, addiction, psychiatric and neurological disorders. Additional information is available at www.PinneyAssociates.com.

I support balanced kratom regulation that preserves access to a range of natural kratom-derived products for the estimated fifty thousand adult kratom consumers in North Dakota, along with potential more than twenty million adult kratom consumers nationally whose needs and product preferences vary. Such regulation can draw on a strong evidence base, largely developed by researchers and institutions supported by the National Institutes of Health, the National Institute on Drug Abuse (NIH/NIDA), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA). Highlights of this research, including ongoing studies, are summarized on these organizations' kratom science websites, in the FDA summary documents released on July 28, 2025 (FDA 2025a, b; c; d), and the DEA's Notices of Intent to schedule 7-OH and other substances (DEA 2026).

I have also attached summaries of kratom abuse potential and safety, along with website links to peer-reviewed publications and submissions to the FDA and DEA. My 2025 and 2026 submissions focus on developments since 2025 related to 7-hydroxymitragynine (7-OH) with updates in kratom science. These also explain why I agree with the DEA, FDA, and NIDA that 7-OH and other synthetic derivatives warrant placement in Schedule I of the Controlled Substances Act (CSA) and therefore should be prohibited from legal marketing and possession except for DEA- and FDA-regulated research, but that natural kratom warrants continued licit consumer access.

Jack E. Henningfield, PhD 4800 Montgomery Lane· Suite 640 · Bethesda, MD 20814 (301) 718-8440

Additional Key Points

Surveys summarized by Henningfield et al. (2024) and Grundmann et al. (2025) indicate that the vast majority of natural kratom consumers are adults, most commonly beginning in their mid-twenties or later, who use for health and energy and not recreational effects.

National surveys, including Monitoring the Future and the National Survey on Drug Use and Health, have not found regular youth use of natural kratom products to be widespread. However, I am concerned that some 7-OH marketing approaches (including some products presented as “kratom”) may appeal to youth or others seeking recreational effects. This concern supports a minimum purchase age of 21 for all kratom products and CSA scheduling of 7-OH products.

Consistent with comments made during the August 12, 2026, Working Group meeting, numerous U.S. and international surveys show that people use kratom primarily for health and well-being, including use in place of coffee and other caffeinated beverages. Many report that kratom has been more effective, acceptable, and helpful in restoring daily functioning than FDA-approved medicines. These include use for energy and endurance, mental acuity, relieving stress, and to promote a healthy night’s sleep, relief of pain and depressed mood states (Garcia-Romeu et al., 2020; Grundmann et al., 2022; Smith et al., 2022; Smith et al., 2024; Bath et al., 2019).

As I mentioned, and at least one other commenter mentioned in the Working Group meeting, many veterans report using kratom to manage conditions that in some cases resulted from their service (e.g. pain, depression, and post-traumatic stress disorder). These reports are representative of common reports of kratom use and illustrates the importance of assuring licit regulated access to kratom products. Despite the fact that kratom is not FDA approved for such use, such reports are well documented, and consistent with reasons for use reported by adults in the general population. The distinguished combat veteran, Retired Lieutenant General, United States Marine Corp, and Congressman, 1st District of Michigan, Jack Bergman, has participated in congressional staff kratom science briefings that included presentations by NIDA Director Nora Volkow, myself and others. He has also posted an opinion piece on this issue on his congressional website. It is titled “Let’s Prevent the Feds from Jeopardizing Veteran Addiction Recovery”. It is well worth the two minute read. See it at https://bergman.house.gov/news/documentsingle.aspx?DocumentID=1129 – posted July 28, 2023.

