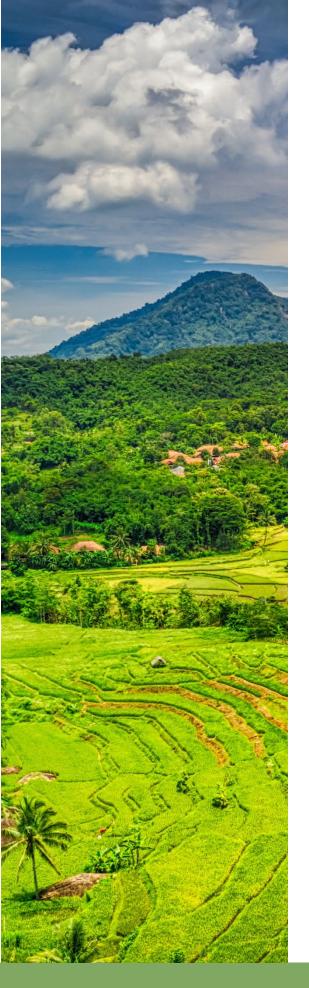


TABLE OF CONTENTS

ntroduction	.3
Consumer Acceptance of Kratom in the U.S	. 4
Regulatory Status of Kratom in the United States and at the UN Commission on	
Narcotic Drugs	.5
Studies Have Shown Kratom to be Generally Safe and Effective	.7
mpact of FDA Import Alerts on Kratom	11
Economic Contributions of Kratom to the Indonesian Farmer Community	16
Economic Contributions of Kratom to the U.S. Economy	19
Conclusion	20
References	22
Appendix: Explanation of the Contribution Categories	25



INTRODUCTION

Kratom (*mitragyna speciosa*) is an evergreen tree found in the tropical and subtropical regions in parts of Southeast Asia and Africa for its energy boosting effects, increased focus, improved mood, and to alleviate pain or as a replacement for more harmful pain medications.

In Southeast Asia, kratom has been commonly used by manual laborers who chew the leaves, either fresh or dried, to reduce fatigue and to enable longer working hours. It is also consumed as a tea in cultural performances as well as in day-to-day consumption. Perhaps most importantly, kratom has long been used to overcome opiate addictions (Swogger et al., 2015; Schimmel et al., 2021).

Numerous studies have confirmed the beneficial uses of kratom as well as the relative lack of harmful side effects. As noted in an extensive assessment of kratom impacts, known as the Henningfield 8-factor analysis, "The scientific and ethnographic literature often describes consumption as primarily motivated by the 'useful,' 'beneficial,' 'labor sustaining,' 'therapeutic,' 'mood' and 'well-being' enhancing, and 'instrumental' benefits, as well as dependence (Pinney Associates, 2016)."

Because of its beneficial effects, worldwide demand for kratom is booming and is increasingly contributing to economic growth. In this analysis, we will show the important economic contributions the kratom industry makes to the United States economy in terms of jobs, economic growth, and tax revenue.

Finally, we will discuss the importance of kratom to the Indonesian economy. It is estimated that 200,000 farmers in Indonesian rely almost entirely on kratom for their livelihood. We will discuss how misguided U.S. trade policies impose significant costs on Indonesian farmers and risks leaving them destitute.



CONSUMER ACCEPTANCE OF KRATOM IN THE U.S.

It is widely reported that kratom was popular with U.S. soldiers in Vietnam because of its energy boosting, increased focus, and pain relief effects. After the war returning U.S. soldiers brought kratom home and continued to self-import for its beneficial effects. At the same time there were hundreds of thousands of South Vietnamese families evacuated to the U.S. that ultimately led to the enactment of the Indochina Migration and Refugee Resettlement Act in 1975 that allowed Vietnamese refugees to enter the U.S. under special status. Concurrently, the Hmong refugees from Laos numbered more than 200,000 since 1975¹ and it is reported Hmong immigrants likely brought kratom consumption practices to the U.S. (Axelrod and Windell, 2012).

Today, it is estimated there are 10-16 million American kratom consumers (Ramanathan et al. 2020) and that number appears to be increasing every year. A consumer survey found that "Kratom is primarily used by a middle-aged (31-50 years), middle-income (\$35,000 and above) population for purposes of self-treating pain (68%) and emotional or mental conditions (66%)" and "Kratom shows a dose-dependent opioid-like effect providing self-reported perceived beneficial effects in alleviating pain and relieving mood disorders. Kratom was primarily used for self-treatment of pain, mood disorders, and withdrawal symptoms associated with prescription opioid use (Grundmann et al., 2017)."

CONSUMER FACTS

10-16

million American kratom consumers

31-50

year-old middle-age users

68%

use for self-treating pain

66%

use for emotional or mental conditions

¹ https://www.migrationpolicy.org/article/foreign-born-hmong-united-states



REGULATORY STATUS OF KRATOM IN THE UNITED STATES AND AT THE UN COMMISSION ON NARCOTIC DRUGS

The U.S. Food and Drug Administration (FDA), based on early data suggesting kratom posed a potential safety risk to the public, initially imposed Import Alerts in 2012 on all kratom raw materials being imported into the U.S. and those Import Alerts remain in effect today. In addition, the FDA aggressively distributed kratom warnings to state authorities advising kratom should be banned as a Schedule I substance. Six states, Wisconsin (2014); Indiana (2014); Arkansas (2015); Alabama (2016); Vermont (2016); and Rhode Island (2017), followed the FDA guidance and added kratom to their banned substances lists.

