

**MDMA AND PSILOCYBIN FOR MENTAL
HEALTH:
DECONSTRUCTING THE CONTROLLED
SUBSTANCES ACT’S USAGE OF “CURRENTLY
ACCEPTED MEDICAL USE”**

ABSTRACT

MDMA and psilocybin are drugs that exhibit almost never-before-seen relief—including complete remission—from debilitating mental health disorders including Post Traumatic Stress Disorder (PTSD) and Treatment-resistant depression. Doctors, however, are unable to legally prescribe them outside of tightly-controlled research trial settings because of the drugs’ categorization under Schedule I of the Controlled Substances Act (CSA)—the Act’s most restrictive schedule—by the Drug Enforcement Agency (DEA). Legal scholarship on the subject, unfortunately, is not commensurate with the pace of recent progress in both the medical and commercial fields. Further, while state and local efforts to decriminalize, regulate, and provide access to MDMA and psilocybin may offer some hope, unless the drugs are reclassified to a less restrictive schedule on the federal level under the CSA, the state-by-state patchwork approach would inevitably create inequities in patient access to these potentially life-saving drugs and expose patients to federal prosecution, notwithstanding their compliance with state or local laws.

*This Note examines the federal structural legal barriers that hinder patient access to MDMA and psilocybin. It begins by providing a historical backdrop of the legal and political reasons the drugs were banished to the CSA’s most restricted category, Schedule I, over fifty years ago. It then demonstrates that the DEA, in the decades that followed, exceeded its administrative authority in interpreting the Controlled Substances Act’s undefined requirement that Schedule I be reserved for drugs and substances with “no currently accepted medical use.” Concomitantly, federal circuit courts have, by and large, upheld the DEA’s interpretations under *Chevron v. Natural Resources Defense Council*, a 1984 U.S. Supreme Court decision that requires federal courts to defer to permissible agency constructions of ambiguous federal statutory provisions.*

*This Note presents aspects of three recent U.S. Supreme Court decisions that clarify the *Chevron* standard, and argues that the DEA’s interpretation is no longer warranted deference under U.S. Supreme Court law. Ultimately, this Note proposes an alternative statutory interpretation of*

“currently accepted medical use” that comports both with current Supreme Court jurisprudence and with the CSA’s public health purpose.

INTRODUCTION

Jonathan Lubecky, a veteran, recently recovered from Post-Traumatic Stress Disorder (PTSD) that had resulted from traumas he suffered during his deployment in Iraq in 2006.¹ After returning from Iraq and for five years thereafter,² his daily reality centered around one goal—how to take his own life.³ He attempted suicide five times, all near-successful.⁴ “When all seemed lost,” he turned to the club drug MDMA—but legally—as part of a clinical trial.⁵ After only three treatment sessions, his crippling symptoms disappeared.⁶ According to Jonathan, MDMA saved his life.⁷ His message to fellow veterans battling PTSD: “[MDMA] treatment is the reason my son has a father instead of a folded flag.”⁸

Jonathan is not alone.⁹ Mental illness is a public health crisis that affects almost one in five Americans annually.¹⁰ Compounding this mass human suffering is a profound economic impact: in 2010, “the global direct and indirect economic costs of mental disorders were estimated at US \$2.5 trillion,”¹¹ and that figure is “expected to double by 2030.”¹² And the approximately 15 million PTSD sufferers are among the worst off:¹³ no

1. *Today* (NBC television broadcast Nov. 5, 2021), <https://www.today.com/video/new-research-shows-how-psychedelic-drug-can-help-people-with-ptsd-125464645835>.

2. Matt Saintsing, *PTSD Breakthrough*, DAV (May 5, 2020), <https://www.dav.org/learn-more/news/2020/ptsd-breakthrough/> [<https://perma.cc/3GBM-RC7W>].

3. See *Today*, *supra* note 1 (“Every single day, no matter how good or bad the day was, my brain was trying to figure out how to kill myself.”)

4. Erich Wenzel, *Jonathan Lubecky on PTSD, MDMA Therapy, and Healing*, FEEDING CURIOSITY (Aug. 19, 2020), <https://feedingcuriosity.net/podcast/jonathan-lubecky>.

5. Saintsing, *supra* note 2.

6. *Today*, *supra* note 1.

7. *Id.*

8. *Id.*

9. Will Stone, *MDMA, or Ecstasy, Shows Promise as a PTSD Treatment*, NPR (Aug. 14, 2019, 11:40 AM), <https://www.npr.org/sections/health-shots/2019/08/14/746614170/mdma-aka-ecstasy-shows-promise-as-a-ptsd-treatment> [<https://perma.cc/3T2M-5W52>]. Saj Razvi, a psychotherapist in one of the clinical trials, “observed hundreds of hours of these sessions” and reported “they can sometimes look tough, almost like a ‘bad trip,’ but the process leads to emotional breakthroughs that otherwise ‘may take months or years to accomplish.’” *Id.*

10. See Mason Marks, *Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles*, 21 N.Y.U. J. LEGIS. & PUB. POL’Y 69, 71 (2018); *Mental Illness*, NAT’L INST. MENTAL HEALTH, <https://www.nimh.nih.gov/health/statistics/mental-illness.shtml> [<https://perma.cc/V2GV-X8UX>].

11. Sebastian Trautmann, Jürgen Rehm & Hans-Ulrich Wittchen, *The Economic Costs of Mental Disorders*, 17 EMBO REPS. 1245, 1245 (2016), <https://www.embopress.org/doi/epdf/10.15252/embr.201642951>.

12. *Id.* at 1246.

13. PTSD: National Center for PTSD, U.S. DEP’T OF VETERANS AFFS. (Sept. 10, 2021), https://www.ptsd.va.gov/understand/common/common_adults.asp [<https://perma.cc/3R9U-5NW7>].

disorder-specific drug has been developed since 2002, and those currently available have shown little, if any efficacy.¹⁴ In fact, studies have found that the most commonly used psychiatric drugs—selective serotonin re-uptake inhibitors (SSRIs)—do not alleviate symptoms in up to fifty percent of patients with depression.¹⁵ Prospects for new treatments are dim: pharmaceutical companies reduced research and development of new psychiatric drugs by seventy percent over the last decade.¹⁶

Put simply, the United States healthcare system is woefully ill-equipped to offer effective treatment for up to twenty percent of its population.¹⁷ Yet two experimental drugs, 3,4-Methylenedioxymethamphetamine (MDMA) and psilocybin, have shown phenomenal promise.¹⁸ In fact, the Food and Drug Administration (FDA) in 2017 granted “breakthrough therapy” status for MDMA-assisted psychotherapy¹⁹ following several recent studies that demonstrated “significant relief” for PTSD patients.²⁰ One of those studies

14. Stone, *supra* note 9.

15. Alison Little, *Treatment-Resistant Depression*, 80 AM. FAM. PHYSICIANS 167, 167 (2009) (reporting that up to two-thirds of patients do not benefit from a single SSRI); Natalia Olchanski et al., *The Economic Burden of Treatment-Resistant Depression*, 35 CLINICAL THERAPEUTICS 512, 513 (2013) (reporting that approximately one in three patients with depression did not improve even after treatment with four “different vigorous and sequential” antidepressants). Richard C. Shelton, Olawale Osuntokun, Alexandra N. Heinloth & Sara A. Corya, *Therapeutic Options for Treatment-Resistant Depression*, 24 CNS DRUGS 131, 133 (2010) (reporting “that remission is achieved in only about one-third of depressed patients in response to treatment with one antidepressant,” and that, among patients who do not respond to two antidepressants, the success rate of utilizing multiple antidepressant treatments “drops precipitously”).

16. Mary O’Hara & Pamela Duncan, *Why ‘Big Pharma’ Stopped Searching for the Next Prozac*, GUARDIAN (May 10, 2016, 4:12 PM), <https://www.theguardian.com/society/2016/jan/27/prozac-next-psychiatric-wonder-drug-research-medicine-mental-illness> [<https://perma.cc/5K7N-DSWU>]. See also Richard A. Friedman, *A Dry Pipeline for Psychiatric Drugs*, N.Y. TIMES (Aug. 19, 2013), <https://www.nytimes.com/2013/08/20/health/a-dry-pipeline-for-psychiatric-drugs.html> [<https://perma.cc/8RVS-74LF>] (“Yet even though 25 percent of Americans suffer from a diagnosable mental illness in any year, there are few signs of innovation from the major drug makers.”). The decline in innovation is attributable to “a series of failed clinical trials” in which new treatments were largely ineffective, leading pharmaceutical companies to stop innovating in this field and to conclude that “developing new psychiatric drugs is too risky and too expensive.” *Id.*

17. Mason M. Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 652 (2020).

18. See *id.* at 654; see also *infra* notes 20–25 and accompanying text.

19. Janet Burns, *FDA Designates MDMA as ‘Breakthrough Therapy’ for Post-Traumatic Stress*, FORBES (Aug. 28, 2017, 3:58 PM), <https://www.forbes.com/sites/janetwburns/2017/08/28/fda-designates-mdma-as-breakthrough-therapy-for-post-traumatic-stress/#5724cd917460> [<https://perma.cc/LP8N-EF5B>]. Section 902 of the Food and Drug Administration Safety and Innovation Act defines “breakthrough therapy” as a drug that is “intended . . . to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies. . . .” 21 U.S.C. § 356.

