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Kratom Crackdown: How the DEA Abused Its Emergency Scheduling Authority Under the Controlled Substances Act

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Kratom Crackdown: How the DEA Abused Its Emergency Scheduling Authority Under the Controlled Substances Act

OLIVIA CASTILLO*

The Drug Enforcement Administration wields tremendous power at scheduling a new drug or substance on an emergency basis under the Controlled Substances Act. The DEA newly leveled this power at a plant—kratom—with the potential to curb the menacing opioid epidemic in North America. This unprecedented effort has generated considerable controversy. Many individuals remonstrated the agency’s action, especially those facing life-threatening hardships because of the opioid crisis. Members of Congress also took a stand against the DEA’s unrivalled move to schedule kratom, suggesting that the agency had abused the emergency scheduling authority delegated by the legislative branch.

This Comment explores the interplay between the DEA’s rulemaking authority, the public’s democratic participation in the DEA’s rulemaking process, and the legislative branch’s delegation of authority and oversight of the DEA’s rulemaking in the specific case of kratom.

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INTRODUCTION

Karisa Rowland has carried out a simple ritual she claims saved her life.¹ Every morning, since 2014, she takes a bag of green powder from her fridge, stirs about a teaspoonful into a mug with water, and drinks it like a cup of tea.² Not long ago, Rowland struggled with a serious prescription opioid dependence.³ After making it through several back surgeries, she began taking pills—hydrocodone, fentanyl, and oxycodone—to cope with her chronic pain.⁴ Upon hitting an all-time low, Rowland mustered the courage to end the nightmare she was living.⁵ After years of prescription opioid dependence, a plant from Southeast Asia—kratom—was her salvation.⁶ Rowland’s story is not uncommon. The United States is in the throes of a prescription opioid epidemic described as “the deadliest drug crisis in American history.”⁷ From Florida to California, millions of Americans wake up each day to face a serious prescription opioid dependence.⁸ In 2015, an estimated 3.8 million people (aged twelve or older) had a substance use disorder involving prescription pain relievers.⁹ Rowland is also part of a growing number of kratom

¹ See Lauren Silverman, *All Things Considered: Kratom Advocates Speak Out Against Proposed Government Ban* (NPR radio broadcast Sept. 12, 2016), <https://tinyurl.com/hn4wv2u> (interviewing Karisa Rowland) [hereinafter *All Things Considered*].

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ Maya Salam, *The Opioid Epidemic: A Crisis Years in the Making*, N.Y. TIMES (Oct. 26, 2017), <https://tinyurl.com/yapn4oru>.

⁸ Opioids are a class of drugs that include heroin and prescription pain relievers, such as oxycodone, hydrocodone, codeine, morphine, and fentanyl. These substances are chemically related and interact with opioid receptors on nerve cells in the body and brain to produce euphoria and pain relief. *Drugs of Abuse: Opioids*, NAT’L INST. ON DRUG ABUSE, <https://tinyurl.com/ycm9zbx7> (last visited Mar. 31, 2018).

⁹ U.S. DEP’T HEALTH & HUM. SERVS., SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., PUB. NO. SMA 16-4984, KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2015

advocates in America who use the Asian plant for its promising effects in treating chronic pain and alleviating opioid addiction.¹⁰ The American Kratom Association estimates that there are three to five million kratom consumers in the United States.¹¹ Just as kratom's rapid popularity attracted the interest of many Americans suffering from chronic pain and prescription opioid addiction, so too U.S. government officials became interested in kratom and its effects.¹²

On August 30, 2016, the Drug Enforcement Administration announced its intent to place two kratom components—mitragynine and 7-hydroxymitragynine—into Schedule I of the Controlled Substances Act.¹³ In the press release announcing its action, the DEA justified the emergency scheduling of kratom based on a finding that it posed an imminent hazard to the public safety.¹⁴ The next day, the DEA published an official notice of intent in the *Federal Register*,¹⁵ beginning the thirty-day countdown until kratom would become a Schedule I controlled substance, placing it alongside heroin, LSD, and marijuana.¹⁶

NATIONAL SURVEY ON DRUG USE AND HEALTH 8 (2016), <https://tinyurl.com/y7o2jh8q>.

¹⁰ See *All Things Considered*, *supra* note 1.

¹¹ *American Kratom Association Factsheet*, AMERICAN KRATOM ASS'N, <https://tinyurl.com/yazlk9l4> (last updated Oct. 3, 2016). The American Kratom Association is a non-profit organization, launched in early 2015, representing the growing number of kratom users—including doctors, lawyers, teachers, and law enforcement officers—and working to help protect their ability to use kratom for improved health and well-being. *About Us*, AMERICAN KRATOM ASS'N, <http://www.amerikankratom.org/about> (last visited Jan. 10, 2017).

¹² Since 2013, kratom has been on the DEA's watch list. DRUG ENF'T ADMIN., OFF. OF DIVERSION CONTROL, *Kratom (Mitragyna speciosa korth)*, <https://tinyurl.com/yal58sde>; see also U.S. DEP'T OF JUST., DRUG ENF'T ADMIN., DRUGS OF ABUSE: DEA RESOURCE GUIDE 84 (2017), <https://tinyurl.com/jxy2mlz> (listing kratom as a drug and chemical of concern).

¹³ Press Release, Drug Enf't Admin., DEA Announces Intent to Schedule Kratom (Aug. 30, 2016), <https://tinyurl.com/yb8ev8uy>.

¹⁴ *Id.*

¹⁵ Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I, 81 Fed. Reg. 59,929 (proposed Aug. 31, 2016) (to be codified at 21 C.F.R. 1308) [hereinafter *Kratom Scheduling Notice*].

¹⁶ 21 U.S.C. § 812(c) (2012) (listing controlled substances under Schedule I).

The DEA invoked the emergency scheduling authority under the CSA¹⁷ in an unprecedented move to take rapid action against a natural, botanical substance with a history of safe use and promising medicinal benefits.¹⁸ Worse yet, the DEA initially sought to ban kratom with no opportunity for a public comment period.¹⁹ After the DEA's swift action, kratom advocates became justifiably concerned.²⁰ How can kratom pose an imminent hazard to public safety? How can a government agency make such a significant decision without giving the public a chance to comment? Why does the DEA have this power? What, if anything, can Congress do about it? Where does this leave kratom advocates?

This Comment presents a unique observation into the mechanism of a federal agency's rulemaking authority and the interplay between public participation and congressional oversight into a federal agency's rulemaking process. In Parts I and II, I present the backdrop to the DEA's proposed emergency scheduling of kratom. Specifically, in Part I, I trace the events that led to kratom's rapid popularity in the United States, including the menacing opioid epidemic, and I present the therapeutic qualities of kratom that make it a viable alternative to enslaving prescription opioids.

In Part II, I sketch the statutory scheduling framework under the CSA and decipher the specific provision under which the DEA decided to control kratom, the so-called emergency scheduling authority. I set out, in detail, the purpose, legislative history, and relevant agency decisional precedent of the emergency scheduling authority.

In Part III, I probe the DEA's analysis and evidence considered in reaching its perfunctory decision to control kratom on an emergency basis. I show that kratom does not meet the legal criteria required for emergency scheduling, that kratom is not a substance that Congress intended to control with the emergency scheduling authority, and that the application of such authority to kratom is a significant departure from relevant agency decisional precedent. Given these considerations, I argue in Part IV that the DEA committed an

¹⁷ *Id.* § 811(h).

¹⁸ See discussion *infra* Section I.B.

¹⁹ Kratom Scheduling Notice, *supra* note 15, at 59,933 ("The DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act . . . do not apply to this notice of intent.")

²⁰ *All Things Considered*, *supra* note 1.

ultra vires act and disregarded legislative directive. Indeed, the DEA overstepped its statutory authority by invoking the emergency scheduling authority to control a natural, botanical substance. Lastly, I highlight the importance of congressional oversight into a federal agency's rulemaking authority and conclude with an overview on what kratom advocates can expect going forward.

My argument is not that the DEA lacks the authority to proceed with the scheduling of kratom under the formal scheduling process, which offers a greater opportunity for review and discussion by all members of the public. I argue only that the DEA may not invoke the emergency scheduling authority to control a natural, botanical substance (or any similar substance) in the absence of evidence that such emergency scheduling is necessary to avoid an imminent hazard to the public safety, which is harmonious with the directive of Congress. If the DEA can employ the emergency scheduling authority as it desires, if it can disregard legislative directive defined by Congress, and if it can deprive the public of participation in the rulemaking process—a vital cog in any democracy—with only minimal reprimands, then it is time to rethink the significant rulemaking power wielded by such federal agencies and the need for substantial congressional oversight of their rulemaking authority.

I. THE NEED FOR KRATOM: HOW WE GOT HERE

A. *The Menacing Opioid Epidemic*

In 1860, Dr. Oliver Wendell Holmes, the physician father of Supreme Court Justice Holmes, declared of the medicine of his day: “I firmly believe that if the whole materia medica, *as now used*, could be sunk to the bottom of the sea, it would be all the better for mankind, —and all the worse for the fishes.”²¹ Less than half of the pills

²¹ The entirety of Dr. Holmes' statement contains specific exclusions for opium, anesthetics, and wine, and concludes with a caveat:

Throw out opium, which the Creator himself seems to prescribe, for we often see the scarlet poppy growing in the cornfields, as if it were foreseen that wherever there is hunger to be fed there must also be pain to be soothed; throw out a few specifics which our art did not discover, and is hardly needed to apply; throw out wine, which is a food, and the vapors which produce the miracle of anesthesia, and I firmly believe that if the whole materia medica, *as now used*, could be sunk to the

prescribed by physicians today had been conceived back then. Now, the opioid epidemic is responsible for killing more Americans each year than both car accidents and gun-related crimes.²²

The prescription opioid epidemic is not limited to addiction; it also covers taking medication for attaining recreational highs or taking medication prescribed for someone else.²³ Prescription controlled substances generally fall into three categories: (1) pain relievers, also known as painkillers, analgesics, or opioids; (2) depressants used to treat anxiety or insomnia; and (3) stimulants used to treat attention-deficit/hyperactivity disorder.²⁴

The number of opioid prescriptions dispensed by U.S. pharmacies over the last decade shows how the current opioid epidemic has been years in the making. From 2006, the number of opioid prescriptions steadily increased until it peaked in 2012 at more than 255 million prescriptions dispensed—plenty to give every American adult his or her own bottle of pills.²⁵ A rise in opioid-related deaths soon followed. In 2015, there were 33,091 opioid overdose deaths alone.²⁶ The latest figures show more than 64,000 Americans died from drug overdoses in 2016—with over 20,000 overdose deaths

bottom of the sea, it would be all the better for mankind, —and all the worse for the fishes. But to justify this proposition, I must add that the injuries inflicted by over-medication are to a great extent masked by disease.

Oliver Wendell Holmes, *Currents and Counter-Currents in Medical Science*, in OLIVER WENDELL HOLMES, *MEDICAL ESSAYS 1842–1882*, 202–03 (1883) (citation omitted).

²² Niall McCarthy, *Drugs Are Killing More Americans Than Road Crashes [Infographic]*, FORBES (Nov. 17, 2016), <https://tinyurl.com/ybm76zbs>; Christopher Ingraham, *Heroin Deaths Surpass Gun Homicides for the First Time, CDC Data Shows*, WASH. POST: WONKBLOG (Dec. 8, 2016), <https://tinyurl.com/ycwnmazz>.

²³ ERIN BAGALMAN ET AL., CONG. RESEARCH SERV., R43559, *PRESCRIPTION DRUG ABUSE 1* (2014).

²⁴ *Id.*

²⁵ *Opioid Overdose: U.S. Prescribing Rate Maps*, CTR. FOR DISEASE CONTROL & PREVENTION, <https://tinyurl.com/y9pxrrzt> (last updated July 31, 2017).

²⁶ Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, 65 *MORBIDITY & MORTALITY WKLY. REP.* 1445 (Dec. 30, 2016), <https://tinyurl.com/y75mnbnc>.

related to fentanyl and other synthetic opioids.²⁷ Based on these numbers, 175 people die each day from an opioid overdose.²⁸ If this is not daunting enough, the life expectancy for Americans declined in 2016 for the first time since 1993—a result of rising fatalities from an array of deteriorating health problems including drug overdoses.²⁹

The origin of this epidemic goes back to the 1990s, a decade that spawned a wave of support for alternative treatments for chronic pain in America.³⁰ Previously, the inadequate treatment of pain by physicians, which caused unnecessary patient suffering,³¹ grew from fears of investigation or state disciplinary action by regulatory agencies for prescribing opioids to manage chronic pain.³² As a result, physicians under-prescribed opioids to their patients, even though prescribing them for pain management was a legitimate medical practice.³³ Indeed, physicians' fears were warranted since some state board policies contained statements and recommendations that discouraged the use of opioid analgesics for pain management.³⁴

Then, in 1997, the Federation of State Medical Boards in the United States organized two expert panels on pain, policy, and regulation to encourage compassionate pain management.³⁵ The task force developed the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, which was disseminated to all

²⁷ *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE, <https://tinyurl.com/pa2zgw2> (last updated Sept. 2017).

²⁸ *Id.*

²⁹ Lenny Bernstein, *U.S. Life Expectancy Declines for the First Time Since 1993*, WASH. POST (Dec. 8, 2016), <https://tinyurl.com/gnnt89b>.

³⁰ See William Brangham, *Opioid Addiction Is the Biggest Drug Epidemic in U.S. History: How'd We Get Here?*, PBS NEWSHOUR: AMERICA ADDICTED (Sept. 29, 2017), <https://tinyurl.com/yanh7cm8>.

³¹ See Ameet Sarpatwari et al., *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L. & POL'Y REV. 463, 465 (2017) ("The origins of the surge in prescription opioid use can be traced to increased awareness of the widespread prevalence and under-treatment of pain.").

³² David E. Joranson et al., *Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change*, 23 J. PAIN & SYMPTOM MGMT. 138, 139 (2002).

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 142.

state medical boards for consideration.³⁶ As part of a public forum to receive comments on drafting the model guidelines, a representative of the DEA offered a written statement which stated in part: “The guidelines will help physicians comply with acceptable pain management standards and will help [the] DEA and other regulators determine whether such treatment is appropriate”³⁷ The end goal was for the guidelines to “help ensure patient access to needed controlled substances for pain management.”³⁸

Following the introduction of the guidelines, physicians began prescribing more opioids to patients with chronic pain.³⁹ Needless to say, big pharmaceutical companies quickly jumped on the bandwagon and fueled an aggressive marketing campaign to sell opioids.⁴⁰ The rate of opioid prescriptions began to snowball with “retail purchases of methadone, hydrocodone, and oxycodone in the United States increas[ing] 13-fold, 4-fold, and 9-fold, respectively.”⁴¹ This increase in legitimate sales of opioids triggered a proliferation of these addictive substances for nonmedical uses.⁴² The impact of this pharmacoepidemic has been most evident in rural states, especially West Virginia, which witnessed the nation’s largest increase in drug overdose mortality rates from 1999 to 2004.⁴³

³⁶ Joranson et al., *supra* note 32, at 142.

