A Grim Spoon….. For Your Kratom: How the DEA Lost in Court Banning MDMA and How They Might Lose Again …

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Part One: Introduction to Kratom and Grinspoon

I. Landscape

Part one of this paper will first introduce what Kratom is as a substance. It will be followed by a discussion of the key provisions of the 1987 First Circuit Case, *Grinspoon*. It will then explain why *Grinspoon's* holding is relevant in today's regulatory climate with the FDA and DEA opening their eight-factor analysis pursuant to a potential Kratom scheduling decision. Part two covers the extensive timeline of relevant events beginning with the passage of the Controlled Substances Act and ending with the present regulatory action aimed at Kratom. Part three will discuss, per *Grinspoon*, the relevant legal standards required for Attorney General scheduling of a substance. Namely, it will discuss the 21 U.S.C. § 811(h) standard and why the first round of scheduling failed, the standard of high potential for abuse under 21 U.S.C. § 811(a), and safe and accepted medical use under 21 U.S.C. § 811(c). Part four will apply the standards of Part three in the context of Kratom; looking specifically at the pharmacological profile of Kratom as a mild substance with minimal harm impacts, and huge potential to aid in the fight against addiction. Part five will conclude that a potential *Chevron* challenge to a scheduling decision has a high probability of success based on prior court decisions and Kratom's pharmacological profile.

II. Kratom

Kratom, *Mitragyna speciosa*, is a tropical evergreen tree in the coffee family.[1] The psychoactive component of the tree is the leaf. It is ground up by producers and then made into a tea.[2] Its effects are said to be stimulating at low doses and more sedating at higher doses.[3] While it is active on the opioid receptors as an agonist, it is not an opioid because it is not semi-synthetic, synthetic, nor is it derived from the poppy plant (depending on how one defines opioid).[4] The scheduling of MDMA in *Grinspoon* is analogous to Kratom, and this note hopes to impart the lessons of the *Grinspoon* fight with the DEA.

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[1] Eduardo Cinosi et. Al. Following "the Roots" of Kratom (Mitragyna speciosa): The Evolution of an Enhancer from a Traditional Use to Increase Work and Productivity in Southeast Asia to a Recreational Psychoactive Drug in Western Countries, NATIONAL INSTITUTE OF HEALTH, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4657101/ (November 10, 2015).
[2] *Id.*
[3] *Id.*
[4] *Id.*

III. *Grinspoon* Explored:

In January of 1984 the Drug Enforcement Agency (DEA) submitted a document under the CSA entitled Schedule 1 Control Recommendation of 3,4–methylenedioxymethamphetamine (MDMA) it concluded based on medical literature and DEA sources that MDMA satisfied the section 21 U.S.C. § 811 and 812 criteria for abuse in that it 1) had a high potential for abuse, 2) lacked an accepted medical use, 3) and lacked a safe medical route of administration.[5] In March of 1984 the DEA submitted the matter for approval to the Department of Health and Human Services as mandated by 21 U.S.C.A. § 811(a).[6] Led by Dr. Tocus, the Department of Health and Human Services found that the lack of accepted FDA approval constituted a lack of accepted medical use and allowed the matter to proceed.[7] Following requests for hearing and petitions, the DEA submitted the matter to the DEA Administrative Law Judge (ALJ) for a hearing and the court found that proposal failed to meet all three sections of the § 812 and 811 standards.[8] The administrator, ignoring the ALJ findings, nonetheless moved to schedule. On November 13, 1986 the Administrator of the DEA offered a final rule placing MDMA into schedule one of the Controlled Substances Act pursuant to 21 U.S.C. § 812.[9] The final ruling was based on the Administrator's novel articulation of the statute's accepted and safe medical use provision. He claimed that safe and accepted medical use meant the FDA had both evaluated the substance for safety and approved its usage.[10]

The caselaw surrounding administrative challenges to the DEA emergency scheduling power is sparse and largely the questions surrounding such issues are analyzed under the two prong *Chevron* test. If a clear articulation of the statute has been given by Congress, it shall control, if not the regulation may not be arbitrary and capricious upon a viewing of the entire record of the decision.[11]