Acting on the recommendation of the FDA, the Drug Enforcement Administration (DEA) published a Notice of Intent to schedule kratom's alkaloids under the Federal Controlled Substances Act (CSA) on August 31, 2016.² That recommendation and was subsequently withdrawn by the DEA on October 13, 2016 for lack of sufficient evidence to justify a ban.³

A second scheduling recommendation by the FDA was submitted to the DEA on November 17, 2017, that but recommendation was formally withdrawn by the Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS) on August 16, 2018 citing "disappointingly poor evidence and data and a failure to consider overall public health."

In 2021, the UN Commission on Narcotic Drugs (UNCND) received a request from the FDA and some other member nations to internationally schedule kratom's alkaloids. The UNCND formally requested a review by the Expert Committee on Drug Dependence (ECDD) at the

² https://www.govinfo.gov/content/pkg/FR-2016-08-31/pdf/2016-20803.pdf

³ https://www.govinfo.gov/content/pkg/FR-2016-10-13/pdf/2016-24659.pdf

⁴ https://twitter.com/drgiroir/status/1395874443726102533

World Health Organization (WHO). Following a comprehensive review of all evidence and data on kratom, the ECDD on December 1, 2021, unanimously determined that there was insufficient evidence to recommend scheduling of kratom to the UNCND and recommended its current surveillance status.

...the Expert Committee on Drug Dependence... unanimously determined that there was insufficient evidence to recommend scheduling of kratom...

Three states that previously imposed kratom bans are now reconsidering those bans: Arkansas, Wisconsin, and

Rhode Island. The Rhode Island Department of Health has reportedly concluded that kratom does not meet the criteria for scheduling under Rhode Island law⁵ and it is expected kratom will be removed from their Schedule I list of controlled substances. The Wisconsin Controlled Substances Board is also conducting a review to determine if kratom meets their statutory requirements.⁶ Finally, the Arkansas Secretary of Health has on ongoing review of whether kratom was appropriately scheduled in that state.

In 2022, Kratom sales remain legal and largely unregulated in 44 states. There are 7 states that have enacted legislation commonly referred to as the Kratom Consumer Protection Act (KCPA): Utah (2019); Georgia (2019); Arizona (2019); Nevada (2019); Oklahoma (2020); Oregon (2022); and Colorado (2022). The KCPA provides consumer protection regulations on kratom vendors that require compliance with good manufacturing practices, no adulteration or use of synthesized kratom alkaloids, proper labeling, and age restrictions to protect the sale of unsafe or adulterated kratom products.

At the federal level, the Protecting Consumer Access to Kratom from Government Overreach Act⁷ sponsored by U.S. Senator Mike Lee (Utah) and U.S. Congressman Mark Pocan (Wisconsin) proposes the following regulatory framework for kratom in the US:

Protects kratom from FDA overregulation and creation of de-facto regulatory bans using import alerts or FDA enforcement actions on restricting manufacturing or sales of kratom products based on the FDA's own classification of kratom as an adulterated food, dietary supplement, dietary ingredient, or as a new dietary ingredient requiring registration. These decisions will have to be based on scientific evidence and data, not the FDA's bias against kratom.

⁵ Letter from Representative Brian Patrick Kennedy, Speaker Pro Tempore, Rhode Island House of Representatives, to Dr. Utpala Bandy, Interim Director of the Rhode Island Department of Health, November 1, 2022.

⁶ Wisconsin Controlled Substances Board, Agenda for November 11, 2022, Agenda Item H, https://dsps.wi.gov/Documents/BoardCouncils/CSB/20221111CSBFullPacketEditable.pdf

⁷ Bill number not yet assigned.

- Establishes an inter-agency Kratom Research Task Force to coordinate and report to the Congress on a quarterly basis on all research on kratom being funded by the federal government. The Task Force will hold public meetings with experts to increase public awareness of kratom research and will require the FDA to publish records of this research on the FDA website.
- Enacts requirements for full transparency for all government-funded research on kratom that addresses current evidence and data on consumer safety and addiction issues and creates an open platform for the public to comment on the use of kratom and its effects.⁸

STUDIES HAVE SHOWN KRATOM TO BE GENERALLY SAFE AND EFFECTIVE

In the past there were concerns that kratom use might pose significant risks to consumers. The primary concerns included the possible presence of dangerous or harmful substances, possible harmful effects of kratom use, and the potential for abuse and dependency.

Those concerns have largely been laid to rest by a rapidly growing body of peer-reviewed scientific literature. Indeed, since 2018 there have been more than 100 studies investigating kratom use which have found that, for the most part, kratom is used for its beneficial effects of health and well-being rather than for recreational purposes and that the health risks of kratom use are low.



Consumers bear a responsibility to select kratom products that have been tested for contaminants, manufactured in compliance with accepted good manufacturing practices, and that are properly labeled. In addition, as is true for other consumer products, kratom should be responsibly consumed.

Abuse Potential

There are two primary psychoactive constituents of kratom that account for its pharmacological effects. Those are mitragynine (MG) and 7-hydroxymitragynine (7-HMG), which constitute about 60 and 2 percent of the plant's alkaloids, respectively. Recent research now show that 7-HMG is actually a metabolite derived from the drying process for raw kratom leaves or, as recent research suggests, the human body metabolizes MG into 7-HMG after ingestion (Berthold et al.,

⁸ Summary: The Protecting Consumer Access to Kratom from Government Overreach Act (*The Federal Kratom Consumer Protection Act*)



2022). Levels of the remaining alkaloids are de minimis or, as characterized by Christopher McCurdy, PhD., "[k]ratom is a complex symphony orchestra of alkaloids." Numerous studies have been conducted on the abuse potential of kratom and have found it to be low in comparison to drugs that are typically abused.