³⁷ *Id.* at 142–43.

³⁸ *Id.* at 143 (footnote omitted).

³⁹ Physicians must be registered with the DEA to prescribe such controlled substances or be exempted by regulation from registration. 21 U.S.C. § 822 (2012); *see also* JOSEPH T. RANNAZZISI & MARK W. CAVERLY, DRUG ENF’T ADMIN., PRACTITIONER’S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 7 (2006), <https://tinyurl.com/y76hfeok> [hereinafter DEEA PRACTITIONER’S MANUAL].

⁴⁰ *See* Sarpatwari et al., *supra* note 31, at 466 (“Purdue Pharma successfully contributed to and capitalized on the medical establishment’s changing view of pain management.”).

⁴¹ Aron J. Hall et al., *Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities*, 300 J. AM. MED. ASS’N 2613, 2613 (2008) (footnote omitted).

⁴² *Id.*

⁴³ *Id.* A study of all state residents who died of unintentional pharmaceutical overdoses in West Virginia in 2006, found that most overdose deaths were associated with nonmedical use and diversion of pharmaceuticals, mostly from opioid analgesics. *Id.*

Middle-aged white Americans are the most vulnerable group suffering from “diseases of despair”—overdoses, alcoholism, and suicide.⁴⁴

The epidemic’s unsettling numbers have prompted serious action to combat opioid dependence across the United States. In October 2015, President Barack Obama announced a nationwide plan in which more than 540,000 health care providers were to complete training on appropriate opioid prescribing.⁴⁵ The Obama administration also proposed \$1.1 billion in new funding to address the prescription opioid epidemic, with over \$900 million to support cooperative agreements with states to expand access to medication-assisted treatment for opioid addiction.⁴⁶ President Obama confirmed that much remains to be done to properly address the opioid epidemic.⁴⁷ This includes seeing the opioid crisis as a public health problem rather than solely as a drug enforcement concern.⁴⁸ Despite efforts by President Obama to tackle the opioid epidemic, the DEA pursued its own agenda and undermined such efforts by trying to control a plant that might be the remedy so many opioid-dependent Americans need.

B. *Kratom: A New Hope?*

For centuries, humans have turned to plant-derived substances to treat diseases, manage the stresses of life, and attain altered states

⁴⁴ Anne Case & Angus Deaton, *Rising Morbidity and Mortality in Midlife Among White Non-Hispanic Americans in the 21st Century*, 112 PNAS 15,078, 15,079 (2015); Bernstein, *supra* note 29; Olga Khazan, *Middle-Aged White Americans Are Dying of Despair*, ATLANTIC (Nov. 4, 2015), <https://tinyurl.com/nedzl9n>.

⁴⁵ Press Release, Office of the Press Sec’y, FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use (Oct. 21, 2015), <https://tinyurl.com/hnwupg8>.

⁴⁶ Press Release, Office of the Press Sec’y, FACT SHEET: President Obama Proposes \$1.1 Billion in New Funding to Address the Prescription Opioid Abuse and Heroin Use Epidemic (Feb. 2, 2016), <https://tinyurl.com/ya8njqvz>; *see also* Gardiner Harris, *Obama Seeks More Than \$1 Billion to Fight Opioid Abuse*, N.Y. TIMES (Feb. 2, 2016), <https://tinyurl.com/yacce71>.

⁴⁷ Barack Obama, *The President’s Role in Advancing Criminal Justice Reform*, 130 HARV. L. REV. 811, 858–60 (2017) (addressing opioid misuse and addiction).

⁴⁸ *Id.* at 858–59 (noting that “the opioid epidemic is a public health problem that requires a public health response”).

of consciousness.⁴⁹ Despite the advancement of pharmaceuticals and medical practices, many people still use herbal or botanical remedies either as alternatives to, or in combination with, conventional medical care.⁵⁰ In 2012, one in three U.S. adults used complementary health approaches to relieve pain.⁵¹ Americans are willing to spend money on complementary health alternatives with total out-of-pocket spending adding up to \$30.2 billion in 2012.⁵² Small wonder, then, that a plant with promising medical uses—like kratom—is widely accepted among Americans who wish to alleviate disruptive pains and serious opioid addiction.

Kratom (*mitragyna speciosa*) is a plant indigenous to Southeast Asia, found primarily in Thailand and Malaysia.⁵³ Kratom belongs to a small genus in the *Rubiaceae* family, which also includes the coffee plant.⁵⁴ The major chemical compound in kratom, mitragynine, constitutes about 66% of the plant's total alkaloidal content.⁵⁵ Kratom has been used in Southeast Asia for hundreds of years mostly by farmers, laborers, and fisherman to offset fatigue while working in hot temperatures.⁵⁶ The leaves can be chewed or steeped into teas to treat fever, analgesia, diarrhea, coughing, hypertension, opiate withdrawal, and even depression.⁵⁷ In small doses, kratom

⁴⁹ See Walter C. Prozialeck et al., *Pharmacology of Kratom: An Emerging Botanical Agent with Stimulant, Analgesic and Opioid-Like Effects*, 112 J. AM. OSTEOPATHIC ASS'N 792, 792 (2012).

⁵⁰ See *id.*; ANDREW CHEVALLIER, ENCYCLOPEDIA OF HERBAL MEDICINE 9 (3d ed. 2016) (“From the earliest of times, herbs have been prized for their pain-relieving and healing abilities, and today we still rely on the curative properties of plants in about 75 percent of our medicines.”).

⁵¹ U.S. DEP'T OF HEALTH & HUM. SERVS., NAT'L INSTS. OF HEALTH, *Use of Complementary Health Approaches in the U.S.: What Complementary and Integrative Approaches Do Americans Use?*, <https://tinyurl.com/y8mmgqzn> (last modified Sept. 24, 2017).

⁵² *Id.*

⁵³ KRATOM AND OTHER MITRAGYNINES: THE CHEMISTRY AND PHARMACOLOGY OF OPIOIDS FROM A NON-OPIUM SOURCE ix (Robert B. Raffa ed., 2015) [hereinafter KRATOM AND OTHER MITRAGYNINES].

⁵⁴ Sasha W. Eisenman, *The Botany of Mitragyna speciosa (Korth.) Havil. and Related Species*, in KRATOM AND OTHER MITRAGYNINES, *supra* note 53, at 57, 58.

⁵⁵ Vedanjali Gogineni et al., *Phytochemistry of Mitragyna speciosa*, in KRATOM AND OTHER MITRAGYNINES, *supra* note 53, at 77, 79.

⁵⁶ Eisenman, *supra* note 54, at 57.

⁵⁷ KRATOM AND OTHER MITRAGYNINES, *supra* note 53, at ix.

produces a stimulant-like effect similar to coffee.⁵⁸ In high doses, kratom produces an opioid-like effect, helpful for managing opioid withdrawal symptoms.⁵⁹

Despite its centuries-long history and extensive use in Southeast Asia, kratom has only recently captured the attention of Westerners as a botanical supplement.⁶⁰ The growth of kratom in the United States is partly due to its expanded availability on the Internet.⁶¹ Various websites have surfaced describing kratom's myriad uses.⁶² An increasing number of posts and blogs come from individuals using kratom to self-treat chronic pain or wean off addiction to opioids such as heroin and prescription pain relievers.⁶³

Although early publications muddled the therapeutic benefits of kratom,⁶⁴ recent studies have described the plant as a natural alternative for the treatment of opioid addiction.⁶⁵ Reports of kratom being used to treat opioid withdrawal symptoms were published as early as 1932.⁶⁶ But no study examined the perceived benefits of kratom to manage opioid withdrawal symptoms until 2010, when 136 active kratom users in northern Malaysia were surveyed.⁶⁷ The study found that most users relied on kratom to suppress opioid

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ See Prozialeck et al., *supra* note 49, at 793.

⁶¹ *Id.* (discussing kratom's increased Internet presence); see also Eisenman, *supra* note 54, at 68 (same).

⁶² Prozialeck et al., *supra* note 49, at 793 (describing the content of websites on kratom).

⁶³ *Id.*

⁶⁴ Eisenman, *supra* note 54, at 67 (“Early documents confused the situation, with most referring to the use of [kratom] as an opium substitute while other early reports spoke of its use as an anti-opium plant or an opium remedy.”) (citation and internal quotation marks omitted).

⁶⁵ See, e.g., Edward W. Boyer et al., *Self-Treatment of Opioid Withdrawal Using Kratom* (*Mitragynia speciosa korth*), 103 *ADDICTION* 1048, 1049 (2008) [hereinafter Boyer I]; Edward W. Boyer et al., *Self-Treatment of Opioid Withdrawal with a Dietary Supplement, Kratom*, 16 *AM. J. ON ADDICTIONS* 352, 352 (2007).

⁶⁶ Khem Singh Grewal, *Observations on the Pharmacology of Mitragynine*, 46 *J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS* 251, 251 (1932).

⁶⁷ Balasingam Vicknasingam et al., *The Informal Use of Ketum* (*Mitragynia speciosa*) *for Opioid Withdrawal in the Northern States of Peninsular Malaysia and Implications for Drug Substitution Therapy*, 21 *INT'L J. DRUG POLICY* 283, 283 (2010).

withdrawal symptoms because it was a cheap alternative with no serious side effects despite prolonged use.⁶⁸ The first published U.S. study to report the prevalence and motivations for kratom use among a sample of substance users enrolled in treatment found that persons use kratom for a variety of reasons, “including as an alternative for addressing drug dependence and chronic pain, for reducing anxiety, and to improve well-being.”⁶⁹ Further, withdrawal symptoms from kratom are less severe than from prescription opioids, with symptoms usually disappearing after one to three days.⁷⁰ Although still in its infancy, Western research on kratom shows that it holds the potential to be used as an effective treatment alternative for opioid addiction.⁷¹

C. *The DEA Threatens to Ban Kratom*

Despite recent scientific evidence of kratom’s palliative effects, on August 31, 2016, the DEA published a notice in the *Federal Register* stating its intent to place mitragynine and 7-hydroxymitragynine, two main kratom compounds, into Schedule I of the CSA.⁷² The agency justified this action based on a finding that the scheduling of kratom’s main compounds was necessary to avoid an imminent hazard to public safety.⁷³ In reaching its decision, the DEA asserted that these compounds have a high potential for abuse, no currently accepted medical use in treatment, and a lack of accepted safety for use under medical supervision.⁷⁴ Together with its notice of intent,

⁶⁸ *Id.* at 287.

⁶⁹ Kirsten Elin Smith & Thomas Lawson, *Prevalence and Motivations for Kratom Use in a Sample of Substance Users Enrolled in a Residential Treatment Program*, 180 DRUG & ALCOHOL DEPENDENCE 340, 344 (2017).

⁷⁰ Darshan Singh et al., *Traditional and Non-Traditional Uses of Mitragynine (Kratom): A Survey of the Literature*, 126 BRAIN RES. BULL. 41, 44 (2016) (noting physical withdrawal symptoms include lethargy, irritability, frequent yawning, runny nose, muscular pain, cramps, joint pain, and diarrhea) [hereinafter *Kratom: Survey of the Literature*]; Boyer I, *supra* note 65, at 1049 (finding that kratom alleviates potentially severe opioid withdrawal, yet cessation of kratom use itself appears to be associated with modest withdrawal symptoms).

⁷¹ *Kratom: Survey of the Literature*, *supra* note 70, at 45 (noting “kratom holds the potential to be developed as a treatment option for opiate dependence”).

⁷² Kratom Scheduling Notice, *supra* note 15.

⁷³ *Id.* at 59,929.

⁷⁴ *Id.* at 59,930. These are the requirements for placement of a substance into Schedule I of the CSA. 21 U.S.C. § 812(b) (2012). Thus, a substance meeting the

the DEA provided a three-factor analysis as required under an emergency scheduling action.⁷⁵ The publication provided for thirty days' notice to place kratom into Schedule I.⁷⁶ The DEA also stated its belief that the public comment requirements of the Administrative Procedure Act⁷⁷ were not applicable to the emergency scheduling action.⁷⁸

D. *The Public Outcry*

The DEA's ill-considered notice of intent to schedule kratom did not go unnoticed. Within a week, a petition calling on President Obama to weigh in on the DEA's unprecedented action reached over 100,000 signatures.⁷⁹ Hundreds of kratom advocates rallied at the White House.⁸⁰ Supporters held "I Am Kratom" signs while others offered brewed kratom tea in red Solo cups to anyone who wanted a try.⁸¹ Attendees at the rally included a former heroin addict who traveled from North Carolina, a physics teacher from Virginia who

statutory requirements for temporary scheduling may only be placed into Schedule I. *Id.* § 811(h)(1).

⁷⁵ DRUG ENF'T ADMIN., *Mitragynine and 7-Hydroxymitragynine: Background Information and Evaluation of 'Three Factor Analysis' (Factors 4, 5 and 6) for Temporary Scheduling* (Aug. 2016), <https://tinyurl.com/ydz4blaq> [hereinafter *Kratom Three Factor Analysis*]. This evaluation contains the DEA's assertions with respect to the finding of an imminent hazard to the public safety based on three factors: (1) the substance's history and current pattern of abuse, (2) the scope, duration, and significance of abuse, and (3) what, if any, risk there is to the public health. *See* 21 U.S.C. § 811(h)(3).

⁷⁶ Kratom Scheduling Notice, *supra* note 15, at 59,933. Under the Administrative Procedure Act's requirements for notice and comment, agencies must generally allow at least thirty days to pass between the publication of a proposed rule and its effective date. 5 U.S.C. § 553(d).

⁷⁷ 5 U.S.C. § 553(c).

⁷⁸ Kratom Scheduling Notice, *supra* note 15, at 59,933.

⁷⁹ *Please Do Not Make Kratom a Schedule I Substance*, WE THE PEOPLE (Aug. 30, 2016), <https://tinyurl.com/ycdznrwa> (archiving petition website); *see also* Nick Wing, *More Than 100,000 People Urge Obama to Stop the DEA from Banning Kratom*, HUFFPOST (Sept. 7, 2016), <https://tinyurl.com/j6oofxj>.

⁸⁰ Steven Nelson, *Kratom Advocates Sip Tea and Seethe at White House Rally Against DEA Ban*, U.S. NEWS & WORLD REP. (Sept. 13, 2016), <https://tinyurl.com/gqpeetf>.