In *Grinspoon*, the issue was whether the DEA Administrator's novel articulation of safe and accepted medical use violated his discretionary power pursuant to 21 U.S.C. § 811.[12] The Court held he had in fact overstepped his discretion.[13] The 1st Circuit vacated the rule and remanded for findings consistent with their opinion.[14] Congress in creating § 811, articulated a clear and controlling standard that was to be applied.[15] Namely that the substance was to be placed on Schedule One only upon a finding that it had a high potential for abuse, lack of accepted medical use, and lack of safe medical abuse.[16] The Court further held that the government's argument that the term accepted and safe medical use was akin to FDA approval

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[5] Grinspoon v. Drug Enf't Admin., 828 F.2d 881 (1st Cir. 1987).
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *See generally* Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).
[12] Grinspoon, 828 F.2d 881 (1st Cir. 1987).
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*

was not within the meaning of the statute.[17] In short, the court held that the Administrator in doing so had, in essence, replaced prongs two and three of § 811, with FDA evaluation and approval.[18] This reading of the statute violated Chevron; and therefore, the case was vacated and sent back to the Administrator for further consideration consistent with the opinion.[19]

It is important to note as part of the decision's dictum the court signaled that this was not a permissible construction of the statute. The Court signaled that the DEA, in creating the rule, was potentially arbitrary and capricious and therefore, again, in violation of its discretionary powers.[20]

Upon remand to the agency, the Administrator rearticulated his interpretations of safe and accepted medical and resubmitted the ban. MDMA was subsequently banned permanently where it remains to this day.[21]

IV. Grinspoon's Importance in the Modern Legal Landscape:

Through all of the noise of the legal landscape following the 2016 presidential election *Grinspoon* is incredibly relevant to the modern legal landscape. First there are still questions as to what the safe and accepted medical use standard actually is. Out of deference to the Agency's power to interpret statutes within their discretionary purview, the First Circuit declined to read prongs two and three as meaning "the opinion of the medical community". Furthermore, because the Administrator essentially sidestepped the court on remand there is again lingering questions as to what a permissible reading of the § 811 provisions might look like.

Lastly, Administrative Law Challenges are incredibly salient under this new administration with challenges to FCC net neutrality and the cancelation of DACA. Perhaps the most pressing matter that relies on *Grinspoon* is a potential § 811(a) scheduling decision by the DEA. In August of 2016 the DEA placed a notice of intent to place Kratom on Schedule One of the Controlled Substances Act.[22] Public outcry and wide criticism of the DEA's decision forced the Acting Administrator, Chuck Rosenberg, to back down.[23] He handed the decision to the broader department of HHS (FDA is a sub-constituent of HHS that handles scientific evaluation) for an 8-factor evaluation as required by § 811(a).[24] The decision still awaits a final ruling, however, based on increased FDA scrutiny of Kratom, and negative signaling by the DEA the decision may come incredibly soon perhaps as of writing this final Note. In exploring *Grinspoon*, case law, regulations, and statutes this Note will elucidate what an appropriate and efficacious § 811(a) standard might look like and how it will potentially apply to future court challenges.

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[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] 81 FR § 59929 (2016).
[23] Kratom Proponents Present 120,000-Signature Petition To White House, AMERICAN KRATOM ASSOCIATION, https://www.prnewswire.com/news-releases/kratom-proponents-present-120000-signature-petition-to-white-house-to-stop-dea-rush-to-ban-coffee-like-herb-in-us-seek-opportunity-to-comment-300327979.html (Sept. 14, 2016).
[24] 81 FR § 70652 (2016).

Part Two

I. Timeline of events

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (Controlled Substances Act or CSA) of 1970 which as the name suggests was designed to curtail a rising wave of drug abuse throughout the country.[25] The law additionally established the current scheduling system and sought to differentiate between drugs of abuse and those with medical use.[26]

The original version Controlled Substances Act included § 811(a) which allows the AG to add to the corresponding schedules based on a binding recommendation from the department of Health and Human Services (HHS).[27] Scheduling decisions under § 811(a) are subject to judicial review through the APA § 701[28] presumption of judicial review over agency decisions. Furthermore, § 811(a) provides for formal rulemaking as stipulated in 5 U.S.C. § 556 and 557.[29] 28 U.S.C § 510 allows the attorney general to delegate this function to the DEA, therefore, statutory language does not reflect the procedural reality of Executive Branch scheduling.[30]

