Comment on the Proposed 7OH Threshold: Life-Saving NIH.gov Lab Data

- IN GOD'S PLANTS WE TRUST -

Docket HHS-OASH-2026-0232

VIATL NOTE: PLEASE READ ALL HIGHLIGHTED CONTENT FIRST

Submitted to: Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Submitted by: Sterling Carl Tucker, Founder, GOD'S KRATOM KINGDOM

Date: September 8, 2026

Subject: NIH.GOV DATA PROVING NATURALLY OCCURRING 7OH SAFETY - Alternative Threshold Methodology for Botanical Mitragyna speciosa Material

Requested action: I respectfully ask HHS and DEA not to criminalize unenhanced, natural, god-made kratom leaf powder, regardless of what 7OH the plant produces naturally. There is ZERO scientific data to even suggest that it will benefit our health as Americans to have a fixed, naturally occurring plant and godmade 7-hydroxymitragynine concentration ceiling. This document contains a massive amount of peer-reviewed NIH.gov published lab data to support protecting 7OH liberty.

We should not make a law that destroys the life & health of Americans for peaceful possession or consumption of kratom, a plant made by the maker of the animal kingdom. 7OH is a naturally occurring (GOD-MADE) compound. I ask HHS to protect & preserve my proven life-saving health needs for kratom 7OH as an AMERICAN worker & tax payer.

Please do not allow anyone to endanger my health by taking away my food, aka plants, given to us Americans by our Maker, so we behave well. Please look out for working-class family citizens like myself. There is no legitimate data to support the false claim that naturally occurring 7OH is an imminent public-health risk. No controlled human trials establish or even slightly suggest that botanical material becomes an imminent hazard at 0.050% rather than at another value.

NIH.GOV PUBLISHED LAB-DATE ABOUT 7OH:

"By any of our assessments, it appears that the risk of overdose death is >1000 times greater for opioids than for kratom." https://pubmed.ncbi.nlm.nih.gov/31647958/

A godsend piece of scientific data about **7-OH from NIH.gov** regarding **kratom's potential to END THE EPIDEMIC:**

"Data also suggest that kratom has the potential to prevent opioid overdoses, a rising killer in the U.S. population."

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5601368/

"The most significant advantage of kratom is that it has not caused any overdose deaths."

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5601368/

"In a previous report, both mitragynine and 7-OH were found to display G protein-biased agonism at the mu-opioid receptor,8 a concept which gained significance in drug discovery over the recent years, where G protein-biased mu-opioid receptor agonists may deliver the desired analgesia without the unwanted side effects."

"Overall, this work provides knowledge that can be used for creating novel pain therapeutics based on kratom. The Mitragyna alkaloid scaffold represents an attractive framework for the development of functionally biased opioid modulators, which may exhibit improved therapeutic profiles as analgesic drugs. In particular, respiratory safety is of major importance to clinicians due to the risk of fatal outcomes and because

respiratory suppression is the primary cause of opioid-related overdose mortality. **The pharmacological profile of 7-OH as a partial G protein-biased agonist at the mu-opioid receptor would signify a desirable, wide analgesia-respiratory depression therapeutic wndow."i**

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6598155

"By any of our assessments, it appears that the risk of overdose death is >1000 times greater for opioids than for kratom." https://pubmed.ncbi.nlm.nih.gov/31647958/

The most significant difference from opioids is that, even at very high doses, kratom is much less likely to depress respiration (to a fatal degree) than classical opioids (Singh, Narayanan et al., 2018, 2016; Varadi et al., 2016).

Executive summary

FDA's 2025 assessment reports that 341 consumer-supplied kratom samples contained 7-OH ranging from below 0.005% to 0.21%, with a mean of 0.01%. **The maximum FDA self-reported data for naturally occurring 7OH exceeds the proposed 0.050% cutoff by over 400%. This supports asking HHS to explain how it distinguished natural variation, processing effects, and deliberate enrichment when choosing the boundary.** [2, 3]

- Primary request: exempt verifiably unenhanced dried leaf from being criminalized, regardless of the amount of 7OH the plant naturally made.
- **If HHS retains a numerical botanical line, do not use 0.050% as it is not close to what the kratom plant can & does naturally produce.** There is ZERO data to support the false claim that naturally occurring 7oh is an imminent public-health risk!

I have manufactured and sold kratom products in the United States for nearly a decade. My experience includes large botanical lots (+2,000 pound shipments), routine third-party laboratory testing, and massive direct communication with thousands of American kratom consumers. I support accurate labeling and proportionate consumer protections. I oppose criminalizing unenhanced leaf solely because its measured 7-OH concentration exceeds a fixed threshold.

America's commitment to liberty should guide this decision alongside the shared goal of protecting public health. Kratom is the most important part of my physical & emotional health & happiness. Peaceful adult possession or consumption of a plant or its naturally occurring compounds should not lead to imprisonment or forfeiture of property. Why would we destroy an American's life & lock them up over a life-saving plant like kratom? There are literally millions of Americans who explain how it has made them a patient, productive, polite person because when humans feel good, they act good.

My minimum request in this threshold proceeding is an express exemption for verifiably unenhanced leaf, regardless of its naturally occurring 7-OH concentration. I am willing to consider a separate approach to other 7-OH products if access to naturally occurring 7OH is fully protected, but this comment does not endorse criminal penalties for those God-made products.