⁸¹ *Id.*

takes kratom to treat arthritis, and a Colorado kratom shop owner who recovered from alcoholism.⁸²

While the DEA was inundated with comments from kratom users,⁸³ members of Congress were organizing their own backlash.⁸⁴ Representatives Mark Pocan and Matt Salmon drafted a “Dear Colleague” letter in a bipartisan effort to delay the DEA’s imminent kratom ban.⁸⁵ The Pocan-Salmon letter, signed by fifty-one members of Congress, urged the DEA to delay its decision on the placement of kratom into Schedule I and to “provide ample time for public comment on this significant decision.”⁸⁶ The letter mentioned a federally funded study conducted by the University of Massachusetts and the University of Mississippi on the use of kratom as a remedy for opioid addiction.⁸⁷ Researchers of this study applied for a patent identifying the kratom compound, mitragynine, as a beneficial treatment for addictive drugs besides opiate derivatives.⁸⁸

Notable Senators penned a similar letter petitioning the DEA to postpone its emergency action to schedule kratom.⁸⁹ The Senate letter seemed to cast greater doubt on the DEA’s exercise of the emergency scheduling authority. Indeed, the Senators insisted that the

⁸² *Id.* The Colorado kratom shop owner claimed that his store was shut down by local officials after kratom was banned in the state. *Id.*

⁸³ See Christopher Ingraham, *The DEA Wants to Ban Another Plant. Researchers Say the Plan is ‘Insane.’*, WASH. POST: WONKBLOG (Sept. 15, 2016), <https://tinyurl.com/y8zgxphj>.

⁸⁴ Nick Wing, *Congress Calls Out DEA for Unilateral Move to Expand the War on Drugs*, HUFFPOST (Sept. 26, 2016), <https://tinyurl.com/zo5jzxn>.

⁸⁵ Steven Nelson, *Dozens of Congressmen Ask DEA Not to Ban Kratom Next Week*, U.S. NEWS & WORLD REP. (Sept. 23, 2016), <https://tinyurl.com/zkqaxej>.

⁸⁶ Letter from Mark Pocan et al., U.S. Reps., to Charles P. Rosenberg, Acting Adm’r, Drug Enf’t Admin. (Sept. 26, 2016) (on file with author) (addressing concerns from twenty-eight Democrats and twenty-three Republicans, including two medical doctors, who represent congressional districts from twenty-four states, including Florida, California, Georgia, Colorado, Virginia, New York, and Texas).

⁸⁷ *Id.* For more information on the study see, Barbara Lago, *New Hope for Addicts*, UNIV. MISS. NEWS (Jan. 25, 2013), <http://news.olemiss.edu/new-hope-for-addicts/>.

⁸⁸ U.S. Patent Application No. 12/623,064 (filed Nov. 20, 2009).

⁸⁹ Sanders, *Hatch and Nine Other U.S. Senators Urge DEA To Halt Push to Ban Natural Herb Kratom*, BOTANICAL EDUC. ALL., <https://tinyurl.com/ychlzh4e> (last visited Jan. 10, 2017).

DEA should arrange a public comment period and “outline its evidentiary standards to Congress regarding the justification for [the] proposed action.”⁹⁰ The letter further emphasized that “the use of this emergency authority for a natural substance is unprecedented.”⁹¹ Senator Cory Booker of New Jersey stressed that an “increasing body of research has shown kratom’s potential value as a treatment for a number of conditions.”⁹² By the time the DEA received these congressional letters, numerous news reports had popped up further criticizing the DEA’s hasty decision to ban kratom.⁹³ The message was clear: The DEA had targeted a natural, botanical substance that might be a solution to the U.S. opioid epidemic.⁹⁴

E. *The DEA Backpedals*

On October 13, 2016, the DEA, facing a storm of public and congressional criticism, reversed its decision to invoke the emergency scheduling authority to place kratom into Schedule I of the

⁹⁰ Letter from Orrin G. Hatch et al., U.S. Senators, to Charles P. Rosenberg, Acting Adm’r, Drug Enf’t Admin. (Sept. 30, 2016) (on file with author) [hereinafter Senate Letter to DEA].

⁹¹ *Id.*

⁹² Letter from Corey A. Booker et al., U.S. Senators, to Charles P. Rosenberg, Acting Adm’r, Drug Enf’t Admin. (Sept. 29, 2016) (on file with author) (attaching an open letter from Andrew Kruegel and ten other scientists). Senator Booker referenced an open letter to Congress sent by eleven scientists from well-respected research institutions expressing “grave concern” about the DEA’s proposed action against kratom. *Id.*

⁹³ See, e.g., Angus Chen, *Kratom Drug Ban May Cripple Promising Painkiller Research*, SCI. AM. (Sept. 27, 2016), <https://tinyurl.com/y7tflts6>; Douglas Main, *War Veteran on Kratom: DEA Taking Away Right to a Manageable Life*, NEWSWEEK (Sept. 15, 2016), <https://tinyurl.com/gm8ef4s>; Nick Wing, *Feds Declare War on Herb Touted as a Solution to Opioid Addiction*, HUFFPOST (Aug. 30, 2016), <https://tinyurl.com/z6nvzjo>; Baynard Woods, *Federal Crackdown on Drug Some Say Treats Opioid Addiction Faces Backlash*, GUARDIAN (Sept. 11, 2016), <https://tinyurl.com/ydddvj77>.

⁹⁴ Nick Wing, *Some Say Kratom Is a Solution to Opioid Addiction. Not If Drug Warriors Ban It First*, HUFFPOST (Mar. 3, 2016), <https://tinyurl.com/zd7x9uw>.

CSA.⁹⁵ While viewed as a shocking move by some drug policy experts,⁹⁶ the DEA's backpedaling came as a respite for many kratom advocates.⁹⁷ The DEA heeded the concerns of Congress and decided to allow an official public comment period until December 1, 2016.⁹⁸ The DEA recognized the various comments from the public challenging the notice to outlaw kratom.⁹⁹ It also asked the Food and Drug Administration to expedite a scientific and medical evaluation and scheduling recommendation for the two main kratom compounds.¹⁰⁰

Allowing an opportunity for public comment by all interested parties was a step in the right direction. But whether the public's comments on kratom will be heard and considered by the DEA remains to be seen.¹⁰¹ DEA spokesman Russell Baer made clear: "This withdrawal of our notice of intent to temporarily schedule kratom should not be misconstrued . . . [the] DEA still firmly believes

⁹⁵ Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-Hydroxymitragynine into Schedule I, 81 Fed. Reg. 70,652 (proposed Oct. 13, 2016) (to be codified at 21 C.F.R. 1308) [hereinafter *Withdrawal of Kratom Scheduling*].

⁹⁶ See Christopher Ingraham, *The DEA Is Withdrawing a Proposal to Ban Another Plant After the Internet Got Really Mad*, WASH. POST: WONKBLOG (Oct. 12, 2016), <https://tinyurl.com/y9zzauqo> (quoting a leading expert on drug policy at the Brookings Institution saying, "The DEA is not one to second-guess itself, no matter what the facts are"); Press Release, Drug Pol'y All., *In Unprecedented Move, Drug Enforcement Administration Withdraws Emergency Kratom Ban*, (Oct. 11, 2016), <https://tinyurl.com/y9cgglwt>.

⁹⁷ Lauren Silverman, *Good News for Some Folks in Pain: DEA Delays Ban on Kratom Until at Least December*, KERA NEWS (Oct. 12, 2016), <https://tinyurl.com/h7eda4q>; Lauren Silverman, *Kratom Gets Reprieve from Drug Enforcement Administration*, NPR: SHOTS (Oct. 12, 2016), <https://tinyurl.com/zttt6by> [hereinafter Silverman, *Kratom Gets Reprieve*].

⁹⁸ *Withdrawal of Kratom Scheduling*, *supra* note 95, at 70,652.

⁹⁹ *Id.* DEA spokesman Russell Baer confirmed that they received more than 2,000 phone calls since August of that year in opposition to the kratom ban. Silverman, *Kratom Gets Reprieve*, *supra* note 97.

¹⁰⁰ *Withdrawal of Kratom Scheduling*, *supra* note 95, at 70,653.

¹⁰¹ See Jonathan Weinberg, *The Right to Be Taken Seriously*, 67 U. MIAMI L. REV. 149, 150–51 (2012) (arguing that the public's participation in government rulemaking is "a two-way dialogic commitment," and that "we should focus less on the individual's ability to comment than on the government's obligation to hear, engage, and respond").

kratom is dangerous and is harmful.”¹⁰² As time has shown, the DEA systematically rejects scientific evidence when determining the proper scheduling of substances under the CSA.¹⁰³

II. STATUTORY SCHEDULING FRAMEWORK UNDER THE CSA

In 1970, Congress enacted the CSA under Title II of the Comprehensive Drug Abuse Prevention and Control Act.¹⁰⁴ The CSA created five categories or schedules for the allocation of various plants, drugs, and chemicals based on the substance’s medical use, potential for abuse, and safety or dependence liability.¹⁰⁵ Schedule I, the most restrictive category, contains substances that have “a high potential for abuse,” have “no currently accepted medical use in treatment in the United States,” and lack “accepted safety use . . . under medical supervision.”¹⁰⁶ Substances in this group include heroin, LSD, ecstasy, and (to this day) marijuana.¹⁰⁷ Schedule II includes substances that are also subject to abuse but are accepted for medical use in the United States.¹⁰⁸ For these substances, there is an awareness that abuse “may lead to severe psychological or physical dependence.”¹⁰⁹ Schedule II substances include morphine and opium.¹¹⁰ Substances in Schedules III through V all have a currently

¹⁰² Steven Nelson, *DEA Withdraws Kratom Ban, Opens Public Comment Period*, U.S. NEWS & WORLD REP. (Oct. 12, 2016), <https://tinyurl.com/y9m3gyc8>.

¹⁰³ DRUG POLICY ALL. & MAPS, *THE DEA: FOUR DECADES OF IMPEDING AND REJECTING SCIENCE 2* (June 6, 2014), <https://tinyurl.com/mcoaf7g> (describing the DEA’s most common tactics “to maintain the existing, scientifically unsupported drug scheduling system and to obstruct research that might alter current drug schedules”); *see also* Christen D. Shepherd, Comment, *Lethal Concentration of Power: How the D.E.A. Acts Improperly to Prohibit the Growth of Industrial Hemp*, 68 UMKC L. REV. 239, 242 (1999) (arguing that the DEA controls industrial hemp through an arbitrary and capricious interpretation of “marijuana” despite qualities of hemp that make it a valuable agricultural commodity).

¹⁰⁴ Pub. L. No. 91-513, tit. II, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–904 (2012)).

¹⁰⁵ BRIAN T. YEH, CONG. RESEARCH SERV., RL34635, *THE CONTROLLED SUBSTANCES ACT: REGULATORY REQUIREMENTS 1* (2012).

¹⁰⁶ 21 U.S.C. § 812(b)(1)(A)–(C) (2012).

¹⁰⁷ *Id.* § 812(c); *see also* DEA PRACTITIONER’S MANUAL, *supra* note 39, at 5.

¹⁰⁸ 21 U.S.C. § 812(b)(2)(A)–(B).

¹⁰⁹ *Id.* § 812(b)(2)(C).

¹¹⁰ DEA PRACTITIONER’S MANUAL, *supra* note 39, at 5.

accepted medical use in treatment in the United States, with gradually lower potentials for abuse and severity of dependence.¹¹¹ Under the CSA, Congress authorized the Attorney General to schedule, transfer between schedules, or remove a substance from a schedule.¹¹² Then, in 1973, the Attorney General delegated the performance of these tasks to the Administrator of the DEA.¹¹³

A. *Formal or Permanent Scheduling*

The CSA provides a statutory framework for the federal government to regulate the lawful production, possession, and distribution of controlled substances.¹¹⁴ Because serious consequences can arise when substances are scheduled,¹¹⁵ the CSA created a multifactorial procedure with various administrative safeguards to have a substance controlled, or added, under the proper schedule.¹¹⁶ Congress, through the CSA, demanded careful review of a substance's medical use, potential for abuse, and safety or dependence liability.¹¹⁷ The CSA also requires the evaluation and recommendations, with re-

¹¹¹ 21 U.S.C. § 812(b)(3)–(5). For a more detailed analysis of the regulatory structure of the CSA and its classification scheme, see Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 332 (2013) (arguing the CSA's system of scheduling lacks uniformity and stifles much needed research into substances with potential medical uses, particularly those placed in Schedule D).

¹¹² 21 U.S.C. § 811(a); *see also* *Touby v. United States*, 500 U.S. 160, 162 (1991); Exec. Order No. 11,727, 3 C.F.R. 785–86 (1971–1975), *reprinted as amended in* 21 U.S.C. § 801 app. at 507–08.

¹¹³ 38 Fed. Reg. § 18,380 (1973). In *Touby*, the Supreme Court approved this subdelegation of power to schedule substances. 500 U.S. at 164. Because the Attorney General delegated this authority to the DEA Administrator, the term “Administrator” will be used in place of the term “Attorney General” throughout the remainder of this Comment.

¹¹⁴ YEH, *supra* note 105, at 1.

¹¹⁵ *See* 21 U.S.C. § 841(b) (listing mandatory minimum drug penalties for different controlled substances).

¹¹⁶ Under the CSA, the term “control” as defined by section 802(5) means “to add a drug or other substance, or immediate precursor, to a schedule under [Section 812 of the Act], whether by transfer from another schedule or otherwise.”

¹¹⁷ YEH, *supra* note 105, at 1 (citing 21 U.S.C. §§ 811–812).

spect to a substance's proper schedule, from two federal departments and three federal agencies.¹¹⁸ This "intra-agency coordination" serves as a system of internal checks in which specific functions are assigned to the appropriate agency.¹¹⁹ For example, the recommendations made by the Department of Human Health & Services are binding on the Administrator as to scientific and medical matters because that agency is tasked with protecting the health of all Americans.¹²⁰

The formal process to schedule a substance begins when the Administrator gathers all necessary data and subsequently requests from the Secretary of HHS a scientific and medical evaluation and recommendation as to whether a substance should be controlled.¹²¹ For such evaluations, HHS must consider eight factors about the substance's potential for abuse, medical use, and dependence liability.¹²² After evaluating these factors, HHS makes a recommendation

¹¹⁸ The two federal entities involved in the scheduling process are the Department of Justice and the Department of Health and Human Services; the specific federal agencies are the DEA, the FDA, and the National Institute on Drug Abuse. YEH, *supra* note 105, at 1–2.

¹¹⁹ Jennifer Nou, *Intra-Agency Coordination*, 129 HARV. L. REV. 421, 421 (2015) (describing ways in which an agency's organizational choices can influence rulemaking outcomes); cf. Gillian E. Metzger, *The Interdependent Relationship Between Internal and External Separation of Powers*, 59 EMORY L.J. 423, 427–34 (2009) (noting the interaction between internal executive procedures and constitutional separation of powers implications).