Two studies that compared the self-administration in rats of morphine to MG found that it does

Both studies concluded that MG does not have abuse potential and reduces intake of more harmful drugs. not substitute for morphine (Hemby et al., 2018) or heroin (Yue et al., 2018). In fact, MG self-administration was similar to saline. In other words, the rats had a much lower affinity for MG than morphine and heroin. Both studies found that pretreating the rats with MG reduced the self-administration of both morphine and heroin. Both studies concluded that MG does not have abuse potential and reduces intake of more harmful drugs.

Hemby et al. (2018) did find, however, that 7-HMG does substitute for morphine and engenders and maintains self-administration, meaning that it has high abuse potential. However, 7-HMG occurs at non-detectable levels in natural kratom leaves and is not present at all in many kratom derivatives, so it is not likely to blame for the pharmacological effects reported by kratom users (Henningfield et al., 2022a). As a result of these findings, the researchers recommended that the levels of 7-HMG in the kratom marketed to consumers be regulated to avoid abuse potential.

A third study, using self-administered intracranial stimulation in rats, also showed that "kratom alkaloids do not have abuse potential (Behnood-Rod et al., 2020)."

https://nihrecord.nih.gov/2022/06/24/mccurdy-studies-whether-kratom-can-reduce-opioid-withdrawal-ease-pain

Four additional animal studies found that kratom does not induce physiological dependence and that it alleviates symptoms associated with morphine withdrawal (Harun et al., 2020; Hassan et al., 2020; Wilson et al., 2020; Johari et al., 2021).

Survey Data on Abuse Potential

As noted by Henningfield et al (2022a), "These findings [from animal studies] are consistent with new US survey data showing relatively low self-reported kratom addiction rates, with most people describing MG use to manage pain, depression, anxiety, opioid and other drug use disorders and withdrawal, and to increase alertness, focus and work performance. In addition, kratom dependence and withdrawal are generally weaker and more readily self-managed relative to opioids."

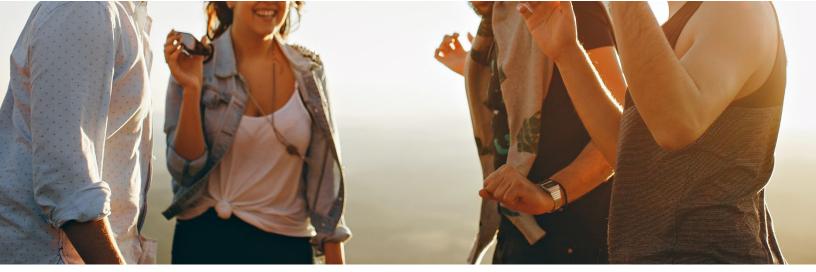
A survey (Garcia-Remeu et al., 2020) of 2,798 kratom users showed that the primary reasons for kratom use among survey respondents were pain relief (91.3%) and mood related issues such as anxiety (67.2%) and depression (65%). Respondents rated the efficacy of these uses on a scale from 0 (not at all) to 100 (extremely). Respondents rated kratom efficacy for treating pain (83.2), anxiety (76.7), and depression (76.5).

Others reported using kratom for post-traumatic stress (29.6%) or bipolar mood (24.6%) disorders and rated the efficacy at 60.2 and 51.4 percent respectively.



Among respondents, 19 percent reported adverse kratom-related effects with another 12.8 percent reporting possible adverse effects. Of those, only one percent said the severity of the effects were extreme and 1.9 percent sought medical treatment for adverse effects. Mild adverse effects were reported by 63 percent and most said the effects lasted less than a day (86%). Finally, 9.5 percent said they experienced kratom-related withdrawal symptoms.

An anonymous online survey of 2,867 kratom users found that "Kratom was used primarily to relieve pain (endorsed by 48 percent of respondents), for anxiety, PTSD, or depression (22%), to increase energy or focus (10%) and to help cut down on opioid use and/or relieve withdrawal (10%). Over 90 percent of respondents who used it in place of opioids indicated that it was helpful to relieve pain, reduce opioid use, and relieve withdrawal. The reported incidence of bad adverse reactions was 13 percent, and reactions were overwhelmingly mild and self-managed (Coe et al., 2019)."



Smith et al. (2022) conducted a survey of 129 kratom users. Most of the respondents had used kratom more than 100 times and had previously used or are currently using kratom more than four times per week. Less than half reported themselves to be current regular kratom uses. The survey found that nearly 80 percent experienced acute effects with every dose which began within minutes and dissipated within hours. Acute effects were largely beneficial. Higher dose amounts over longer periods of time, however, were associated with unwanted effects.

Smith et al. (2021) examined a sample of 280 Reddit posts from between June 2019-July 2020 that mentioned kratom use. The results of this research validated and were generally consistent with many of the findings of past surveys. The researchers found that, "Overall, desirable effects were wide-ranging, and included mood enhancement, increased energy, cognitive alertness, analgesia, and relaxation." Many of the posts also mentioned adverse effects, such as "GI upset, fatigue, memory lapses, irritability, and restlessness." Addiction was also mentioned as an unwanted effect. However, odds of becoming addicted were associated with high dosage use. Withdrawals from addiction were "typically described as mild-moderate." A minority described withdrawal as severe.

Another internet survey of 1,842 kratom users (Covvey et al., 2020) found that those who reported kratom use in their lifetime were "largely between 25-44 years old, male, employed, and at higher educational levels." Even though the survey did not specifically report reasons for kratom use, many respondents reported past opioid use and/or drug addiction treatment which is suggestive of self-management of addiction consistent with other findings

Product Purity

It has been discovered that some kratom products on the market are contaminated or have unknown levels of mitragynine (Prozialeck et al. 2019; Prozialeck et al. 2020). However, "A scheduling imposed kratom ban would likely worsen these problems because kratom marketing would not discontinue and consumer demand would not cease, rather marketing would switch

from regulatable lawful to illicit kratom suppliers (Henningfield et al. 2022a)." It would be preferable to institute a system of inspection and testing to ensure product purity.

