

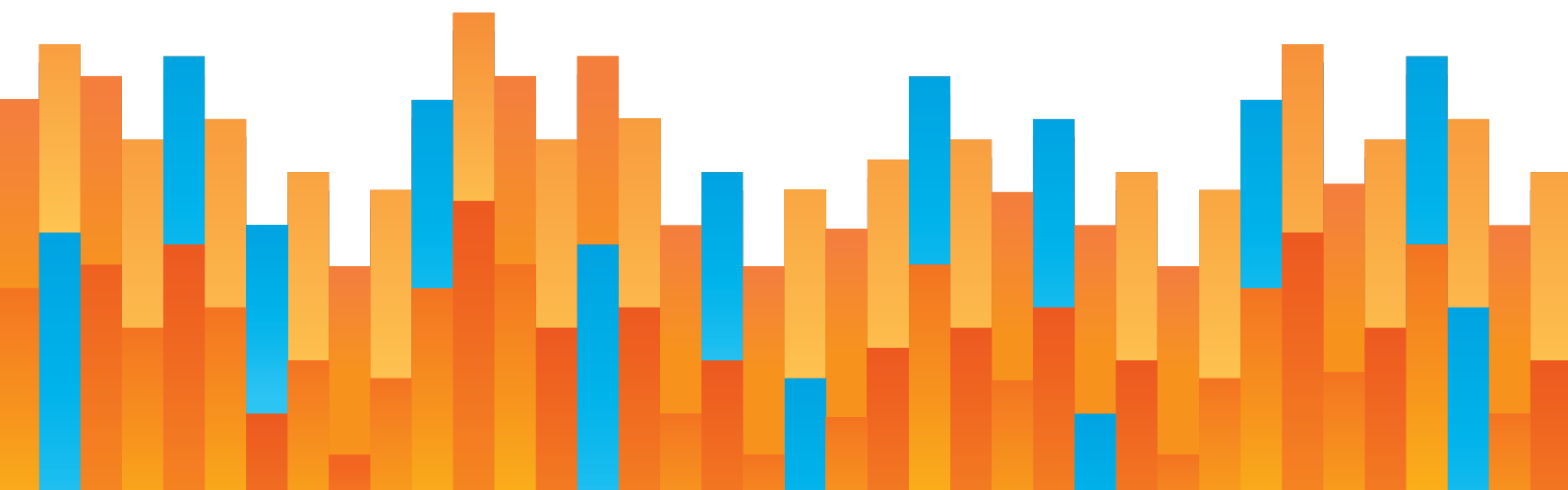


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NEW MARKET ENTRANTS AND UNCERTAIN DRUG POLICY IN THE UNITED STATES: KRATOM AND DELTA-8 THC ILLUSTRATE TRADEOFFS

by Nathaniel Wilson
Project Director: Adrian T. Moore

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PART 1

INTRODUCTION

Humans are naturally curious. When we see something new and unfamiliar it elicits an almost uncontrollable response. Even if for just a brief moment, we become enthralled with the new, unless and until we are satisfied it is not something we care about. This is why companies market products by the register in places like gas stations and liquor stores.¹ A particular sect of these products tends to be marketed as stimulants, enhancers, and/or sedatives.² Depending on the state, it may not be out of the ordinary for the patron of a gas station to walk in and find a product marketed as a “legal high,” something that mirrors the illicit. At one point or another, that same patron, in that same gas station, could likely find several more products sold as “herbal remedies” designed to increase stamina or offer pain relief. Products like these are not only sold in gas stations and liquor stores but can also be found in increasing supply all over the internet, sometimes imported from other countries. The attention that these products demand necessarily makes one consider a number of questions. What are these products? Are they safe? Can they be trusted as they are marketed? Are they legal? The bottom line is that the wariness of the reasonable consumer should fluctuate depending on where these products are purchased, as the quality of the product is evidently variable. Some of these products are downright unsafe, while others

¹ John Quelch and Kristina Cannon-Bonventre, “Better Marketing at the Point of Purchase,” *Harvard Business Review*, Nov. 1983, <https://hbr.org/1983/11/better-marketing-at-the-point-of-purchase>.

² Jeremy Glass, “I Spent a Week Doing Gas Station Drugs, These Are My Findings,” *Thrillist*, Mar. 13, 2014, <https://www.thrillist.com/vice/the-great-gas-station-drug-test>.

may be virtually harmless. Undoubtedly, some products are more worthy than others, with the capability of having legitimate applications beyond mere recreation. However, these applications may never be discovered because, from a public policy standpoint, these products all get lumped together, doomed to a furtive abyss.



The attention that these products demand necessarily makes one consider a number of questions. What are these products? Are they safe? Can they be trusted as they are marketed? Are they legal?



This brief focuses on two substances that fit the above description. They are each regularly sold to consumers across the country and are gaining in popularity, especially among younger demographics. Delta-8 THC is a relatively new phenomenon that has been introduced into consumer markets across the country, though it has been a known derivative of the cannabis plant for decades. The brief will discuss the legality of delta-8 THC, including the significant role of the 2018 Farm Bill, in this analysis. Additionally, it examines whether or not delta-8 THC is truly legal at the federal level today and provides a forward-looking analysis as to any potential changes that are likely to come in the future. This brief then explores concerns that a business has to contend with if it wants to manufacture and sell delta-8 products, as well as the policy considerations for regulators who want to focus their sights on these particular products. After discussing delta-8, this brief turns to kratom, a substance similarly besieged by incoherent government policy as it gets regularly sold to consumers across the country. Kratom, which is marketed as an herbal supplement, is another substance that has been around for a long time but has seen a recent rise in interest for its potential recreational and therapeutic applications. As with delta-8, this brief discusses the legal environment surrounding kratom, as well as the policy considerations that must factor into an effective regulatory scheme for this particular substance. The concluding discussion forges the overall approach that should be taken when dealing with new market entrants in these “underground” markets.

PART 2

DELTA-8 THC

THC, as it is popularly understood, is more accurately referred to as delta-9-tetrahydrocannabinol. Historically, it is the cannabis plant component that has made the plant so popular, or infamous—depending on the reader. Delta-9 THC is a naturally occurring chemical compound that is sourced from the cannabis plant. Additionally, it may be synthetically produced.³ It is one of more than 100 such chemical compounds, called cannabinoids, that have been isolated from the cannabis plant to date.⁴ CBD (cannabidiol) is another example of a cannabinoid, one that has gotten a lot of attention in the past few decades. The rise in popularity of CBD and other cannabinoids shows that there are growing markets for cannabis-derived products that are not entirely dependent on the plant's seemingly marquee component. This much is evidenced by the booming hemp industry, expected to be worth more than \$15 billion by 2027.⁵ Due in part to the promise of the hemp industry, another cannabinoid that is currently positioned to draw a big market is delta-8-tetrahydrocannabinol.