¹²⁰ *About HHS*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/about/index.html> (last visited Jan. 10, 2017). The recommendation on the initial scheduling of a substance is binding only to the extent that if HHS recommends that a drug or substance not be controlled, the DEA may not add it to its schedules. YEH, *supra* note 105, at 2 (citing 21 U.S.C. § 811(b)).

¹²¹ 21 U.S.C. § 811(b); see also *United States v. Nasir*, No. 5:12-CR-102-JMH, 2013 WL 5373691, at *1 (E.D. Ky. Sept. 25, 2013).

¹²² Specifically, the eight factors for the scheduling criteria include: (1) the substance's actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) what, if any, risk there is to the public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a currently controlled substance. 21 U.S.C. § 811(c).

as to the appropriate schedule for the substance.¹²³ The Administrator then must consider the same eight factors prior to initiating administrative proceedings for control of the substance.¹²⁴ After the Administrator concludes this extensive evaluation, he or she must make specific findings about the drug or substance that governs the schedule in which it will be placed.¹²⁵ The Administrator initiates proceedings for control of the substance through rulemaking pursuant to the APA, which demands an opportunity for public comment and a hearing for all interested parties.¹²⁶

B. *Emergency or Temporary Scheduling*

In addition to the formal scheduling procedure, the CSA allows for an expedited process by which the Administrator can place a drug or substance, on a temporary basis, into Schedule I when doing so is necessary to avoid an imminent hazard to public safety.¹²⁷ Instead of the eight factors required for permanent scheduling, in a temporary scheduling action the Administrator is only required to consider three factors with respect to a finding of an imminent hazard.¹²⁸ These are the substance's "history and current pattern of abuse," its "scope, duration, and significance of abuse," and "what, if any, risk there is to the public health."¹²⁹ In evaluating these factors, the Administrator must also consider the substance's "actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution."¹³⁰

Despite its departure from the formal scheduling process, the Administrator must satisfy the requirements of Section 812(b) for

¹²³ *Id.*

¹²⁴ *Id.* § 811(c)(1)–(8) (listing factors the Administrator must consider when determining control or removal of a substance from the schedules).

¹²⁵ *Id.* § 812(b) ("[A] drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or substance.").

¹²⁶ *Id.* § 811(a); 5 U.S.C. § 553(d).

¹²⁷ 21 U.S.C. § 811(h)(1); *Id.* § 811(c)(4)–(6); *see also* *Touby v. United States*, 500 U.S. 160, 163 (1991); YEH, *supra* note 105, at 2.

¹²⁸ 21 U.S.C. § 811(h)(3).

¹²⁹ *Id.* *See also Touby*, 500 U.S. at 166; YEH, *supra* note 105, at 2–3.

¹³⁰ 21 U.S.C. § 811(h)(3).

adding a substance to each of the five schedules.¹³¹ Thus, as the Supreme Court specified,

apart from the “imminent hazard” determination required by [Section 811(h)], the [Administrator], if he wishes to add temporarily a drug to schedule I, must find that it “has a high potential for abuse,” that it “has no currently accepted medical use in treatment in the United States,” and that “[t]here is a lack of accepted safety for use of the drug . . . under medical supervision.”¹³²

Moreover, the Administrator may not issue a temporary scheduling order until thirty days after a notice of the proposed scheduling is published in the *Federal Register*.¹³³ The Administrator must then transmit notice to the Secretary of HHS and consider any comments submitted by the Secretary in response to such scheduling.¹³⁴

The most significant difference from the formal scheduling process is that compliance with the APA’s notice-and-comment requirements is not necessary under a temporary scheduling action.¹³⁵ Thus, it allows the Administrator to bypass, for a limited time, several requirements, including an opportunity for public participation. The Administrator may temporarily schedule a substance for two years, and possibly up to three years, if formal scheduling procedures are initiated.¹³⁶ Also, a temporary scheduling order is not subject to judicial review.¹³⁷ The notion, at least, is that because it fea-

¹³¹ *Touby*, 500 U.S. at 167 (noting that Section 812(b) “speaks in mandatory terms, drawing no distinction between permanent and temporary scheduling”).

¹³² *Id.* (quoting 21 U.S.C. § 812(b)(1)).

¹³³ 21 U.S.C. § 811(1)(A); *see also Touby*, 500 U.S. at 166.

¹³⁴ 21 U.S.C. § 811(h)(4); *see also Touby*, 500 U.S. at 166.

¹³⁵ 21 U.S.C. § 811(h)(1); *see also Touby*, 500 U.S. at 163 (“Rather than comply with the APA notice-and-hearing provisions, the [Administrator] need provide only a 30-day notice of the proposed scheduling in the Federal Register.”).

¹³⁶ 21 U.S.C. § 811(h)(2). A temporary scheduling order is vacated once the substance is scheduled pursuant to the formal scheduling process. *Id.* § 811(h)(5).

¹³⁷ *Id.* § 811(h)(6). *But see Touby*, 500 U.S. at 170 (Marshall, J., concurring) (“We must read the [CSA] as preserving judicial review of a temporary scheduling order in the course of a criminal prosecution in order to save the Act’s delegation of lawmaking power from unconstitutionality.”).

tures fewer procedural requirements, emergency scheduling empowers the government to respond faster to the peril posed by dangerous new drugs or substances.¹³⁸

1. PURPOSE

Congress amended the CSA in 1984 to include the emergency scheduling authority.¹³⁹ This amendment was enacted under the Comprehensive Crime Control Act¹⁴⁰ to combat the designer drug problem.¹⁴¹ The purpose for the amendment, confirmed by its legislative history,¹⁴² was to allow the Administrator “to control a substance on a temporary basis without meeting the prior notice and hearing requirements,” under the permanent scheduling process, “if such action was necessary to avoid an imminent hazard to the public safety.”¹⁴³ Put simply, this new scheduling authority allowed the government to save time and catch alleged drug traffickers faster.¹⁴⁴ As Justice O’Connor explained,

[i]t takes time to comply with [the formal scheduling] procedural requirements. From the time when law enforcement officials identify a dangerous new drug, it typically takes 6 to 12 months to add it to one of the schedules. Drug traffickers were able to take advantage of this time gap by designing drugs that were

¹³⁸ See *Touby*, 500 U.S. at 164.

¹³⁹ Dangerous Drug Diversion Control Act of 1984, Pub. L. No. 98-473, § 508, 98 Stat. 2070, 2071 (codified as amended at 21 U.S.C. § 811(h)).

¹⁴⁰ Pub. L. No 98-473, 98 Stat. 1976 (codified as amended in scattered sections of 18 U.S.C.).

¹⁴¹ *Touby*, 500 U.S. at 163; see also Note, *The Emergence and Emergency of Designer Drugs: Subdelegation of the Power Temporarily to Schedule in Light of United States v. Spain*, 14 AM. J. CRIM. L. 257, 258–61 (1988) (discussing the history of designer drugs).

¹⁴² See discussion *infra* Section II.B.2.

¹⁴³ S. REP. NO. 98-225, at 264 (1983), as reprinted in 1984 U.S.C.C.A.N. 3182, 3446; see also H.R. REP. NO. 98-835, pt. 1, at 11–13 (1984).

¹⁴⁴ See *United States v. Emerson*, 846 F.2d 541, 550 (9th Cir. 1988) (Wiggins, J., dissenting) (“I believe the plain intent of Congress was to establish an expedited system of review in order to criminalize the possession, manufacturing, and distribution of newly-developed ‘designer’ drugs *before* they became public health hazards.”).

similar in pharmacological effect to scheduled substances but differed slightly in chemical composition, so that existing schedules did not apply to them. These “designer drugs” were developed and widely marketed long before the Government was able to schedule them and initiate prosecutions.¹⁴⁵

The crux of the emergency scheduling authority is a requirement that the scheduling of a substance be necessary to avoid an imminent hazard to public safety.¹⁴⁶ Yet, the CSA does not define “imminent hazard,” nor does it reference a potential definition elsewhere in the Code.¹⁴⁷ Insight into the meaning of this term can be found in congressional discussions during the drafting and consideration of the statutory provision. In response to questions presented by Congress concerning the emergency scheduling authority, then-Administrator Francis Mullen specified:

The use of the term “imminent hazard to the public safety” is based on several factors. The “imminent hazard” implies a need for immediate response to a drug trafficking and abuse situation that has occurred with such rapidity and with insufficient warning that normal control mechanisms would result in a large number of deaths and injuries or the continuance of an uncontrolled trafficking situation The burden would be on the Government to prove that such an urgency exists and that the public safety would be jeopardized during the period that a drug would remain uncontrolled during routine scheduling action.¹⁴⁸

To be sure, the menace of a sudden drug trafficking and abuse epidemic was a grave concern for the DEA and its primary objective

¹⁴⁵ *Touby*, 500 U.S. at 163 (citing S. REP. NO. 98-225, at 264).

¹⁴⁶ 21 U.S.C. § 811(h) (2012).

¹⁴⁷ *Id.* § 802 (no reference to “imminent hazard” in definitions).

¹⁴⁸ *Diversion of Prescription Drugs to Illegal Channels and Dangerous Drug Diversion Control Act: Hearing on H.R. 4698 Before the Subcomm. on Crime of the H. Comm. on the Judiciary*, 98th Cong. 401 (1985) (letter of Francis M. Mullen, Jr., Adm’r, DEA) [hereinafter *Mullen Letter*].

for the emergency scheduling authority.¹⁴⁹ The DEA claimed, “it is the total drug trafficking and abuse situation not a finite number of deaths and injuries that would define an imminent hazard.”¹⁵⁰

As an example of a situation of imminent harm, Administrator Mullen pointed to the synthetic drugs being produced in clandestine laboratories.¹⁵¹ The Administrator discussed two analogs of the hallucinogen PCP (phencyclidine)¹⁵² that produced similar qualitative effects.¹⁵³ When regulation of PCP was increased during the late 1970s, clandestine operators turned to these non-controlled analogs to succeed in the illegal drug trade.¹⁵⁴ Because these PCP analogs were not scheduled substances under the CSA, law enforcement could not prosecute the traffickers selling the drug analogs on the street as PCP.¹⁵⁵

In retrospect, the DEA claimed that had the emergency scheduling authority been in place, these substances could have been controlled at least ten months and possibly twelve months earlier, thus allowing law enforcement to prosecute these traffickers.¹⁵⁶ The DEA maintained that the emergency scheduling authority would be “used infrequently and only in the most extreme cases where the time needed for the routine scheduling process would work to the detriment of the public safety.”¹⁵⁷

2. LEGISLATIVE HISTORY

A Senate committee report sheds light on what Congress intended when it enacted the emergency scheduling authority.¹⁵⁸ Similar to the concerns expressed by the DEA, Congress recognized that permanent scheduling could take from six to twelve months, during

¹⁴⁹ *See id.*

¹⁵⁰ *Id.* at 402 (internal quotation marks omitted).

¹⁵¹ *Id.* at 401.

¹⁵² *See* STEPHEN B. KLEIN & B. MICHAEL THORNE, *BIOLOGICAL PSYCHOLOGY* 170–71 (2007) (explaining that hallucinogens, like PCP, can severely alter a person’s state of consciousness, including perceptions of time and distance).

¹⁵³ *Mullen Letter, supra* note 148, at 402.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 404.

¹⁵⁸ S. REP. NO. 98-225, at 264 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 3182, 3446.

which time “enforcement actions against traffickers are severely limited and a serious health problem may arise.”¹⁵⁹ Thus, Congress enacted the emergency scheduling authority to allow the DEA Administrator to temporarily schedule a substance without “await[ing] the exhaustive medical and scientific determinations ordinarily required when a drug is being considered for control.”¹⁶⁰ The emergency scheduling authority was designed to allow the Administrator “to respond quickly to protect the public from drugs of abuse that appear in the illicit traffic too rapidly to be effectively handled under the lengthy routine control procedures.”¹⁶¹

During floor debates, members of Congress stated that the emergency scheduling authority provides “an expedited procedure to control chemicals that mimic the effects of hallucinogenic drugs, such as PCP,”¹⁶² and “will enable us to rapidly control newly developed chemicals, sometimes called designer drugs, that are similar to controlled drugs.”¹⁶³ In a similar vein, a House of Representatives committee hearing report highlights as an issue of serious concern to the legislature: A “substantial development of new psychotropic substances by underground chemists seeking to evade the controls on specific compounds.”¹⁶⁴

3. RELEVANT AGENCY DECISIONAL PRECEDENT

The emergency scheduling authority has been an indispensable law enforcement tool used by the DEA to control highly dangerous substances.¹⁶⁵ The DEA envisioned the emergency scheduling authority as a tool to target two specific types of substances: (1) new drugs of abuse that are of clandestine origin and (2) newly abused

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* at 265.

¹⁶¹ *Id.* at 264–65.

¹⁶² 130 CONG. REC. H9679 (daily ed. Sept. 18, 1984) (statement of Rep. Hughes).

¹⁶³ *Id.* at H9682 (statement of Rep. Rodino).

¹⁶⁴ H.R. REP. NO. 98-835, pt. 1, at 9 (1984).

¹⁶⁵ Since 1984, the DEA has invoked the emergency scheduling authority to schedule approximately sixty-three substances. U.S. DEP’T OF JUST., DRUG ENF’T ADMIN., LISTS OF: SCHEDULING ACTIONS; CONTROLLED SUBSTANCES; REGULATED CHEMICALS (2018), <https://tinyurl.com/yagncyx9>.

drugs that are marketed in an uncontrolled status.¹⁶⁶ A review of substances scheduled under the emergency scheduling authority highlights flaws in the DEA's action to schedule kratom—a natural, botanical substance.

In 1985, the DEA first invoked the emergency scheduling authority to control 3-methylfentanyl, a synthetic analog to fentanyl.¹⁶⁷ The DEA's notice referenced legislative history of the then-newly enacted emergency scheduling authority.¹⁶⁸ Perhaps wary of its new authority, the DEA emphasized that fentanyl analogs were “examples of such designer drugs which Congress clearly intended to subject to the emergency scheduling authority as imminent hazards to the public safety.”¹⁶⁹ To meet its burden of proof, the DEA cited overwhelming evidence that the fentanyl analog was attributable to at least thirty-one overdose deaths, of which twenty-six had occurred just eight months prior to the proposed scheduling.¹⁷⁰ Moreover, the DEA emphasized that impurities, precursors, and by-products discovered in samples of the fentanyl analog showed that it originated from clandestine laboratories.¹⁷¹

The DEA exercised the emergency scheduling authority to control various synthetic analogs to the notorious rave or “club drug”

¹⁶⁶ *Diversion of Prescription Drugs to Illegal Channels and Dangerous Drug Diversion Control Act: Hearing on H.R. 4698 Before the Subcomm. on Crime of the H. Comm. on the Judiciary*, 98th Cong. 129 (1985) (statement of Gene R. Haislip, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin.).