Potential Harmful Effects

The primary cause of opioid-induced death is respiratory depression, which is the "neural depression of respiratory drive which, together with a decreased level of consciousness and obstructive sleep apnea, cause ventilatory insufficiency (Baldo and Rose, 2022)." Because kratom alkaloids bind themselves to opioid receptors, this has raised concerns that kratom use may also lead to respiratory depression and death.

However, studies have found little evidence of respiratory depression related to kratom use. Two of the more recent studies have confirmed these findings. Hill et al. (2022) found only limited respiratory depression effects in mice from MG and that those effects hit a ceiling beyond a certain dose. Another study that compared the respiratory depression effects of MG and oxycodone, found that, MG did not produce "respiratory depression at doses many times higher than known to be taken by humans (Henningfield et al. 2022c)."

In summary, MG "is a partial agonist with respect to respiratory depression, meaning that its maximal effects at all tested doses do not produce lethal respiratory depression. The mitragynine metabolite 7-hydroxymitragynine is more potent than morphine on the guinea pig ileum muscle twitching test but that test is not necessarily relevant to lethality, and 7-hydroxymitragynine also appears to be a partial agonist with respect to its respiratory effects (Henningfield et al., 2022b)."

IMPACT OF FDA IMPORT ALERTS ON KRATOM

Kratom raw materials are largely imported from Southeast Asia, with an estimated 95 percent of kratom raw materials currently exported to the U.S. originating in Indonesia. ¹⁰ The recent removal of the ban on kratom in Thailand and imposition of new standards for commercial export of kratom raw materials to global markets ¹¹ will result in more competition on pricing but the Import Alert bars legitimate competitive models having desired impacts in both quality and competitive pricing.



¹⁰ https://www.painnewsnetwork.org/stories/2019/7/5/is-indonesia-banning-kratom-exports

¹¹ https://tna.mcot.net/english-news-861082

The potential for major Indonesian kratom trade disruption has increased with the announcement by the Thai Ministry of Finance and the Office of the Narcotics Control Board of plans to enable licensing and issuance of electronic documents for the exporting or importing of kratom leaves. ¹² This new kratom export/import system supports the Thai government's goal to make kratom a global cash crop, particularly with the expressed commitment to establish a supply chain for traceability of kratom material to the tree of origin. In addition, U.S. vendors report significant sourcing of kratom raw material from Africa where fewer supply chain obstacles exist as compared to Indonesia.

However, the FDA has issued two import alerts related to kratom without regard to its source -- one regarding unapproved new drugs (Import Alert 66-41) and one regarding dietary supplements (Import Alert 54-15). Import Alert 66-41 provides for detention without physical examination of unapproved new drugs where there is "evidence of marketing or promotion" of the



product¹⁴ where associated therapeutic claims are made. Assuming there are no marketing or promotional materials accompanying the kratom at the time of entry, Import Alert 66-41 would seem to be inapplicable. The FDA does have statutory enforcement authority over any specific kratom product that is marketed with therapeutic claims that is not supported with required clinical data under requirements of a new drug application (NDA).

Import Alert 54-15 applies to dietary supplements and bulk dietary ingredients that are kratom and states "[k]ratom is a botanical that qualifies as a dietary ingredient....When marketed as a dietary ingredient, the FDA also considers kratom to be a new dietary ingredient...."¹⁵ It prohibits the importing of kratom because it considers the importation of kratom without an NDI

The Human and Economic Impacts of the Kratom Industry in the United States and Indonesia

 $^{^{12}\} https://www.pattayamail.com/thailandnews/thailand-facilitates-legal-agreement-on-data-linking-for-kratom-import-and-export-417158$

¹³ The FDA has issued two import alerts related to kratom—one regarding dietary supplements (Import Alert 54-15) and one regarding unapproved new drugs (Import Alert 66-41). These import alerts apply to importers and not to a domestically manufactured, distributed, or sold kratom in the United States.

¹⁴ Import Alert 66-41.

¹⁵ Import Alert 54-15.

notification¹⁶ an adulterated product as "there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."¹⁷ The FDA requires a manufacturer and distributor of a dietary supplement to obtain an NDI if that dietary supplement contains a new dietary ingredient. ¹⁸ However, the FDA's policies have never and do not now place this burden on an importer of raw materials that is not manufacturing or operating at the retail level.

The FDA has never found that all kratom products are adulterated. As with other food products, the FDA has taken targeted enforcement action against specific kratom manufacturers if they have been found to market kratom as an unapproved drug. Specifically, the FDA has issued Warning Letters to a number of kratom companies for making unproven medical claims, including opioid treatment claims. ¹⁹ The FDA has not taken enforcement action against all kratom companies deeming kratom unapproved or adulterated.

The FDA issued a voluntary and mandatory recall to a number of kratom manufacturers in 2018 due to a salmonella outbreak.²⁰ Since then, there have not been any actions taken by the FDA or reports on any salmonella in kratom raw materials or products. Improved processing and testing standards appear to indicate that preventative measures for such contamination both in Indonesia and the U.S. have been effective.

The Grey Market Effects of the FDA Kratom Import Alert

The FDA Import Alert technically applies to all kratom raw materials exported to the U.S. rather than being targeted to specific kratom exporters with identifiable unsafe products, and that effectively removes kratom from legitimate commodity trading channels. Significant consumer

¹⁶ The Dietary Supplement Health and Education Act of 1994 (DSHEA) states the term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994." A manufacturer or distributor must submit safety data to the FDA 75 days before introducing the product into the marketplace, and that submission is known as a "New Dietary Ingredient Notification (NDIN)."