I was asked how kratom use compares with cannabis use. Although both kratom and cannabis are widely reported to be used for health and well-being (DHHS, 2023; Henningfield et al., 2024; Grundmann et al., 2025), the evidence has shown that whereas a substantial share of cannabis use is recreational, most kratom use is not for recreational effects. In addition, much cannabis use, particularly recreational use, involves smoking. By contrast, most kratom consumption in the United States and globally is oral, including chewed leaves in Southeast Asia, brewed tea-like preparations, and swallowed powdered leaves. This pattern also differs from recreational opioid and

stimulant use, where smoking, injection, and nasal insufflation (“snorting”) are common routes used to intensify euphoric effects. In this respect, kratom and mitragynine use more closely resemble caffeinated beverage and related product use, where strong and rapid euphoria is generally not the primary motivation.

Regarding my support for CSA scheduling of 7-OH products, I discuss this in my 7-OH CSA eight-factor analysis (8FA) (Henningfield, Wang et al., 2025) and in my recent comment to DEA, FDA, and NIDA (Henningfield and Wang, 2026). In brief, I recommend scheduling concentrated and synthetic 7-OH products while preserving lawful access to natural botanical kratom products that contain only low, naturally occurring levels of 7-OH. I agree with the DEA that 7-OH but not kratom meets the statutory standard for “morphine-like addiction liability” including potential morphine like respiratory depressant effects (See DEA and FDA documents and notices in References). I also recommend clear threshold definitions, validated analytical methods, enforcement discretion for individual consumers, substance-specific surveillance, pathways to appropriate healthcare, and measures to avoid disrupting legitimate research and product development (See Henningfield and Wang 2026 comment to FDA and DEA in References).

Questions have been raised regarding the quantity of naturally occurring 7-OH in kratom products and the 7-OH in the body as a result of metabolism of mitragynine following kratom consumption. It has long been recognized that 7-OH concentrations in natural kratom leaf are very low and do not appear to contribute meaningfully to kratom’s safety profile or abuse-related risks. Similarly, animal and human studies have characterized the levels of 7-OH that may appear in the blood of animals and humans following kratom or mitragynine ingestion and documented that this form of 7-OH exposure was not associated with serious adverse events (See discussion by 2026 DEA and FDA and Henningfield and Wang notices and comments in References).

The evidence that such naturally occurring 7-OH in low levels in kratom products and as a result of kratom ingestion was considered in the 2025 DHHS recommendation to schedule (and thereby ban licit sale of 7-OH and three synthesized substances, and not natural kratom. The DEA clearly agreed and designed its 7-OH scheduling approach so as not to have the unintended consequence of banning natural kratom with low levels of 7-OH as may naturally occur as discussed in its threshold approach in its Notice of Intent to schedule 7-OH)

Similarly, many state kratom consumer regulations have limited the amount of 7-OH allowed in products to not exceed 2% of the alkaloid content and recommended that products with higher levels be considered adulterated.

The forgoing concerns about 7-OH’s effects as may occur following ingestion of highly concentrated 7-OH products, but not natural kratom products are consistent with the 7-OH performance standard approach in DEA’s notice to intent to schedule 7-OH with the threshold being defined as:

(A) Any botanical material of the plant Mitragyna speciosa, also known as kratom, and contains more than 0.050 percentage of 7-hydroxymitragynine on a dry weight basis, or

(B) Any alternative article to that described in (A), that is:

i. Resulting from synthetic methods and containing 7-hydroxymitragynine present in amounts greater than 0.050 percentage by weight/weight, weight/volume, or volume/volume or greater than 1.00 milligram of 7-hydroxymitragynine in the article, or

ii. Material derived from Mitragyna speciosa and further processed to manufacture alternative dosage forms such as extracts, concentrates, processed edibles, or pressed pills, and which may have materials that have been exposed to chemical, thermal, or other methods leading to chemical transformations that result in 7-hydroxymitragynine present in amounts greater than 0.050 percentage by weight/weight, weight/volume, or volume/volume, or greater than 1.00 milligram of 7-hydroxymitragynine in the article.

That unusual carve-out to allow products with low levels of a Schedule I substances was developed by DEA, as in many state kratom regulations, so that natural kratom products containing such low levels of 7-OH are not banned inadvertently. It matters because the CSA is normally read to prohibit any amount of a controlled substance in products that are not themselves controlled. A similar rare exception appeared in the 2018 Farm Bill (officially known as the Agriculture Improvement Act of 2018), which allowed raw hemp flower and crop material to be marketed and possessed at or below 0.3% delta-9 THC, making hemp and CBD products that met that standard lawful.