³ “PubChem Compound Summary for CID 16078, Dronabinol,” National Center for Biotechnology Information, 2021, <https://pubchem.ncbi.nlm.nih.gov/compound/Dronabinol>.

⁴ “Cannabis (Marijuana) and Cannabinoids: What You Need To Know,” National Center for Complementary and Integrative Health, <https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know>.

⁵ “Industrial Hemp Market Worth \$15.26 Billion By 2027,” Grand View Research, Feb. 2020, <https://www.grandviewresearch.com/press-release/global-industrial-hemp-market>.

Distinguishing it from delta-9, the National Cancer Institute describes delta-8 THC as “an analogue of tetrahydrocannabinol (THC) with antiemetic (nausea-reducing), anxiolytic, appetite-stimulating, analgesic, and neuroprotective properties...[that] exhibits a lower psychotropic potency than delta-9-tetrahydrocannabinol (delta-9-THC), the primary form of THC found in cannabis.”⁶ In molecular composition, delta-8 differs from delta-9 only by the location of a double bond on their respective carbon chains.⁷ However, this small difference at the molecular level brings with it a significantly different profile to the consumer. Users report effects similar but less intense than those experienced with delta-9 THC.⁸ As part of the findings in a study published in 1995, delta-8 was shown to provide “antiemetic (nausea-reducing) effects without the uncomfortable aspects of the ‘high’ brought on by delta-9.”⁹



In molecular composition, delta-8 differs from delta-9 only by the location of a double bond on their respective carbon chains.... Users report effects similar but less intense than those experienced with delta-9 THC.



Delta-8 is naturally occurring in very small quantities, with dried cannabis flower typically containing less than 1% of the compound.¹⁰ In fact, it is actually only created as a

⁶ NCI, “Drug Dictionary,” National Cancer Institute at the National Institutes of Health, <https://www.cancer.gov/publications/dictionaries/cancer-drug/def/delta-8-tetrahydrocannabinol?redirect=true>.

⁷ D. Civantos, “Delta-8-THC: A secondary cannabinoid with amazing medical and recreational potential,” DINA FEM Seeds, Nov. 9, 2019, <https://www.dinafem.org/en/blog/delta-8-thc-medical-recreational-potential/>.

⁸ Chris Dewildt, “Delta 8 THC: What Is It And What Does It Do?” Growers Network, Mar. 29, 2019, <https://growersnetwork.org/processing/delta-8-thc/>.

⁹ Timothy Anderson, “Atomic Bonds: The Increasing Relevance of Delta-8-THC,” *CannabisNow*, June 23, 2020, <https://cannabisnow.com/atomic-bonds-the-increasing-emergence-of-delta-8-thc/>.

¹⁰ Dave Kriegel, “Delta 8 THC: Creating a New Buzz for Cannabis,” Vaping360, Oct. 28, 2020.

byproduct of the degradation of the delta-9 compound.¹¹ Thus, in order to turn this cannabinoid into a usable product, it must undergo a process of extraction or synthetization. One might accomplish this by various existing processes. One way is to extract the compound from plant matter using a “thin film” distillation process.¹² Since delta-8 only naturally occurs as the delta-9 compound degrades over time, no current genetics are available to optimize delta-8 levels in a given plant or strain. Though, growers are currently using selective breeding to attempt to maximize the amount of delta-9 compound that will degrade into delta-8, producing delta-8-rich genetic strains. In the meantime, delta-8 is extracted similarly across all variations of the cannabis plant, most commonly from hemp plants due to its growing availability nation-wide.



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After sourcing, the appropriate plant material must go through a distillation process exposing it to intense variations in temperature and pressure that isolate the delta-8 compound. While this process is common for extracting other distillates from the cannabis plant, it is not the most economical or efficient way to process delta-8 distillate. A second, patented process converts CBD to tetrahydrocannabinols through isomerization.¹³ There is growing interest around the isomerization process because CBD naturally occurs in far greater quantities than delta-8 does. From an economic standpoint, this makes the process

¹¹ Arno Hazekamp, et al., “Cannabis: From Cultivar to Chemovar II – A Metabolomics Approach to Cannabis Classification,” *Cannabis and Cannabinoid Research*, 2016, 202-215. <https://www.liebertpub.com/doi/full/10.1089/can.2016.0017>.

¹² “Delta 8: How it’s made,” Delta 8 Science, <https://delta8.science/how-to-make-delta-8/>.

¹³ U.S. Patent US-7399872-B2.

far more enticing to manufacturers. As a result, the isomerization process is quickly taking over the hemp industry as the primary means of acquiring delta-8 to meet the demand for final product.¹⁴

2.1

LEGAL STATUS OF DELTA-8-THC



The current legal status of delta-8-THC is not quite clear. Nonetheless, delta-8 products are still being sold online and in stores around the country. Thus, vendors that choose to manufacture and sell these products are operating within a legal gray area.



The current legal status of delta-8-THC is not quite clear. Nonetheless, delta-8 products are still being sold online and in stores around the country. Thus, vendors that choose to manufacture and sell these products are operating within a legal gray area. At the moment, they profit from a budding market as federal and state enforcement remains shackled by uncertainty, but depending on how public policy turns, these businesses risk asset forfeiture and other adverse outcomes in the future. Currently, the legality likely turns on interpretations of the Controlled Substances Act, the 2018 Agricultural Improvement Act (the Farm Bill), Federal Rules administered by the Drug Enforcement Agency, as well as state laws and regulations.

It is best to begin this legal analysis by looking at how delta-8 THC might fall under the scheduling of the Controlled Substances Act. The CSA places drugs in one of five schedules based, in part, on the potential they have to cause harm to the user. Schedule I drugs or other substances are deemed as having “a high potential for abuse...no currently accepted medical use...[and] a lack of accepted safety...under medical supervision.”¹⁵ Notoriously,

¹⁴ Anderson, “Atomic Bonds: The Increasing Relevance of Delta-8-THC.”

¹⁵ Controlled Substances Act, 21 U.S.C. § 812(b)(1)(A)-(C), 1970.

marijuana is one of the substances that is currently listed under Schedule I, alongside drugs such as methamphetamine and heroin. Listed separately, tetrahydrocannabinols also find themselves under Schedule I of the CSA.¹⁶ Absent any exceptions or further specifications in the law, this Schedule I status of tetrahydrocannabinols would seem to make it clear that delta-8-THC is a federally illegal substance. This very well may have been the case for several years, but the passage of the 2018 Farm Bill added a layer of complexity to this analysis when it excluded hemp and its derivatives from Schedule I, while also prompting the DEA to amend its regulations surrounding the hemp industry.



In terms of cannabis regulation, the 2018 Farm Bill's primary achievement was removing hemp from its previous Schedule I status.