20. Burns, *supra* note 19. See also Allison A. Feduccia et al., *Breakthrough for Trauma Treatment: Safety and Efficacy of MDMA-Assisted Psychotherapy Compared to Paroxetine and Sertraline*, FRONTIERS IN PSYCHIATRY (Sept. 12, 2019), <https://www.frontiersin.org/articles/10.3389/fpsyt.2019.00650/full> (presenting clinical trial evidence

showed that 67 percent of the participants “no longer met the diagnostic criteria for PTSD” after just two months of treatment.²¹ MDMA works by reducing the activity in the amygdala, the fear-processing part of the brain: when the fear is calmed, patients feel safe in processing their traumatic memories with professional therapists with a positive perspective.²²

As for psilocybin, the FDA granted the same status twice in 2019 for the treatment of severe depression in patients who have not improved from traditional antidepressants.²³ A Johns Hopkins University study published last year found that psilocybin “was four times more effective than traditional antidepressants.”²⁴ Psilocybin profoundly impacts the brain and can have long-term therapeutic effects by “wiping away depressive symptoms” in many patients with major depressive disorders.²⁵ According to Johns Hopkins University neuropharmacologist Roland Griffiths, psilocybin is distinguishable from traditional pharmaceuticals because it produces “enduring meaning and belief changes People feel

showing that “MDMA-assisted psychotherapy was superior . . . in terms of safety and efficacy compared to the two approved SSRIs for treatment of PTSD”); Michael C. Mithoefer et al., *3,4-methylenedioxymethamphetamine (MDMA)-Assisted Psychotherapy for Post-Traumatic Stress Disorder in Military Veterans, Firefighters, and Police Officers: A Randomized, Double-Blind, Dose-Response, Phase 2 Clinical Trial*, 5 LANCET PSYCHIATRY 486, 486 (2018) (finding MDMA-assisted psychotherapy in controlled settings “effective and well-tolerated in reducing PTSD symptoms in veterans and first responders”).

21. Jennifer M. Mitchell et al., *MDMA-Assisted Therapy for Severe PTSD: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study*, 27 NATURE MED. 1025, 1026 (2021).

22. *Today*, *supra* note 1.

23. Yasemin Saplakoglu, *FDA Calls Psychedelic Psilocybin a ‘Breakthrough Therapy’ for Severe Depression*, LIVE SCI. (Nov. 25, 2019), <https://www.livescience.com/psilocybin-depression-breakthrough-therapy.html> [<https://perma.cc/JW3N-5TAS>]. Studies have shown that psilocybin is safe, and efficacious for treatment-resistant depression. Robin L. Carhart-Harris et al., *Psilocybin with Psychological Support for Treatment-Resistant Depression: An Open-Label Feasibility Study*, 3 LANCET PSYCHIATRY 619, 619, 627 (2016). For example, one randomized, double-blind study demonstrated that a single dose of psilocybin “produced substantial and enduring decreases in depressed mood and anxiety along with increases in quality of life and decreases in death anxiety in patients with a life-threatening cancer diagnosis.” Roland R. Griffiths et al., *Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients with Life-Threatening Cancer: A Randomized Double-Blind Trial*, 30 J. PSYCHOPHARMACOLOGY 1181, 1195 (2016).

24. Adam Piore, *Magic Mushrooms May Be the Biggest Advance in Treating Depression Since Prozac*, NEWSWEEK (Sept. 22, 2021, 5:00 AM), <https://www.newsweek.com/2021/10/01/magic-mushrooms-may-biggest-advance-treating-depression-since-prozac-1631225.html> [<https://perma.cc/A3U2-6XW5>] (citing Alan K. Davis et al., *Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial*, 78 JAMA PSYCHIATRY 481 (2021)).

25. Saplakoglu, *supra* note 23; *see also* Carhart-Harris et al., *supra* note 23; Griffiths et al., *supra* note 23. Researchers at Imperial College London reported that, in a study of twelve patients who had been clinically depressed for an average of 17.8 years, all twelve markedly improved after one week of psilocybin treatment, and five were completely cured after three months. Zoe Cormier, *Magic Mushroom Drug Lifts Depression in Human Trial: Psilocybin Shows Higher Remission Rate than SSRI Drugs in a U.K. Study*, SCI. AM. (May 17, 2016), <https://www.scientificamerican.com/article/magic-mushroom-drug-lifts-depression-in-human-trial1/#> [<https://perma.cc/2Y4G-T243>]. Before the study, none of the twelve had responded to SSRIs or even electroconvulsive therapy (ECT). *Id.*

‘reorganized’ in a way they don’t with other drugs.”²⁶ And because psilocybin therapy is four times as likely to be effective than SSRIs “with more enduring benefits,”²⁷ *Newsweek’s* October 2021 issue cover hailed it as possibly “the biggest advance in treating depression since Prozac.”²⁸

Despite having shown promise for almost half a century,²⁹ MDMA and psilocybin are still not legally available to patients, largely because the federal government, decades ago, hastily categorized them under Schedule I of the Controlled Substances Act (CSA).³⁰ A drug’s placement on Schedule I subjects it to severe restrictions by the Drug Enforcement Administration (DEA) and, as a consequence, researchers’ access to that drug is tremendously hindered, delayed, and often cost-prohibitive.³¹

Unique to Schedule I drugs is their legal characterization of having “no currently accepted medical use.”³² Rescheduling a drug from Schedule I to another, less restrictive schedule is a complex administrative process.³³

26. Zoe Cormier, *Psilocybin Treatment for Mental Health Gets Legal Framework*, SCI. AM. (Dec. 1, 2020), <https://www.scientificamerican.com/article/psilocybin-treatment-for-mental-health-gets-legal-framework/> [https://perma.cc/Z24X-NV3F]. University of California in San Francisco neuroscientist Robin Carhart-Harris explained it this way:

[Psilocybin can] shut down a specific constellation of brain structures known as the “default mode network.” This network is most active when our mind wanders—when we are daydreaming. It gives us that voice we hear in our heads, which is often hyperactive in depressed and anxious patients who are tormented by negative thought loops.

Piore, *supra* note 24.

27. Alan K. Davis et al., *supra* note 24; Mason Marks, Opinion, *A Strategy for Rescheduling Psilocybin*, SCI. AM. (Oct. 11, 2021), <https://www.scientificamerican.com/article/a-strategy-for-rescheduling-psilocybin/> [https://perma.cc/6&KP-XYUM].

28. Piore, *supra* note 24.

29. Kai Kupferschmidt, *All Clear for the Decisive Trial of Ecstasy in PTSD Patients*, SCI. (Aug. 26, 2017), <https://www.science.org/news/2017/08/all-clear-decisive-trial-ecstasy-ptsd-patients> [https://perma.cc/3FSD-BWT2]. According to David Nutt, a neuropsychopharmacologist at Imperial College London, it has “been obvious for 40 years that [certain illegal mind-altering] drugs are medicines,” but he acknowledged the FDA’s designation as “a huge step in acceptance.” *Id.*

30. See Jasen B. Talise, *Take the Gatekeepers to Court: How Marijuana Research Under a Biased Federal Monopoly Obstructs the Science-Based Path to Legalization*, 47 SW. L. REV. 449, 467–68 (2018); *Controlled Substances*, U.S. DRUG ENF’T ADMIN., https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf [https://perma.cc/M2SL-YRNR]; see also discussion *infra* Section I.A.

31. Marks, *supra* note 10, at 74. Pursuant to the CSA and its implementing regulations, Schedule I drugs are subject to “strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.” *Gonzales v. Raich*, 545 U.S. 1, 14 (2005) (citations omitted). The requirements can be time-consuming and onerous. Marks, *supra* note 10, at 89. According to DEA estimates, researchers usually have to wait nine months in order to receive a license to research Schedule I drugs. Shaunacy Ferro, *Why Doctors Can’t Give You LSD (But Maybe They Should)*, POPULAR SCI. (Apr. 16, 2013, 10:00 PM), <https://www.popsoci.com/science/article/2013-04/new-science-lsd-therapy/> [https://perma.cc/S88Q-27RF]. In addition to the DEA’s own requirements, researchers have to navigate a maze of other federal agencies’ separate requirements, including the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA). See Talise, *supra* note 30, at 457 (“Various administrative entities, each requiring their own individual stacks of paperwork, must give their approval.”)

32. 21 U.S.C. § 812(b)(1)(B).