1 Evidence for the botanical threshold is unjustifiable.

DEA proposes a 0.050% dry-weight threshold for botanical Mitragyna speciosa material. A boundary supposedly intended to exclude unenhanced leaves should be supported by representative authenticated leaf samples and validated measurements. The FDAs own natural, unenhanced levels of kratom samples were over 400% above the 0.05% limit, which is unjustifiable & directly contradicts the FDAs own findings of natural levels. Marketplace samples alone cannot establish natural variation. **I ask HHS to publish the evidence connecting its selected threshold to both product identity and risk. [2, 3]**

Evidence	**Reported 7-OH**	Interpretation

Evidence	Reported 7-OH	Interpretation
341 consumer-supplied samples summarized by FDA	<0.005-0.21%; mean 0.01%	Origin of high samples not established
King's Kratom raw organic dried sample (May 2019)	0.352% by UPLC	Reporting basis and origin require confirmation
KINGSKRATOM powder leaf sample (Nov. 2019)	0.228% by UPLC	Reporting basis and origin require confirmation

Evidence note: The two recovered percentage-based COAs are distinct reports with a simple mean of 0.290%. This small set is not an estimate of my historical average or of the natural population distribution. The reports describe botanical samples and UPLC testing that can be conducted when wild-harvested from the best wild kratom trees in Indonesia.

2 Concentration and human exposure.

A percentage is not a human dose. Actual exposure depends on serving mass, route, frequency, product matrix, absorption, co-use, and the balance of other alkaloids. DEA acknowledges that natural leaf contains a complex alkaloid matrix and that isolated or semi-synthetic formulations present a distinct profile. **No controlled human trials establish or even slightly suggest that botanical material becomes an imminent hazard at 0.050% rather than at another value.**

NIH/NIDA therefore distinguishes the general respiratory profile of kratom leaf or mitragynine from laboratory findings involving 7-OH; it does not support treating a low concentration in full-spectrum leaf as equivalent to rapidly delivered isolated 7-OH. [4, 8, 9]

The hypothesis that mitragynine and the complete alkaloid matrix may modify 7-OH's effects is scientifically plausible but is not yet established as a neutral-sum mechanism in humans. I therefore ask HHS to preserve that distinction and support research rather than assume equivalence between leaf and isolate.

Kratom has MITRAGYNINE with 7OH which transforms the response to 7OH. Mitragynine causes respiratory stimulation; consuming mitragynine with natural 7oh in kratom DOES NOT cause significant respiratory depression, according to NIH.GOV published lab data included in this submission.

3 Manufacturer experience and documentary evidence

My company has sold unenhanced, wild-harvested botanical kratom for nearly a decade. I have received hundreds of unsolicited consumer reports describing improved function, work capacity, or quality of life, frequently in the context of pain. **Over the past DECADE, I have not received even one single report alleging a serious adverse event from our botanical leaf, which has set records for proven naturally occurring 7oh.** These observations are not a controlled clinical study, so they should not be treated as incidence data; they are real-world signals supporting continued access, surveillance, and rigorous research rather than accidental criminalization of botanical lots.

Before I found botanical kratom, I experienced severe adverse reactions to prescribed opioids. On two occasions, I regained consciousness in an emergency room after becoming unconscious due to new prescriptions, experiences that I understood as close calls from accidental prescription overdose. Botanical kratom is the GOD-MADE alternative I personally choose to avoid returning to those dangerous man-made drugs sold by doctors. I do not offer that experience as a clinical trial or as proof of how every consumer will respond. I offer it because policy must account for a foreseeable consequence: some people who lose access to botanical kratom will return to prescription or illicit opioids, with well-documented proven overdose risks of preventable death.

4 Public Health and Proportionate Regulation

Pain carries profound personal and economic consequences. Loss of an option on which consumers rely will cause some to return to prescription or illicit opioids. CDC recorded 54,045 opioid-involved overdose deaths in 2024 alone. That figure underscores why substitution effects and consumer displacement deserve examination. [11] The known +50,000 AMERICAN DEATHS that happen every year are caused by MAN-MADE opioids. NONE of the overdose deaths are from Kratom alone. Kratom is thousands of times safer when considering death statistics.

Every product, even water, can result in death if misused. Whether it's a car, a hammer, food, or playing sports, ALL of them result in death some of the time. That does NOT mean we should outlaw all those things! It means there should be clear accurate warnings. This is the LAND of LIBERTY! Not the land of paranoid anti-plant tyrants.

I respectfully ask HHS to identify the deaths and serious adverse events attributed specifically to 7-OH, distinguish isolated or enhanced products from unenhanced leaf, explain co-exposures and uncertainty in causal attribution, and relate the evidence to the proposed threshold. Comparisons with acetaminophen or NSAIDs should account for exposure and patterns of use. Raw death totals cannot establish comparative safety, and incomplete surveillance cannot establish an absence of risk.

NSAIDs also have meaningful gastrointestinal, renal, and cardiovascular risks. A frequently cited 1999 review estimated approximately 107,000 annual hospitalizations and 16,500 deaths from NSAID-related gastrointestinal complications among arthritis patients alone. Lab data & death counts CLEARLY show that over the counter NSAIDs are far more dangerous than the most exaggerated 7OH death claims.