In terms of cannabis regulation, the 2018 Farm Bill's primary achievement was removing hemp from its previous Schedule I status. Prior to the bill's passage, federal law did not differentiate between marijuana and hemp. After the Farm Bill, hemp is now defined as the cannabis plant and any of its parts, "including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."¹⁷ Thus, the legal distinction between marijuana and hemp is solely dependent upon the content of delta-9 tetrahydrocannabinol. This leaves delta-8 with no legal effect on distinguishing between marijuana and hemp, but it can potentially benefit from the distinction. Now that hemp is federally legal, delta-8 has the potential to be legally extracted from the crop. Seemingly making this explicit, the Farm Bill amended the CSA's scheduling of tetrahydrocannabinols by adding that the Schedule I status continues to apply "except for tetrahydrocannabinols in hemp (as defined under section 1639 of title 7)".¹⁸ However, one must turn to agency interpretation of the statute to gain further insight, as there are still layers to be added to this legal analysis.

¹⁶ Ibid.

¹⁷ 7 U.S.C. § 5940 (a)(2).

¹⁸ Controlled Substances Act, 21 U.S.C. § 812(b)(1)(A)-(C), 1970.



Statutory interpretations embodied in the rules imposed by the DEA have some of the greatest potential to dramatically impact the legal landscape upon which delta-8 must stand.



The federal agency whose primary responsibility it is to regulate federal drug laws is the Drug Enforcement Agency. Statutory interpretations embodied in the rules imposed by the DEA have some of the greatest potential to dramatically impact the legal landscape upon which delta-8 must stand. Effective August 21, 2020, the DEA published an Interim Final Rule designed to implement and codify in its CSA regulations the statutory amendments that the 2018 Farm Bill passed into law.¹⁹ The DEA’s Interim Final Rule reads, “the AIA does not impact the control status of synthetically derived tetrahydrocannabinols...*all synthetically derived tetrahydrocannabinols remain schedule I controlled substances.*”²⁰ This language was likely responding, at least in part, to the growing market proliferation of delta-8 products. Assuming this language is to remain part of the DEA’s regulatory approach, the issue is whether or not delta-8 should be considered synthetically derived.

Conveniently, the DEA did not provide a definition of “synthetic” or “synthetically derived” with its legal distinction between synthetically and non-synthetically derived tetrahydrocannabinols, nor can such a definition be found in the Controlled Substances Act. The closest analogue available in anticipating how the DEA might enforce this language is the agency’s treatment of K2 or Spice—substances or chemicals collectively considered synthetic cannabinoids.²¹ Similar to how delta-8 products are currently sold, products

¹⁹ Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639 (Aug. 21, 2020) (to be codified at 21 C.F.R. pt. 1308 and 21 C.F.R. pt. 1312).

²⁰ Ibid.

²¹ “Synthetic Cannabinoids (K2/Spice) Drug Facts,” National Institute on Drug Abuse, Feb. 5, 2020. <https://www.drugabuse.gov/publications/drugfacts/synthetic-cannabinoids-k2spice>.

containing K2 or Spice once proliferated as “legal” substitutes to marijuana.²² Prior to the introduction of stricter regulations, these products could be found in stores or purchased online as “herbal incense.”²³ Chemicals like K2 and Spice were designated as Schedule I substances in 2011 after the DEA exercised its emergency scheduling authority in response to the unregulated market prevalence of products containing these chemicals.²⁴



If the DEA’s understanding of what constitutes “synthetic” is consistent, then delta-8 products should enjoy a little grace, but the issue could ultimately come down to whether a specific manufacturer employs a distillation or isomerization process.



Synthetic cannabinoid products like Spice or K2 contain chemicals manufactured in a laboratory that are intended to mimic the effects of delta-9 THC.²⁵ Manufacturers concoct these chemicals into a liquid form and then spray that liquid onto plant matter so that it can then be smoked or otherwise consumed in a manner much like marijuana.²⁶ If the DEA’s understanding of what constitutes “synthetic” is consistent, then delta-8 products should enjoy a little grace, but the issue could ultimately come down to whether a specific manufacturer employs a distillation or isomerization process. It would be difficult to argue that delta-8, which undergoes a distillation process from plant matter, is anything other than organically derived. On the flip side, the ever-increasing popularity of turning CBD

²² Daniel DeNoon, “FAQ: K2, Spice Gold, and Herbal ‘Incense’, WebMD, <https://www.webmd.com/mental-health/addiction/news/20100305/k2-spice-gold-herbal-incense-faq#1>.

²³ Ibid.

²⁴ U.S. Drug Enforcement Administration, “Chemicals Used In ‘Spice’ And ‘K2’ Type Products Now Under Fed. Control and Regulation, March 1, 2011.

²⁵ Ashley Yeager, “How K2 and Other Synthetic Cannabinoids Got Their Start in the Lab,” *The Scientist*, Nov. 27, 2018, <https://www.the-scientist.com/news-opinion/how-k2-and-other-synthetic-cannabinoids-got-their-start-in-the-lab-65145>.

²⁶ Ibid.

into THC arguably involves a process of synthetization.²⁷ Since manufacturers find the isomerization process more economically advantageous, the DEA could significantly constrain the supply of delta-8 by considering THC isomerized from CBD as “synthetically-derived.” However, if growers end up successful in their attempts to produce cannabis strains with more-concentrated amounts of delta-8, then this would offer a lot of opportunities for those invested in the cannabinoid, regardless of the DEA’s ultimate approach toward “synthetically-derived” tetrahydrocannabinols.

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For the time being, federal law appears to create an opening for a legal market where delta-8 THC products may be bought and sold. As an interesting caveat, the DEA does have delta-8 THC included on its listing for tetrahydrocannabinols in an online version of its “Orange Book,” which alphabetically lists substances regulated by the agency.²⁸ “Delta-8 THC” can be found under “Other Names” for tetrahydrocannabinols (DEA# 7370) in this publication.²⁹ Despite this apparent complication, the “Orange Book” has no legal force, and the preceding analysis on delta-8’s legality remains accurate, though subject to an uncertain future.³⁰ Rod Kight, an attorney who represents cannabis industry clients, maintains that it is “clear that D8 derived from hemp is lawful pursuant to the 2018 Farm Bill, which exempts from the CSA ‘all’ cannabinoids from hemp with a D9 concentration that does not exceed 0.3%.”³¹ Delta-8 THC that is derived from cannabis with a delta-9

²⁷ Jessica McKeil, “How Delta-8 THC is Made in the Lab,” Cannabis Tech, March 29, 2021, <https://www.cannabistech.com/articles/how-delta-8-is-made-in-the-lab/>.

²⁸ U.S. Drug Enforcement Agency, “Controlled Substances – Alphabetical Order,” July 20, 2021, https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.

²⁹ Ibid.