33. See Marks, *supra* note 10, at 115.

43. Alicia Victoria Lozano, *New California Bill Would Decriminalize Psychedelics, Expunge Criminal Records*, NBC NEWS (Feb. 18, 2021, 1:22 PM), <https://www.nbcnews.com/news/us-news/new-california-bill-would-decriminalize-psychedelics-expunge-criminal-records-n1258261> [https://perma.cc/X8ET-ZY5H].

physical health conditions,⁴⁴ following Connecticut's enactment of a similar measure.⁴⁵ As of this writing, eleven additional states are proposing similar measures.⁴⁶

These state and local measures are significant for two reasons that may be in tension. On one hand, they demonstrate that many American voters acknowledge the therapeutic effects of certain Schedule I drugs. However, their conflict with the CSA exposes patients who, while acting consistently with state or local law, risk prosecution and incarceration by the federal government “unless federal drug regulation is updated.”⁴⁷

Legal scholarship on the subject, unfortunately, has not kept pace with the momentum in both the medical and commercial fronts.⁴⁸ Over the last two years, medical research papers on the subject have multiplied: 139 papers were published on psilocybin in 2020, almost twice as many as in 2019.⁴⁹ On the commercial front, companies are already seeking patents on psilocybin formulations.⁵⁰ As of this writing, three such companies are publicly listed in the United States, and in Canada, more than two dozen are listed, with an estimated collective value of more than \$4.5 billion.⁵¹ On the legal front, however, “there is no systematic research being done on

44. A Study on the Use of Alternative Therapies for Treating Post-Traumatic Stress Disorder, 2021 Tex. Sess. Law Serv. Ch. 983 (West).

45. Joyce E. Cutler, *Texas the Latest State to Legalize Psychedelic Medical Research*, BLOOMBERG L. (June 23, 2021, 4:40 AM), <https://news.bloomberglaw.com/pharma-and-life-sciences/texas-the-latest-state-to-legalize-psychedelic-medical-research> [https://perma.cc/H2KU-QV9Y].

46. Marisa Fernandez, *States Want to Study Possible Mental Health Benefits of Psychedelics*, AXIOS (July 2, 2021), <https://www.axios.com/states-fund-psychedelic-research-mental-health-ec6a4b6b-62fd-4ff0-aecf-38d07cf00d65.html> [https://perma.cc/PN8L-KZFY].

47. Marks, *supra* note 17, at 655.

48. See *Announcing the Project on Psychedelics Law and Regulation (POPLAR) at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School*, PETRIE-FLOM CTR. FOR HEALTH LAW POL'Y, BIOTECHNOLOGY, & BIOETHICS AT HARV. L. SCH. (June 30, 2021), <https://petrieflom.law.harvard.edu/resources/article/petrie-flom-center-launches-POPLAR> [https://perma.cc/JKH9-TUKE]; Ritika Dubey, *POPLAR: Harvard's Psychedelic Law, Policy Initiative*, TRUFFLE REP. (Aug. 10, 2021), <https://www.truffle.report/poplar-harvards-psychedelic-law-policy-initiative/> [https://perma.cc/A6FR-D55V].

49. Dubey, *supra* note 48.

50. See, e.g., Ann Harrison, *Researchers Examine Psilocybin Patent Claims*, LUCID NEWS (Apr. 23, 2020), <https://www.lucid.news/researchers-examine-psilocybin-patent-claims/> [https://perma.cc/79UC-4QJ4].

51. Sam Dean, *This Hedgefunder Took Ayahuasca. It Changed His Life—and His Perspective on Investment*, L.A. TIMES (Sept. 30, 2021, 5:00 AM), <https://www.latimes.com/business/story/2021-09-30/hedge-fund-investor-boosts-psychedelic-therapy-startups>. Elon Musk predicts that “[a]s the new generation gets into political power, . . . we will see greater receptivity to the benefits of psychedelics.” *Id.*

psychedelics law.”⁵² This Note aims to contribute in ongoing efforts to fill this gap.⁵³

This Note argues that federal rescheduling is more effective than a patchwork of state laws because, by virtue of the preemption doctrine, federal rescheduling would provide immediate and nationwide relief for suffering Americans.⁵⁴ Further, rescheduling is possible under the current statutory framework because current DEA regulations are inconsistent with the plain text of the CSA.⁵⁵ Part I of this Note provides the legal and historical backdrop of the CSA and its stymying effects on MDMA and psilocybin research. It then summarizes the legal evolution of rescheduling requirements under DEA regulations that interpret the descriptive language of Schedule I drugs under the CSA. Part II demonstrates the illegality of those regulations in their current state, arguing that they are inconsistent with the plain text of the CSA. Part III in turn proposes regulatory criteria for Schedule I drugs that are consistent with the CSA and current federal jurisprudence. Part IV concludes by noting additional considerations and challenges that may nonetheless prevent broad patient access to MDMA and psilocybin.

I. BACKGROUND

A. *How We Got Here: The CSA and the War on Drugs*

Medical experts have found that MDMA and psilocybin are both safe and effective.⁵⁶ In fact, they “appear to have fewer and less severe side effects than many FDA-approved medicines including widely prescribed psychiatric drugs.”⁵⁷ These findings are not all new: experts began

52. *Id.*

53. A promising development on the legal front is a new research initiative, the Project on Psychedelics Law and Regulation, announced in June 2021 by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School to “promote safety, innovation, and equity in psychedelics research, commerce, and therapeutics.” *Announcing the Project on Psychedelics Law and Regulation (POPLAR) at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School*, *supra* note 48.

54. See *Gonzales v. Raich*, 545 U.S. 1, 9 (2005) (holding that the CSA preempted a state law permitting marijuana cultivation for medicinal purposes); see also Sam Kamin, *The Limits of Marijuana Legalization in the States*, 99 IOWA L. REV. BULL. 39 (2014) (detailing the practical consequences of the discontinuity between marijuana regimes across states). In addition to criminal liability, the conflict between federal and state drug regulation creates challenges in employment, banking, and contract law. *Id.* at 44–47.

55. See discussion *infra* Section I.B.

56. See *supra* note 23 and accompanying text.

57. Marks, *supra* note 17, at 659. Professor Mason Marks cites a Johns Hopkins University study which demonstrated that just one dose of psilocybin “significantly reduced depression and anxiety in people with life-threatening cancer diagnoses” with no significant side effects, and “the benefits persisted for up to six months.” *Id.* (citing Roland R. Griffiths et al., *supra* note 23, at 1195).

researching and publishing their findings of the potential therapeutic effects of MDMA, psilocybin, and other psychedelic drugs over fifty years ago.⁵⁸ But, according to Professor Mason Marks, these drugs became mischaracterized and eventually “miscategorized” as a result of the U.S. war on drugs.⁵⁹ President Richard Nixon’s administration associated psychedelic drugs with the countercultural movements of 1960s,⁶⁰ and the CSA—including its quintessential scheduling regime—was born as a “cornerstone” of the war on drugs.⁶¹ But decades later, one of President Nixon’s top aides and Watergate co-conspirators, John Ehrlichman, revealed that war on drugs was actually fabricated “as a political tool” against racial minorities and political dissidents.⁶² Confirming, in point-blank fashion, that the CSA was “hardly based on evidence-based dialogue,”⁶³ Ehrlichman bluntly admitted during a 1994 interview published in a 2016 Harper’s Magazine exposé:

We knew we couldn’t make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did.⁶⁴

58. See, e.g., Anthony K. Busch & Warren C. Johnson, *L.S.D. 25 as an Aid in Psychotherapy: Preliminary Report of a New Drug*, 11 DISEASES NERVOUS SYS. 241, 241–43 (1950); J. Carranza-Acevedo, *Hallucinogens vs. Psychotherapy*, 113 BRITISH J. PSYCHIATRY 1156, 1156–57 (1967); Jonathan O. Cole & Martin M. Katz, *The Psychotomimetic Drugs*, 187 JAMA 758, 760 (1964). In fact, a 2016 analysis of nineteen studies of psychedelics as therapeutics published between 1949 and 1974 reported that 79% of patients in those studies exhibited clinical improvement. James JH Rucker, Luke A. Jelen, Sarah Flynn, Kyle D. Frowde & Allan H. Young, *Psychedelics in the Treatment of Unipolar Mood Disorders: A Systematic Review*, 30 J. PSYCHOPHARMACOLOGY 1220, 1224–25 (2016).

59. Marks, *supra* note 17, at 666.

60. *Id.* at 667. See DAN BAUM, SMOKE AND MIRRORS: THE WAR ON DRUGS AND THE POLITICS OF FAILURE 10–11 (1996); Deborah Ahrens, *Drug Panics in the Twenty-First Century: Ecstasy, Prescription Drugs, and the Reframing of the War on Drugs*, 6 ALB. GOV’T L. REV. 397, 402 (2013). See also Deborah Ahrens, *Methademic: Drug Panic in an Age of Ambivalence*, 37 FLA. ST. U. L. REV. 841, 851–52 (2010) [hereinafter Ahrens, *Methademic*] (positing that federal drug policy during “the 1960s and early 1970s was less about reducing the possible personal or social harms associated with drug use than it was about reinforcing the majority’s status,” and that drug policy during this period “was often a proxy for cultural contestation between competing social groups”). Another catalyst was the fact that, at the time, President Nixon was concerned with delivering on his law-and-order platform, but the federal government had almost no domestic policing authority. BAUM, *supra*, at 13.