¹⁶⁷ Schedules of Controlled Substances; Temporary Placement of 3-Methylfentanyl Into Schedule I, 50 Fed. Reg. 11,690 (proposed Mar. 25, 1985) (to be codified at 21 C.F.R. 1308) [hereinafter *Scheduling of Fentanyl*]. Fentanyl is a narcotic analgesic in Schedule II of the CSA. 21 U.S.C. § 812(c) (2012).

¹⁶⁸ The scheduling notice cited House Report 98-835: “This new [emergency scheduling] procedure is intended by the Committee to apply to what has been called ‘designer drugs,’ new chemical analogs or variations of existing controlled substances, or other new substances, which have a psychedelic, stimulant or depressant effect and have a high potential for abuse.” *Scheduling of Fentanyl*, *supra* note 167, at 11,690.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 11,691. Twenty of the overdose deaths occurred in the San Francisco Bay area where the fentanyl analog had been identified in powder samples. The scheduling notice also emphasized that “concentrations of the fentanyl-like substance in the body fluids of the overdose victims, in many cases, were extremely low (less than 1 ng/ml) which is consistent with the use of an extremely potent substance.” *Id.*

¹⁷¹ *Id.*

MDMA, or ecstasy.¹⁷² In 1987, the DEA first controlled two MDMA analogs by temporarily placing N-ethyl MDA and N-hydroxy MDA into Schedule I of the CSA.¹⁷³ Among other relevant evidence, the DEA found that both substances were produced in clandestine laboratories and shared similar pharmacological effects with MDMA.¹⁷⁴ As evidence of the substances' adverse effects on public health and safety, the DEA pointed to incidents where the substances were found in the blood of several persons stopped by police for speeding, for driving while intoxicated, or for car accidents.¹⁷⁵ Similarly, there were reported instances of emergency room admissions of person who used these substances and whose reason for admission ranged from bizarre behavior to loss of consciousness.¹⁷⁶

The emergency scheduling authority was newly invoked by the DEA to control five synthetic cannabinoids.¹⁷⁷ These substances are a class of chemical compounds biologically similar to THC, an active compound in marijuana, and are abused for their psychoactive properties.¹⁷⁸ In its final scheduling order, the DEA declared that the rise of these five synthetic cannabinoids represents a recent phenomenon in the U.S. designer drug market.¹⁷⁹ These substances are typically laced in herbal incense products and plant food, thus making

¹⁷² 3,4-methylenedioxy-methamphetamine (MDMA) is a synthetic drug that alters mood and perception. It is chemically like both stimulants and hallucinogens, producing feelings of increased energy, pleasure, emotional warmth, and distorted sensory and time perception. NAT'L INST. ON DRUG ABUSE, DRUGFACTS: MDMA (ECSTASY/MOLLY) (rev. Oct. 2016), <https://tinyurl.com/hhxbpc5>.

¹⁷³ Schedules of Controlled Substances; Temporary Placement of N-ethyl MDA and N-hydroxy MDA into Schedule I of the Controlled Substances Act, 52 Fed. Reg. 30,175 (proposed Aug. 13, 1987) (to be codified at 21 C.F.R. 1308) [hereinafter Scheduling of MDMA Synthetic Analogs].

¹⁷⁴ *Id.* at 30,176.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids into Schedule I, 76 Fed. Reg. 11,075 (proposed Mar. 1, 2011) (to be codified at 21 C.F.R. 1308) [hereinafter Scheduling of Five Synthetic Cannabinoids].

¹⁷⁸ *Id.*

¹⁷⁹ *Id.* at 11,076.

their discovery by law enforcement challenging.¹⁸⁰ Evidence from U.S. poison centers showed a spike in the number of calls related to synthetic cannabinoids—from 112 calls to over 2,700 calls—all during a nine-month span.¹⁸¹

In February 2016, the DEA scheduled one of the latest synthetic cannabinoids to hit the illicit market, named MAB-CHMINACA.¹⁸² As part of its final order, the DEA stated its belief that synthetic cannabinoids were first introduced into the designer drug market in Europe as herbal incense before their initial discovery by U.S. Customs and Border Protection in late 2008.¹⁸³ These designer drug products, laced with synthetic cannabinoids, are often sold under the guise of herbal incense or potpourri.¹⁸⁴ Traffickers continue to contrive ways to circumvent law enforcement efforts to control these harmful substances, thus showing a lack of regard for public health and safety.¹⁸⁵ As evidence of the imminent hazard to public safety posed by MAB-CHMINACA, the DEA pointed to state public health entities' reporting of over 2,000 overdoses and at least thirty-three deaths across eleven states that were attributed to the misuse of synthetic cannabinoids.¹⁸⁶

Although these cases of emergency scheduling involve distinct chemical compounds, they share one common thread: These substances were viewed as rapidly emerging synthetic analogs of currently controlled substances with a recognized high potential for abuse.¹⁸⁷ Because these substances were befitting of the emergency scheduling authority as imminent hazards to public safety, the DEA

¹⁸⁰ *Id.*

¹⁸¹ *Id.* Specifically, on March 24, 2010, the American Association of Poison Control Centers reported that, since 2009, U.S. poison centers had received 112 calls from fifteen states related to synthetic cannabinoids. Just nine months later, the number of calls increased to over 2,700 from forty-nine states and the District of Columbia. *Id.*

¹⁸² Schedules of Controlled Substances: Temporary Placement of the Synthetic Cannabinoid MAB-CHMINACA into Schedule I, 81 Fed. Reg. 6,171 (proposed Feb. 5, 2016) (to be codified at 21 C.F.R. 1308) [hereinafter Scheduling of MAB-CHMINACA].

¹⁸³ *Id.* at 6,172.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at 6,173.

¹⁸⁷ *See supra* text accompanying notes 167, 173, 177, 182.

judiciously complied with Congress' directive and properly exercised such authority without the need for any justification for its actions—until now, with its precipitous scheduling of kratom.

III. KRATOM DOES NOT MEET THE LEGAL CRITERIA FOR EMERGENCY SCHEDULING

With this backdrop, the purpose of the emergency scheduling authority becomes clear. It was enacted to keep designer drugs—that is, newly synthesized analogs of popular drugs of abuse controlled under the CSA¹⁸⁸—off the streets while the permanent scheduling procedure was initiated.¹⁸⁹ But the DEA has never invoked this authority to control a natural, botanical substance because such a substance is not one that Congress intended for the emergency scheduling authority.¹⁹⁰ As will be discussed, the DEA has failed to present a valid justification to invoke the emergency scheduling authority to schedule kratom under the statutory requirements of the CSA.

A. *Strike One: The DEA Has Not Met Its Burden of Showing that Kratom Represents an Imminent Hazard to Public Safety*

The emergency scheduling authority allows for control of a substance only when necessary to avoid an imminent hazard to public safety.¹⁹¹ The burden is on the DEA to prove that an urgency exists and that public safety would be endangered were the substance left uncontrolled during the period of ordinary scheduling procedure.¹⁹² As shown, the DEA's three-factor analysis and evidence presented on its finding of an imminent hazard with respect to kratom are insufficient to overcome such a high statutory burden.

¹⁸⁸ *United States v. Reece*, 956 F. Supp. 2d 736, 738 (W.D. La. 2013) (“A controlled substance analogue is a ‘designer drug’ that resembles a controlled substance in molecular structure and actual or intended physiological effect.”).

¹⁸⁹ 21 U.S.C. § 811(h)(5) (2012) (an order issued under the temporary scheduling authority “shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under [the formal scheduling process] with respect to such substance”).

¹⁹⁰ See discussion *supra* Section II.B.2.

¹⁹¹ 21 U.S.C. § 811(h)(1).

¹⁹² *Mullen Letter*, *supra* note 148, at 401.

1. KRATOM DOES NOT HAVE A HIGH POTENTIAL FOR ABUSE

For decades, kratom has been consumed worldwide by different persons to treat various health concerns.¹⁹³ Despite its recent popularity in the United States, the use of kratom can hardly be considered a new craze in the illicit drug market. The situation that has developed over the past years with kratom consumers in North America does not rise to the level of an uncontrolled trafficking situation. Moreover, the safe and sensible use of kratom by American consumers does not establish actual abuse. Simply put, kratom does not have a high potential for abuse, as the DEA claimed in its scheduling notice.¹⁹⁴

Although referenced throughout the CSA, the term “abuse” is not defined.¹⁹⁵ Some guidance for analyzing a substance’s abuse for purposes of scheduling can be gleaned from the Act’s legislative history.¹⁹⁶ Congress emphasized that “a key criterion for controlling a substance . . . is the substance’s potential for abuse.”¹⁹⁷ When referring to the term “potential for abuse,” the legislature looked to the definition contained in the Federal Food, Drug and Cosmetic Act.¹⁹⁸ Under this definition, a finding that a substance has a potential for abuse is made when:

- (1) there is evidence that individuals are taking the [substance] in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community or
- (2) there is significant diversion of the [substance] from legitimate channels or
- (3) individuals are taking the [substance] on their own initiative rather than [based on medical advice from a licensed practitioner] or
- (4) the drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having

¹⁹³ *Kratom: Survey of the Literature*, *supra* note 70, at 42 (describing myriad uses of kratom).

¹⁹⁴ Kratom Scheduling Notice, *supra* note 15, at 59,933.

¹⁹⁵ 21 U.S.C. § 802 (no reference to “abuse” in definitions).

¹⁹⁶ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. REP. NO. 91-1444, 91st Cong., 2d Sess. (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4601.

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

a potential for abuse to make it likely that the [substance] will have the same potentiality for abuse.¹⁹⁹

When considering these factors, one conclusion arises: Kratom does not have a high potential for abuse akin to currently controlled substances like fentanyl.²⁰⁰

First, there is limited evidence that persons are consuming kratom in amounts sufficient to create a hazard to their health or to the safety of others around them.²⁰¹ Indeed, there have been no reported overdose deaths related to kratom alone.²⁰² The DEA's reliance on a report published by the Centers for Disease Control and Prevention on kratom exposures reported to U.S. poison centers reveals how the DEA's notice is grounded on flawed reasoning.²⁰³ The DEA concluded that the CDC's report is evidence that there is an increase in the number of persons abusing kratom.²⁰⁴ But a closer look at the 660 calls reported by the CDC reveal that many, if not all, adverse medical outcomes were associated with consumption of

¹⁹⁹ *Id.*

²⁰⁰ 21 U.S.C. § 812(c) (listing fentanyl in Schedule II).

²⁰¹ As Dr. Jack Henningfield, a leading expert in addiction medicine, concluded in a 127-page analysis, "kratom has a low potential for abuse and a low dependence liability and there is insufficient evidence of personal harm, adverse health effects or detriment to the public health to warrant control under the CSA." ASSESSMENT OF KRATOM UNDER THE CSA EIGHT FACTORS AND SCHEDULING RECOMMENDATION, PINNEY ASSOCIATES 65 (Nov. 28, 2016), <https://tinyurl.com/ybmxoqwk>.

²⁰² Marcus L. Warner et al., *The Pharmacology and Toxicology of Kratom: From Traditional Herb to Drug of Abuse*, 130 INT'L J. LEGAL MED. 127, 134 (2016) (noting that there is no solid evidence that kratom has caused death).

²⁰³ Mehruba Anwar et al., *Notes from the Field: Kratom (Mitragnyna speciosa) Exposures Reported to Poison Centers – United States, 2010–2015*, 65 MORBIDITY AND MORTALITY WKLY. REP. 748, 748 (2016), <https://tinyurl.com/ya3srmkp> (finding the number of calls received by U.S. poison centers on reported kratom exposures increased tenfold from twenty-six in 2010 to 263 in 2015).

²⁰⁴ *Kratom Three Factor Analysis*, *supra* note 75, at 17 ("Evidence from poison control centers in the United States also shows that there is an increase in the number of individuals abusing kratom.").

substances other than kratom.²⁰⁵ The DEA's analysis of poison control data references a single death involving exposure to kratom, paroxetine (an antidepressant), and lamotrigine (an anticonvulsant and mood stabilizer).²⁰⁶ The 660 calls received by U.S. poison centers in a six-year period is quite telling when compared to the number of calls about other uncontrolled substances. To put that number in perspective, a total of 14,919 exposures to hand sanitizer, which can cause alcohol poisoning, were reported during a seven-month span in 2015 alone.²⁰⁷ The DEA's reliance on data from U.S. poison centers does not establish that kratom alone causes an imminent harm or even a substantial likelihood of an immediate threat of abuse.

Second, there is overwhelming evidence that kratom has been legally bought as a botanical substance for decades in the United States and abroad.²⁰⁸ As discussed in more detail, kratom is not being diverted from legitimate channels into the illicit drug market like other substances that Congress considered when it drafted the CSA.²⁰⁹ As to the third consideration, it is difficult to evaluate the extent to which persons consume kratom on their own initiative rather than based on medical advice because kratom is a product that is widely available online without the need for a prescription.²¹⁰

Nor does kratom mimic a drug already scheduled as having a high potential for abuse under the CSA.²¹¹ While some studies have shown that kratom exhibits opioid-like activity, a more recent molecular study found that the primary alkaloids present in kratom—

²⁰⁵ Anwar et al., *supra* note 203, at 748. The most commonly reported substances consumed in combination with kratom were ethanol, other botanicals, benzodiazepines, narcotics, and acetaminophen. *Id.*

²⁰⁶ *Kratom Three Factor Analysis*, *supra* note 75, at 19, tbl. 2 (citing Anwar et al., *supra* note 203, at 748).

²⁰⁷ AM. ASS'N OF POISON CONTROL CTRS., ALERTS: *Hand Sanitizer*, <http://www.aapcc.org/alerts/hand-sanitizer/> (last visited Jan. 10, 2017).

²⁰⁸ See Prozialeck et al., *supra* note 49, at 794 (noting that a wide variety of kratom products are readily available from Internet-based suppliers and specialty stores).

²⁰⁹ See discussion *supra* Section II.B.2.

²¹⁰ See Prozialeck et al., *supra* note 49, at 794.