³⁰ Patrick Williams, “Delta-8 THC in the DEA’s Orange Book: What It Means,” HempGrower, May 14, 2021, <https://www.hempgrower.com/article/delta-8-thc-dea-drug-enforcement-administration-orange-book-what-it-means/>

³¹ Ibid.

concentration exceeding 0.3% is a controlled substance based on the earlier interpretation of the law, so delta-8's inclusion in the "Orange Book" does not lead to any inconsistencies, but rather is just a situation that may be necessary for consumers and businesses to monitor going forward.



At the state level, products containing delta-8 THC are subject to varied treatment. In a majority of states, these products are neither banned nor regulated.



At the state level, products containing delta-8 THC are subject to varied treatment. In a majority of states, these products are neither banned nor regulated.³² However, several states have taken steps to address the ambiguity created by federal law in this area. As of July 2021, 17 states have moved to either restrict or outright ban the market for products containing delta-8 THC.³³ Alaska, Arizona, Arkansas, Colorado, Delaware, Kentucky, Idaho, Iowa, Mississippi, Montana, New York, North Dakota, Rhode Island, Utah, and Vermont have all passed legislation or implemented regulations that effectively ban delta-8 THC.³⁴ In Kentucky, state law follows federal law when it comes to the control of Schedule I substances, and the Kentucky Department of Agriculture actually interprets federal law as designating delta-8 THC a Schedule I substance.³⁵ In a letter to Kentucky hemp license holders, KDA General Counsel Joe Bilby acknowledged that the 2018 Farm Bill created an exemption for cannabis containing no more than 0.3% delta-9 THC, but maintained that "there is no equivalent exemption for Delta-8 THC."³⁶ Recall that the concentration of

³² Brandon Dunn, "Updated: Delta-8 legality map," Greenway, July 14, 2021, <https://mogreenway.com/2021/07/14/delta-8-legality-map/>.

³³ Ibid.

³⁴ Theresa Bennett, "More States Take Action Against Delta-8 THC," HempGrower, June 21, 2021, <https://www.hempgrower.com/article/states-that-ban-delta-8-thc-update-new-york-north-dakota-vermont/>.

³⁵ Kentucky Department of Agriculture, "Opinion Letter on the Scheduling Status of Delta-8 THC." April 19, 2021.

³⁶ Ibid.

delta-9 THC only determines whether cannabis will be considered hemp, and that *all* cannabinoids derived from hemp—including tetrahydrocannabinols, are exempt from Schedule I status. That being the case, the KDA’s interpretation of federal law is, at best, questionable. It is entirely possible that Kentucky officials are aware of how weak this argument is; nonetheless they are putting it forward because such an interpretation leads to prohibiting delta-8 products within the state, while circumventing more traditional and slower means of policy formation.³⁷



Other states have moved to regulate the manufacture and sale of products containing delta-8 THC. Michigan is the most recent example.



Other states have moved to regulate the manufacture and sale of products containing delta-8 THC. Michigan is the most recent example. On July 13, 2021, Gov. Gretchen Whitmer signed into law several amendments to the state’s established regulations over the manufacture and sale of cannabis products.³⁸ Once in effect, the new Michigan laws will regulate delta-8 products the same as products containing marijuana. The amended law distinguishes between “marihuana” and “hemp” based on total THC content, rather than creating a distinction based on delta-9 THC alone.³⁹

³⁷ Steven Gothrinet, “Kentucky Hemp Association Furious Over Delta-8 THC Raids,” Hemp Gazette, July 20, 2021, <https://hempgazette.com/news/kentucky-hemp-delta-8-hg1485/>.

³⁸ Melissa Schiller, “Michigan Governor Signs Legislation to Regulate Delta-8 THC,” HempGrower, July 14, 2021, <https://www.hempgrower.com/article/michigan-governor-signs-legislation-to-regulate-delta-8-thc/>.

³⁹ (2021) Mich. Pub. Act 56.

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POLICY CONSIDERATIONS AND APPROACH TOWARD REGULATING DELTA-8 THC

Proponents of delta-8 should feel confident that the DEA’s approach toward delta-8 products will be different than that which was seen in the case of synthetic cannabinoids like K2 or Spice. For one, there doesn’t appear to be evidence of the health risks that accompany K2/Spice. The National Institute of Drug Abuse reported that, in 2010 alone, more than 11,000 ER visits nation-wide could be attributed to the use of synthetic cannabinoids like K2/Spice.⁴⁰ Serious side effects of its use include violent behavior, increased heart rate, and extreme paranoia.⁴¹ The active chemicals in these products are believed to be four to five times as potent as organically derived delta-9 THC.⁴² As a result, products containing these synthetic cannabinoids result in relatively prevalent overdoses. Though available research may be limited, Delta-8 has not been shown to cause such severe effects. In fact, various studies show potential legitimate medical application for delta-8. Different studies demonstrate delta-8’s ability to combat anxiety and nausea, and even the potential to reduce the size of cancerous tumors.⁴³ Nonetheless, more studies must be done before the safety of delta-8 products can be definitively backed by science.

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Different studies demonstrate delta-8’s ability to combat anxiety and nausea, and even the potential to reduce the size of cancerous tumors.

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⁴⁰ “The Effects and Dangers of K2,” American Addiction Centers, Dec. 13, 2020, <https://americanaddictioncenters.org/synthetic-cannabinoids/k2>.

⁴¹ Ibid.

⁴² Travis Heath, et al., “Acute Intoxication Caused by a Synthetic Cannabinoid in Two Adolescents,” *The Journal of Pediatric Pharmacology and Therapeutics*, 17, 2012, 177.

⁴³ “What Does Research Say About the Medical Benefits of Delta 8 THC,” Delta 8 Oils, Aug. 13, 2020, <https://www.delta8oils.com/medical-benefits-of-delta-8/>.

Another reason for a different regulatory approach to delta-8 products is that they are manufactured and sold in a non-clandestine manner. When popular, most of the synthetic cannabinoids were sold in packaging marked as “not for human consumption” in an attempt to conceal the intended purpose of the products.⁴⁴ This made it abundantly clear that the distributors lacked confidence in the safety of the products they were putting on the market and were deliberately trying to avoid criminal liability. This type of marketing scheme, where products are sold under the guise of an ulterior use from what is clearly intended, is extremely dangerous to the unwitting consumer. Though it notifies the consumer that the product is not approved for consumption, the very fact that it can be legally purchased in stores conveys the false sense that any risk assumed will be negligible. In contrast to this marketing scheme, vendors sell delta-8 products explicitly, and with an emphasis placed on transparency, to the consumer. Though some products on the market should not be trusted at face value, the most prominent delta-8 product vendors make an effort to educate the consumer of what delta-8 THC is, the effects of its use, and provide assurance about the quality of the products they sell.⁴⁵



Though it notifies the consumer that the product is not approved for consumption, the very fact that it can be legally purchased in stores conveys the false sense that any risk assumed will be negligible.