In 1984 Congress amended the Controlled Substances Act to allow the Attorney general to temporarily schedule substances under § 811(h). Under § 811(h) the Attorney General must find that there was an imminent threat to public health through a high potential for abuse, no safe medical use, and no accepted medical use.[31] Judicial Review is precluded in emergency scheduling actions per 21 U.S.C. § 811(h)(6).[32] In general, this provision was contemplated in response to synthetic drugs which outpaced the ability of Congress to pass legislation due to the creative ability of chemists to slightly alter molecules while still achieving similar physiological effects.[33]

In September 1987 the case *Grinspoon* was decided, establishing that safe and accepted medical use was not akin to FDA approval as noted above. Presently *Grinspoon* is good law in the First Circuit. However, the court declined to adopt the "safe and accepted medical use within the medical community" standard.[34] In 2004, the Ninth Circuit in *Hemp Industries* concluded that the DEA's interpretive rule scheduling natural hemp products failed Chevron and could only

[25] *See* Pub. Law 91-513 § 101 (declaring the purpose of the Controlled Substance Act to be curtailing the flow of illegal drugs and ensure substances with medical uses are accessible in the structure of a scheduling system); 28 U.S.C. § 510 (2018) (permitting the AG to delegate functions to officers, or employees at his discretion).
[26] *Id.*
[27] 21 U.S.C. § 811 (a) (2012).
[28] 5 U.S.C. § 701 (2012).
[29] 21 U.S.C. § 811 (a) (2012).
[30] 28 U.S.C. § 510 (2012).
[31] *See* House Report No. 98-835, Part 1, to Accompany H.R. 5656, Dangerous Drug Diversion Control Act of 1984, June 12, 1984 Reports: 98th Congress: Document No. 17 at 11.
[32] 21 U.S.C. § 811(h)(6).
[33] *Id.*
[34] Grinspoon, 828 F.2d 881, 893 (1st Cir. 1987).

be done through legislative action.[35] In *Hemp Industries* the Ninth Circuit permanently enjoined the DEA from passing a rule banning hemp products.[36]

Fast forward twelve years to 2016, on August 31, of 2016 using the temporary scheduling provisions, the DEA handed down a notice and comment rule of intent to schedule Kratom.[37] The DEA cited increases in calls to poison control, and alleged deaths in guiding their action.[38] The acting Administrator decided that under the provisions of the Notice of Intent to Schedule, public comment would be foregone under 5 U.S.C. § 553 of the APA, which allows the Administrator to forego comment based on good cause. [39] The acting Administrator, not realizing the amount of public disdain for his decision, was flooded with calls, specifically to the DEA and the Department of Health and Human Services. [40] Under immense public pressure; a "We the People Petition" that received more than 120,000 signatures[41]; and multiple Congressional Dear Colleague Letters featuring fifty-one signers in the House and eleven in the Senate[42]; the Administrator relented withdrawing the Notice of Intent and opening up a public comment period.[43] During this public comment period 20,000 plus comments were submitted with 99.1% of respondents opposing the DEA action.[44] Following this withdrawal of Notice of Intent, the DEA handed the issue to the FDA for an expedited scientific review[45] based on the 8 factor test required by 21 U.S.C. § 811 (a)(c) .[46] Most recently the FDA has returned negative signs regarding Kratom in a press release titled, *On the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse* (The FDA Press Release). The FDA claimed that Kratom is an opioid with the same hazardous potential of other opioids.[47] Presently, the decision is in the DEA's hands with the FDA providing the same data of dubious

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[35] Hemp Industries Ass'n v. Drug Enforcement Administration, 357 F.3d 1012 (9th Cir. 2004).
[36] *Id.*
[37] 81 FR § 59929 (2016).
[38] *Id.*
[39] 5 U.S.C § 553 (2012).
[40] Steven Nelson, *DEA Withdraws Kratom Ban, Opens Public Comment Period*, USNEWS AND WORLD REPORT https://www.usnews.com/news/articles/2016-10-12/dea-withdraws-kratom-ban-opens-public-comment-period (Oct. 12, 2016).
[41] Kratom Proponents Present 120,000-Signature Petition To White House, AMERICAN KRATOM ASSOCIATION, https://www.prnewswire.com/news-releases/kratom-proponents-present-120000-signature-petition-to-white-house-to-stop-dea-rush-to-ban-coffee-like-herb-in-us-seek-opportunity-to-comment-300327979.html (Sept. 14, 2016).
[42] *Dear Colleague Letter (Prevent Drug Enforcement Agency Overreach And Preserve Consumer Access To Natural Herbal Supplement Kratom) September, 2016*, US HOUSE OF REPRESENTATIVES https://www.scribd.com/document/325084831/Dear-Colleague-for-Kratom-Letters-to-Outside-Organizations#from_embed; *Dear Colleague Letter (Hatch Senate Letter) September 30, 2016,* http://216.30.191.148/SenateKratomLetterFinal.pdf.
[43] 81 FR § 70652 (2016).
[44] Nick Wing, DEA Asked Public To Comment On Its Proposed Kratom Ban And 99 Percent Opposed It, HUFFINGTON POST https://www.huffingtonpost.com/entry/dea-kratom-ban-comments_us_589374f1e4b06f344e4074fa (Feb. 2, 2017).
[45] 81 FR § 70652 (2016).
[46] 21 USC § 811 (2012)
[47] Scott Gottlieb, 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, FEDERAL DRUG ADMINISTRATION https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm (Feb. 6, 2018).