Over 15,000 elderly Americans are KILLED every year due to NSAIDs, dangerous molecules that are not needed when an American has kratom to help with their pain. It is evil to take natural, god-made plants & force us on dangerous, noneffective death-causing gas station drugs like NSAIDs. PLEASE do not allow such cruel harm to my health as an American to occur. I need kratom; my maker made it for me & all his favorite animals. Human is an animal, IDK how anyone does not understand that fact. Plants/treats are what create good behavior & health in all animals, especially humans. Please do not harm American health & happiness by taking away the people's right to choose what plants they want to eat.

5 Requested determination

I respectfully request that HHS advise the Attorney General and DEA to:

- Decline to use 0.050% by dry weight as a stand-alone Schedule I boundary for botanical Mitragyna speciosa material.
- Exclude verifiably unenhanced leaf from temporary scheduling regardless of the naturally occurring 7-OH concentration, using the provenance, process, and testing criteria above.
- At minimum, delay any numerical botanical threshold until a transparent, validated study establishes natural variation, analytical uncertainty, processing effects, and a human risk relationship.

A policy should account for the harms it may create as well as those it seeks to prevent. I share the agencies' goal of preventing injury and protecting families! THANK YOU for caring about our health! I ask HHS to pursue that goal while preserving individual choice, access to unenhanced kratom, and the livelihoods of Americans who depend on it. I know, as certain as the sunrise, that criminalizing natural, God-made plants will greatly harm my health & the health, happiness & productivity of millions of my fellow Americans. It is a crime to violate American liberty. Kratom is UNQUESTIONABLY safer than tobacco or alcohol or man-made opioids! HHS and DEA, we love you, please don't cause Americans to be locked into cages over GOD-MADE PLANTS.

VITAL SCIENTIFIC PUBLISHED LAB-DATA REGARDING 7OH:

The following is a cut-and-paste from my kratom business:

"Among these alkaloids, 7-hydroxymitragynine showed the most potent opioid effect on the electrically-stimulated contraction (pD (2) = 8.38 +/- 0.12). The potency, calculated using pD (2) values, was 30- and 17-fold higher than that of mitragynine and morphine, respectively. Antagonism of naloxone on concentration-response curves for 7-

hydroxymitragynine confirmed its opioid effect. These results suggest that the opioid effect of M. speciosa is mostly based on the activity of 7-hydroxymitragynine." https://pubmed.ncbi.nlm.nih.gov/15770543/

Additionally, mitragynine pseudoindoxyl developed analgesic tolerance more slowly than morphine, showed limited physical dependence, respiratory depression, constipation, and displayed no reward or aversion in CPP/CPA assays, suggesting that analogs might represent a promising new generation of novel pain relievers.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5344672/

Here is an important Godsend bit of scientific data about 7-OH from NIH.gov about kratom's potential to end the epidemic! Kratom saves by preventing the way too common lethal side effect of respiratory depression & other common side effects from painkillers:

"In a previous report, both mitragynine and 7-OH were found to display G protein-biased agonism at the mu-opioid receptor,8 a concept which gained significance in drug discovery over the recent years, where G protein-biased mu-opioid receptor agonists may deliver the desired analgesia without the unwanted side effects."

"Overall, this work provides knowledge that can be used for creating novel pain therapeutics based on kratom. The Mitragyna alkaloid scaffold represents an attractive framework for the development of functionally biased opioid modulators, which may exhibit improved therapeutic profiles as analgesic drugs. In particular, respiratory safety is of major importance to clinicians due to the risk for fatal outcomes and because respiratory suppression is the primary cause of opioid-related overdose mortality. The pharmacological profile of 7-OH as a partial G protein-biased agonist at the mu-opioid receptor would signify a desirable, wide analgesia-respiratory depression therapeutic window."
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"The most significant advantage of kratom is that it has not caused any overdose deaths.""Data also suggest that kratom has the potential to prevent opioid overdoses, a rising killer in the U.S. population."https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5601368/

DID YOU KNOW THAT IBUPROFEN & OVER-THE-COUNTER NSAIDs KILL OVER 16,000 AMERICANS PER YEAR?

GOOGLE SEARCH THIS: "How many Americans die from ibuprofen annually?"

Americans have a life-threatening condition of suffering that is killing so many people, but we can and will change this growing epidemic with this plant made by the creator of this earth. Please share the SAVE THY NEIGHBOR kratom awareness movement by sharing life-saving information about kratom from NIH.gov

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6598155/

We are in this industry to serve our country and the American people and end a problem that is currently taking one innocent American citizen's life every 11 minutes; every 11 minutes, another American is found dead! More needed and wanted American lives are taken from the opioid epidemic than were taken from all terrorist acts combined! Beyond any shadow of a doubt, kratom is the only way I was able to free myself from ending up dead from an opioid! I'm so grateful that I have something that is able to help alleviate my pain from scoliosis and yet not take away my ability to work! That is the magic of kratom: it takes away the pain for me without taking away my ability to perform well or my ability to focus strongly, or my ability to always treat others kindly. I would not be where I am in life with productivity and my ability to contribute to society without kratom.

The future of our country, in the future of each and every human as an individual and their family, is all controlled and determined by the way humans feel. It is so important that we start making plants that control the way humans feel part of our daily conversation so that they can become part of every human life, and every human will feel happy and be productive every day instead of the daily tragedies that the news is always full of, literally every day.