The problem with a lack of regulation over delta-8 products is not that delta-8 itself is a menace to society, but that the unregulated market may lead to some risks that the individual consumer cannot easily manage. For example, vape products have some uncertainty about the risks of unregulated heavy metals in vape liquids. Anything that gets inhaled into the lungs is likely to cause a health risk, but contaminants like heavy metals make this risk far greater. Providing information to consumers, at a minimum, and

⁴⁴ Cmdr. Lisa McWhorter, *There's a Reason The Package Says 'Not For Human Consumption'*, Navy Medicine Live, <https://navymedicine.navylive.dodlive.mil/archives/894>.

⁴⁵ “What is Delta 8 THC?” 3Chi, <https://www.3chi.com/delta-8-thc/>.

establishing either voluntary or mandatory standards for hazardous materials in vape products could make sense, but would also be difficult to implement given currently available research.⁴⁶ Despite any difficulties facing regulation in this area, no evidence supports the concern that delta-8 products are likely to cause an impending public health crisis. If there is going to be regulation in this area, it should primarily focus on protecting the individual consumer. In regard to using delta-8 THC products recreationally, societal interests would be best served by government regulation that ensures product consistency. The known risks of these products are not weighty enough to support criminalization. In fact, there are strong interests in promoting further study of this cannabinoid so its applications beyond pure recreation may be more fully understood.



In regard to using delta-8 THC products recreationally, societal interests would be best served by government regulation that ensures product consistency. The known risks of these products are not weighty enough to support criminalization.



⁴⁶ Monique Williams, et al., “Effects of Mode, Method of Collection and Topography on Chemical Elements and Metals in the Aerosol of Tank-Style Electronic Cigarettes,” *Scientific Reports*, 9, 2019; and Konstantinos E. Farsalinos and Brad Rodu, “Metal emissions from e-cigarettes: a risk assessment analysis of a recently-published study,” *International Forum for Respiratory Research*, 7-8, November 2, 2018, 321-26.

PART 3

KRATOM

Mitragyna speciosa, commonly known as kratom, is a tree-like plant indigenous to Southeast Asia, particularly Thailand.⁴⁷ It is a part of the coffee family.⁴⁸ For centuries, the plant has been chewed or ground up into powder and consumed for spiritual and medicinal purposes due to the stimulating and sedating effects of its two active chemicals, mitragynine and 7-hydroxymitragynine.⁴⁹ Users report an effect similar to that of coffee when taken in small doses and a more opiate-like effect when taken in heavy doses.⁵⁰ Kratom is similar to delta-8 in that both substances have become increasingly popular in the United States in recent years, and both have sparked a current nation-wide discussion concerning appropriate regulatory measures. These trends are even more established for kratom as they have been ongoing for the better part of two decades. Though similar to delta-8 in this respect, the discussion surrounding kratom is much more embroiled with opposition due to serious concern over the substance's potential for abuse. Nevertheless, kratom can be readily

⁴⁷ Peter Grinspoon, MD, "Kratom: Fear-worthy foliage or beneficial botanical?," Harvard Health Blog, August 7, 2019, <https://www.health.harvard.edu/blog/kratom-fear-worthy-foliage-or-beneficial-botanical-2019080717466>.

⁴⁸ Ibid.

⁴⁹ Eduardo Cinosi, et al., "Following "the Roots" of Kratom (*Mitragyna speciosa*): The Evolution of an Enhancer from a Traditional Use to Increase Work and Productivity in Southeast Asia to a Recreational Psychoactive Drug in Western Countries," *BioMed Research International*, 2015, <https://doi.org/10.1155/2015/968786>.

⁵⁰ Ibid.

purchased online and in stores through “head shops,” where the substance is sold in capsules or in powder form and is typically marketed as a dietary supplement.⁵¹ Additionally, “kratom bars” have been established in some states, providing menu items where the substance is mixed into a tea-like beverage.⁵² One establishment in Arizona even sold products containing the substance in a vending machine.⁵³ These developments are indicative of kratom’s presence in the marketplace, one unfettered by a lack of coherent policy on its manufacture and sale. However, the discussion regarding the need for regulation rages on and is likely to demand a governmental response at some point.



...kratom can be readily purchased online and in stores through “head shops,” where the substance is sold in capsules or in powder form and is typically marketed as a dietary supplement.



3.1

LEGAL STATUS OF KRATOM

The legal status of kratom seems clear on the surface but experiences considerable turbulence as the substance is subject to much controversy, thus producing ever-evolving federal regulatory efforts. At the federal level, kratom is not currently a controlled substance. However, the DEA has attempted to schedule the substance, and there are likely to be further efforts in the future. Additionally, the FDA has an ongoing track record of getting involved in its regulation since kratom is often sold as an orally consumed herbal remedy. DEA and FDA efforts largely comprise all that is being done at the federal level, but various states and municipalities have taken it upon themselves to issue their own bans

⁵¹ A head shop is a shop specializing in drug paraphernalia.

⁵² Justin Grant, “Bar review: No booze, but kratom, kava, kombucha at Mad Hatters,” *Tampa Bay Times*, Aug. 4, 2016, <https://www.tampabay.com/things-to-do/food/spirits/bar-review-no-booze-but-kratom-kava-kombucha-at-mad-hatters/2288213/>.

⁵³ Liz O’Connell, “A Tucson sub shop vending machine that attracts drug-enforcement interest,” *El Inde*, Dec. 21, 2016, <https://arizonasonoranewsservice.com/?p=19514>.

on kratom. To understand the legal environment surrounding this substance, it is best to compare federal measures with state and local approaches.



In August of 2016, the DEA announced its intent to essentially ban kratom by placing the two major compounds found in kratom—mitragynine and 7-hydroxymitragynine—on Schedule I of the CSA.



The DEA lists kratom as a Drug and Chemical of Concern.⁵⁴ These are drugs and chemicals that, though not listed as controlled substances, are considered by the DEA to pose a health risk to the public.⁵⁵ In August of 2016, the DEA announced its intent to essentially ban kratom⁵⁶ by placing the two major compounds found in kratom—mitragynine and 7-hydroxymitragynine—on Schedule I of the CSA. As it did with K2/Spice, the DEA planned on exercising its emergency scheduling authority under Section 201 of the CSA, which authorizes the DEA to issue a temporary scheduling of a substance where it is deemed “necessary to avoid an imminent hazard to the public safety.”⁵⁷ The agency primarily cited findings of adverse health effects on users as well as a tendency for abuse as its main justifications to invoke its emergency scheduling authority.⁵⁸ This would have effectively banned kratom at the federal level for at least two years. However, this announcement met stiff opposition, even resulting in protests in front of the White House.⁵⁹ As a result, the DEA backed off its initial plan and proceeded to solicit comments from the public.⁶⁰

⁵⁴ U.S. Drug Enforcement Administration, “Drug Fact Sheet, Kratom,” April 2020.