²¹¹ See *id.* at 797 (noting that “many anecdotal reports suggest that [kratom] may be less addictive than classical opioids”); *All Things Considered*, *supra* note 1 (explaining that the main chemical in kratom, mitragynine, binds to some of the same receptors as opioids, providing some pain relief and feelings of euphoria but not the same high) (statement of pharmacologist David Kroll).

mitragynine and 7-hydroxymitragynine—are an unusual class of opioid receptor modulators with distinct pharmacological properties.²¹² The study found that mitragynine binds to several non-opioid receptors, thus exhibiting both agonist and antagonist effects at the main opioid receptors in the central nervous system.²¹³ In sum, research shows that the value of kratom warrants careful evaluation to determine its true potential as an alternative in both pain management and opioid addiction.²¹⁴ As one research study puts it: “[A]ny blanket illegalization of kratom poses the danger of casting out the baby with the bathwater.”²¹⁵

2. KRATOM USE DOES NOT CONSTITUTE DIVERSION FROM LEGITIMATE CHANNELS

The DEA’s analysis confounds evidence on the widespread use of kratom with actual abuse.²¹⁶ To be sure, there is substantial evidence on the worldwide use of kratom because it is a botanical substance with numerous therapeutic benefits.²¹⁷ But the DEA’s assumption that evidence on the use of kratom constitutes actual abuse is a non sequitur. The DEA’s analysis is doubtful because it fails to recognize that kratom has been available for many years through legitimate channels.²¹⁸

²¹² Andrew C. Kruegel et al., *Synthetic and Receptor Signaling Explorations of the Mitragyna Alkaloids: Mitragynine as an Atypical Molecular Framework for Opioid Receptor Modulators*, 138 J. AM. CHEM. SOC’Y 6754, 6754 (2016).

²¹³ *Id.* at 6762. Drugs can function as agonists or antagonists to either help or inhibit the transmission of neural impulses. Those that mimic or enhance the activities of a neurotransmitter are called agonists, whereas those that block or inhibit the effects of a neurotransmitter are known as antagonists. KLEIN & THORNE, *supra* note 152, at 152. As to the other kratom alkaloid, the study found that 7-hydroxymitragynine is not present in all extracts of plant material, so the potential influence of this compound to the effects of kratom is not typical. Kruegel et al., *supra* note 212, at 6762.

²¹⁴ *Kratom: Survey of the Literature*, *supra* note 70, at 45.

²¹⁵ *Id.*

²¹⁶ *Kratom Three Factor Analysis*, *supra* note 75, at 12–14 (citing kratom’s increased availability and widespread distribution as evidence of increased abuse).

²¹⁷ See discussion *supra* Section I.B.

²¹⁸ *Id.*

Small business owners who cater to Americans consuming kratom for its health benefits can hardly be equated to the drug traffickers the DEA originally intended to prosecute with the aid of the emergency scheduling authority.²¹⁹ Thus, an increase in kratom use is not a proper indicator of an uncontrolled trafficking situation for which the DEA sought enactment of the emergency scheduling authority.²²⁰ Further, American suppliers of kratom are not clandestinely importing, manufacturing, or distributing the botanical substance. To the contrary, they are openly selling kratom in health food stores and smoke shops across the country.²²¹

3. KRATOM IS ALLEVIATING A PUBLIC HEALTH THREAT, NOT CREATING ONE

In both its notice of intent and three-factor analysis, the DEA claims there have been numerous deaths associated with kratom,²²² yet not one report in the scientific literature cited by the DEA found that kratom is lethal by itself. These published studies all describe ingestion of kratom together with pharmaceuticals or controlled substances.²²³ A recent publication confirmed the finding of other published studies: “Although death has been attributed to kratom use,

²¹⁹ *Mullen Letter*, *supra* note 148, at 401–02.

²²⁰ *See id.*

²²¹ *See* Kristy Totten, *Las Vegas Business Owner Fights Kratom Ban*, NEV. PUB. RADIO (Sept. 26, 2016), <https://tinyurl.com/y8gpczyn>.

²²² Kratom Scheduling Notice, *supra* note 15, at 59,932; *Three Factor Analysis on Kratom*, *supra* note 75, at 21.

²²³ Ritva Karinen et al., *An Accidental Poisoning with Mitragynine*, 245 FORENSIC SCI. INT'L e29, e29 (2014) (reporting the death of a middle-aged man in Norway whose autopsy findings revealed therapeutic concentrations of zopiclone, citalopram, and lamotrigine in the blood, as well as mitragynine); Robert Kronstrand et al., *Unintentional Fatal Intoxications with Mitragynine and O-Desmethyltramadol from the Herbal Blend Krypton*, 35 J. ANALYTICAL TOXICOLOGY 242, 243, 246 (2011) (attributing nine deaths in Sweden to Krypton, which is a blend of mitragynine, or kratom, and O-desmethyltramadol, the main metabolite of the commercial opioid Tramadol, and also noting that several other psychotropic drugs were detected in each victim and could have contributed to death); Iain M. McIntyre et al., *Mitragynine ‘Kratom’ Related Fatality: A Case Report with Postmortem Concentrations*, 39 J. ANALYTICAL TOXICOLOGY 152, 155 (2015) (reporting the death of a twenty-four-year-old man who ingested therapeutic concentrations of venlafaxine, diphenhydramine, mirtazapine, and ethanol, or alcohol, in addition to mitragynine); Michael F. Neerman et al., *A Drug Fatality Involving Kratom*, 58 J. FORENSIC SCI. S278, S279 (2013) (reporting the

there is no solid evidence that kratom was the sole contributor to an individual's death."²²⁴ Thus, it is not reasonable to assume, as the DEA has, that kratom is the lone culprit for each of these reported deaths, especially when some of the other reported substances, like the sleeping pill temazepam, have been linked to an increased risk of death.²²⁵

Throughout its three-factor analysis, the DEA relies on a CDC report on kratom incidents related to U.S. poison centers.²²⁶ Yet, the DEA failed to fact-check the sources cited in the report. In the two-page report, the CDC claims that incidents have linked kratom use with deaths, citing two sources for its assertion.²²⁷ But both sources reported no actual deaths from kratom use.²²⁸ The CDC publication also reports that deaths have been attributed to kratom in the United States, but it only cites to a newspaper article for this unfounded claim.²²⁹ The DEA overlooked significant discrepancies in the sources it cited and relied upon to reach its decision that kratom poses an imminent hazard to public safety.

autopsy findings of a seventeen-year-old male with elevated concentrations of dextromethorphan, diphenhydramine, temazepam, and 7-amino-clonazepam in the blood, as well as kratom).

²²⁴ Warner et al., *supra* note 202, at 134.

²²⁵ Daniel F. Kripke et al., *Hypnotics' Association with Mortality or Cancer: A Matched Cohort Study*, 2 *BMJ OPEN* 1, 1 (2012), <http://bmjopen.bmj.com/content/2/1/e000850.full> (finding that patients receiving prescriptions for temazepam and other hypnotics suffered over four times the mortality as the matched hypnotic-free control patients); Alice Park, *Study: Sleeping Pills Linked with Early Death*, *TIME* (Feb. 28, 2012), <https://tinyurl.com/7jrqzfs>.

²²⁶ *Kratom Three Factor Analysis*, *supra* note 75, at 10–12, 17, 19–21.

²²⁷ Anwar et al., *supra* note 203, at 748.

²²⁸ Mathias B. Forrester, *Kratom Exposures Reported to Texas Poison Centers*, 32 *J. ADDICTIVE DISEASES* 396, 397 (2013) (reporting “there were no deaths”); Satariya Trakulsrichai et al., *Kratom Abuse in Ramathibodi Poison Center, Thailand: A Five-Year Experience*, 45 *J. PSYCHOACTIVE DRUGS* 404, 406 (2013) (reporting “no mortality in this study”).

²²⁹ Anwar et al., *supra* note 203, at 748. In turn, the newspaper article reported the suicide of a twenty-two-year-old male by a self-inflicted gunshot wound. Erin Coleman, *Anguished Parents Say Exotic Drug Kratom Is the Cause of Son's Suicide*, *ATLANTA J. CONST.* (May 19, 2015), <https://tinyurl.com/yaebwvy4>. Such news is not sufficient, let alone actual, causal evidence of kratom's public health threat.

Further, the DEA has frowned upon the use of kratom as a replacement for other opioids.²³⁰ As far as the DEA is concerned, the fact that people are weaning themselves from opioid addiction with a less dangerous, naturally-derived substance is irrelevant. But this is evidence of kratom's growing reputation as a potential antidote to the menacing opioid epidemic in the United States.²³¹ Indeed, many users who have incorporated kratom into their lives have found a new hope in managing their opioid addiction, while others look to the plant as a therapeutic alternative to the prescription painkillers that ruined their lives.²³² A sample from the over 23,000 comments posted as part of the DEA's modified comment process corroborates kratom's therapeutic benefits:

Kratom has allowed me to get off prescription drugs that were causing me a lot of harm. Additionally, I now have less anxiety allowing me to be a better father, a better employer and a better person. Kratom has saved my life plain and simple. And it has never once harmed me in any way.²³³

* * *

I use kratom for inoperable back pain and have been successfully using it to reduce [the] need for synthetic opiates like hydrocodone. Kratom has proven

²³⁰ Kratom Scheduling Notice, *supra* note 15, at 59,930. ("In the United States, kratom is misused to self-treat chronic pain and opioid withdrawal symptoms, with users reporting its effect to be comparable to prescription opioids.")

²³¹ Saskia de Melker & Melanie Saltzman, *If Kratom Helps Opioid Addicts, Why Might DEA Outlaw It?*, PBS: NEWSHOUR (Jan. 15, 2017), <https://tinyurl.com/z23lrmq>.

²³² *All Things Considered*, *supra* note 1; Alexa Tsoulis-Reay, *The Intriguing Therapeutic Potential of a Little-Known Plant from Southeast Asia*, THE CUT (Jan. 27, 2017), <https://tinyurl.com/zhjhpda> (reporting the success stories of three kratom users across the country).

²³³ Comment on FR Doc # 2016-24659, DEA Proposed Rule: Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I; Withdrawal, Comment Submitted by Ryan Richardson, REGULATIONS.GOV (Nov. 28, 2016), <https://www.regulations.gov/document?D=DEA-2016-0015-8577>.

to me personally to be a safe, reasonable alternative Banning this benevolent herb would, to me, represent a real setback.²³⁴

* * *

I was addicted to opiates for years, kratom gave me the means to stop using opiates without the crippling side effects of withdraw[al]s. I originally was prescribed opiate painkillers by my doctor for joint pain due to arthritis without knowing the grip they would have on me. Over time I lost my family over the effects of opiates, kratom gave me my life back, I've been able to maintain a normal life with the help of kratom.²³⁵

These comments show that the rise in kratom use in the United States is partly in response to the havoc that prescription opioids have caused many persons. While conceding the abuse of prescription opioids,²³⁶ the DEA failed to acknowledge the adverse impact that the proposed emergency scheduling of kratom would produce on the overall public health. Persons relying on kratom to self-treat their opioid addiction will have one grim decision to make: Continue using kratom and face the possibility of criminal charges, or revert to the same prescription opioids that ruined their lives.²³⁷ Some

²³⁴ Comment on FR Doc # 2016-24659, DEA Proposed Rule: Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I; Withdrawal, Comment Submitted by Shawn Hamilton, REGULATIONS.GOV (Nov. 26, 2016), <https://www.regulations.gov/document?D=DEA-2016-0015-7324>.

²³⁵ Comment on FR Doc # 2016-24659, DEA Proposed Rule: Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I; Withdrawal, Comment Submitted by Eric Vanvliet, REGULATIONS.GOV (Nov. 21, 2016), <https://www.regulations.gov/document?D=DEA-2016-0015-6167>.

²³⁶ *Kratom Three Factor Analysis*, *supra* note 75, at 2 (“The well-documented misuse and abuse of opioids and their impact on communities is a public health and safety epidemic in the United States.”).

²³⁷ Karisa Rowland is one such person who would rather face criminal charges than return to prescription painkillers: “I’m the one in pain. The people making these laws, they’re not the ones going through this pain; they’re not the ones

kratom advocates have already faced this catch-22 in the seven states that have banned kratom, including some states that have incorrectly classified the herbal supplement as an opiate derivative or synthetic drug.²³⁸ Although it is too early to predict whether these state kratom bans will impact overdose deaths from prescription opioids, a county in Alabama witnessed 103 overdose deaths during the first half of 2016, coinciding with the onset of the state's kratom ban.²³⁹

B. *Strike Two: Kratom Is Not a Substance that Congress Intended to Control with the Emergency Scheduling Authority*

Congress envisioned the emergency scheduling authority as an emergency control.²⁴⁰ Thus, the legislature enacted this authority to be used only if a substance creates an imminent hazard to public safety.²⁴¹ Kratom is neither a new drug that appeared too rapidly to be addressed by ordinary scheduling procedures²⁴² nor a new designer drug created by underground chemists seeking to evade DEA controls under the CSA—as Congress considered during enactment of the emergency scheduling authority.²⁴³

The finding of an imminent hazard serves to justify the DEA's action to bypass the administrative safeguards of the formal scheduling process, including the public's participation in the agency's

whose families have broken up. I found life and I have no intention of letting it go." *All Things Considered*, *supra* note 1.

²³⁸ ALA. CODE § 20-3-23 (2016) (listing kratom compounds as synthetic drugs under Schedule I); ARK. ADMIN. CODE § 007.07.2 (West 2016) (listing kratom compounds as opium derivatives under Schedule I); IND. CODE § 35-31.5-2-321 (2016) (listing kratom compounds as synthetic drugs); TENN. CODE ANN. § 39-17-4521 (West 2015); 21 R.I. GEN. LAWS § 21-28-2.08 (listing kratom under Schedule I); VT. ADMIN. CODE 12-5-23:4.0 (2016); WIS. STAT. § 961.14 (2016).

²³⁹ Carol Robinson, *Jeffco Sees 25 Heroin, Fentanyl Deaths in June; 103 Fatal Overdoses So Far in 2016*, AL.COM (July 11, 2016), <https://tinyurl.com/zd4ljp7>.

²⁴⁰ S. REP. NO. 98-225, at 264 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 3182, 3446.

²⁴¹ 21 U.S.C. § 811(h) (2012).

²⁴² S. REP. NO. 98-225, at 264–65. In fact, kratom use dates back to 1836. Eisenman, *supra* note 54, at 66. The plant was first described by a Dutch botanist, Pieter Willem Korthals, while working for the Dutch East India Company from 1830 to 1837. *Id.* at 59.