¹⁷ Import Alert 54-15.

¹⁸ 21 C.F.R. § 190; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Draft Guidance for Industry, August 2016, available at https://www.fda.gov/media/99538/download.

¹⁹ Manufacturers may not lawfully make medical claims about a food product such as that the product prevents, treats or mitigates a disease or illness without FDA approval. *See e.g., Cali Botanicals, LLC Warning Letter*, FDA.gov, June 2019, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cali-botanicals-llc-575320-06112019; *KratomNC Warning Letter*, FDA.gov, June 2019, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kratomnc- 576964-05162019.

²⁰ FDA orders mandatory recall for kratom products due to risk of salmonella, FDA.gov, April 2018, available at https://www.fda.gov/news-events/press-announcements/fda-orders-mandatory-recall-kratom-products-due-risk-salmonella.



demand in the U.S., and the heavy reliance on kratom by more than 200,000 Indonesian farmers²¹ for their livelihood as their only reasonable support for their families, have combined to circumvent the Import Alert.

The FDA Import Alerts disrupt traditional commodity trading where manufacturers refuse to pay for raw materials until it is received at their facilities, and only after the kratom raw materials have been tested for contaminants to assure that kratom material can be safely manufactured into finished products. The Import Alerts unfairly put Indonesian kratom farmers at significant economic risk in two specific ways:

- Every shipment of kratom raw material to the U.S. is at high-risk of being seized by U.S. Customs, so kratom vendors are unwilling to pay suppliers until the shipment arrives at their manufacturing facilities. Indonesian kratom farmers are forced to sell kratom raw materials at significantly reduced prices to brokers who then assume the risks. In turn, those brokers sell kratom raw materials at premium prices to account for the risks they assume because of the Import Alert.
- Like all botanical products, kratom is highly susceptible to microbial and processing contamination, and without supply chain regulations supervised by the government to reduce this contamination there is a high risk that raw material will be unusable by a manufacturer. Any government regulation would require certifications and a paper trail that would give the FDA a list of exporters to place on the Import Alert "Red List" and shut down key parts of kratom supply chain designed to improve the safety of kratom raw materials.

The Human and Economic Impacts of the Kratom Industry in the United States and Indonesia

²¹ https://www.borneohale.com/aka-discussed-kratom-with-moeldoko-indonesian-president-official/

The FDA kratom Import Alert has an ongoing significant negative impact on those 200,000 Indonesian farmers who rely almost exclusively on kratom crops for their livelihood to support their families. Prices for kratom raw materials are suppressed by brokers who purchase kratom materials from farmers because of the grey market operates outside of an unauthorized sales channel where there is no accountability. These brokers then sell the kratom materials to processors who process the kratom materials into a fine powder for packaging and export. These processors understand the importance of producing contaminant free kratom powder, so they have made investments in food-grade stainless steel equipment to reduce the risk of contaminated kratom raw materials they process. The brokers and processors generally make substantial profits while the farmers are paid disproportionately low prices for their kratom crops.

The Black-Market Impacts of the FDA Kratom Import Alert

Using a variety of internet social media platforms, a significant number of kratom farmers have created a robust black market for kratom sales in the U.S. These direct sales provide higher prices for kratom for individual farmers, but there are no adequate supplies of clean water to wash kratom leaves prior to drying, the customary practice in remote villages is to dry leaves on tarps on the ground where they are exposed to multiple sources of contaminants, and they typically use WWII-era coffee grinders to produce kratom powder that are sources of significant metal contamination in the kratom materials.



Indonesian officials conservatively estimate the Black-Market kratom trade to be 40 - 45 percent of the overall kratom exports to global markets. If the FDA Import Alert were removed, the Black-Market for kratom would largely disappear in favor of a secure supply chain for kratom processed to conform to standards that produce kratom meeting the minimum FDA contaminant standard for botanical food products. It

would also clear the way for the Indonesian government to ban all kratom shipments that were not processed through the approved supply chain to assure their purity.

The FDA Import Alert also blocks the Indonesian government from imposing regulations that would legitimize the kratom supply chain, allow for appropriate regulations, and assess tariffs to reimburse the government for their enforcement efforts.

The FDA kratom Import Alert also puts American consumers at significant safety risks. Kratom products sold and shipped directly to consumers in the U.S. from remote villages where kratom is typically processed with contaminated water, suspect drying and grinding procedures, and no reliable safety standards for packaging and shipping collectively puts consumers at substantial

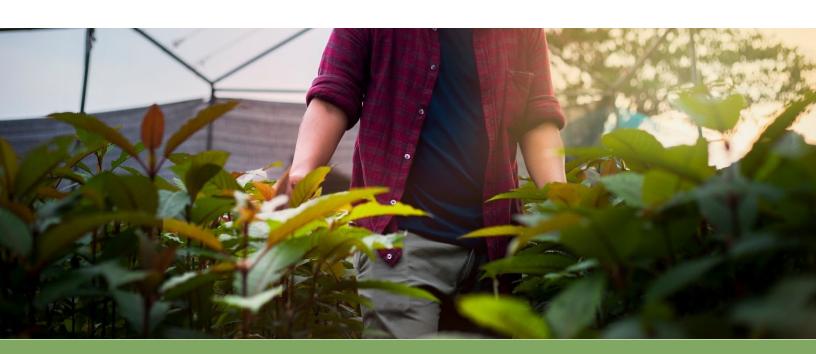
risk of consuming unsafe kratom products. Under these conditions, there is no reliably consistent method to eliminate contaminated kratom materials with dangerous microbes like salmonella and E. coli, or screening for the presence of heavy metals.