⁵⁵ U.S. Drug Enforcement Administration, “Drugs of Concern,” <https://www.dea.gov/taxonomy/term/311>

⁵⁶ U.S. Drug Enforcement Administration, “Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I,” Federal Register, 81, 59, 929, Aug. 31, 2016 (to be codified at 21 C.F.R. 1308). [Here after referred to as 2016 DEA Kratom Announcement].

⁵⁷ Controlled Substances Act, 21 U.S.C. § 811(h)(1).

⁵⁸ 2016 DEA Kratom Announcement.

⁵⁹ Brett Erikson, “Kratom users protest imminent ban,” *Chemical & Engineering News*, Sept. 14, 2016, <https://cen.acs.org/articles/94/i37/Kratom-users-protest-imminent-ban.html>.

⁶⁰ U.S. Drug Enforcement Administration, Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-Hydroxymitragynine Into Schedule I, 81 FR 70,652, Oct. 13, 2016.



The FDA has also played a significant role in the federal response to kratom and is arguably even more active than the DEA, exercising jurisdiction over the substance as an unapproved dietary supplement.



The FDA has also played a significant role in the federal response to kratom and is arguably even more active than the DEA, exercising jurisdiction over the substance as an unapproved dietary supplement.⁶¹ The agency has explicitly warned consumers against products containing kratom, stating that “there are no FDA-approved uses for kratom, and the agency has received concerning reports about the safety of kratom.”⁶² It even refers to the substance as an opioid.⁶³ Beginning in 2012, the FDA issued an import alert for unapproved drugs, identifying kratom as a “product subject to Detention Without Physical Examination (DWPE).”⁶⁴ They added to this alert in 2014, specifying that all dietary supplements and bulk dietary supplements containing *mitragyna speciosa* or kratom are subject to DWPE.⁶⁵ This remains the agency’s current guidance on imported kratom products.⁶⁶ In addition to the alerts, the FDA has ordered seizure of several kratom shipments from other countries. Between 2014 and 2016, at the FDA’s request, the U.S. Marshals seized more than \$5.5 million worth of products labeled as containing *mitragyna speciosa* or kratom.⁶⁷

⁶¹ U.S. Food & Drug Administration, “Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom,” Nov. 14, 2017.

⁶² U.S. Food & Drug Administration, “FDA and Kratom,” Sept. 11 2019.

⁶³ U.S. Food & Drug Administration, “FDA oversees destruction and recall of kratom products; and reiterates its concerns on risks associated with this opioid,” Feb. 21, 2018, [here after referred to as 2018 FDA Kratom Announcement].

⁶⁴ Kiersen Commons, “Cracking Down on Kratom: FDA Investigations, Enforcement, Seizure, and Recall of Products Reported to Contain Kratom,” Food and Drug Law Institute, 2018, <https://www.fdl.org/2018/08/update-cracking-down-on-kratom-fda-investigation-enforcement-seizure-and-recall-of-products-reported-to-contain-kratom/>.

⁶⁵ U.S. Food & Drug Administration, “Import Alert 54-14,” June 11, 2019, https://www.accessdata.fda.gov/cms_ia/importalert_1137.html.

⁶⁶ U.S. Food & Drug Administration, “Import Alert 54-15,” April 08, 2021.

⁶⁷ FDA and Kratom Announcement.

Domestically, over the past few years the FDA has issued warning letters to kratom distributors that market their products with various medical claims.⁶⁸ The agency has also worked with distributors that have agreed to voluntarily recall and destroy their own products that contain kratom.⁶⁹ In May 2021, the FDA seized approximately \$1.3 million worth of products containing kratom from a distributor based in Florida.⁷⁰ Reaffirming the agency's position on the matter, the FDA's associate commissioner for regulatory affairs stated, "the FDA will continue to exercise our full authority under the law to take action against these adulterated dietary supplements."⁷¹

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In May 2021, the FDA seized approximately \$1.3 million worth of products containing kratom from a distributor based in Florida.

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In July 2021, going beyond national policy, the FDA began soliciting public comment to inform the United States' position on kratom regarding international drug treaties.⁷² In particular, the United States is party to the 1971 Convention on Psychotropic Substances, an international agreement signed by 34 countries that controls substances with a high potential for abuse.⁷³ As mandated by the treaty, the World Health Organization's independent advisory board, called the Expert Committee on Drug Dependence (ECDD),

⁶⁸ U.S. Food & Drug Administration, "FDA issues warnings to companies selling illegal, unapproved kratom drug products marketed for opioid cessation, pain treatment and other medical uses," June 25, 2019.

⁶⁹ 2018 FDA Kratom Announcement.

⁷⁰ U.S. Food & Drug Administration, "FDA Announces Seizure of Dietary Supplements Containing Kratom," May 21, 2021.

⁷¹ Ibid.

⁷² U.S. Food & Drug Administration, International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F-MDMB-BICA (4F-MDMB-BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut: Request for Comments, 86 Fed. Reg. 39038, July 23, 2021, [here after referred to as FDA International Drug Scheduling Notice].

⁷³ United Nations, "Convention on Psychotropic Substances," February 21, 1971, 1019 U.N.T.S. 175. https://www.unodc.org/pdf/convention_1971_en.pdf

convened for its 44th meeting in October 2021.⁷⁴ The ECDD meeting gives member states an opportunity to provide information and exercise influence on substances that should be reviewed for scheduling under the treaty.⁷⁵ Thus, U.S. officials were recently able to lobby the international community in regard to their concerns over kratom. In its notice for public comment leading up to this meeting, the FDA made it clear that its position had not wavered, stating “kratom is abused for its ability to produce opioid-like effects” and “kratom can lead to a number of health impacts.”⁷⁶ Though action from the ECDD on this matter has yet to be seen, scheduling kratom via international treaty would restrict it in and among member states.⁷⁷ Therefore, a successful appeal to the international community could derail a legitimate kratom industry in the United States.



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At the state level, the legality of kratom varies quite dramatically. In most states, products containing kratom remain unregulated as they are federally. However, some states have passed legislation governing the manufacture, sale, possession, and use of kratom. The state legislatures in Arizona, Georgia, Utah, and Nevada have all passed their own versions of the Kratom Consumer Protection Act (KCPA).⁷⁸ Similar legislation is currently being considered in various other state legislatures across the country.⁷⁹ The KCPA allows for kratom to be legalized while also imposing regulations on its manufacture and sale, so as

⁷⁴ World Health Organization, “Forty-fourth Expert Committee on Drug Dependence,” <https://www.who.int/news-room/events/detail/2021/10/11/default-calendar/forty-fourth-expert-committee-on-drug-dependence>.

⁷⁵ United Nations, “Convention on Psychotropic Substances,” at Art. 2.

⁷⁶ FDA International Drug Scheduling Notice.

⁷⁷ United Nations, “Convention on Psychotropic Substances.”