²⁴³ H.R. REP. NO. 98-835, pt. 1, at 9 (1984).

decisionmaking.²⁴⁴ Thus, the emergency scheduling authority ensures the creation of a balance between public safety and public participation.²⁴⁵ Congress decided that public safety takes preference over the democratic process inherent in the CSA, through the requirements of the APA, only in exigent circumstances.²⁴⁶ Absent such circumstances, the public's participation in the DEA's decision making must prevail.²⁴⁷ Indeed, this specific stance was endorsed by U.S. Senators who reached out to the Administrator and urged the DEA to take appropriate steps to delay the kratom ban to allow for a public comment period.²⁴⁸ The Senators reiterated:

Congress has established a specific set of review protocols for scheduling decisions . . . that allows for the full engagement of consumers, researchers, health professionals, law enforcement officials, and other stakeholders. Given the long reported history of Kratom use, coupled with the public's sentiment that it is a safe alternative to prescription opioids, we believe using the regular review process would provide for a much-needed discussion among all stakeholders.²⁴⁹

Because kratom has been a widely accessible botanical substance for years in the United States, there is no indication that kratom is being diverted in the manner Congress foresaw when it enacted the emergency scheduling authority.²⁵⁰ Congress was concerned with the abuse of legitimate pharmaceutical drugs and their

²⁴⁴ *Touby v. United States*, 500 U.S. 160, 163 (1991).

²⁴⁵ *Grinspoon v. Drug Enf't Admin.*, 828 F.2d 881, 891 (1st Cir. 1987) (noting that "Congress has already done the balancing and determined that the risk of ongoing abuse amounting to an 'imminent hazard to the public safety' justifies temporary scheduling without a hearing").

²⁴⁶ *United States v. Reece*, 956 F. Supp. 2d 736, 745 (W.D. La. 2013) ("When Congress enacted 21 U.S.C. § 811(h), it created a procedure that is, in essence, an exception to the general procedural requirements of the [APA] and the Congressional Review Act.").

²⁴⁷ 21 U.S.C. § 811(a) (2012) (requiring an opportunity for a hearing pursuant to APA rulemaking procedures).

²⁴⁸ Senate Letter to DEA, *supra* note 90.

²⁴⁹ *Id.*

²⁵⁰ See discussion *supra* Section II.B.2.

diversion from legitimate channels.²⁵¹ Some of the principal avenues of diversion that Congress considered include the establishment of sham clinics for “distributing prescription drugs or issuing prescriptions for such drugs under the cover of a legitimate medical practice,” and also the “development of new psychotropic substances by underground chemists seeking to evade the controls on specific compounds.”²⁵² Neither of these categories of diversion apply to kratom because it is a botanical substance that is openly sold in legitimate businesses across the United States.²⁵³

C. *Strike Three: The Application of the Emergency Scheduling Authority to Kratom Is a Significant Departure from Relevant Agency Decisional Precedent*

While it is well-settled that the doctrine of stare decisis does not bind administrative agencies as it does courts,²⁵⁴ uniformity and consistency of agency decisions is essential to dispel any situations of arbitrary rulemaking.²⁵⁵ From its first application of the emergency scheduling authority in 1985, the DEA has targeted rapidly emerging synthetic analogs of presently controlled substances under the CSA.²⁵⁶ These highly dangerous substances satisfied all the legal criteria required under the emergency scheduling authority, including a high potential for abuse, diversion from legitimate channels, and clandestine manufacture.²⁵⁷ These factors are stark evidence of the substance’s imminent hazard to public safety and valid reasons for the DEA to exercise this powerful scheduling authority.²⁵⁸ The same cannot be said of the DEA’s proposed emergency scheduling action of kratom.

Kratom does not fit into either category of substances for which the DEA originally sought the emergency scheduling authority. It is

²⁵¹ H.R. REP. NO. 98-835, pt. 1, at 7 (1984).

²⁵² *Id.* at 8–9.

²⁵³ See discussion *supra* Section III.A.2.

²⁵⁴ *Pre-Fab Transit Co. v. United States*, 595 F.2d 384, 387 (7th Cir. 1979).

²⁵⁵ *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63–65 (1956) (discussing uniformity and consistency of agency decisions in the context of the doctrine of primary jurisdiction); *accord R-C Motor Lines, Inc. v. United States*, 350 F. Supp. 1169, 1172 (M.D. Fla. 1972), *aff’d mem.* 411 U.S. 941 (1973).

²⁵⁶ See discussion *supra* Section II.B.3.

²⁵⁷ 21 U.S.C. § 811(h) (2012).

²⁵⁸ *Id.*

neither a new drug of abuse of clandestine origin nor a newly abused drug marketed in an uncontrolled status.²⁵⁹ Kratom does not resemble the synthetic analogs of dangerous substances controlled by the DEA for their abusive psychoactive properties.²⁶⁰ Moreover, kratom is not being sold or marketed under the guise of herbal incense or potpourri as the latest synthetic cannabinoid that the DEA controlled.²⁶¹ Instead, kratom is sold as a safe herbal dietary supplement to treat chronic pain and is viewed as an alternative to self-treat symptoms from opioid withdrawal.²⁶²

Further, kratom does not constitute an imminent hazard to public safety similar to designer drugs.²⁶³ For example, the first synthetic analog controlled by the DEA—fentanyl—caused thirty-one overdose deaths²⁶⁴ and the latest synthetic cannabinoid—MAB-CHMINACA—caused at least thirty-three overdose deaths.²⁶⁵ In sharp contrast, to date, there have been no reported overdose deaths from kratom alone.²⁶⁶ To be sure, the fifteen deaths linked to kratom cited by the DEA have all been either related to co-ingestion of an herbal blend called Krypton (that was contaminated) or included administration of other substances.²⁶⁷ Furthermore, there have been no reports that kratom is causing persons to engage in bizarre behavior or to engage in harmful activities that would put others around them

²⁵⁹ See discussion *supra* Sections I.B., III.A.2.

²⁶⁰ See *supra* Section II.B.3.

²⁶¹ Scheduling of MAB-CHMINACA, *supra* note 182, at 6,172.

²⁶² *Kratom: Survey of the Literature*, *supra* note 70, at 43.

²⁶³ See *supra* Section II.B.3 (discussing precedent of the emergency scheduling authority).

²⁶⁴ Scheduling of Fentanyl, *supra* note 167, at 11,691.

²⁶⁵ Scheduling of MAB-CHMINACA, *supra* note 182, at 6,173.

²⁶⁶ Boyer I, *supra* note 65, at 1049 (noting that “although mitragynines [kratom] agonize mu-opioid receptors, respiratory depression, coma, pulmonary edema and death have not . . . been associated with human kratom ingestion”); Warner et al., *supra* note 202, at 134 (noting that there is no solid evidence that kratom has caused death).

²⁶⁷ *Kratom Three Factor Analysis*, *supra* note 75, at 20–26; *Kratom: Survey of the Literature*, *supra* note 70, at 45 (noting that individual case reports linking kratom use to adverse reactions or fatalities involved persons who used kratom together with other substances).

in danger, similar to MDMA synthetic analogs controlled by the DEA.²⁶⁸

The DEA's action detracts from prior applications of the emergency scheduling authority because the agency has never exercised such authority to control a natural, botanical substance. It has never tried to control a substance with a long-reported history of safe and responsible use that is available through legitimate avenues. Above all, the DEA has never exercised the emergency scheduling authority without satisfying the statutory burden—that is, finding a substance poses an imminent hazard to the public safety—with sufficient evidence.

IV. LEGAL CONSEQUENCES OF THE DEA'S CONDUCT AND THE NEED FOR CONGRESSIONAL OVERSIGHT

A. *The DEA's Conduct Constitutes an Ultra Vires Act*

The Constitution commands all legislative powers to be vested in a Congress.²⁶⁹ The nondelegation doctrine arises from the constitutional mandate “that Congress may not constitutionally delegate its legislative power to another branch of Government.”²⁷⁰ Essentially, the nondelegation doctrine is embedded in the “principle of separation of powers that underlies our tripartite system of Government.”²⁷¹ Yet, the Supreme Court has continuously espoused that the nondelegation doctrine does not foreclose Congress from seeking help from its coordinate branches to carry out its legislative duties.²⁷² Thus, Congress may broadly legislate, “leaving a certain degree of discretion to executive or judicial actors,” without running afoul of the Constitution.²⁷³ As long as Congress “lays down by leg-

²⁶⁸ Scheduling of MDMA Synthetic Analogs, *supra* note 173, at 30,176 (noting persons stopped by police for speeding or driving while intoxicated as evidence of the MDMA synthetic analog's adverse effects on the public health and safety).

²⁶⁹ U.S. CONST. art. I, § 1.

²⁷⁰ *Touby v. United States*, 500 U.S. 160, 165 (1991).

²⁷¹ *Id.* at 165 (quoting *Mistretta v. United States*, 488 U.S. 361, 371 (1989)).

²⁷² *Id.* (citing *Mistretta*, 488 U.S. at 372).

²⁷³ *Id.*

islative act an intelligible principle to which the person or body authorized to act is directed to conform, such legislative action is not a forbidden delegation of legislative power.”²⁷⁴

When Congress enacted the CSA, it authorized the Attorney General to control the addition or removal of substances, or the transfer of a substance from one schedule to another.²⁷⁵ For each of these grants of authorization, Congress required the Attorney General to follow specified procedures.²⁷⁶ The Attorney General promulgated regulations delegating to the DEA Administrator these powers under the CSA, including the power to schedule substances on a temporary basis under the emergency scheduling authority.²⁷⁷

In *Touby v. United States*, the Supreme Court considered whether Section 201(h) of the CSA unconstitutionally delegates legislative power to the Attorney General and, in turn, whether the Attorney General’s subsequent delegation to the DEA Administrator was authorized by statute.²⁷⁸ After a careful analysis of the pertinent statutes, the Court held that Congress had “meaningfully constrain[ed] the Attorney General’s discretion to define criminal conduct,” and that such “restrictions satisfy the constitutional requirements of the nondelegation doctrine.”²⁷⁹ The Court found the statute’s “imminent hazard to the public safety” requirement to be an intelligible principle confining the Attorney General’s discretion to schedule controlled substances on a temporary basis.²⁸⁰ In mandating such a stringent standard to trigger the emergency scheduling authority, Congress delineated the Attorney General’s, and by extension, the DEA’s actions.²⁸¹

²⁷⁴ *Id.* (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)).

²⁷⁵ *Id.* at 162.

²⁷⁶ *Id.*

²⁷⁷ *Id.* at 164; *see also* 28 C.F.R. § 0.100(b) (2016) (delegating “functions vested in the Attorney General by the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended”).

²⁷⁸ *Touby*, 500 U.S. at 162.

²⁷⁹ *Id.* at 167.

²⁸⁰ *Id.* at 165.

²⁸¹ *Id.* at 166–67; *see also* *Stark v. Wickard*, 321 U.S. 288, 309 (1944) (“When Congress passes an Act empowering administrative agencies to carry on governmental activities, the power of those agencies is circumscribed by the authority granted.”).

Where agency action breaches a specific statutory directive, this results in the overstepping of the agency's delegated authority and ultimately in an unconstitutional invasion of Congress' legislative powers.²⁸² Although federal agencies may well be better equipped to exercise discretion concerning complicated matters, it is critical to our democratic government to maintain that "except in a few areas constitutionally committed to the Executive Branch, the basic policy decisions governing society are to be made by the Legislature."²⁸³

The statutory command under the emergency scheduling authority demands a clear-cut finding by the DEA that the scheduling of a substance into Schedule I is necessary to avoid an imminent hazard to public safety.²⁸⁴ Such a demanding standard of proof requires specific evidence of the three factors set forth in the statute.²⁸⁵ The DEA's justifications, thus far, have not shown that kratom constitutes an imminent hazard to public safety.²⁸⁶ Indeed, the DEA's reliance on erroneous evidence in its analysis "renders illusory the mandatory language of the statutory scheme."²⁸⁷ By broadening the scope of the emergency scheduling authority to schedule kratom, the DEA abused its discretion under the statutory directive. Consequently, the DEA's unprecedented action to ban kratom under the emergency scheduling authority constitutes an *ultra vires* act.²⁸⁸

Because the DEA has not met its burden of proof—that is, a finding that scheduling kratom is necessary to avoid an imminent hazard to public safety—it has not satisfied the statutory directives

²⁸² See Evan J. Criddle, *When Delegation Begets Domination: Due Process of Administrative Lawmaking*, 46 GA. L. REV. 117, 121–22, 137–38 (2011) (arguing that due process concerns with arbitrary decisionmaking entail that Congress channel delegated administrative power through substantive, structural, and procedural constraints).

²⁸³ *Mistretta v. United States*, 488 U.S. 361, 415 (1989) (Scalia, J., dissenting).

²⁸⁴ 21 U.S.C. § 811(h) (2012).

²⁸⁵ *Id.* § 811 (h)(3).

²⁸⁶ See discussion *supra* Part III.

²⁸⁷ *Japan Whaling Ass'n v. Am. Cetacean Soc.*, 478 U.S. 221, 243 (1986) (Marshall, J., dissenting).

²⁸⁸ When a federal agency exercises authority beyond that authorized by Congress, those actions are *ultra vires*. *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (For agencies, both the "power to act and how they are to act is authoritatively prescribed by Congress, so that when they act improperly, no less than when they act beyond their jurisdiction, what they do is *ultra vires*").

imposed by Congress, and thus is not authorized to invoke the emergency scheduling authority.²⁸⁹ Nevertheless, as will be discussed, Congress has the means to correct the actions of a federal agency that has exceeded the bounds of its statutory authority.

B. *The Congressional Review Act: Kratom's Last Hope?*

“Quite as important as legislation is vigilant oversight of administration.”²⁹⁰ The Congressional Review Act,²⁹¹ enacted in 1996, is an oversight tool that Congress may use to overturn a rule issued by a federal agency.²⁹² Rulemaking authority is granted to federal agencies to implement provisions of a law passed by Congress.²⁹³ Because Congress is the branch of government most accountable to the people, it has an interest in safeguarding that federal agencies remain faithful to congressional intent when issuing rules.²⁹⁴

Under the CRA, prior to a rule taking effect, an agency must submit the final rule to Congress and to the Comptroller General of the Government Accountability Office.²⁹⁵ Members of Congress have a specified period of time in which to submit and act on a joint resolution disapproving the rule.²⁹⁶ If both houses pass the resolution, it is sent to the President for signature or veto.²⁹⁷ If the President vetoes the resolution, Congress can vote to override the veto.²⁹⁸

The CRA, however, does not apply to proposed rules or orders issued by an agency because neither satisfies the CRA's definition of a rule.²⁹⁹ The CRA differentiates between an agency's rules and

²⁸⁹ Cf. *City of Arlington*, 569 U.S. at 297 (“No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority.”).

²⁹⁰ WOODROW WILSON, CONGRESSIONAL GOVERNMENT: A STUDY IN AMERICAN POLITICS 297 (1885).

²⁹¹ Pub. L. No. 104-121, tit. II, subtit. E, 110 Stat. 868 (1996) (codified at 5 U.S.C. §§ 801–808 (2012)).

²⁹² MAEVE P. CAREY ET AL., CONG. RESEARCH SERV., R43992, THE CONGRESSIONAL REVIEW ACT: FREQUENTLY ASKED QUESTIONS 1 (2016).