quality used by the DEA in the ill-fated Notice of Intent to schedule.[48] *Grinspoon* provides a roadmap for a successful court challenge to an § 811(a) scheduling decision.

Part 3.

II. Legal Standard for Schedule I?

Present caselaw, regulatory guidance, and statutory authority regarding DEA emergency scheduling establish two generally accepted notions:

1) high abuse potential is as is generally defined in the legislative history[49]
2) and that per *Grinspoon* safe and accepted medical use is not akin to FDA approval.[50]

This Notecontends that the DEA lacks the requisite statutory power to schedule Kratom under the present legal standard; looking to *Grinspoon*, specifically, for guidance. There is a generally accepted reading of Schedule I standards as seen in *Grinspoon*. Each prong of this understanding will be elaborated upon and applied in the context of Kratom.

A. Legislative Purpose of the 1984 Section 811 (h) Amendment: Why the DEA lost the first round.

The legislative history succinctly and clearly lays out the reasoning behind allowing the Attorney General to have the immense power of temporarily scheduling substances—the new and unprecedented wave of "designer drugs" which illicit chemists produce by slight changes to existing chemical structures resulting in a different de facto drug with substantially similar effects.[51] In HR No. 98-835 the House Committee on the Judiciary stated:

> This new procedure (811 (f)) 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. Examples of such drugs include PCE and PHP which have been clandestinely developed and manufactured to imitate the effects of the controlled psychedelic drug, PCP.[52]

Furthermore, two dear colleague letters signed and introduced correspondingly by representatives Dave Brat (R) and Jared Polis (D), and Senator Orrin Hatch note the unprecedented nature of a notice of intent to schedule a botanical through the emergency process. *See Dear Colleague Letter (Polis Brat Letter)*[53] (noting that using emergency

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[48] *Id.*
[49] *See generally* Grinspoon, 828 F.2d 881 (1st Cir. 1987).
[50] *Id.*
[51] Designer Drugs Lead to Designer Legislation, NATIONAL ASSOCIATION OF ATTORNEYS GENERAL, http://www.naag.org/publications/naagazette/volume-8-number-2/designer-drugs-lead-to-designer-legislation.php.
[52] House Report No. 98-835, Part 1, to Accompany H.R. 5656, Dangerous Drug Diversion Control Act of 1984, June 12, 1984 Reports: 98th Congress: Document No. 17 at 11 (1984).
[53] *Dear Colleague Letter (Polis Brat Letter) December 20, 2017* https://polis.house.gov/uploadedfiles/kratom_fda_health_advisory_letter.pdf.

scheduling on an herbal supplement was unprecedented in DEA history); *Dear Colleague Letter (Hatch Senate Letter)* (establishing that the present standard for triggering emergency scheduling was an immediate public health threat generally reserved for illegal street drugs that have an unsafe record). [54] This mounting opposition to DEA scheduling from the broader public, Congress, and the Senate forced the DEA's hand and arguably prompted the DEA to step down and remand the issue to the proper HHS channels per § 811 (a). The prerequisite finding the DEA, through AG delegation, must make is that of a high potential for abuse.[55]

B. High potential for Abuse

Though high potential for abuse was contested (per MDMA) in *Grinspoon*, both parties readily accepted that the statutory history and Controlled Substances Act provide sufficient guidance as to what constitutes a drug of abuse.[56] Furthermore, the DEA releases an annual report titled, *DRUGS OF ABUSE I 2017 EDITION: A DEA Resource Guide* [57] making clear that the DEA uses the *Grinspoon* standard of abuse requiring four criteria:

> (1) There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.
> (2) There is significant diversion of the drug or other substance from legitimate drug channels.
> (3) Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner.
> (4) The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug will have the same potential for abuse as such drugs.[58]

For the purposes of this Note this will be the adopted standard for high potential for abuse.