61. Marks, *supra* note 17, at 667.

62. Dan Baum, *Legalize It All: How to Win the War on Drugs*, HARPER’S MAG. (Apr. 2016), <https://harpers.org/archive/2016/04/legalize-it-all/> [https://perma.cc/SH92-LBY3].

63. Talise, *supra* note 30, at 452 (citations omitted).

64. Baum, *supra* note 62.

President Nixon succeeded.⁶⁵ Over the last five decades, the war on drugs has devastated racial minorities “by incarcerating millions, disrupting families, and reinforcing social inequality,”⁶⁶ and raised the United States to the highest incarcerator of its citizenry among all nations worldwide on a per capita basis.⁶⁷ At the same time, MDMA and psilocybin became the collateral damage of the war on drugs.⁶⁸ The CSA was the war’s primary arsenal,⁶⁹ which Congress enacted in 1970 as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 to address drug abuse and to “control the legitimate and illegitimate traffic in controlled substances.”⁷⁰ The CSA was originally intended to be “sufficiently flexible” to handle the “ever-changing drug scene.”⁷¹ However, the emphasis on control restrictions to tackle illicit drug use has come at the expense of the curtailment of legitimate medical research.⁷²

The CSA’s classification system is its “cardinal feature.”⁷³ Controlled drugs are categorized into five schedules⁷⁴ “based on their accepted medical uses, their potential for abuse, and their psychological and physical effects on the body.”⁷⁵ Schedule I drugs are considered “the most dangerous substances, possessing no redeeming value as medicines.”⁷⁶ Therefore, the CSA subjects them “to the most severe controls.”⁷⁷ For example, drugs in Schedule I “are the only category of drugs that doctors may never

65. Marks, *supra* note 17, at 667.

66. *Id.* See also Ira Glasser & Loren Siegel, *When Constitutional Rights Seem Too Extravagant to Endure: The Crack Scare’s Impact on Civil Rights and Liberties*, in *CRACK IN AMERICA: DEMON DRUGS AND SOCIAL JUSTICE* 229, 242 (Craig Reinerman & Harry G. Levine eds., 1997) (citing the rise in drug arrests from less than 200,000 in 1968 to 1.2 million annually following the CSA’s enactment, and disproportionately skewed towards Black Americans).

67. Ahrens, *Methademic*, *supra* note 60, at 842–43 (citations omitted).

68. Marks, *supra* note 17, at 666.

69. Baum, *supra* note 62, at 67–75 (noting the increase in the federal drug-enforcement from \$65 million in 1969 to \$719 million in 1974).

70. *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). See also Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified at 12 U.S.C. §§ 801–971, 42 U.S.C. § 257a) (introducing the CSA as “[a]n Act . . . to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse”).

71. ROBERT L. BOGOMOLNY, MICHAEL R. SONNENREICH & ANTHONY J. ROCCOGRANDI, *A HANDBOOK ON THE 1970 FEDERAL DRUG ACT* 5 (1975).

72. Jasen B. Talise argues that the emphasis on drug control have had a “discriminate impact” on legitimate medical research. Talise, *supra* note 30, at 468–69. Indeed, Mr. Talise aptly quotes Heffter Research Institute founder Mark Geyer: “The goal wasn’t to stop scientists, the goal was to stop street use . . . but the side effect of that was that even legitimate research was curtailed.” *Id.* (citing Ferro, *supra* note 31).

73. *Raich*, 545 U.S. at 13.

74. 21 U.S.C. § 812.

75. *Raich*, 545 U.S. at 13.

76. *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 (D.C. Cir. 1991).

77. *Id.*

prescribe.”⁷⁸ Section 812(b) of the CSA provides the statutory criteria that set forth the findings required for each of the five schedules.⁷⁹ For a drug to be placed in Schedule I, the CSA requires that:

- (A) The drug or other substance has a high potential for abuse;
- (B) The drug or other substance has no currently accepted medical use in treatment in the United States;
- (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.⁸⁰

Unlike Schedule I drugs, all drugs in Schedules II to V have, *inter alia*, a “currently accepted medical use.”⁸¹ Thus, a drug can be placed in Schedule I only if it has “no currently accepted medical use.”⁸²

Drugs can travel between schedules.⁸³ Section 811(a) describes this process, empowering the Attorney General to initiate rulemaking proceedings to reschedule a drug “on his own motion,” or at the request of either of the Secretary of Health and Human Services (HHS) or “any interested party.”⁸⁴ The Attorney General has historically delegated this authority to the DEA.⁸⁵ Before initiating rulemaking proceedings, however, the Attorney General (or the DEA) must gather “the necessary data” and request a “scientific and medical evaluation” and recommendation from HHS.⁸⁶ Section 811(c) enumerates eight factors the Attorney General must consider in making a rescheduling determination for a drug:

- (1) Its 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.

78. Talise, *supra* note 30, at 452 n.31.

79. § 812(b).

80. § 812(b)(1) (emphasis added).

81. 21 U.S.C. § 812(b)(2)–(b)(5).

82. *See* § 812(b).

83. *See* § 811.

84. § 811(a).

85. *See* Marks, *supra* note 10, at 116.

86. § 811(b).

- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under [subchapter I of 21 U.S.C.].⁸⁷

According to the CSA's original drafters, including former director of the Bureau of Narcotics and Dangerous Drugs (the DEA's predecessor agency) Michael Sonnenreich, "[t]he intent of the scheduling system and its greatest value is its practicality and ability to adjust the regulatory framework."⁸⁸ The drafters emphasized the importance of the scheduling system's adaptability to "changing social circumstances," and warned that using it solely for expanding drug restrictions and control would essentially defeat its purpose.⁸⁹

Even though "Congress contemplated that the classification set forth in the [CSA] as originally passed would be subject to continuing review by the executive officials concerned,"⁹⁰ in practice, instances of drug reschedulings have been sparse. Over a forty-year period, the DEA rescheduled a drug from Schedule I to Schedule II only five times.⁹¹ Over the same period, the DEA entirely removed a drug from Schedule I only twice.⁹² In its original incarnation, the CSA may have "balanced law enforcement and public health concerns," but subsequent amendments during the 1970s War on Drugs tipped the balance in favor of the DEA's interests.⁹³ Over the next several decades, the CSA became more concerned with convicting drug offenders, largely leaving behind its original public health concerns.⁹⁴

B. Legal Evolution of Rescheduling Under § 811

The only statutory difference between Schedule I and the other four schedules is that Schedule I substances have "*no* currently accepted medical use,"⁹⁵ whereas the other four *do* have a "currently accepted medical use."⁹⁶

87. § 811(c).

88. BOGOMOLNY, SONNENREICH & ROCCOGRANDI, *supra* note 71, at 28.

89. See *id.* at 75–76 ("The true test of this system will be in loosening restraints when justified. A scheme that is directed only towards tighter and tighter controls will, in time, lose its most important attributes, flexibility and the capacity to adjust to changing social circumstances.").

90. Nat'l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll, 497 F.2d 654, 656 (D.C. Cir. 1974).

91. Marks, *supra* note 10, at 116. For example, the DEA in 1984 moved the drug Sufentanil, a powerful opioid, from Schedule I to Schedule II, and in 1986, the DEA also moved the THC drug Marinol from Schedule I to Schedule II. *Id.*

92. *Id.*

93. *Id.* at 88.

94. See *id.*

95. See 21 U.S.C. § 812(b)(1) (emphasis added).

96. See § 812(b)(2)–(b)(5).

It follows that if a drug has a “currently accepted medical use,” it cannot legally be scheduled in (or remain in) Schedule I: the DEA must move the drug to Schedules II–V, or remove it entirely from the CSA.⁹⁷ However, Congress never defined the phrase “currently accepted medical use” when enacting or amending the CSA.⁹⁸

Since 1992, the DEA has required that a drug meet a conjunctive five-part test to satisfy the “currently accepted medical use” standard (the “1992 Test”):

- 1) whether a drug’s chemistry is known and reproducible;
- 2) whether there are adequate safety studies;
- 3) whether there are adequate and well controlled studies proving efficacy;
- 4) whether the drug is accepted by qualified experts; and
- 5) whether the scientific evidence is widely available.⁹⁹

The 1992 Test remains the prevailing legal standard today by virtue of the judicial deference courts have afforded DEA interpretations of “no currently accepted medical use” pursuant to the *Chevron* doctrine.¹⁰⁰ In 1984, the Supreme Court decided *Chevron v. Natural Resources Defense Council*,¹⁰¹ ushering in an era of judicial deference to agency interpretations of civil statutes.¹⁰² Essentially, *Chevron* instructs courts to follow a two-step process when reviewing an agency’s interpretation of a statute.¹⁰³ First, courts must ask “whether Congress has directly spoken to the precise question at issue.”¹⁰⁴ “If the intent of Congress is clear,” courts and federal agencies “must give effect to the unambiguously expressed intent of Congress.”¹⁰⁵ If, on the other hand, courts determine that “Congress has not directly addressed the precise question at issue,” courts must not “simply

97. See *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 (D.C. Cir. 1991) (“Drugs can be ‘re-scheduled’ or ‘de-scheduled’ only if the DEA makes certain statutorily mandated findings.”).