⁷⁸ Josh Long, “State legislators seek kratom meeting with FDA commissioner,” Natural Products Insider, June. 18, 2020, <https://www.naturalproductsinsider.com/regulatory/state-legislators-seek-kratom-meeting-fda-commissioner>.

⁷⁹ “State-by-State Kratom Developments,” American Kratom Association, <https://www.amerikanratom.org/advocacy/aka-in-your-state.html> (visited Dec. 13, 2020).

to mitigate health risks associated with the clandestine nature of some products currently on the market. While proponents of kratom are pushing legislation to legalize it, states that criminalize the substance in some form or another are considering and passing their own laws. Kratom is outright banned in six states: Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin.⁸⁰ Various cities and counties across the country have also instituted bans, including San Diego, Denver, and Sarasota County.⁸¹

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3.2

POLICY CONSIDERATIONS AND APPROACHES TO REGULATING KRATOM

Regulating kratom is far more complex than delta-8 because the known risks are far more substantial. The problem with developing a convincing argument for or against the use of kratom, in any capacity, is the fact that so little research has been done on its effects. Most of what is known about it largely comes from anecdotal evidence and popular understanding. Research on kratom’s health effects is ongoing, but currently lacks a scientific consensus and raises possible concerns. The issue, thus, becomes whether the potential risks outweigh the potential benefits in such a way that its use cannot be legitimately justified.

Proponents of kratom tout its ability to aid individuals who suffer from opioid addiction and symptoms of withdrawal.⁸² Mitragynine is thought to act on the opioid receptors within the

⁸⁰ “Kratom Legality 2020: Map, Legal Status, and Ban Updates,” Kraoma, <https://kraoma.com/kratom-legality-united-states/>.

⁸¹ Ibid.

⁸² Alan Schwarz, “Kratom, an Addict’s Alternative, Is Found to Be Addictive Itself,” *The New York Times*, Jan. 2, 2016, https://www.nytimes.com/2016/01/03/us/kratom-an-addicts-alternative-is-found-to-be-addictive-itself.html?_r=0.

brain as a viable substitute for opiate dependencies such as morphine and heroin.⁸³ While the pain-relieving properties provide promise for opioid addicts, abuse of its opioid effects concerns regulators, creating a double-edged sword. This is often the main point of contention on kratom's potential applications. Proponents argue that kratom could be a solution to the opioid crisis that has run rampant across the country in the past decade, and there is evidence to back up their argument. Scientists at the University of Florida recently found that kratom possesses "significant pain-relieving effects" and "also demonstrated benefits in treating opioid withdrawal."⁸⁴ But government officials remain skeptical, dismissing most of these health claims as unfounded and likely to mislead the public. More studies will need to be done before there can be a clear resolution to this argument.



While the pain-relieving properties provide promise for opioid addicts, abuse of its opioid effects concerns regulators, creating a double-edged sword.



Though proponents view kratom as a valuable herbal remedy with the potential for important applications beyond recreation, this does not completely dispel the concerns raised by government agencies and health officials. Both the DEA and the FDA maintain that kratom is a dangerous substance that presents a legitimate threat to users. Reported side effects include chills, nausea, vomiting, dizziness, hallucinations, seizures, and even coma and death.⁸⁵ In 2019, the CDC reported that kratom killed 91 people over a 17-month

⁸³ David Kroll, "Recreational drug kratom hits the same brain receptors as strong opiates," *Chemical and Engineering News*, June 3, 2016, <https://cen.acs.org/articles/94/i23/Recreational-drug-kratom-hits-same.html>.

⁸⁴ Matthew Splett, "Kratom tea study stirs up new support for relieving opioid dependence," *UFHealth*, Oct. 20, 2020, <https://ufhealth.org/news/2020/kratom-tea-study-stirs-new-support-relieving-opioid-dependence>.

⁸⁵ "Kratom: Unsafe and ineffective," *MayoClinic*, June 3, 2020, <https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/kratom/art-20402171>.

period.⁸⁶ Toxicology reports found kratom to be the only substance present in seven of these deaths.⁸⁷ Unsurprisingly, the FDA has cited this report as part of its justification for a kratom ban. Though alarming, this report and others bear scrutiny, as they could be misleading. Federal agencies have previously relied upon similar data to support their position against kratom, and a vast majority of the deaths included in the dataset occurred in people who had more dangerous substances in their system, such as fentanyl.⁸⁸ In one report, “the FDA even included a homicide victim who was shot in the chest, just because the man was on kratom at the time.”⁸⁹ Additionally, some adverse effects associated with kratom use could be due to the presence of contaminants, rather than due to the substance itself. As studies show, there can be no doubt that kratom has a distinct profile of effects on the user, but contaminants, such as heavy metals and salmonella, have been found in kratom products.⁹⁰



To be clear, any substance that has the potential to cause dependence also carries the potential to cause societal harm, but this is not likely to be remedied by the enforcement of criminal sanctions.



⁸⁶ Harmeet Kaur, “More deaths have been associated with kratom than previously known, CDC study finds,” *CNN*, Apr. 13, 2019, <https://www.cnn.com/2019/04/12/health/kratom-deaths-cdc-study/index.html>.

⁸⁷ Emily O’Malley Olsen, et al., “Notes from the Field: Unintentional Drug Overdose Deaths with Kratom Detected – 27 States, July 2016–December 2017,” *Center for Disease Control*, Apr. 12, 2019.

⁸⁸ James Craven, *What is Kratom and What Should We Do About It?*, (Los Angeles: Reason Foundation, September, 2018. <https://reason.org/wp-content/uploads/kratom-risks-benefits-how-it-should-be-used.pdf>.

⁸⁹ *Ibid.*

⁹⁰ U.S. Food and Drug Administration, “Laboratory Analysis of Kratom Products for Heavy Metals,” April 3, 2019, <https://www.fda.gov/news-events/public-health-focus/laboratory-analysis-kratom-products-heavy-metals>; and U.S. Food and Drug Administration, “FDA Investigated Multistate Outbreak of Salmonella Infections Linked to Products Reported to Contain Kratom,” June 9, 2018 <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigated-multistate-outbreak-salmonella-infections-linked-products-reported-contain-kratom>.

Clearly kratom is controversial, with compelling evidence for differing perspectives on the substance's potential applications and consumption risks. However, there is no compelling evidence in support of criminalization. Beyond the potential health effects on the user, nothing suggests that kratom poses an imminent threat to the public.⁹¹ To be clear, any substance that has the potential to cause dependence also carries the potential to cause societal harm, but this is not likely to be remedied by the enforcement of criminal sanctions. Moreover, a 2020 survey of over 2,500 kratom users conducted by Johns Hopkins showed that less than 3% of users suffered from moderate to severe substance abuse disorders.⁹² More research needs to be completed so that the community can better understand the associated risks of kratom use. As it has done with cannabis and other drugs with unknown potential as medication, criminalizing kratom would significantly hamper the discovery of valuable information that could vindicate kratom's many supporters. In lieu of further study, regulations should be geared toward ensuring that the kratom on the market is clear of unwanted additives. The Kratom Consumer Protection Act embodies that type of approach by accommodating the development of a kratom industry while also providing quality assurance to the consumer.