Let's make our lives in this part of American history the happiest and most productive of all time. We absolutely can, and we absolutely will, if we can control and change the way humans feel as individuals, and Kratom gives me the ability to do that without fail!

Thank you for being part of my life. I'm here to make your life awesome. Together, we can make life on Earth anything we decide it's going to be, and it can be everyone's definition of perfect. So let's get to it. I hope to hear from you soon, and to serve you forever.

As Americans, we have a huge advantage as USA citizens by being able to access the United States National Library of Medicine & the National Institutes of Health. With this source, we get access to the information that can save 1 American life every 11 minutes!!! THIS IS A REALLY BIG DEAL—saving more Americans' lives from early & preventable death than forever removing terrorism. More innocent lives are taken from opioids by accident than any act of terrorism. It is a terrifying fact, and kratom has always been my lifesaving plant to keep me safe in my American pursuit of happiness. Please share the SAVE THY NEIGHBOR kratom awareness movement by sharing lifesaving information about kratom from NIH.gov https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6598155/

We are here to contribute to your life! Together, we can contribute so much to our country & save 1 American life every 11 minutes. We are here to always guarantee the best product and be the best contribution to your life—improving it in a sustainable way. We are here to create a product of perfection & evolve the Kratom industry with a product that will work wonders to help end our country's opioid epidemic, which is currently taking over 100 AMERICAN LIVES PER DAY! Together we can change this tragic fact as we work to make life & the pursuit of happiness the safe path it was meant to be!

Passionately pursuing American health and happiness,

Sterling Carl Tucker

GOD'S KRATOM KINGDOM

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The World's Strongest Lab-Verified Kratom

LET'S MAKE AMERICA SAFE & PRODUCTIVE WITH KRATOM

MORE LIVE SAVING NIH.GOV PUBLISHED INFORMATION ABOUT 7OH FROM NIH:

Direct quote from the USA National Library of Medicine & National Institutes of Health:

UNVEILING 7-HYDROXYMITRAGYNINE AS THE KEY ACTIVE METABOLITE

Debilitating pain is a constant backdrop of daily life, resulting in personal suffering, substantial health costs, and an economic burden for society. Pain is not only a disabling symptom of many medical conditions but also a disease state in its own right. With its prevalence in 20–30% of the adult population, chronic pain affects more people than heart disease, cancer, and diabetes combined and will continue to grow as our population ages.1 Pain medicine represents one of the most rapidly developing medical specialties of today, with effective pain control being a therapeutic priority. Chronic pain is still poorly managed because of the lack of efficacious therapies and significant adverse side effects of currently available analgesic drugs.2 Now, the article of Kruegel et al. presents different pain therapeutics based on a natural product, Mitragyna speciosa, and new insights into its pharmacology and analgesic activity.3

Opioids are highly effective analgesics and the most widely prescribed class of medications in the US.4 Most opioid analgesics (e.g., morphine, fentanyl, and oxycodone) used in clinical practice target mu-opioid receptors.2 Medical use and misuse of opioids have strongly increased in the past decades. It has emerged as a major public health threat due to the dramatic rise in opioid-related overdose deaths (over 47 000 in 2017 or 67.8% of all drug overdose deaths) and diagnoses of opioid-use disorder (addiction) associated with prescription opioids (1.8 million in 2016). The cost of the opioid epidemic in the US is estimated to be $80 billion annually.4,5

Medicinal plants are tremendous sources of new drug candidates. Lately, there has been a renewed interest in natural product research due to the failure of alternative drug discovery methods to deliver many lead compounds in key therapeutic areas such as pain. Mitragyna speciosa, known as “kratom”, a plant native to Southeast Asia, has been used traditionally as a stimulant and analgesic and for the treatment of opioid ddiction.6 During the past years, kratom use has

become increasingly popular in the US, where the consumption of kratom leaves was reported as an efficacious treatment of pain, particularly in cases where other available treatments have either failed or caused intolerable side effects.7 A significant number of users have also reported use of kratom as a tool to stop or reduce the use of prescription or illicit opioids—a potential application that is nowadays gaining high attention given the ongoing opioid abuse epidemic in the US.

Given the unique and fascinating pharmacology surrounding mitragynine, the major alkaloid in kratom, Kruegel et al.3 present a systematic study on the metabolism-dependent mechanism for the analgesic effects of mitragynine. It offers a possible explanation for the apparently safer profile of mitragynine compared to classical opioids. In their report, the authors rationalized the importance of 7-hydroxymitragynine (7-OH) as an active metabolite of mitragynine and a key mediator of its analgesic activity, thus providing the essential in vivo link signifying the pharmacological relevance of 7-OH