In addition to safety concerns, economic scams are common in the Kratom Black Market. U.S. consumers are provided fake testing reports; the kratom materials are often diluted with non-kratom botanical materials to increase weight and volume; and it is common for payments made by consumers to be received and no products are sent.

ECONOMIC CONTRIBUTIONS OF KRATOM TO THE INDONESIAN FARMER COMMUNITY

There are an estimated 26 million farmers in Indonesia, but the economics of participation in the agricultural sector are eroding annually, and it is more difficult for farming families to keep their children engaged in farming activities. In the remote farming regions, many of the base crops like rubber and palm oil have experienced wild fluctuations in pricing and demand. Kratom has emerged as a more stable commodity because it grows in the wild, requires little cultivation work, and can be harvested on a regulator rotation.

It is reported that the average daily revenue for farmers in Indonesia of 55.503 rupia $(Rp)^{22}$ which is a negligible amount per day. Kratom farmers can earn an average of Rp 80,000 to 100,000 per day (\$5.25 - \$6.60 per day USD) during the harvest. Kratom is increasingly attractive for farmers because a kratom tree only needs about 9 months to grow, which compared



to a rubber plant that takes 4-5 years. In 2018, when the price of rubber decreased, farmers shifted to kratom production. It is estimated that one farmer can export up to 10 tons of kratom per month.

The volatile fluctuations of commodity crop pricing for rubber and palm oil plants makes kratom a more stable and reliable economic option for most farmers in the Borneo region. But that marketplace is artificially restricted by conditions created by the Import Alert where unscrupulous brokers pay unfair prices to farmers for kratom materials.

The volatile fluctuations of commodity crop pricing ... makes kratom a more stable and reliable economic option...

The issue of "Fair Trade" for pricing of kratom raw materials has emerged as an issue of controversy in an effort to support impoverished farmers and their families in Indonesia. In a *Joint Statement on Kratom Commerce in Indonesia and the United States* executed in August 2022, leading kratom processor groups and the American Kratom Association affirmed the commitment for accountability so that kratom farmers and their families "are not subject to abusive economic practices that improperly interfere with fair and competitive trade pricing for harvested kratom raw materials." The Statement specifically states farmers "should not be subjected to unfair trade practices where they are paid an unreasonably low price based on current market pricing for the harvested kratom materials by brokers, processors, or vendors who exploit the poverty or living conditions of the farmers and their families."

However, the Fair Trade pricing movement typically relies upon a voluntary direct trade relationship between farmers and fair trade organizations in the U.S. and Europe. There are two specific barriers to such agreements:

- The regulatory bans on kratom imports into the U.S. and Europe do not allow for implementing such agreements;
- A significant black-market volume of kratom exports from Indonesia are direct transactions between Indonesian farmers and consumers in the U.S. and Europe using

²³ Joint Statement on Kratom Commerce in Indonesia and the United States, signed at a meeting with the Indonesian Chief of Staff to the President of Indonesia, August 2022.



social media platforms that unfairly undercuts the price for kratom from Indonesian processors who have invested in food-grade processing facilities to reduce the risk of contaminated kratom materials to satisfy FDA concerns.

Fair trade pricing is a movement that can work when the commodity is not restricted by unfair regulations and consumers can choose to purchase products from companies who have committed to pay a fair price to kratom farmers. Setting a compulsory floor price on kratom raw materials should not be confused with being a part of the global fair-trade movement.

Removal of current import alerts, establishment of a sustainable supply chain that meets safety requirements of the FDA for botanical products, and elimination of the kratom black-market through government regulations will provide consumers with the confidence in the safety of kratom products so that a true Fair Trade certification program could be established.

Some in the Indonesian government have recognized the problem, and the importance of developing a sustainable supply chain that includes economic and product safety components. The Indonesian Ministry of Finance and the Directorate of General Customs and Excise reported an estimated 20.22 percent year-to-year increase in kratom exports from 2021 to 2022 to various global markets, including the U.S. The report noted that a threatened ban on kratom by the BNN proposed for 2024 will have a significant negative impact on kratom farmers in Kalimantan. The Indonesian Directorate General of Human Rights recommends new research among relevant Ministries/Institutions on any impacts on the health, ecological, and socio-economic aspects that might inform a future domestic policy on kratom.²⁴

²⁴ Report from the Indonesian Ministry of Finance and the Directorate of General Customs and Excise, 2022.

ECONOMIC CONTRIBUTIONS OF KRATOM TO THE U.S. ECONOMY

In addition to the benefits that enhance the quality of life for those who consume kratom, it also contributes positive value to the U.S. economy. Not only has it allowed many to resume productive lives that were short-circuited by debilitating pain, mental health issues or addictions, but it also provides jobs, enlarges the tax base and increases U.S. gross domestic product (GDP). In this section, we provide estimates of those economic contributions.

Based on discussions with knowledgeable industry insiders, available import data, and estimates of the numbers of kratom consumers and average consumption per consumer, we estimate that the industry had \$1.5 billion in sales in 2020 (up from \$1.3 billion in 2019). This estimate is conservative compared to other analyses.²⁵

Based on these inputs, we estimate that the U.S. kratom sector accounted for a total 8,850 jobs, \$492.6 million in labor income and contributed a total of \$703.6 million to U.S. GDP.

Impact	Employment	Labor Income	Value Added
Direct	5,036	\$251,537,000	\$299,070,000
Indirect and Induced	3,814	\$241,022,000	\$404,554,000
Total	8,850	\$492,559,000	\$703,624,000

Tax Payments by Kratom Industry

Economic activity attributable to kratom sales is taxed at the federal, state, and local levels. The taxes take a variety of forms, including income taxes on company profits and employee wages, property taxes on equipment and structures, and excise taxes on output. The next table provides details on the type of taxes collected on economic activity attributable to U.S. kratom sales.