C. Safe and Accepted Medical Use

Based on the evidence provided by the court in *Grinspoon* and the Legislative History it is likely that the test for Medical Use will straddle somewhere between FDA approval on one disallowed end and "consensus of the medical community" on the other. For the predictive purposes of this paper, a substance will be deemed to have medical use if it has such substantial evidence that a reasonable physician would conclude it has both "safe and accepted medical use". Under this standard weight will be given to FDA approval but per *Grinspoon* it is not dispositive.[59] Safe and accepted medical use was hotly contested in *Grinspoon* and there is still

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[54] *Dear Colleague Letter (Hatch Senate Letter) September 30, 2016* http://216.30.191.148/SenateKratomLetterFinal.pdf.
[55] 21 U.S.C. § 811(a)
[56] Grinspoon, 828 F.2d 893 (1st Cir. 1987).
[57] DRUGS OF ABUSE I 2017 EDITION: A DEA Resource Guide, DRUG ENFORMENT ADMINISTRATION https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf (2017).
[58] *Id.* at *8.*
[59] Grinspoon, 828 F.2d 893 (1st Cir. 1987).

questions as to what the requisite standard is and should be in the context of scheduling decisions. Furthermore, the *DEA Resource Guide* unfortunately offers no guidance as to what their accepted standard is for medical use.[60] Based on recent FDA action the commissioner has signaled rhetoric akin to an FDA approval standard. In the *FDA Press Release* Commissioner Gottlieb, perhaps unwisely, signaled a reiteration of what is essentially the *Grinspoon* argument stating, "The FDA stands ready to evaluate evidence that could demonstrate a medicinal purpose for kratom. However, to date, we have received no such submissions and are not aware of any evidence that would meet the agency's standard for approval."[61] This statement essentially links medical use to data that is of FDA quality.

Though the court did not adopt a medical consensus standard in *Grinspoon*, the Prettyman Commision, authored by the Kennedy Administration, submitted a list of recommendations to Congress. Congress during the CSA hearings in turn replied with their proposed actions to conform the law to the recommendations.[62] Recommendation Twenty provides: "That federal regulations be amended to reflect the general principle that the definition of legitimate medical use of narcotic drugs . . . are primarily to be determined by the medical profession."[63] Congress did in fact adopt this recommendation with "Section 4 of the reported bill, providing for determinations by the secretary of health, education, and welfare (Now FDA) of appropriate methods of professional practice in the medical treatment of narcotic addicts."[64] It is fairly evident from the legislative history that the delegation of scientific evaluation to HHS-FDA was intended to have the effect of reflecting what is essentially the consensus of the medical community. This is of course based on the fact that Congress read the Prettyman recommendation, accepted its conclusions, and amended the bill to reflect the recommendation. It seems as though the passage of time and regulatory ossification has potentially perverted the seemingly clear purpose of the HHS evaluation amendment. It is more likely that an accepted medical use standard will likely reflect some degree of the consensus of the medical field.

Part 4.

I. Kratom? To schedule or not to schedule?

Section Four of this Note contends that Kratom is not within the Schedule I statutory purview of 811§ (a)(c). Based on *Chevron, Grinspoon, and Hemp Industries* if a substance is not within the purview of the Controlled Substances Act it can only be barred through legislative action. First, Kratom fails to satisfy the 8-Factor test because it doesn't meet the DEA's accepted standard for high abuse potential based on available scientific evidence and the findings of *Grinspoon*; Second, it fails to meet the DEA's criteria for lack of safe and accepted medical use based on research studying the pharmacological structure of Kratom.