In a previous report, both mitragynine and 7-OH were found to display G protein-biased agonism at the mu-opioid receptor,8 a concept which gained significance in drug discovery over the recent years, where G protein-biased mu-opioid receptor agonists may deliver the desired analgesia without the unwanted side effects. In their latest work published in ACS Central Science,3 the authors have proven that, besides the conversion of mitragynine to 7-OH via chemical oxidation, mitragynine can also undergo biotransformation in vitro in both mouse and human liver preparations to 7-OH, with cytochrome P450 3A4 as the main metabolic pathway (Figure Figure11). In both microsome preparations, 7-OH was the major metabolite and was produced concomitant with the disappearance of mitragynine. The metabolic conversion was more efficient in human liver microsomes suggesting that an appreciation of interspecies differences is likely to be important for understanding the pharmacology of mitragynine. Mitragynine as well as 7-OH were highly stable in mouse plasma, indicating that plasma metabolism does not contribute significantly to the biotransformation of these alkaloids. 7-OH was reported earlier as having much higher analgesic potency in mice after subcutaneous (s.c.) administration compared to mitragynine and morphine.6 Using genetic approaches, the authors demonstrated in vivo that mitragynine and 7-OH produce analgesic effects acting through a mu-opioid receptor-dependent mechanism.3 They have demonstrated that metabolic conversion of mitragynine to 7-OH occurred also in vivo, where both alkaloids were detected in the plasma and brain, confirming that 7-OH is formed as a metabolite of mitragynine and that it enters the brain. Further, the authors have proven in mice that 7-OH contributes to the analgesic activity of mitragynine as a metabolite when comparing the pain response of compounds given at equianalgesic s.c. doses and confirmed this by quantifying concentrations of 7-OH in the brain, thus being consistent with 7-OH as the primary mediator of central analgesic activity. At the same time, other groups independently described the formation of 7-OH as a metabolite of mitragynine in vitro and in vivo.9,10

However, pharmacokinetic studies will be required to elucidate the importance of 7-OH as a mitragynine metabolite in man, where the interspecies differences in the metabolic processes must be carefully considered. Overall, this work provides knowledge that can be used for creating novel pain therapeutics based on kratom. The Mitragyna alkaloid scaffold represents an attractive framework for the development of functionally biased opioid modulators, which may exhibit improved therapeutic profiles as analgesic drugs. In particular, respiratory safety is of major importance to clinicians due to the risk for fatal outcomes and because respiratory suppression is the primary cause of opioid-related overdose mortality. The pharmacological profile of 7-OH as a partial G protein-biased agonist at the mu-opioid receptor would signify a desirable, wide analgesia-respiratory depression therapeutic window. Many challenges still lie ahead in the process of solving the current opioid epidemic.

Will this plant save 47,000 American lives per year? It depends on your choice of conversation...

So is kratom really a good way to avoid pain & a high risk of accidental death? According to the International Journal of Drug Policy, quoting several renowned doctors & pain specialists:

The most significant difference from opioids is that, even at very high doses, kratom is much less likely to depress respiration (to a fatal degree) than classical opioids (Singh, Narayanan et al., 2018, 2016; Varadi et al., 2016). Further, at the molecular level, mitragynine has a chemical structure that is quite different from classical opioids such as morphine, which are mostly derived from the alkaloids of the opium poppy (Adkins et al., 2011; Kruegel & Grundmann, 2018; Prozialeck et al., 2012; Takayama, 2004). Recent studies indicate that even though mitragynine acts on opioid receptors, its overall molecular actions are quite different from those of classical opioids (Henningfield et al., 2018; Prozialeck et al., 2012). In two recent studies, Varadi et al. (2016) and Kruegel et al. (2016)demonstrated that mitragynine and several related compounds act as G protein-biased agonists at the mu-opioid receptor (MOR). In other words, although they activated G

protein-mediated signaling pathways, much like classical opioids, they did not activate the β-arrestin-2 signaling pathway, which has been implicated as a mediator of some opioid-induced side effects, including respiratory depression (Raehal & Bohn, 2014; Schmid et al., 2017). Accordingly, the avoidance of β-arrestin-2 activation may in part explain the apparent respiratory safety of kratom, despite other opioid-like effects. These studies also showed mitragynine to be a partial agonist at MOR, as compared to most classical opioids, which are full agonists. Partial activity is also expected to attenuate the severity of side effects. For example, buprenorphine, a partial agonist at MOR, exhibits a dose ceiling for respiratory depression (Dahan et al., 2005).

Importantly, the improved side effect profile of mitragynine and related compounds has also been supported by preliminary animal studies. An early study with mitragynine demonstrated attenuated respiratory depression and constipation for this compound compared to the classical opioid morphine in several animal species (Macko, Weisbach, & Douglas, 1972). Further, the Varadi study (Varadi et al., 2016) demonstrated in mice that a mitragynine-derived compound, mitragynine pseudoindoxyl, induced marked analgesic effects, but with attenuated respiratory depression, slower development of tolerance, and lower rewarding effects than morphine. Accordingly, both the natural compounds in kratom (e.g. mitragynine) and synthetic derivatives thereof may represent a new class of opioid-acting drugs with an improved window between therapeutic effects and negative side effects.

As a result of its ability to interact with opioid receptors, mitragynine is often referred to as an "opioid". On the other hand, a large volume of evidence indicates that mitragynine produces physiological, biochemical and behavioral effects that differ from those of classical opioids. Even though some effects of mitragynine may involve partial activation of MOR, mitragynine is able to interact with many other receptors that classical opioids do not bind (Boyer et al., 2008). In light of this evidence, mitragynine and its analogs can best be described as "atypical opioids" (Raffa, Pergolizzi, Taylor, Ossipov, & Group, 2018), and may actually represent a unique class of drugs.