98. Talise, *supra* note 30, at 453–54; § 812(b)(1). In fact, “the only portion of the Schedule I criteria that Congress has expressly defined in the CSA” is the term “United States.” Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV’T L. REV. 331, 342 (2013) (citing *Grinspoon v. DEA*, 828 F.2d 881, 885 (1st Cir. 1987)).

99. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,506 (Mar. 26, 1992).

100. See, e.g., *Grinspoon*, 828 F.2d at 885; *All. for Cannabis Therapeutics*, 930 F.2d at 939; *Ams. for Safe Access v. DEA*, 706 F.3d 438, 449–50 (D.C. Cir. 2013).

101. *Chevron U.S.A., Inc. v. Nat’l Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

102. See Nicholas R. Bednar, *What to Do About Chevron: Nothing*, 72 VAND. L. REV. 151, 151 (2019).

103. *Chevron*, 467 U.S. at 842–43.

104. *Id.* at 842.

105. *Id.* at 842–43.

impose” their own interpretation of the statute.¹⁰⁶ Instead, “if the statute is silent or ambiguous,” courts should defer to the agency’s interpretation only if the agency’s interpretation is “based on a permissible construction of the statute.”¹⁰⁷

Based on *Chevron*, federal courts, by and large, have deferred to the DEA’s interpretation of “currently accepted medical use.”¹⁰⁸ In that respect, three federal appellate decisions shed light on the extent to which federal courts have deferred to DEA interpretations under *Chevron*: *Grinspoon v. DEA*,¹⁰⁹ *Alliance for Cannabis Therapeutics v. DEA*,¹¹⁰ and *Americans for Safe Access v. DEA*.¹¹¹

1. *Grinspoon v. Drug Enforcement Administration*

1987 marked a significant year in federal appellate court Schedule I rescheduling disputes under the CSA.¹¹² In *Grinspoon v. Drug Enforcement Administration*, Dr. Lester Grinspoon, a Harvard University researcher, petitioned the First Circuit Court of Appeals for a review of the DEA’s issuance of a final rule classifying MDMA as a Schedule I substance.¹¹³ The First Circuit remanded Grinspoon’s MDMA rescheduling petition to the DEA for reconsideration because the DEA had erroneously interpreted “currently accepted medical use” to mean a drug must have Food & Drug Administration (FDA) “interstate marketing approval.”¹¹⁴ The court reasoned that, even though FDA interstate marketing approval was *sufficient* to prove that a drug had an accepted medical use, such approval was not *necessary* according to the CSA.¹¹⁵ Under *Chevron*, the First Circuit found the DEA’s interpretation “contrary to congressional intent.”¹¹⁶

Regardless, the DEA on remand adopted the FDA criteria, delineating eight “characteristics” that a drug must have for it to have an “accepted medical use”:

[1] scientifically determined and accepted knowledge of its chemistry; [2] the toxicology and pharmacology of the substance in

106. *Id.* at 843.

107. *Id.*

108. *See, e.g., Grinspoon v. DEA*, 828 F.2d 881, 891 (1st Cir. 1987); *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 (D.C. Cir. 1991); *All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994); *Ams. for Safe Access v. DEA*, 706 F.3d 438, 440–41 (D.C. Cir. 2013).

109. 828 F.2d 881 (1st Cir. 1987).

110. 930 F.2d 936 (D.C. Cir. 1991).

111. 706 F.3d 438, 440–41 (D.C. Cir. 2013).

112. *Grinspoon*, 828 F.2d at 881.

113. *Id.*

114. *Id.* at 888–91.

115. *Id.* at 886–87.

116. *Id.* at 885.

animals; [3] establishment of its effectiveness in humans through scientifically designed clinical trials; [4] general availability of the substance and information regarding the substance and its use; [5] recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks; [6] specific indications for the treatment of recognized disorders; [7] recognition of the use of the substance by organizations or associations of physicians; and [8] recognition and use of the substance by a substantial segment of the medical practitioners in the United States.¹¹⁷

These eight factors continued to constitute the DEA's interpretation of "currently accepted medical use" under the CSA until 1991.¹¹⁸

2. Alliance for Cannabis Therapeutics v. Drug Enforcement Administration

In 1991, petitioner Alliance for Cannabis Therapeutics (ACT) challenged the eight-factor test at the U.S. Court of Appeals for the District of Columbia Circuit in an appeal from the DEA's denial of ACT's petition to reschedule marijuana.¹¹⁹ In *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration*, the court found unreasonable three of eight factors the DEA had relied on in denying ACT's petition because they were "logically impossible to satisfy,"¹²⁰ but deferred to the DEA's interpretation with respect to the remaining five because the CSA did not "precisely" define the term "currently accepted medical use."¹²¹ In accepting the DEA's interpretation, the court reasoned it was "obliged" under *Chevron* to defer to the DEA's interpretation because it was "reasonable."¹²²

On remand, the DEA relied on FDA standards again.¹²³ It used the five remaining factors in making its determination:

- 1) whether a drug's chemistry is known and reproducible;
- 2) whether there are adequate safety studies;

117. Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act; Remand, 53 Fed. Reg. 5156, 5157–58 (Feb. 22, 1988).

118. See *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 938 (D.C. Cir. 1991) (noting in 1991 that the DEA had reaffirmed the eight-factor test in a proceeding below that had denied a marijuana rescheduling petition).

119. *Id.* at 936.

120. *Id.* at 937.

121. *Id.* at 939.

122. *Id.*

123. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,504–06 (Mar. 26, 1992).

- 3) whether there are adequate and well controlled studies proving efficacy;
- 4) whether the drug is not accepted by qualified experts; and
- 5) whether the scientific evidence is not widely available.¹²⁴

To date, the DEA has relied on the 1992 Test in making Schedule I rescheduling determinations.¹²⁵

3. *Americans for Safe Access v. Drug Enforcement Administration*

The D.C. Court of Appeals has deferred to the DEA not only for its interpretations of the CSA language governing Schedule I,¹²⁶ but also for its own interpretations of the 1992 Test.¹²⁷ With respect to the test's third factor—determining whether a drug has “adequate and well controlled studies proving efficacy”—the DEA has required a showing of “adequate, well-controlled, well-designed, well-conducted, and well-documented studies.”¹²⁸ In *Americans for Safe Access v. Drug Enforcement Administration*, the D.C. Circuit upheld the DEA's denial to reschedule marijuana as a Schedule III, IV, or V drug. The case turned on the application of the third factor of the 1992 Test: whether there were “adequate and well controlled studies proving efficacy.”¹²⁹ In its denial below, the DEA had interpreted this requirement to mean that “the effectiveness of a drug must be established in well-controlled, well-designed, well-conducted, and well-documented scientific studies.”¹³⁰ Although the court noted that the DEA had relied on the FDA's interpretation of what constitutes an “adequate and controlled” study for that agency's review of applications for new drugs under a different law, it did not find such an interpretation unreasonable.¹³¹

124. *Id.* at 10,506.

125. *See e.g.*, Denial of Petition to Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40,552 (July 8, 2011); Denial of Petition to Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53,767 (Aug. 12, 2016).

126. *See All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 (D.C. Cir. 1991); *All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

127. *See Ams. for Safe Access v. DEA*, 706 F.3d 438, 450 (D.C. Cir. 2013).

128. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,505 (Mar. 26, 1992).

129. *Ams. for Safe Access*, 706 F.3d at 450.

130. *Id.* (quoting Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. at 40,579).

131. *Id.* at 451–52.