Kratom sales generated \$68 million in federal taxes and another \$88 million state and local taxes, for a total of \$156 million in 2020.

²⁵ In 2016, the Botanical Education Alliance (BEA) conducted a survey of 163 business owners that sell kratom, of which 157 participated. From that survey, the BEA extrapolated sales numbers for the rest of the industry (approximately 10,000 kratom vendors), to come up with total \$5 billion in lost revenue per year were kratom to be outlawed.

	Tax Category	Direct	Indirect and Induced	Total
Federal	Corporate Income Taxes	\$ 714,000	\$4,080,000	\$4,794,000
	Personal Taxes	\$ 20,651,000	\$20,294,000	\$40,945,000
	Indirect Business Taxes ²⁶	\$(17,821,000)	\$(14,049,000)	\$(31,870,000)
	Social Insurance Contributions	\$30,286,000	\$ 24,331,000	\$54,617,000
	Federal Total	\$ 33,830,000	\$ 34,656,000	\$68,486,000
State & Local	Corporate Income Taxes	\$263,000	\$1,503,000	\$1,766,000
	Personal Taxes	\$ 6,260,000	\$6,058,000	\$12,318,000
	Indirect Business Taxes	\$40,682,000	\$32,072,000	\$72,754,000
	Social Insurance Contributions	\$440,000	\$ 353,000	\$793,000
	State and Local Total	\$47,645,000	\$39,986,000	\$87,631,000
Federal, State & Local Total		\$81,475,000	\$74,624,000	\$156,099,000

CONCLUSION

The FDA imposed its first Import Alert on kratom in 2012 as a precursor to submitting its two

recommendations for kratom's alkaloids to be classified as Schedule I substances under the CSA. The body of scientific evidence on the safety profile of kratom has changed dramatically since 2012, and every independent analysis of kratom has concluded there is insufficient evidence to support the FDA's claims that kratom poses a significant safety risk to consumers. Despite that, the FDA has circumvented the CSA and has arguably usurped Congressional intent in creating a de-facto ban on kratom using its discretionary Import Alert authorities.

... every independent analysis of kratom has concluded there is insufficient evidence to support the FDA's claims that kratom poses a significant safety risk to consumers.

²⁶ The negative numbers for indirect federal business taxes are accounted for by the very large Paycheck Protection Program payments made directly to U.S. businesses as a result of the COVID-19 pandemic.

The existing kratom Import Alerts put consumers at significant health risks:

- The Indonesian government and responsible kratom exporters are unable to create sustainable supply chain systems and processes to comply with FDA standards for quality and safety of kratom raw materials exported to the United States.
- A black-market for kratom raw materials has developed for internet-based transactions between kratom farmers and small kratom vendors or consumers where none of those materials are subject to safety requirements for botanical products exposing consumers to substantial safety risks.
- Poor Indonesian farmers are forced to accept unfair prices for kratom harvests because no payments are made until raw materials are received by vendors and then tested for contaminants. The Import Alerts completely disrupt supply chains that would allow for fair pricing to be received by farmers.

The FDA's bias against kratom directly interferes with competitive free market systems that traditionally allow for competition on product quality and price and allows consumers to make informed decisions on kratom products they may choose to maintain their health and well-being.

The FDA's aggressive attacks on kratom has caused confusion among state and local government leaders, arguably led to inaccurate reports by medical examiners and coroners on alleged kratom deaths, and has failed to heed the warning issued by Dr. Giroir that interference with consumer access to kratom would create "a significant risk of immediate public health consequences for potentially millions of users if kratom or its components" are banned.

REFERENCES

Axelrod BN, Windell J (2012). Dissertation solutions: a concise guide to planning, implementing, and surviving the dissertation process. Rowman & Littlefield Education, Lanham, Md, p 56 in E-book.

Baldo, B.A., Rose, M.A. (2022). Mechanisms of opioid-induced respiratory depression. Archives of Toxicology. 96:2247–2260.

Behnood-Rod, A., Chellian, R., Wilson, R., Hiranita T., Sharma, A., Leon, F., McCurdy, C.R., McMahon, L.R., Bruijnzeel, A.W. (2020). Evaluation of the rewarding effects of mitragynine and 7- hydroxymitragynine in an intracranial self-stimulation procedure in male and female rats. *Drug Alcohol Depend*. 215 (108235).

Berthold, E.C., Kamble, S.H., Raju K.S., Kuntz M.A., Senetra A.S., Mottinelli M., León, F., Restrepo L.F., Patel A., Ho, N.P., Hiranita, T., Sharma, A., McMahon, L.R., Christopher R. McCurdy, C.R. (2022). The Lack of Contribution of 7-Hydroxymitragynine to the Antinociceptive Effects of Mitragynine in Mice: A Pharmacokinetic and Pharmacodynamic Study. *Drug Metabolism and Disposition*. 50 (2): 158-167.

Coe, M.A., Pillitteri, J.L., Sembower, M.A., Gerlach, K.K., and Henningfield, J.E. (2019). Kratom as a Substitute for Opioids: Results from an Online Survey. *Drug Alcohol Depend* 202:24–32.

Covvey, J.R., Vogel, S.M., Peckham, A.M., and Evoy, K.E. (2020). Prevalence and Characteristics of Self-Reported Kratom Use in a Representative US General Population Sample. *J. Addict. Dis.* 38 (4): 506–513.

Garcia-Romeu, A, Cox, DJ, Smith, KE, Dunn, KE, Griffiths, RR (2020). Kratom (Mitragyna speciosa): User demographics, use patterns, and implications for the opioid epidemic. *Drug and Alcohol Dependence*. 208: 107849.