As citizens of the United States of America, each and every one of us has the incredible life advantage of learning what actually works and what doesn't work based on medical data obtained from a non-bias group, and our country's NIH hub is the perfect place to do the job. I believe, as our founding fathers did, that each of us has a RIGHT to LIFE, LIBERTY, & the pursuit of HAPPINESS. It is called the "pursuit" of happiness because happiness is not something that we obtain & then have forever, but rather something that we feel while living in a way the contributes to each other which requires continual action. So let's pursue happiness by being caring humans that look out for each other & share lifesaving information directly from the USA National Institutes of Health.

Kratom is a TRILLION-dollar godsend for the American economy. People do what they feel like doing; when they feel good, they do good. Please do not allow our nation to attack itself by putting American workers in cages over plants. It is no different from caging humans over religion. GOD is my religion, and GOD made the plants for me to be patient, polity, productive & positive with. They make me a significantly more valuable member of our nation. PLEASE PROTECT OUR HEALTH & PRESERVE OUR PLANTS!

Closing Statement to the BOSS HHS and DEA

My Big Brother, aka My Government 💪🤝💕

First of all, thank you so infinitely much for having this public comment period and caring to listen to us American workers!! Whenever anything is requested of me by my government, I will always do everything possible to successfully fulfill the request.

THIS DOCUMENT CONTAINS SUBSTANTIAL QUALIFYING SCIENTIFIC LAB DATA TO NOT EVEN SLIGHTLY CONSIDER MAKING KRATOM ILLEGAL BASED ON ITS NATURALLY OCCURRING 7OH LEVELS.

I am an American Kratom manufacturer. I have over a decade of experience with kratom around the clock. Very few people, if any, have as much education and expertise about 7oh from firsthand experience as I do. I've owned a business from the age of 12; at 14, I was featured in several newspapers and then on KXLY Channel 4 News. At 15 years old, Idaho State Senator Larry Craig asked me to teach the youth of Idaho how to start and run a business successfully, and I still own and am successfully running my business thanks to kratom.

I am confident I am one of the top experts in our country regarding 7oh safety science. I say that because this plant literally saved my life, so I love researching it and everything about it. Kratom is my profession and also my obsession because it literally saves lives. I have done a massive amount of research on nih.gov over the last decade and have included a lot of it here for you. I was an honor student at Utah State University and have collected a trove of nih.gov peer-reviewed scholarly articles published establishing incredible life-saving health benefits of Kratom and 7oh.

I am a sincere, kind, loving, caring, contributing, peaceful, productive, profitable American business owner, father, son, friend, and citizen. My brother is a Utah State trooper; I am from an LDS family of 10 children. Please do not destroy my life, health, happiness, hope, and everything by making my God-made Kratom plant illegal because of its 7oh levels. I don't care if people make 7OH isolate or tablets illegal. I care that my natural, whole, organic, wild-harvested Kratom leaf is not taken from me or made illegal due to the minuscule level of naturally occurring Kratom 7OH alkaloid levels suggested at 0.05%.

PLEASE do not make any Kratom illegal. This law is supposedly intended to not make the plant illegal, but it is unquestionably going to make the plant illegal based on my decade of experience as a large Kratom manufacturer in our country due to the minuscule 7OH level cap that is proven incredibly inaccurate, even by the FDA's own samples of naturally occurring 7OH, which was over 400% higher than the suggested limit. This irrational, minuscule, naturally occurring 7OH cap would unquestionably destroy the lives of so many Americans, making harmless, hard-working people categorized as criminals because of their food.

Making Kratom illegal will harm our economy, American productivity, our country's core beliefs in Liberty, and our moral standing with our maker for taking his plants away from his people in his country. Please reach out to me, and I will provide you with a massive amount of NIH.gov-published scientific data to unquestionably establish its importance and life-saving benefits for us Americans.

This submission has a ton of NIH.gov copy-and-paste quotes stating the incredible life-saving benefits that Kratom brings to us Americans. We have a growing opioid overdose epidemic, and taking away the safest opioid that we are aware of is the most guaranteed way to increase the epidemic. Each and every life that is taken will be on our hands for not seeking to protect life and Liberty—to choose what we want for our health instead of being forced. There is zero data that I have ever seen to suggest that any amount of Kratom extract, isolate, or anything like that is as dangerous as ibuprofen and over-the-counter nonsteroidal anti-inflammatory drugs, which painfully kill over 15,600 elderly arthritis patients per year and put over 100,000 in the emergency room. With the most absurd, exaggerated, falsified claims about 7OH, there has never been a number even slightly close to that proven, established number from gas-station NSAIDs.

I am going to write to HHS and Robert Kennedy separately, but I'm also going to include this in the main document because it is monumental for our country's prosperity. Anyway, I would like to present a proposition that will improve liberty and generate an additional new $3 trillion dollars per year of government revenue. I know that sounds impossible, but I have a guaranteed method of doing it and making this current administration the most popular, loved administration in human history, one that will get Nobel Peace Prizes for winning and ending the war on drugs. The People's Safer Substance Source. It creates a government-controlled multi-trillion-dollar annual superpower, but this document is about kratom laws, not economic opportunities, though I just want to mention it.