C. *The Decline of Chevron*

The *Chevron* doctrine has visibly waned in recent years.¹³² Professor Nathan Richardson posits that it is

not the influential doctrine it once was and has not been for a long time. It has been eroded from the outside as a series of exclusions have narrowed its scope, and has been hollowed out from the inside as [Supreme Court] Justices have become ever more willing to find clear meaning in statutes, thereby denying deference to agencies.¹³³

Since 2018, the *Chevron* doctrine has evolved in three significant respects. Justice Kennedy first signaled this in a 2018 concurring opinion in *Pereira v. Sessions*, where he cautioned against “reflexive deference” to agency interpretations.¹³⁴ Instead, in 2019, Justice Kagan in *Kisor v. Wilkie* urged federal judges to tackle “hard interpretive conundrums” before waving “the ambiguity flag.”¹³⁵ Justice Kagan clarified when and how a federal agency is allowed to interpret its own rule.¹³⁶ Justice Kagan provided courts with three “important markers” to help identify when an agency’s interpretation of its own ambiguous rule warrants deference.¹³⁷

First, the interpretation must represent the agency’s “authoritative” or “official” position rather than an “ad hoc statement not reflecting the agency’s views.” . . . Second, *the interpretation must implicate the agency’s expertise*. This marker is based on the assumption that agencies have a more “nuanced understanding of the regulations they administer.” And if an agency “has no comparative expertise in resolving a regulatory ambiguity, Congress presumably would not

132. See, e.g., *King v. Burwell*, 576 U.S. 473, 486 (2015) (finding *Chevron* inapplicable to Internal Revenue Service (IRS) rule because the subject matter was of “deep economic and political significance” and because it was inconceivable that Congress intended the IRS to craft health insurance regulations); *Michigan v. EPA*, 576 U.S. 743, 759 (2015) (finding environmental regulation an unreasonable construction of a statute); *Perez v. Mortgage Bankers Ass’n*, 575 U.S. 92, 1212 (2015) (Scalia, J., concurring in the judgement) (signaling support for *Chevron* to be “uprooted”).

133. Nathan Richardson, *Deference Is Dead (Long Live Chevron)*, 73 RUTGERS L. REV. 441, 441 (2021).

134. *Pereira v. Sessions*, 138 S. Ct. 2105, 2120 (2018) (Kennedy, J., concurring). Indeed, Justice Kennedy went further:

[I]t seems necessary and appropriate to reconsider . . . the premises that underlie *Chevron* and how courts have implemented that decision. The proper rules for interpreting statutes and determining agency jurisdiction and substantive agency powers should accord with constitutional separation-of-powers principles and the function and province of the Judiciary.

Id. at 2121 (Kennedy, J., concurring).

135. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019).

136. *Id.*

137. *Id.* at 2406.

grant it that authority.” And third, the agency’s interpretation must reflect “fair and considered judgment.”¹³⁸

Second, also in 2019, a majority of the Court in *SAS Institute v. Iancu* emphasized that “[e]ven under *Chevron*, [courts] owe an agency’s interpretation of the law no deference unless, after ‘employing traditional tools of statutory construction,’ [courts find themselves] unable to discern Congress’s meaning.”¹³⁹

Third, the Court has cautioned against *Chevron* deference in the interpretation of dual-application statutes (such as the CSA), even in the application of a civil provision of such statutes.¹⁴⁰ Instead, “if a law has both criminal and civil applications, the rule of lenity governs its interpretation in both settings.”¹⁴¹ The rule of lenity, in turn, requires courts to choose the more lenient interpretation “when there are two rational readings of a criminal statute, one harsher than the other.”¹⁴² The harsher application is appropriate “only when Congress has spoken in clear and definite language.”¹⁴³

II. ANALYSIS

A. *The Impact of Iancu*

As noted above, recent Supreme Court decisions continue to erode the *Chevron* standard.¹⁴⁴ Notably, in 2019 the *Iancu* Court clarified that even under *Chevron*, courts must not defer to agency interpretations unless, “after ‘employing traditional tools of statutory construction,’ [courts find themselves] unable to discern Congress’s meaning.”¹⁴⁵

Applying the traditional tools of statutory construction in interpreting “currently accepted medical use” yields a result very different from the 1992 Test. This Part continues by analyzing the 1992 Test under the directive

138. Lacey Ferrara, Comment, *A New Auer: Overview and Analysis of the Supreme Court’s Decision in Kisor v. Wilkie*, 70 CASE W. RES. L. REV. 217, 230–31 (2019) (emphasis added).

139. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018).

140. *Whitman v. United States*, 574 U.S. 1003, 1005 (2014) (Scalia, J., concurring in denial of certiorari). Although Justice Scalia’s concurrence in this context does not carry mandatory precedential effect, the principle has been recognized in earlier cases and reflects the Court’s current attitude on the issue. See *infra* note 141 and accompanying text.

141. *Whitman*, 574 U.S. at 1005. In *Whitman*, Justice Scalia highlighted several cases in which the Court upheld this proposition. *Id.* (citing *Leocal v. Ashcroft*, 543 U.S. 1, 11–12 n.8 (2004); *United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 518 n.10 (1992) (plurality opinion); *id.* at 519, (Scalia, J., concurring in the judgment). The premise underlying applying the rule of lenity is that “only the legislature may define crimes and fix punishments.” *Whitman*, 574 U.S. at 1005.

142. *McNally v. United States*, 483 U.S. 350, 359 (1987).

143. *Id.* at 359–60.

144. See discussion *supra* Section I.B.

145. *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018).

provided by *Iancu*.¹⁴⁶ As this analysis will demonstrate, the 1992 Test is incompatible with the plain meaning of sections 811 and 812 of the CSA. Ultimately, this author proposes a modified test for “currently accepted medical use” that better comports with the relevant statutory language.

Although the principal canons of statutory construction are familiar to most readers, a brief review is helpful. When interpreting a statute, federal courts first interpret words of a statute according to their plain meaning.¹⁴⁷ Second, “the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.”¹⁴⁸ Finally, courts also consult legislative history when interpreting ambiguous language.¹⁴⁹

1. Plain Meaning

The natural starting point in a plain meaning analysis is the ordinary-meaning rule.¹⁵⁰ The Supreme Court instructs that a statute should be interpreted according to “the ordinary public meaning of its terms at the time of its enactment.”¹⁵¹ Accordingly, the table below illustrates the definitions of the words contained in “currently accepted medical use” according to Webster’s Third New International Dictionary’s 1969 edition.¹⁵²

Word	Definition
“current”	“In genuine knowledge, acceptance use or practice; prevalent, accustomed, general; commonly accepted, engaged in, followed, used, or practice; in vogue; contemporary” ¹⁵³
“currently”	“Fluently, readily; at present <~ engaged in scientific research <~ running at the local theater>” ¹⁵⁴

146. *Id.*

147. *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1825 (2020) (Alito, J., dissenting).

148. *Davis v. Michigan Dep’t of Treas.*, 489 U.S. 803, 809 (1989).

149. *See, e.g., Gen. Elec. Co. v. Gilbert*, 429 U.S. 125, 143 (1976) (noting the significance of the, albeit brief, legislative history of Title VII of the Civil Rights Act in the context of sex discrimination). *But see Bostock*, 140 S. Ct. at 1750 (noting that “legislative history can never defeat unambiguous statutory text”).

150. ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 69 (2012) (“The ordinary-meaning rule is the most fundamental semantic rule of interpretation.”).

151. *Bostock*, 140 S. Ct. at 173.

152. WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY (Philip Babcock Gove et al. eds., 1969).

153. *Id.* at 557.

154. *Id.*

“accepted”	“Generally approved; widely used or found <there are three ~ types of pump>; generally agreed upon <~ interpretation of the poem>” ¹⁵⁵
“acceptable”	“Capable or worthy of being accepted <no compromise could ever be ~>” ¹⁵⁶
“medical”	“Of, relating to, or concerned with physicians or with the practice of medicine often as distinguished from surgery” ¹⁵⁷
“use”	“The act or practice of using something” ¹⁵⁸

Simply interchanging “currently accepted” with their respective definitions above indicates that the phrase means “generally agreed upon at present.” Although the temporal element is unambiguous, the phrase “generally agreed upon,” because of its passive voice, is ambiguous vis-à-vis its subject. Put differently, “generally agreed upon” by whom? Was Congress referring to private medical professionals, researchers, or the general public? The plain meaning analysis thus does not extinguish the ambiguity surrounding “accepted.”

2. Overall Statutory Scheme

The plain meaning analysis can be supplemented by reading the statutory language in its context, with a view of its place in the overall statutory structure of the CSA.¹⁵⁹ Section 811 authorizes the Attorney General to add, remove, and reschedule substances.¹⁶⁰ Subsection 811(a) also specifically identifies the HHS Secretary as a party able to request the Attorney General to adjust a drug’s scheduling status, even though “any interested party” can similarly petition the Attorney General.¹⁶¹ It is noteworthy that Congress singled out the HHS Secretary, notwithstanding her legal empowerment under subsection 811(a) as a potential “interested party.”¹⁶² Significantly, subsection 811(b) requires the Attorney General, “before initiating proceedings under subsection 811(a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules,” to

155. *Id.* at 11.

156. *Id.*

157. *Id.* at 1402.

158. *Id.* at 2523.

159. See *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) (“Statutory language . . . cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.”) (internal quotation marks omitted).

160. 21 U.S.C. § 811(a).