In lieu of further study, regulations should be geared toward ensuring that the kratom on the market is clear of unwanted additives. The Kratom Consumer Protection Act embodies that type of approach by accommodating the development of a kratom industry while also providing quality assurance to the consumer.



⁹¹ Gabe Allen, "Kratom: What Does Science Say About the Controversial Botanical?" *Discover Magazine*, August 3, 2021, <https://www.discovermagazine.com/health/kratom-what-does-science-say-about-the-controversial-botanical>.

⁹² "Natural Herb Kratom May Have Therapeutic Effects And Relatively Low Potential For Abuse or Harm, According To A User Survey," *Johns Hopkins Medicine*, February 3, 2020, <https://www.hopkinsmedicine.org/news/newsroom/news-releases/natural-herb-kratom-may-have-therapeutic-effects-and-relatively-low-potential-for-abuse-or-harm-according-to-a-user-survey>.

PART 4

CONCLUSION

Substances like delta-8 and kratom are new entrants into what has become an “underground” market for “legal” buzzes and highs. The manufacture and sale of various products in this market flourishes as regulators play a game of catch-up to new fads and trendy habits. This underground market’s inherent main feature is the fact that these products are largely unknown to the public and government agencies. This is a problem because the government has a track record of fumbling the responsibility of regulating substances with which it is unfamiliar, tending to default to criminalization when presented with the unknown.⁹³ Such a knee-jerk and thoughtless approach to drug policy diminishes individual rights, with little to no public benefit. History shows that this approach may even create more harm than good, as the country currently reels from gross over-incarceration of those convicted of nonviolent, drug crimes, as well as an opioid epidemic.⁹⁴ In the absence of a clear threat to societal function at large, it is not the government’s job to mandate what the consumer should be able to use or what the business should be able to sell, particularly when that mandate is enforced through criminal sanctions. Additionally, a lack of knowledge regarding a specific substance’s effects is not compelling enough to

⁹³ Andrew Strohman, “The Drawbacks of the Drug-Scheduling Regime,” American Action Forum, February 14, 2020, <https://www.americanactionforum.org/weekly-checkup/the-drawbacks-of-the-drug-scheduling-regime/#ixzz76ORnvsD2>

⁹⁴ “War On Drugs,” History.com, Dec. 17, 2019, <https://www.history.com/topics/crime/the-war-on-drugs>; and “Understanding the Epidemic,” Centers for Disease Control and Prevention, <https://www.cdc.gov/opioids/basics/epidemic.html>.

warrant creating a new class of criminal conduct. There will always be an unknown. Criminalization unnecessarily and unjustly infringes upon the liberty of citizens in a country founded upon the principles of freedom.⁹⁵



In the absence of a clear threat to societal function at large, it is not the government’s job to mandate what the consumer should be able to use or what the business should be able to sell, particularly when that mandate is enforced through criminal sanctions.



Criminalization also requires that the government spend resources that could be better spent elsewhere. In 2015, the U.S. government spent roughly \$3.3 billion incarcerating those convicted of drug-related crimes, while state governments collectively spent roughly \$7 billion.⁹⁶ Not only is it expensive, but criminalization is also remarkably ineffective.⁹⁷ If the government is going to spend resources to address concerns with a particular substance, then it should target ensuring that products containing these substances are manufactured and sold responsibly.

It is time to shift approaches in substance regulation. Criminalization not only casts a senseless shadow over society, but it also ensures that people will be subjected to

⁹⁵ Kyle Strickland et al., *Low-Level, Non-Violent Drug Offenses*, (Columbus, OH: The Ohio State University - Kirwan Institute for the Study of Race and Ethnicity, Race and Criminal Justice, *Ohio Issue 1 and Beyond*, 2018), <http://kirwaninstitute.osu.edu/wp-content/uploads/2018/10/ohio-issue-1.pdf>; and Lauren-Brooke Eisen & Inimai Chettiar, “39% of Prisoners Should Not Be in Prison,” *Time*, December 9, 2016, <https://time.com/4596081/incarceration-report/>.

⁹⁶ Betsy Pearl, “Ending the War on Drugs: By the Numbers,” Center for American Progress, June 27, 2018, <https://www.americanprogress.org/issues/criminal-justice/reports/2018/06/27/452819/ending-war-drugs-numbers/>.

⁹⁷ Ingrid A. Binswanger et al., “Return to drug use and overdose after release from prison: a qualitative study of risk and protective factors,” *Addiction Science and Clinical Practice*, 7(1), March 15, 2012, 3; and “More Imprisonment Does Not Reduce State Drug Problems,” Pew Trusts, March 8, 2018, <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/03/more-imprisonment-does-not-reduce-state-drug-problems>.

hazardous unregulated markets. Human beings have a natural proclivity toward products that produce temporary intoxication, whether it be for recreation or self-medication.⁹⁸ Despite any possible legal ramifications, people are going to find ways to get intoxicated because the inherent demand is likely to always be present. Ignoring this reality when forging drug policy only leads to further harm, both to the individual and to society as a whole, by pushing industries into the black market. The criminal organizations that seek out these illicit markets flourish when government prohibition gifts them monopolies over their supply chains. If the government wishes to remedy the harms caused by substance abuse, a more prudent approach is regulation that ensures safety for consumers, who are the direct victims of unregulated markets, rather than dwelling on every possible risk.



If the government wishes to remedy the harms caused by substance abuse, a more prudent approach is regulation that ensures safety for consumers, who are the direct victims of unregulated markets, rather than dwelling on every possible risk.



Substance use regulation can aim to protect individual interests or societal interests. Alternatively, regulations can be thought of as mitigating either intrinsic or extrinsic harm.⁹⁹ Absent substantial evidence showing that legalization would create an intolerable level of extrinsic harm, government should shore up the dangers of production and sale through careful and narrowly tailored oversight, rather than punish the consumer for making a choice that is not likely to have extrinsic consequences.

⁹⁸ Pat O'Malley and Stephen Mugford, "The Demand for Intoxicating Commodities: Implications for the 'War on Drugs'," *Social Justice*, 18(4), 1991, 49.

⁹⁹ *Ibid.* at 66.

ABOUT THE AUTHOR

Nathaniel Wilson is from West Chester, Ohio. He graduated from Miami University in Oxford, Ohio with a BA in political science, along with minors in business legal studies and business analytics. Nathaniel is currently a third-year student at Ohio State's Moritz College of Law. His interests include drug policy, litigation, and compliance in the cannabis industry.