I used to be so absurdly lazy... I still remember the very first day I ever got kratom. From that first day, I started working a minimum of 8 hours a day as a business owner and would often work 12 to 14 hours voluntarily and intentionally. Kratom enhances my productivity prophetically . The government's Census Bureau used my address for its economic and worker statistic calculations, and I would report to them daily, and my average work week was between 70 and 100 hours, and that is exclusively—and I mean exclusively—for certain because of kratom. If Kratom gets taken from my life, I'm going to be a hippie bum alcoholic living with my mom and dad for the rest of my life 😂 I currently own my own house and I've been here for almost a decade a few blocks away from my parents who I see daily because I love them and I'm a good moral productive kind person because of kratom. Kratom is the only plant I've ever had that consistently helps me feel good without causing any impairment and it actually causes enhancement. I'm a significantly more intelligent patient polite positive pleasant person when I have kratom.

This law that is being suggested having any sort of a maximum value for naturally occurring 7oh in kratom leaf would destroy the lives of a massive number of Americans. No one has anything to gain by taking away Liberty, and we all have literally everything to lose. Tobacco alone is killing over 500,000 Americans per year, why on Earth would that be legal and yet Kratom

is being criminalized when there is no number even close to 500,000 per century accused of Kratom yet there is over 500,000 dead Americans per year proven and known scientifically because of tobacco. In addition to this alcohol poisoning kills over 200,000 Americans per year, it's more dangerous than every illegal drug combined. Why on Earth are our plants even being discussed by anyone when we have known proven Killers like alcohol and tobacco. Also alcohol and tobacco should not be illegal, they should have proper warnings and be government distributed which is the way it is for the most part and that's fine and fair everybody knows the risks if they choose to smoke cigarettes and those that die from it shows that they knew that was a risk. We need to focus on safety which means when someone is saved from being involuntarily hurt. If a product has warnings, just because it's dangerous does not mean anyone should make it illegal. In America we have a constitutional right to property, we are supposed to anyway. Driving a motorcycle is dangerous and results in death every single day, that does not mean we should make motorcycles illegal and put people in cages if we see them driving one. The purpose of government is not to be a mom and dad, it's to be a big brother that looks out for people and in exchange we will look out for Big Brother.

Unfortunately I'm out of time because I have to submit this today. I did not submit this before the last day because I honestly did not think and still do not think that anyone would listen to or care about an American. But maybe I'm wrong, maybe we will see people protect Liberty and look out for us American workers and our health and happiness which will both be permanently destroyed by taking our plants. The seal of our nation has an eagle, in one hand it has leaves, Kratom is a leaf. It is literally the seal of our nation. Please do not violate and destroy our nation and our Liberty and our lives and our health and our happiness by taking our plants from our lives as Americans and putting who knows how many Americans in cages with this new anti-god made plant law. I sincerely love and care about each and every part of our country especially big brothers AKA any government worker because you are what make us a country, you're who's on the world stage representing us all and we sincerely care about and appreciate each and every government worker. Please care about us and do not make us criminals over a plant made by God. I have a sincere desire to always obey the law, and if it's made illegal, I just won't have it anymore and I'm serious going to go be a hippie living with my parents instead of a multi-billionaire American businessman who dominates the Kratom market on an international level adding trillions of dollars to our economy over the next century.

Passionately pursuing American health and happiness,

Sterling Carl Tucker

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References

1. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health. Extension of Comment Period, Docket HHS-OASH-2026-0232, 91 Fed. Reg. 55104 (Aug. 26, 2026). Source

2. Drug Enforcement Administration. Notice of Intent: Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I, 91 Fed. Reg. 40917 (July 6, 2026). Source

3. U.S. Food and Drug Administration. 7-Hydroxymitragynine (7-OH): Analysis of Data and Scheduling Recommendation (July 2025), including the 341-sample summary. Source

4. National Institute on Drug Abuse. Kratom: current research summary, including respiratory distinctions between leaf/mitragynine and 7-OH. Source

5. Todd DA et al. Chemical composition and biological effects of kratom (Mitragyna speciosa): In vitro studies with implications for efficacy and drug interactions. Sci Rep. 2020. Source

6. Sharma A et al. Simultaneous quantification of ten key kratom alkaloids in commercial products. Drug Test Anal. 2019/2021 PMC record. Source

7. Kruegel AC et al. 7-Hydroxymitragynine is an active metabolite of mitragynine and a key mediator of its analgesic effects. ACS Cent Sci. 2019. Source

8. Gonzalez JDZ et al. Mitragynine and 7-hydroxymitragynine: bidirectional effects on breathing in rats. Br J Pharmacol. 2025. Source

9. Henningfield JE et al. Respiratory effects of oral mitragynine and oxycodone in a rodent model. Psychopharmacology. 2022. Source

10. Wolfe MM, Lichtenstein DR, Singh G. Gastrointestinal toxicity of nonsteroidal anti-inflammatory drugs. N Engl J Med. 1999;340:1888-1899. Source

11. Centers for Disease Control and Prevention. FastStats: Drug Overdoses (2024 final mortality data). Source

Availability of Supporting Records

The historical UPLC 7OH laboratory results summarized above are available upon request.

Respectfully submitted,
Sterling Tucker
Founder, God’s Kratom Kingdom

Ai summary of document:

I. Introduction and Core Argument

Document Type: Comment on a Proposed 7OH Threshold (Docket HHS-OASH-2026-0232).

Submitted By: Sterling Carl Tucker, Founder, GOD'S KRATOM KINGDOM.