161. *Id.*

162. *Id.*

“gather[] the necessary data,” and to “request from the [HHS] Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled.”¹⁶³ The subsection, in turn, requires the HHS Secretary to “consider” eight factors during the evaluation.¹⁶⁴ The HHS evaluation is then “binding on the Attorney General as to such scientific and medical matters, and if the [HHS] Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.”¹⁶⁵ The foregoing indicates that Congress granted considerable authority to HHS, requiring the Attorney General not only to seek its evaluation prior to scheduling proceedings, but also requiring the Attorney General to remove a drug from CSA control if HHS so recommends.¹⁶⁶

The considerable authority and deference Congress granted to HHS in section 811 cures the ambiguity noted above: when Congress said “accepted,” they likely meant “accepted by HHS.” The fact that the word “accepted” is followed by the words “medical use” supports this interpretation because HHS is “the U.S. Government’s principal agency for protecting the health of all Americans,”¹⁶⁷ in stark contrast to the Attorney General’s function—the federal government’s “chief law enforcement officer.”¹⁶⁸

The Supreme Court’s evaluation of the Attorney General’s powers under the CSA in *Gonzales v. Oregon*¹⁶⁹ further supports the conclusion that Congress likely did not intend the phraseology it selected—“currently accepted medical use”¹⁷⁰—to be interpreted by the Attorney General. The

163. § 811(b).

164. *Id.* HHS is required to consider eight factors—set forth in subsection 811(c)—with respect to the drug or substance:

- (1) Its 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.
- (8) Whether the substance is an immediate precursor of a substance already controlled under [subchapter I of 21 U.S.C.].

§ 811(c).

165. § 811(b).

166. *See id.* (“[I]f the [HHS] Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.”).

167. *Introduction: About HHS*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (Feb. 28, 2018), <https://www.hhs.gov/about/strategic-plan/introduction/index.html> [<https://perma.cc/AA76-YUSA>].

168. *About the Office*, U.S. DEP’T OF JUST. (July 17, 2018), <https://www.justice.gov/ag/about-office> [<https://perma.cc/Y3Q5-NFAC>].

169. 546 U.S. 243 (2006).

170. 21 U.S.C. § 812(b)(1)(B).

Oregon Court emphasized the limitation on the Attorney General's powers described above when it analyzed the CSA's overall statutory scheme.¹⁷¹ In *Oregon*, the Court noted that the "CSA gives the Attorney General limited powers, to be exercised in specific ways."¹⁷² It emphasized that the Attorney General "can promulgate rules relating only to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute."¹⁷³ The Court also noted that various sections of the CSA use the words "accepted" and "legitimate" interchangeably.¹⁷⁴ Significantly, the Court made clear that "the statutory terms 'public interest' and 'public health' do not call on the Attorney General, or any other executive official, to make an independent assessment of the meaning of federal law."¹⁷⁵

Congress also likely intended to ensure the CSA's schedules be harmonized with the constant variations of what constitutes "accepted" and "legitimate" in the medical community. This can be gleaned by the placement of the word "currently" immediately before "accepted medical use" in § 812(b)(1)(B) of the CSA.¹⁷⁶ Moreover, section 812 requires the Attorney General to update and republish the schedules at least once a year.¹⁷⁷ Viewed together, § 812(b)(1)(B)'s use of the word "currently"¹⁷⁸ is synchronous with subsection 812(a)'s updating requirements.¹⁷⁹ Thus, because the CSA in subsection 811(a) requires the Attorney General to update the schedules at least once a year,¹⁸⁰ and because the ordinary meaning of "currently" in 1969 was "at present,"¹⁸¹ Congress likely intended to tether Attorney General's evaluation of a drug's "accepted medical use" with the medical community's assessment of that drug on an annual basis. Simple logic supports this conclusion: a drug which may not have been known to the medical community as an accepted treatment last year may become "accepted" this year as a result of, say, a successful clinical trial. For example, between 2000 and 2008, the FDA approved twenty-three drugs per year on average.¹⁸² This fact illustrates the continuous evolution of the medical community's evaluation of treatments:

171. *Gonzales*, 546 U.S. at 259.

172. *Id.*

173. *Id.*

174. *Id.* at 257.

175. *Id.* at 263.

176. See 21 U.S.C. § 812(b)(1)(B).

177. § 812(a) ("[T]he schedules . . . be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and . . . on an annual basis thereafter.").

178. § 812(b)(1)(B).

179. See § 812(a).

180. § 811(a).

181. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, *supra* note 152, at 557.

182. See Angelika Batta, Bhupinder Singh Kalra & Raj Khirasaria, *Trends in FDA Drug Approvals Over Last 2 Decades: An Observational Study*, 9 J. FAM. MED. & PRIMARY CARE 105, 105 (2020).

what may not have been an “accepted” drug yesterday may become an “accepted” drug tomorrow. Congress likely recognized this reality when it qualified the phrase “accepted medical use” with the word “currently.”

This line of analysis is supported by the drafters of the CSA. In a book they co-authored following the CSA’s enactment, Robert L. Bogomolny, Michael R. Sonnenreich, and Anthony J. Roccograndi explained that “the intent of the scheduling system and its greatest value is in the practicality and ability to adjust the regulatory framework.”¹⁸³ Its “true test,” they predicted, would be in “loosening restraints when justified. A scheme that is directly only towards tighter and tighter controls will, in time, lose its most important attributes, flexibility, and the capacity to adjust to changing social circumstances.”¹⁸⁴

3. Legislative History

The CSA’s legislative history buttresses the conclusion that Congress was referencing the medical community—and, more particularly, to HHS—when it used the word “accepted” in § 812(b)(1)(B).¹⁸⁵ Legislative history can provide an opportunity to understand a statute’s meaning across different times and contexts,¹⁸⁶ which is instructive in discerning Congress’s understanding of the phrase “currently accepted medical use” when it enacted the CSA. A litigant in the Ninth Circuit, as part of a marijuana rescheduling challenge to the 1992 Test, recently made persuasive arguments as to why the CSA’s legislative history supports an interpretation not dissimilar from the legislative history analysis below.¹⁸⁷

The CSA’s legislative history indeed provides revealing clues. During the CSA’s debate in the Senate, Senator Harold Hughes used the words “accepted,” “recognized,” and “valid” interchangeably:

Classification in the bill depends primarily upon whether there is an accepted medical use for the drug. Because heroin and marihuana have no recognized medical use, they are classified in the same

183. BOGOMOLNY, SONNENREICH & ROCCOGRANDI, *supra* note 71, at 28.

184. *Id.* at 75–76.

185. See 21 U.S.C. § 812(b)(1)(B).

186. See *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1750 (2020). In *Bostock*, The Supreme Court similarly discerned Congress’s intent when it used the words “because of” and “sex” in the Civil Rights Act of 1964 over fifty years later. *Id.* at 1739.

187. Petitioners’ Brief at 53–55, *Sisley v. DEA*, No. 20-71433, 2021 WL 3853049 (9th Cir. Aug. 30, 2021). As of this writing, the litigant’s rescheduling petition was denied on failure of exhaustion grounds. *Sisley*, 2021 WL 3853049, at *6. On the merits, however, Judge Watford acknowledged “the strength of petitioners’ arguments that the [DEA] has misinterpreted the controlling statute by concluding that marijuana ‘has no currently accepted medical use in treatment in the United States.’” *Id.* (Watford, J., concurring).

category. . . . If there is no valid use for a drug, there is a sound reason to impose the strictest manufacturing and record-keeping controls. But criminal sanctions for illegal distribution and use should be based upon the danger to society and the individual, not upon whether there is any valid medical use.¹⁸⁸

Testimony from the bill's original drafters, Michael Sonnenreich and John Ingersoll,¹⁸⁹ shed further light on the meaning of "accepted medical use" as used in the CSA.¹⁹⁰ During the CSA's pre-enactment congressional subcommittee hearings, Sonnenreich explained that:

[S]chedule I drugs . . . are really different from . . . [Schedule] II, III, and IV drugs. It is this basic determination that is not made by any part of the Federal Government. *It is made by the medical community* as to whether or not the drug has medical use or doesn't.¹⁹¹

Sonnenreich further elaborated that "currently accepted medical use":

is a factual determination and normally where [BNDD] get[s] such information is through the [American Medical Association] or [the World Health Organization]. You don't have to be a doctor to find out whether or not it has an accepted medical use in the United States or not. So the fact that you are asking whether it has got accepted medical use is something that a lawyer can find out as well as a doctor. I mean it is not something that you are going out to create research on.¹⁹²

In a book he co-authored following the CSA's enactment, Sonnenreich validated Congress's likely understanding of the word "*accepted*" when he explained that Schedule I is reserved for drugs with "no *legitimate* medical

188. 116 CONG. REC. 36,882 (1970) (emphasis added).

189. GERALD POSNER, PHARMA: GREED, LIES, AND THE POISONING OF AMERICA 256–57 (2020). Michael Sonnenreich drafted the initial version of the bill that was eventually enacted. *Id.* At the time, he was Deputy Chief Counsel of the Bureau of Narcotics and Dangerous Drugs (BNDD), DEA's predecessor agency, and John Ingersoll was its Director. *Grinspoon v. DEA*, 828 F.2d 881, 891–92 (1st Cir. 1987).