Grundmann O. (2017). Patterns of Kratom use and health impact in the US-Results from an online survey. *Drug Alcohol Depend*. 176: 63-70.

Harun, N., Johari, I.S., Mansor, S.M., Shoaib, M. (2020). Assessing physiological dependence and withdrawal potential of mitragynine using schedule-controlled behaviour in rats. Psychopharmacology. 237: 855-867.

Hassan, R., Pike See, C., Sreenivasan, S., Mansor, S. M., Müller, C. P., and Hassan, Z. (2020). Mitragynine Attenuates Morphine Withdrawal Effects in Rats-A Comparison with Methadone and Buprenorphine. Front. Psychiatry 11, 411

Hemby S.E., McIntosh S., Leon F., Cutler S.J., McCurdy C.R. (2019). Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine. *Addict Biol.* 24(5):874-885.

Henningfield J.E., Wang D.W., Huestis M.A. (2022a). Kratom Abuse Potential 2021: An Updated Eight Factor Analysis. Front Pharmacol. 12(776073).

Henningfield, J.E., Huestis, M., Grundmann, O., Garcia-Remeu, A. (2022b). Kratom Science Update: Evidence-Based Facts. https://kratomhealth.science/science/kratom-science-update-evidence-based-facts.

Henningfield, J.E., Rodricks, J.V., Magnuson, A.M., Huestis, M.A. (2022c). Respiratory effects of oral mitragynine and oxycodone in a rodent model. *Psychopharmacology (Berl)*. Epub ahead of print: 36308562.

Hill R, Kruegel AC, Javitch JA, Lane JR, Canals M. (2022) The respiratory depressant effects of mitragynine are limited by its conversion to 7-OH mitragynine. *Br J Pharmacol*. 179(14):3875-3885.

Johari, I.S., Harun, N., Sofian, Z.M., and Shoaib, M. (2021). Pentylenetetrazol-like Stimulus Is Not Produced Following Naloxone-Precipitated Mitragynine Withdrawal in Rats. *Psychopharmacology* 238:3183-3191.

Pinney Associates, "Assessment of Kratom under the CSA Eight Factors and Scheduling Recommendation," November 28, 2016.

Prozialeck, W.C., Avery, B.A., Boyer, E.W., Grundmann, O., Henningfield, J.E., Kruegel, A.C., et al. (2019). Kratom Policy: The challenge of Balancing Therapeutic Potential with Public Safety. *Int. J. Drug Pol.* 70:70–77.

Prozialeck, W.C., Edwards, J.R., Lamar, P.C., Plotkin, B.J., Sigar, I.M., Grundmann, O., et al. (2020). Evaluation of the Mitragynine Content, Levels of Toxic Metals and the Presence of Microbes in Kratom Products Purchased in the Western Suburbs of Chicago. *Int. J. Environ. Res. Public Health* 17(15).

Ramanathan S., McCurdy C.R. (2020). Kratom (Mitragyna speciosa): worldwide issues. *Curr Opin Psychiatry*. (4):312-318.

Schimmel, J., Amioka, E., Rockhill, K., Haynes, C.M., Black J.C., Dart R.C., Iwanicki J.L. (2021). Prevalence and description of kratom (Mitragyna speciosa) use in the United States: a cross-sectional study. Addiction. 116(1):176-181.

Smith, K.E., Rogers J.M., Dunn, K.E., Grundmann, O., McCurdy, C.R., Schriefer, D., Epstein, D.H. (2022). Searching for a Signal: Self-Reported Kratom Dose-Effect Relationships Among a Sample of US Adults with Regular Kratom Use Histories. *Front. Pharmacol.* 13(765917).

Smith K.E., Rogers, J.M., Schriefer, D., Grundmann, O. (2021) Therapeutic benefit with caveats? Analyzing social media data to understand the complexities of kratom use. *Drug Alcohol Depend*. 226(108879)

Swogger, M.T., Hart, E., Erowid F., Erowid, E., Trabold, N., Yee, K., Parkhurst, K.A., Priddy, B.M., and Walsh, Z. (2015). Experiences of Kratom Users: A Qualitative Analysis. J Psychoactive Drugs. 47(5):360-7.

Wilson, L.L., Harris, H.M., Eans, S.O., Brice-Tutt, A.C., Cirino, T.J., Stacy, H.M., et al. (2020). Lyophilized Kratom tea as a Therapeutic Option for Opioid Dependence. *Drug Alcohol Depend*. 216 (108310).

Yue K., Kopajtic T.A., Katz J.L. (2018). Abuse liability of mitragynine assessed with a self-administration procedure in rats. *Psychopharmacology* (Berl). 235(10):2823-2829.

APPENDIX: EXPLANATION OF THE CONTRIBUTION CATEGORIES

The economic contributions of the U.S. kratom industry to the domestic economy include its direct impact plus the economic activity of other industries that supply the industry as well as the induced impacts of spending by industry employees. To quantify these linkages, we rely on the IMPLAN model, an input-output (I-O) model based on federal government data.

- <u>Direct contributions</u>: The impacts directly attributable to the kratom industry, such as employment within an establishment that sells kratom.
- <u>Indirect contributions</u>: The impact of the kratom industry buying goods and services from other industries. In other words, the employment in an industry that supplies goods and services to the kratom industry is indirectly attributable to the kratom industry.
- <u>Induced contributions</u>: The impact of the direct and indirect employees of the kratom industry spending their income.

The IMPLAN model relies on employment data from the U.S. Bureau of Economic Analysis (BEA). To derive the direct, indirect and induced impacts of the kratom industry by applying our estimate of industry sales to the "Retail: Health and Personal Care Stores" sector within the IMPLAN model. This sector corresponds to the North American Industry Classification System (NAICS) code 446000.