Date: September 8, 2026.

Subject: NIH.GOV data proving naturally occurring 7OH safety and an alternative threshold methodology for botanical Mitragyna speciosa material.

Requested Action: Do NOT criminalize unenhanced natural kratom leaf powder regardless of its naturally produced 7OH content.

Main Stance: Opposes a fixed, naturally occurring 7-hydroxymitragynine concentration ceiling due to its potential harm to American health and liberty. Argues that 7OH is a naturally occurring (God-made) compound.

II. Key Scientific Data and Arguments from NIH.gov

Opioid Overdose Prevention: Kratom has the potential to prevent opioid overdoses, a rising killer in the U.S.

No Overdose Deaths: Kratom has not caused any overdose deaths.

G Protein-Biased Agonism: Both mitragynine and 7-OH display G protein-biased agonism at the mu-opioid receptor, potentially delivering analgesia without unwanted side effects like respiratory depression.

Therapeutic Window: The pharmacological profile of 7-OH as a partial G protein-biased agonist signifies a desirable, wide analgesia-respiratory depression therapeutic window.

Novel Pain Therapeutics: Kratom's alkaloid scaffold is attractive for developing functionally biased opioid modulators with improved therapeutic profiles.

III. Executive Summary and Specific Requests

FDA Data Contradiction: FDA's 2025 assessment shows naturally occurring 7-OH in kratom samples up to 0.21% (mean 0.01%), with the maximum exceeding the proposed 0.050% cutoff by over 400%.

Primary Request: Exempt verifiably unenhanced dried leaf from criminalization, regardless of natural 7OH content.

Alternative Request (if threshold retained): Do **not** use 0.050% as it is not representative of natural plant production; there is no data supporting naturally occurring 7OH as an imminent public health risk.

Manufacturer Experience: Nearly a decade of manufacturing and selling kratom with no serious adverse event reports from botanical leaf, supporting continued access.

IV. Detailed Arguments Against the Proposed Threshold

1. Unjustifiable Botanical Threshold:

DEA's proposed 0.050% threshold lacks support from representative authenticated leaf samples and validated measurements.

FDA's own data (up to 0.21%) and the submitter's lab results (0.352%, 0.228%) contradict the proposed limit.

2. Concentration vs. Human Exposure:

Percentage is not a human dose; actual exposure depends on many factors.

No controlled human trials establish 0.050% as an imminent hazard.

NIH/NIDA distinguishes between full-spectrum leaf and isolated 7-OH; the complete alkaloid matrix may modify 7-OH's effects. Mitragynine causes respiratory stimulation, counteracting potential depression from 7OH.

3. Manufacturer Experience and Documentary Evidence:

Decade of selling unenhanced kratom with hundreds of positive consumer reports and zero serious adverse event reports.

Personal experience: Kratom as a safer alternative to prescription opioids, preventing return to dangerous man-made drugs.

4. Public Health and Proportionate Regulation:

Criminalizing kratom will force some users back to prescription/illicit opioids, contributing to the existing overdose crisis (54,045 opioid-involved deaths in 2024).

Kratom is thousands of times safer than man-made opioids based on death statistics.

NSAIDs (e.g., ibuprofen) cause significant deaths (over 15,000 elderly Americans annually) and hospitalizations, making them far more dangerous than kratom.

Calls for HHS to identify deaths specifically attributed to 7-OH, distinguish product types, and explain causal attribution.

V. Requested Determination

Advise the Attorney General and DEA to:

Decline 0.050% as a Schedule I boundary for botanical Mitragyna speciosa.

Exclude verifiably unenhanced leaf from scheduling regardless of natural 7-OH concentration.

At minimum, delay any numerical botanical threshold until transparent, validated studies are conducted.

Emphasizes preserving individual choice, access to unenhanced kratom, and American livelihoods.

VI. Vital Scientific Published Lab-Data Regarding 7OH (Additional NIH.gov Quotes)

Potency: 7-hydroxymitragynine shows potent opioid effects, 30- and 17-fold higher than mitragynine and morphine, respectively.

Reduced Side Effects: Mitragynine pseudoindoxyl shows slower analgesic tolerance, limited physical dependence, respiratory depression, and constipation compared to morphine.

G Protein-Biased Agonism (Reiteration): Both mitragynine and 7-OH display G protein-biased agonism, offering analgesia without unwanted side effects.

Respiratory Safety: 7-OH's pharmacological profile as a partial G protein-biased agonist signifies a desirable, wide analgesia-respiratory depression therapeutic window.

No Overdose Deaths (Reiteration): Kratom has not caused any overdose deaths and has the potential to prevent opioid overdoses.

Key Active Metabolite: 7-hydroxymitragynine is unveiled as the key active metabolite, offering new insights into pain therapeutics.

Atypical Opioids: Mitragynine and its analogs are described as "atypical opioids" due to their unique molecular actions and improved side effect profiles compared to classical opioids.

VII. Conclusion and Call to Action

Kratom is a "trillion-dollar godsend" for the American economy, promoting good behavior and productivity.

Urges protection of health and the preservation of plants, equating criminalizing plants to caging humans over religion.

Emphasizes sharing life-saving information from NIH.gov to combat the opioid epidemic.

Highlights the significant number of American lives lost to opioids (one every 11 minutes) and NSAIDs (over 16,000 annually).