A. Kratom's Profile Lacks a High Potential for Abuse.

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[60] See generally *Id.*
[61] *Id.*
[62] *Id.*
[63] 1970 U.S.C.C.A.N. 4566, 4586
[64] *Id.*

As noted before, *Grinspoon* establishes the present current Four-point standard for high abuse potential.[65] Kratom does not fit within the standard of § 811 (a) and any scheduling order would violate Chevron. Kratom's pharmacological profile has been established by fairly significant study in the University system[66] and National Institute of Health.[67] The common vein in most research establishes that Kratom has significant potential as a treatment for opioid addiction, that Kratom can be differentiated from traditional opiates in its much milder effects on the brain, and its pharmacological profile is largely safe.[68] Studies even suggest a potential beneficial effects on alcoholism, depression, and anxiety.[69] Kratom as a substance does have action on the opioid receptors but it resists classification as a traditional opioid as it is not a synthetic, or semi-synthetic drug derived from the Poppy plant.[70] Furthermore, a leading toxicological review by Dr. William Sawyer (M.D) of the American Board of Forensic Medicine concludes that there are no deaths attributable to Kratom alone and, although it is active on the opioid receptors, it does not cause respiratory depression which is the leading cause of death in overdose scenarios.[71] Based on work by Andrew Kruegal, the active alkaloids of Kratom are only partial agonists, in that they only partially bind to the mu and kappa opioid receptors.[72] Partial agonists bind lightly to these receptors and do not create the same intensity of effect and side effects. [73] Furthermore, there are more than 120 current studies reinforcing the same propositions regarding Kratom's pharmacological profile.[74]

Kratom as applied to the § 811(a) standard for high potential of abuse objectively fails to rise to the level of harm contemplated in *Grinspoon*. Part one of the *Grinspoon* test requires "evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community".[75]

1) If one uses objective data and research on Kratom it passes this first prong. Again, based on surveys it is estimated that there are between three and five million Kratom users in the US, meaning one out of every one hundred Americans uses the substance in one form another. [76] Even with such incredibly high numbers of use there has not been a single death associated with Kratom use alone. The FDA cites forty-four

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[65] *See* DRUG ENFORCEMENT ADMINISTRATION *supra* note 57 at *id*.
[66]Nadia Kounang, Compounds in herbal supplement are opioids, FDA says, CNN, https://www.cnn.com/2018/02/06/health/fda-kratom-opioid-bn/index.html (February 7, 2018).
[67] Idayu, Antidepressant-like effect of mitragynine isolated from Mitragyna speciosa Korth in mice model of depression, .https://www.ncbi.nlm.nih.gov/pubmed/20869223, NATIONAL INSTITUTE OF HEALTH (March 15, 2011).
[68] *Id.*
[69]A Product of Use Not Abuse, BOTANICAL EDUCATION ALLIANCE, https://www.botanical-education.org/kratom-pamphlet/.
[70] *Id.*
[71] *Id.*
[72] Kruegal et al. Synthetic and Receptor Signaling Explorations of the Mitragyna Alkaloids: Mitragynine as an Atypical Molecular Framework for Opioid Receptor Modulators, NATIONAL INSTITUTE OF HEALTH https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5189718/ (May 18, 2016).
[73] *Id.*
[74] *Id.*
[75] Grinspoon, 828 F.2d 893, 900 (1st Cir. 1987).
[76] A Product of Use Not Abuse, BOTANICAL EDUCATION ALLIANCE, https://www.botanical-education.org/kratom-pamphlet/.

deaths associated with Kratom intoxication, however, an analysis by Dr. Jane Babin (JD and PhD in molecular biology) combs through all of the FDA data and in all cases where we have sufficient data, there is the presence of other substances.[77] Nonetheless, assuming arguendo that said data was correct, forty-four deaths out of three to five million is far safer than the FDA portends. Given such high usage numbers, and at most only one death not due to a drug interaction[78], there is insufficient evidence to hold that Kratom creates hazard to a personal user's health. The test also requires an inquiry into safety of the community, Kratom again fails to meet the standards required for a showing of harm to the community; this portion of the test looks towards the downstream consequences of Kratom usage and whether usage will create sufficiently negative consequences for those around a Kratom user. *Pinney Associates*, a harm reduction and medical addiction consulting firm, released their own eight-factor test examining the downstream consequences of Kratom use.[79] They concluded that while high doses of Kratom could cause something akin to a habit, such a habit usually develops in the context of enabling the user to work longer and with more efficiency.[80] *Pinney Associates* likens this profile to coffee dependence which, though a technical habit, is not considered an addiction, because it does not create the same negative use consequences as say hard drugs.[81] Kratom in that respect may cause dependence, however, dependence is not in and of itself a harmful consequence for the community.