7-OH also appears in the bloodstream of kratom consumers as a product of mitragynine metabolism after oral consumption, as it does in several animal species. Yet neither oral nor intravenous mitragynine has been shown to serve as a robust reward in animal abuse potential studies, whereas 7-OH has morphine-like addiction liability (Henningfield et al. 2022, 2024; Reissig et al., 2025). It has likewise long been known that although 7-OH from mitragynine metabolism may contribute to the effects consumers seek, this exposure does not appear to pose a meaningful safety risk. Nonetheless, no level of kratom or mitragynine is risk-free, and labeling should discourage use beyond what is needed to obtain the desired health effects.

My general opinion has changed little since my first CSA 8-Factor Analysis that was submitted to the DEA, FDA & NIDA in 2016 (and published in a peer reviewed journal in 2018) in which I stated: “the very low risk of overdose poisoning and serious adverse events does not mean that they have not and will not occur.” (Henningfield, Fant, and Wang, 2018, p. 53).

At that time my position appeared to be similar to those of NIDA and DEA but differed from FDA's 2017 and 2018 statements suggesting that kratom carried opioid-like risks of death. That was a rare divergence among the three agencies. FDA's position was the outlier, yet it received wide media coverage and still resonates in many public communications today as some organizations and individuals continue to cite those statements that were abandoned by FDA several years ago based on the scientific evidence.

By 2024 with nearly a decade of monitoring and evaluation, FDA's position came more into alignment with that of NIDA's and DEA's. This change was reflected on its website, and still remains at the time of this writing:

> "In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports. However, in these cases, kratom was usually used in combination with other drugs, and the contribution of kratom in the deaths is unclear." (FDA, 2025c)

NIDA's current website states:

> "While there are no uses for kratom approved by the U.S. Food and Drug Administration, people report using kratom to manage drug withdrawal symptoms and cravings (especially related to opioid use), pain, fatigue and mental health problems.2,3,4 NIDA supports and conducts research to evaluate potential medicinal uses for kratom and related chemical compounds.
>
> NIDA also supports research towards better understanding the health and safety effects of kratom use. Rare but serious effects have been reported in people who use kratom, including psychiatric, cardiovascular, gastrointestinal and respiratory problems.1,5 Compared to deaths from other drugs, a very small number of deaths have been linked to kratom products and nearly all cases involved other drugs or contaminants.1,6,7,8,9,10"

Note that one of NIDA's references is to my own peer-reviewed article comparing the risk of death from kratom with that from opioids (Henningfield et al. 2019). That article, co-authored with other leading kratom science experts, concluded: "By any of our assessments, it appears that the risk of overdose death is >1000 times greater for opioids than for kratom. The limitations of the mortality risk estimate warrants caution in individuals with unknown factors such as use of other substances and medications, or other preexisting conditions."

To date, no kratom product or derivative has been submitted to or approved by FDA for the treatment of any medical disorder. Even so, the reasons for use widely documented in numerous U.S. studies support the conclusion that most kratom use in the U.S. is for health and well-being.

Furthermore, evidence from human surveys and animal studies has been promising enough regarding kratom and mitragynine safety and their potential efficacy for addiction

management generally, and for opioid use disorder treatment in particular, that formal efforts are now under way to develop mitragynine as a new drug. In June, 2026, NIDA announced funding and a collaborative effort to commence research that could eventually lead to FDA submission and approval of a mitragynine-containing medicine for the treatment of opioid use disorder. The work will be led by the kratom research program at the University of Florida. See announcement by NIDA at https://nida.nih.gov/news-events/news-releases/2026/6/nih-research-clears-way-for-study-of-experimental-treatment-for-opioid-use-disorder.