²⁹³ *Id.*

²⁹⁴ *Id.*

²⁹⁵ 5 U.S.C. § 801(a)(1)(A) (2012).

²⁹⁶ CAREY ET AL., *supra* note 292, at 1.

²⁹⁷ *Id.*

²⁹⁸ *Id.*

²⁹⁹ *Id.* at 7.

orders.³⁰⁰ A rule is subject to the procedures proscribed in the CRA, while an order is not.³⁰¹ Thus, the DEA's temporary scheduling order is not subject to the CRA until a final rule is published in the *Federal Register*.³⁰² The emergency scheduling authority creates a process that is an exception to the general procedural requirements of the CRA.³⁰³ Despite its non-application to an agency's temporary order, the CRA is useful for overturning agency decisions and serves as a check on delegated legislative authority.³⁰⁴ Nevertheless, Congress has other oversight tools at its disposal that have proved far more effective, including legislative override and the power of the purse, or its appropriations process.³⁰⁵

C. *Going Forward*

President Donald Trump has taken steps to address the drug addiction and opioid crisis, albeit rather slowly. On March 29, 2017, President Trump signed an Executive Order establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis.³⁰⁶ The Commission is chaired by Governor Chris Christie of New Jersey and is tasked to "study ways to combat and treat the scourge of drug abuse, addiction, and the opioid crisis[.]"³⁰⁷ On July

³⁰⁰ *United States v. Reece*, 956 F. Supp. 2d 736, 745 (W.D. La. 2013) (finding that rules and orders are two different things under the CRA).

³⁰¹ *Id.*; see also *United States v. Nasir*, No. 5:12-CR-102-JMH, 2013 WL 5373691, at *3 (E.D. Ky. Sept. 25, 2013) (discussing compliance with the CRA).

³⁰² CAREY ET AL., *supra* note 292, at 7.

³⁰³ *Reece*, 956 F. Supp. 2d at 745.

³⁰⁴ *But see* CAREY ET AL., *supra* note 292, at 7 (noting that the single successful use of the CRA to overturn an agency rule suggests that agencies might not consider the CRA to be a credible threat); Jamelle C. Sharpe, *Judging Congressional Oversight*, 65 ADMIN. L. REV. 183, 208 n.116 (2013) (noting that the CRA "is a redundant and ineffective tool for overturning agency actions with which Congress disagrees"); Note, *The Mysteries of the Congressional Review Act*, 122 HARV. L. REV. 2162, 2169, 2176 (2009) (arguing that the CRA is rarely used, even in situations where it could be most effective).

³⁰⁵ Jack M. Beermann, *Congressional Administration*, 43 SAN DIEGO L. REV. 61, 82–85, (2006) (describing legislative override and the power of the purse among over a dozen formal and informal oversight tools employed by Congress).

³⁰⁶ Exec. Order No. 13,784, 82 Fed. Reg. 16, 283 (Mar. 29, 2017), <https://tinyurl.com/ya2kx75>.

³⁰⁷ *Id.*; see also *President's Commission*, OFF. OF NAT'L DRUG CONTROL POL'Y, <https://tinyurl.com/ycgeapse> (last visited Feb. 21, 2018).

31, 2017, the Commission recommended that the President declare a national emergency³⁰⁸ either under the Stafford Act, which would allocate Federal Emergency Management Agency funds and is directed by the Homeland Security Department,³⁰⁹ or the Public Health Service Act,³¹⁰ which is a more limited response under HHS.³¹¹

Almost three months later, on October 26, 2017, in a much-awaited announcement, President Trump directed the Secretary of HHS to declare the opioid crisis a public health emergency.³¹² But this declaration, under the PHSA, failed to propose new funding to tackle the opioid crisis.³¹³ Democrats blasted President Trump for a halfhearted response to an escalating epidemic. Senator Edward Markey, a Democrat of Massachusetts, cogently stated: “America is hemorrhaging lives by the day because of the opioid epidemic, but President Trump offered the country a Band-Aid when we need a tourniquet[.]”³¹⁴ Indeed, rather than provide emergency funds to states combating the opioid crisis, President Trump asserted: “The best way to prevent drug addiction and overdose is to prevent people from abusing drugs in the first place. If they don’t start, they won’t have a problem.”³¹⁵ This proposition is not a viable solution to the predicament millions of Americans face each day because of life-threatening addiction to opioids. More needs to be done. In sum, the

³⁰⁸ Meeting Minutes of the President’s Comm’n on Combating Drug Addiction and the Opioid Crisis 1 (July 31, 2017), <https://tinyurl.com/yauxdmnl>.

³⁰⁹ Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. No. 93-288, 88 Stat. 143 (1974) (codified as amended at 42 U.S.C. § 5121 *et seq.* (2012)).

³¹⁰ Pub. L. No. 78-410, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. § 201 *et seq.*).

³¹¹ 42 U.S.C. § 319.

³¹² President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis, WHITE HOUSE (Oct. 26, 2017), <https://tinyurl.com/yaygl9uw> [hereinafter Trump is Taking Action].

³¹³ Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a ‘Health Emergency’ but Requests No Funds*, N.Y. TIMES (Oct. 26, 2017), <https://tinyurl.com/yalowmr7>.

³¹⁴ *Id.*

³¹⁵ Trump is Taking Action, *supra* note 312.

Trump administration has not acted with the urgency required to tackle the opioid crisis and much remains the same.³¹⁶

Meanwhile, the FDA continues its vicious hate campaign against kratom. On November 14, 2017, the FDA issued a public health advisory in which FDA Commissioner Scott Gottlieb warned that kratom poses “deadly risks” and expressed concern “that patients believe they can use kratom to treat opioid withdrawal symptoms.”³¹⁷ While acknowledging that the opioid epidemic has reached a “critical point,” the Commissioner maintained: “There is no reliable evidence to support the use of kratom as a treatment for opioid use disorder.”³¹⁸ Despite such denunciation, the Commissioner stated, although perhaps skeptically, that there is a possibility for the FDA to evaluate and consider the potential medicinal benefits of kratom:

While we remain open to the potential medicinal uses of kratom, those uses must be backed by sound-science and weighed appropriately against the potential for abuse. They must be put through a proper evaluative process that involves the DEA and the FDA. To those who believe in the proposed medicinal uses of kratom, I encourage you to conduct the research that will help us better understand kratom’s risk and benefit profile[.]³¹⁹

The FDA also announced that it is actively working to prevent shipments of kratom from entering the United States.³²⁰ The agency is seemingly relentless and will not stop until it finds that kratom poses a safety threat to public health.

Most recently, on February 6, 2018, the FDA released a statement about the agency’s new “scientific analysis providing even

³¹⁶ Brianna Ehley, *Trump Declared an Opioids Emergency. Then Nothing Changed.*, POLITICO (Jan. 11, 2018), <https://tinyurl.com/ycv2ovb8>.

³¹⁷ Press Release, Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA Advisory About Deadly Risks Associated with Kratom (Nov. 14, 2017), <https://tinyurl.com/y7cqajo5>.

³¹⁸ *Id.*

³¹⁹ *Id.*

³²⁰ *Id.*

stronger evidence of kratom compounds' opioid properties."³²¹ The FDA analyzed the chemical structures of the twenty-five most common compounds, including mitragynine and 7-hydroxymitragynine, found in kratom.³²² Using a computational model, FDA scientists concluded that "all of the compounds share the most structural similarities with controlled opioid analgesics, such as morphine derivatives."³²³ The scientists also found, despite over two decades of published scientific literature on kratom's alkaloids,³²⁴ that kratom has a "strong bind" to opioid receptors in the brain, "comparable to scheduled opioid drugs."³²⁵ The FDA also confirmed that it received information on "additional deaths involving the use of kratom"—bringing the total number to forty-four reported deaths since 2011.³²⁶ The FDA concluded: "Based on the scientific information in the literature and further supported by our computational modeling and the reports of its adverse effects in humans, we feel confident in calling compounds found in kratom, opioids."³²⁷ And just like that, the FDA stigmatized kratom by classifying it as an opioid and warned that it should not be used as an alternative to prescription opioids.³²⁸

³²¹ Press Release, Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on the Agency's Scientific Evidence on the Presence of Opioid Compounds in Kratom, Underscoring Its Potential for Abuse (Feb. 6, 2018), <https://tinyurl.com/y9qcmymr> [hereinafter FDA Scientific Evidence on Kratom].

³²² *Id.*

³²³ *Id.* Arguably, if the FDA believes that kratom compounds act like opioids and classifies kratom as an opioid, then its recommendation should be to place kratom under Schedule II, which includes well-known opioids such as morphine. 21 C.F.R. § 1308.12(b)(1) (2017). This scheduling will be beneficial to future research on kratom's palliative effects as a natural alternative to addictive opioids.

³²⁴ *See supra* Section I.B.

³²⁵ FDA Scientific Evidence on Kratom, *supra* note 321.

³²⁶ *Id.* That amounts to merely six deaths a year. Further, kratom did not play a determinative role in a number of reported cases considered by the FDA in its report. Nick Wing, *FDA Releases Kratom Death Data, Undermines Its Own Claims About Drug's Deadly Harms*, HUFFPOST (Feb. 7, 2018), <https://tinyurl.com/yel2fwmf> (noting that "cases include a suicide and a drug overdose victim who tested positive for nine different substances").

³²⁷ FDA Scientific Evidence on Kratom, *supra* note 321.

³²⁸ *See generally* David Kroll, *FDA Weaponizes 'Opioid' Label Against Kratom Consumers*, FORBES (Feb. 9, 2018), <https://tinyurl.com/y8betf9y>; Gigen Mammoser, *Should We Care That Kratom is Classified as an Opioid?*, HEALTHLINE (Feb. 13, 2018), <https://tinyurl.com/yagm2yhj>; Laurie McGinley,

Most unsurprisingly, like the DEA's analysis, the FDA's scientific data on kratom is dubious.³²⁹ Kratom advocates and proponents of alternatives to prescription opioids quickly called out the FDA for its bad science. A group of nine scientists sent a letter to the White House Opioid Crisis Team Leader, Kellyanne Conway, and to the DEA Acting Administrator, Robert Patterson, insisting that "placing kratom into Schedule I will potentially increase the number of deaths of Americans caused by opioids because many people who have found kratom to be their lifeline away from strong opioids will be vulnerable to resumption of that opioid use[.]"³³⁰ An opinion piece by the Washington Post succinctly addressed the FDA's anti-kratom campaign and the DEA's potential future scheduling of kratom:

With the opioid crisis claiming hundreds of lives each week, why would the government list this promising plant as a Schedule I, making research and testing nearly impossible? Whom is the FDA trying to protect – the public or Big Pharma, which loses profits when citizens find a safe, natural, inexpensive alternative to addictive opioids?³³¹

For now, kratom advocates must await the FDA's final scheduling recommendation on kratom, which the DEA will consider in making its scheduling decision.³³² Once it considers all the public comments, as well as the FDA's scientific and medical evaluation, the DEA must decide whether to proceed with the permanent or temporary scheduling of kratom. If it decides to proceed with the permanent scheduling, a new public comment period will be allowed

FDA Ramps Up Warnings About Kratom, Calling Unregulated Herb an 'Opioid', WASH. POST (Feb. 6, 2018), <https://tinyurl.com/yc98pnes>.

³²⁹ See generally Wing, *supra* note 326.

³³⁰ Letter from Jack E. Henningfield et al., U.S. Doctors, to Kellyanne Conway, Counselor to the President & Robert W. Patterson, Acting Adm'r, Drug Enf't Admin. (Feb. 8, 2018) (on file with author); see also Steven Melendez, *Scientists Warn Trump: FDA's War On A Plant Could Worsen Opioid Crisis*, FAST COMPANY (Feb. 9, 2018), <https://tinyurl.com/yapd6fvj>.

³³¹ Carol Grogan, Opinion, *The FDA Is Wrong About Kratom*, WASH. POST (Feb. 14, 2018), <https://tinyurl.com/ycvlsxha>.

³³² Withdrawal of Kratom Scheduling, *supra* note 95, at 70,652.

as required under the CSA.³³³ If it decides instead that the temporary scheduling of kratom into Schedule I is warranted to avoid an imminent hazard to public safety, the DEA must follow statutory procedures, including publishing a new notice of intent in the *Federal Register*. Were the DEA to invoke the emergency scheduling authority once more, it invites a more difficult evidentiary burden, given the statutory requirement of a finding of an imminent hazard to public safety.³³⁴ If it elects this path, the DEA must proceed with caution. With the prior public protest and congressional backlash,³³⁵ the DEA must give an adequate justification for its decision and provide sufficient evidence to show that scheduling kratom under the emergency scheduling authority is indeed necessary to avoid an imminent hazard to public safety. Meanwhile, kratom advocates must continue to speak out against the FDA and the DEA's stigmatization of kratom.³³⁶ The American Kratom Association is leading the way by launching a petition to President Trump to stop the criminalization of American kratom users.³³⁷

CONCLUSION

Under the CSA, the DEA wields tremendous power when it comes to scheduling a new substance on an emergency basis. But the DEA must adhere to specific statutorily-defined criteria when exercising the emergency scheduling authority. Among these legal criteria, the DEA is required to make a finding that the scheduling of a substance is necessary to avoid an imminent hazard to the public safety. This finding must be made based on specific factors delineated by Congress. Kratom advocates and congressional leaders have inundated the DEA with evidence showing that kratom meets none

³³³ 21 U.S.C. § 811(a) (2012) (requiring an opportunity for a hearing pursuant to APA rulemaking procedures).

³³⁴ *Id.* § 811(h).

³³⁵ See discussion *supra* Section I.D.

³³⁶ See Nick Wing, *DEA Asked Public to Comment on Its Proposed Kratom Ban And 99 Percent Opposed It*, HUFFPOST (Feb. 2, 2017), <https://tinnnyurl.com/y7ga8axk>.

³³⁷ *Petition to President Donald J. Trump to Stop the Criminalization of Americans Who Safely Use Kratom*, AM. KRATOM ASS'N, <https://www.surveymonkey.com/r/TRUMPPetition> (last visited Feb. 23, 2018).

of the legal criteria required to invoke the emergency scheduling authority.

Despite evidence of kratom's potential as a therapeutic alternative to the prescription opioids that are killing more Americans each year, the DEA remained steadfast in its inconsiderate decision to ban kratom. By doing so, the DEA ignored the plain intent of Congress and exceeded its authority under the statutory directive, thus committing an *ultra vires* act. Until the DEA reaches a final decision, kratom advocates may hope at best that, with the help of Congress through its oversight tools, the DEA will consider the staggering evidence showing that kratom is a godsend for many Americans battling chronic pain and overcoming prescription opioid addiction.