2) Part two of the test requires that, "There is significant diversion of the drug or other substance from legitimate drug channels". This does not apply in the context of Kratom, all channels of Kratom are presently legal channels of Kratom and because of its present legal status there is no diversion. However, it is important to note that were the DEA to take moves to schedule Kratom it would create the very problem test two was designed to prevent, in that it would create a lucrative black market.
3) Part three of the test is arguably applicable to Kratom users, self reported surveys indicate ingestion of the substance for a variety of self-treatment purposes.[82] The survey was based on the responses of 8409 Kratom users on their methods and reasons for taking the substance. [83] The results showed, "Kratom is primarily used by a middle-aged (31-50 years), middle-income ($35,000 and above) population for purposes of self-treating pain (68%) and emotional or mental conditions (66%).[84]

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[77] Dr. Jane Babin, The FDA Kratom Death Data: Exaggerated Claims, Discredited Research, and Distorted Data Fail to Meet the Evidentiary Standard for Placing Kratom as a Schedule I Controlled Substance, AMERICAN KRATOM ASSOCIATION, https://docs.wixstatic.com/ugd/9ba5da_c4de172860754c0a8db2d3adf2f4e12e.pdf (March 2018).
[78] *See id.*
[79] Pinney Associates, Assessment of Kratom under the CSA Eight Factors and Scheduling Recommendation, PINNEY ASSOCIATES, http://www.pinneyassociates.com/wp-content/uploads/2017/07/Kratom-8-Factor-by-PinneyAssoc-11.28.16.pdf (November 28, 2016).
[80] *Id.*
[81] *Id.*
[82] Grundmann, Patterns of Kratom use and health impact in the US-Results from an online survey, NATIONAL INSTITUTE OF HEALTH, https://www.ncbi.nlm.nih.gov/pubmed/28521200 (July 1, 2017).
[83] *Id.*
[84] *Id.*

This is perhaps the only prong on which a reasonable person might conclude failure of the standard.

4) Part four requires a showing that the substance is so closely related to a substance with high abuse potential that it is likely to cause the same potential for abuse. This question is entirely inapplicable to Kratom, it is not a designer drug, but a naturally occurring leaf without any precursor substance with high abuse potential.

At best the DEA could demonstrate part three of the test. Per the APA, reviewing courts would have the entire record of a formal rulemaking hearing which would provide such evidence of the generally accepted consensus amongst researchers in the field with hundreds of studies saying it is safe.[85] Prong one of *Chevron* states that if the intention of Congress is clear, which it is, then that reading controls and the Agency must conform with Congressional intent. The DEA lacks sufficient evidence of harm to conform to the high potential abuse standard. According to *Grinspoon*, for scheduling orders the substance meeting the abuse standard is dispositive.[86] Furthermore, under *Hemp Industries Association* courts have the power to not only remand, but permanently enjoin the passage of a scheduling rule if it lies outside of the purview of the statute.[87]

B. Kratom's Medical Use Potential

Based on the consensus of the field, Kratom likely could be found to have a medical use consistent with the meaning of the Controlled Substance Act. Congress in drafting the Controlled Substance Act seemingly accepted the "consensus of the medical field" standard based on their action of accepting the *Prettyman Commision's* medical consensus recommendation.[88] However, *Grinspoon*, the only case on point, failed to adopt the standard of the "consensus of the medical field". This leaves open a standard somewhere between FDA approval and the consensus of the medical community. However, the signals by the Commissioner seem to suggest he has adopted something akin to the FDA approval given his prior statement.[89] It stands to reason that any substance which has such sufficient evidence of a medical use that a reasonable physician in the field would likely conclude such use, would be sufficient evidence for a court to find medical use. This standard again gives weight to evidence sufficient to meet FDA approval, but it is not dispositive. Given the work by researchers whose sole focus is the drug, it seems to be well accepted that Kratom has safe and accepted medical use. There are two preeminent experts on the pharmacology of Kratom. First is Christopher McCurdy, pharmacist out of the University of Florida and President of the American Association of Pharmaceutical Scientists. He concluded in a CNN article that, "There's a huge wealth of anecdotal evidence, and some scientific, that there is definite medical potential for this plant. If it's not in the treatment of mild and moderate pain, it's definitely in the treatment of potential opioid withdrawal".[90] Second, is Chris Hemby of High

[85] 5 U.S.C. § 701 (2012).
[86] Grinspoon, 828 F.2d 893 (1st Cir. 1987).
[87] Hemp Industries Ass'n v. Drug Enforcement Administration, 357 F.3d 1012, 1091 (9th Cir. 2004).
[88] *See* H.R.Rep *supra* note 52.
[89] *See* Gottlieb *supra* note 47.
[90] Nadia Kounang, Compounds in herbal supplement are opioids, FDA says, CNN, https://www.cnn.com/2018/02/06/health/fda-kratom-opioid-bn/index.html (February 7, 2018).