NIDA's announcement, included the following statement:

> "This IND is a major step toward expanding treatment options for the millions of Americans struggling with opioid use disorder, which has contributed to historically high overdose mortality rates," said Nora Volkow, M.D., director of NIH's National Institute on Drug Abuse (NIDA).

This is an exciting development for public health, but assembling the portfolio of clinical studies needed to support such a New Drug Application to FDA will likely take five years or longer. In the meantime, NIDA-supported research is guiding policy and efforts to preserve consumers' access to the potential life-saving benefits of kratom.

It was mentioned during the Kratom Working Group meeting that a ChatGPT search found apparently higher rates of kratom associated deaths than suggested by FDA's conclusion, specifically mentioning a CDC report involving 152 kratom associated deaths. I was asked to comment on this potential difference of opinion with FDA.

I commented that this 2019 CDC report illustrates the complexity of attributing deaths to kratom that were apparently not discussed in the ChatGPT assessment quoted in the Kratom Workgroup meeting. As I mentioned in the meeting, the ChatGPT assessment apparently did not discuss other factors and limitations, nor the fact that most of those 152 kratom-associated deaths involved other substances, including in its summary of the Colorado study supporting those conclusions and my assessment.

A published earlier assessment of mine on this topic and the CDC report may help understand the complexities. From Henningfield et al. (2022) Section 3.4.2.3 Kratom Use Associated Mortality:

> "The two most widely cited estimates of kratom associated mortality are based on world-wide reports over nearly 10 years (Food and Drug Administration, 2018; Olsen et al., 2019). FDA's statement noted that all but one involved other substances, and that case was under further investigation. Medical examiners or coroners reported kratom as the cause of death in 91 (59.9%) of 152 kratom positive decedents (out of 27,338 overdose deaths in 27 states), including seven for whom kratom was the only substance positive on postmortem toxicology, although other substances could not be ruled out (Olsen et al., 2019). In approximately 80% of kratom positive or "involved" deaths, decedents had a

history of “substance misuse”, with 65% of cases listing fentanyl as the cause of death, 32.9% heroin, followed by benzodiazepines, prescription opioids, and cocaine.

An earlier study (Gershman et al., 2019) cautioned that comprehensive toxicology might identify other substances contributing or causing death. We are not aware that any of the 93,000 drug overdoses estimated for 2020 included deaths due to kratom. That does not mean that there were no deaths in which kratom was the primary cause or a contributing factor; however, the signal is clearly low.

An assessment of various survey data concluded that the risk of kratom associated death was at least a thousand times lower than for morphine-like opioids (Henningfield et al., 2019). This is consistent with NIDA’s position (National Institute on Drug Abuse, 2019) and with the 2018 DHHS kratom scheduling rescission letter and the conclusions drawn by Assistant Secretary of Health Brett P. Giroir, MD.”

The Colorado study that I mentioned in my oral response and which was cited in the CDC MMWR report evaluated 15 deaths associated with kratom use. That study found that 11 cases involved multidrug ingestion (2-6 drug with 8 cases including opioids). Additional toxicology screening was attempted for the four cases in which police records did not list any substances in addition to mitragynine. In three of the four cases in which residual blood was available for testing, other drugs were found. Residual blood was not available for the fourth decadent (Gershmanet al., 2019).

The key lesson learned by FDA, NIDA and leading researchers is that although kratom cannot be ruled out as having contributed to deaths in which it was listed as causal by medical examiners, if they did not test for other substances, including 7-OH, it is not possible to rule other substances out. Furthermore, to date there has not been a mechanism established by which kratom or mitragynine might cause an overdose death (e.g., such as respiratory depression in the case of opioids), nor has a mitragynine dose been established that is considered lethal despite efforts to establish the lethal dose in animal studies.

Citations and Resources available online and/or on request to Pinney Associates at dwang@pinneyassociates.com.

Jack E. Henningfield, PhD

Vice President, Research, Health Policy, and Abuse Liability

Adjunct Professor of Psychiatry and Behavioral Sciences (Behavioral Biology), Part-time, Department of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine

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