Point University he concludes, "that 7-hydroxymitragynine may have some addictive qualities. But when looking at the plant as a whole, the ratio of that element is so small that kratom overall has very low abuse potential".[91] There are other scientists who have done secondary work on the substance and the conclusion is the same. Three leading researchers, Marc T. Swogger, Ph.D., Oliver Grundmann, Ph.D., Paula N. Brown, Ph.D. in a live stream and printed press release stated:

> Kratom has also been increasingly used as a natural remedy to improve mood and quality of life and as substitutes for prescription and illicit opioids for managing pain, as shown in the recent four published surveys. The current scientific research suggests that kratom provides some pain relief without the dangerous and potentially deadly respiratory suppression induced by classical opioid medications.[92]

This is substantial evidence for a reasonable physician to conclude that Kratom has safe and accepted medical use. A potential Chevron challenges hinges greatly on what standard is adapted. This note acknowledges that none of this evidence is technically of the quality required for the FDA to conclude medical use, however, this is not dispositive. In addressing the First Circuit's omission of a standard for medical use; Reviewing judges should adopt this note's proposed standard. Under that standard there is sufficient evidence for a reasonable physician to conclude safe and accept medical use.

Part 5 Conclusion:

I. Conclusion

A Chevron challenge to a potential § 811(a) scheduling order in the First or Ninth circuit has an extremely high chance of success based on the lack of a high potential for abuse in Kratom and the presence of safe and accepted medical uses. Chevron states that, when determining whether an agency acted in the purview of the statute; if the language is clear it controls; § 811(a) requires a preliminary finding of high potential for abuse to start the rulemaking process, absent a finding of potential for abuse, no scheduling order may be given.[93] A Chevron challenge is permitted pursuant to 5 U.S.C. § 701's presumption of judicial review, absent a specific exemption Agency decisions are subject to review.[94] The in-court review would be on the entire record of a 5 U.S.C. § 556 formal rulemaking and trial like procedure.[95] The standard for high potential for abuse is as is laid out in *Grinspoon* and accepted by the DEA.[96] The standard for medical abuse will likely resemble a reasonable physician test with weight

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[91] *Id.*
[92] Paula N. Brown Four Leading Kratom Researchers Urge FDA To Focus On Science Rather Than Rhetoric, AMERICAN KRATOM ASSOCIATION, https://www.prnewswire.com/news-releases/four-leading-kratom-researchers-urge-fda-to-focus-on-science-rather-than-rhetoric-300610328.html (March 7, 2018).
[93] *See generally* Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).
[94] 21 U.S.C. § 811(a), 5 USC § 701 (2012).
[95] 5 U.S.C § 556 (2012).
[96] *See* Grundmann *supra* note 82.

being given to presence of FDA-worthy data. Because Kratom has a significant body of research demonstrating a lack of high abuse potential and the presence of safe and accepted medical uses the challenge has a high probability of success. Therefore, such a decision should fail either prong of the Chevron test and be considered outside of the purview of the statute. Lastly, Under *Hemp Industries* Courts may permanently enjoin scheduling orders which fall outside of the express meaning of the statute.[97]

This question is incredibly pressing with stakeholders in the botanical industry, science, addiction rehabilitation, and the public at large. Roughly three to five million people could become Federal felons if the DEA moves to schedule. At least two million are former addicts or chronic pain sufferers who, based on anecdotes, have unquestionably turned their lives for the better, the consequences for these otherwise law-abiding citizens could be dire.[98] This note should serve as guidance to courts and the general public of how to resolve the medical use question of *Grinspoon*, and how a scheduling order might be fought in the courts. From a purely human and moral perspective one would like to think that such an order will not come, but this note was written to prepare for the worst.

[97] Hemp Industries Ass'n v. Drug Enforcement Administration, 357 F.3d 1012 (9th Cir. 2004).
[98] *See* Grundmann *supra* note 82.