190. *See, e.g., Bostock*, 140 S. Ct. at 1750 (noting that courts sometimes consult "the understandings of the law's drafters" as evidence to resolve "shifts in linguistic usage or subtle distinctions between literal and ordinary meaning"); *Udall v. Tallman*, 380 U.S. 1, 16 (1965) (giving weight to a law's drafters' understanding of a statute when the interpretative question involved "a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion, of making the parts work efficiently and smoothly while they are yet untried and new") (internal quotation marks omitted).

191. *Drug Abuse Control Amendments—1970: Hearings on H.R. 11701 and HR 13743 Before the Subcomm. on Pub. Health and Welfare of the H. Comm. on Interstate and Foreign Com.*, 91st Cong., 718 (1970) (emphasis added) [hereinafter *Drug Abuse Control Amendments*].

192. *Id.* at 165.

use.”¹⁹³ During the same congressional hearings noted above, John Ingersoll endorsed Sonnenreich’s understanding of “accepted medical use.”¹⁹⁴ Ingersoll elucidated that Schedule I is reserved for those substances “which the medical profession *has already determined* have no legitimate medical use in the United States.”¹⁹⁵ In sum, the CSA’s legislative history reveals that Congress intended to limit Schedule I to illicit drugs for which medical community has found no legitimate or valid use.

B. DEA’s Interpretation of Its Own Rule

Even if the 1992 Test continues to pass legal muster under *Iancu*, it may be deficient because the DEA’s own interpretation of the 1992 Test’s third factor—whether a drug has “adequate and well controlled studies proving efficacy”¹⁹⁶—is ambiguous.¹⁹⁷ In determining whether a drug has adequate and well controlled studies proving efficacy, the DEA has in turn required a showing of “adequate, well-controlled, well-designed, well-conducted, and well-documented studies.”¹⁹⁸ This requirement places an onerous burden on a petitioner because it adds three additional hurdles: an “adequate and well controlled study” must essentially *also* be (1) well-designed, (2) well-conducted, and (3) well-documented.¹⁹⁹ Not only did the DEA render one of its own factors more stringent, it also has not articulated what constitutes a well-designed, well-conducted, and well-documented study, leaving its own interpretation ambiguous.²⁰⁰

Justice Kagan’s markers in *Kisor v. Wilkie* are instructive in evaluating whether deference to the DEA with respect to the third factor is warranted.²⁰¹ The most significant marker of Justice Kagan’s test in this case is the second one—that “the agency’s interpretation must in some way implicate its substantive expertise.”²⁰² The DEA’s interpretation of the third factor of the 1992 Test does not “implicate its substantive expertise” in any

193. BOGOMOLNY, SONNENREICH & ROCCOGRANDI, *supra* note 71, at 27 (emphasis added).

194. See *Grinspoon*, 828 F.2d at 892 (noting that Ingersoll’s testimony limited Schedule I substances to “those drugs that ‘the medical profession has already determined to have no legitimate medical use in the United States.’”).

195. *Drug Abuse Control Amendments*, *supra* note 191, at 678 (statement of John E. Ingersoll, Director, Bureau of Narcotics and Dangerous Drugs) (emphasis added).

196. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,506 (Mar. 26, 1992).

197. Marks, *supra* note 10, at 118–19.

198. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,579 (July 8, 2011).

199. See *id.*

200. See Marks, *supra* note 10, at 119.

201. See discussion *supra* Section I.B.

202. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2406 (2019).

cognizable way. The DEA is a law enforcement agency,²⁰³ whereas interpretation of what constitutes “adequate and well-controlled studies” is a matter that implicates *public health*.²⁰⁴ Indeed, federal regulations concerning “adequate and well-controlled studies” were promulgated by the Food & Drug Administration, an HHS agency.²⁰⁵ HHS, in turn, requires only a “consensus of medical opinion” among “experts” for a drug to meet the “accepted by qualified experts” factor of the 1992 Test.²⁰⁶ It is therefore unlikely that the DEA’s interpretation is legal under *Kisor*’s second marker.

Arguably, though, Justice Kagan’s “markers” may not be dispositive. After all, “markers” are more like guideposts, indicators, or factors of a test rather than elements of a test.²⁰⁷ Indeed, Justice Kagan was clear that the “markers” were created in lieu of an “exhaustive test.”²⁰⁸ However, following *Kisor*,²⁰⁹ federal district courts began rejecting deference to agency interpretations of ambiguous regulations “based on the character and context of the interpretation.”²¹⁰ For example, In *Belt v. P.F. Chang’s China Bistro*, the Eastern District of Pennsylvania did not defer to the Department of Labor’s interpretation of an ambiguous regulation because the interpretation did not meet Justice Kagan’s third marker—it did not reflect the agency’s “fair and considered judgment.”²¹¹ Thus, it is unclear whether the DEA’s interpretation of the third factor of the 1992 Test is entirely illegal, even though it is likely insufficient to meet Justice Kagan’s second “marker.” Regardless, the DEA’s interpretation is at the very least threatened because it unequivocally fails to meet the second marker.

203. The DEA is an agency of the U.S. Department of Justice. DRUG ENF’T ADMIN., HISTORY: THE EARLY YEARS 29, <https://www.dea.gov/sites/default/files/2018-07/Early%20Years%20p%2012-29%20%281%29.pdf> [<https://perma.cc/DPZ5-AH44>].

204. Indeed, federal regulations concerning “adequate and well-controlled studies” were promulgated by the Food & Drug Administration, a Department of Health and Human Services agency. See 21 C.F.R. § 314.126 (2020). The regulations set forth detailed “characteristics” of an “adequate and well controlled study.” See §§ 314.126(b)(1)–(b)(7). Cf. *King v. Burwell*, 576 U.S. 473, 486 (2015) (setting aside an Internal Revenue Service rule and substituting it with a judicial interpretation in part because it was inconceivable that Congress intended the IRS to craft health insurance regulations).

205. See § 314.126.

206. Notice of Denial of Petition, 66 Fed. Reg. 20,038, 20,051–20,052 (Apr. 18, 2001).

207. See Michael R. Smith, *Elements v. Factors*, 39 WYO. LAW. 46, 46–47 (2016). (“A factor test in the law sets out a list of areas of inquiry a court must consider in determining whether a particular legal conclusion can be reached. . . . No single factor is dispositive of the issue.”).

208. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2416 (2019).

209. *Id.*

210. Ferrara, *supra* note 138, at 236.

211. 401 F. Supp. 3d 512, 531 (E.D. Pa. 2019).

C. Applicability (or Lack Thereof) of Chevron to Dual-Application Statutes

The fact that the CSA is a dual-application statute supports a lenient interpretation of “currently accepted medical use.”²¹² Although the Supreme Court has not plainly stated that *Chevron* deference is unwarranted to laws that contemplate both civil and criminal enforcement,²¹³ it has held that “if a law has both criminal and civil applications, the rule of lenity governs its interpretation in both settings.”²¹⁴ As outlined above, the rule of lenity favors a more lenient interpretation of a statute’s provision among two rational readings of the provision. The 1992 Test, which created five distinct and unrelated barriers in the form of a five-factor conjunctive test, cannot be reasonably construed as a lenient interpretation. There is undoubtedly a countless number of possible reasonable interpretations that are more lenient than the 1992 Test. This author’s modest interpretation, proposed below, is but one of many interpretations that could arguably be reasonably characterized as more lenient than the 1992 Test.

III. “CURRENTLY ACCEPTED MEDICAL USE”: A PRAGMATIC WAY FORWARD

Given the considerations and dimensions of the analysis above, a synthesis of the CSA’s structure, purpose, and legislative history illuminates a reasonable interpretation of “currently accepted medical use” for purposes of the Attorney General’s scheduling authority under the CSA, legal under *Chevron* and its progeny: *A drug or substance has “no currently accepted medical use” only if HHS has made a determination within the past year that the drug or substance has no legitimate or valid use in the United States.* This interpretation comports with the CSA’s plain language, structure, purpose, and intent. The DEA is warranted no deference because the traditional tools of statutory construction cure the ambiguity surrounding “currently accepted medical use.”

Further, the proposed interpretation satisfies the rule of lenity, which, as noted above, governs the interpretation of the civil provisions in a dual-application statute.²¹⁵ The rule of lenity favors a more lenient interpretation

212. See Petitioner’s Brief at 68–69, *Sisley v. DEA*, No. 20–71433 (9th Cir. Aug. 30, 2021).

213. See *Whitman v. United States*, 574 U.S. 1003, 1004 (2014) (Scalia, J., concurring in denial of certiorari).

214. *Id.* at 1005. See also *Leocal v. Ashcroft*, 543 U.S. 1, 11–12 n.8 (2004) (applying the rule of lenity to the noncriminal provision of a dual-application statute); *United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 518 n.10 (1992) (plurality opinion) (same); *id.* at 519, (Scalia, J., concurring in the judgment)).

215. See *Whitman*, 574 U.S. at 1004 (Scalia, J., concurring in denial of certiorari).

of a statute's provision among two rational readings of the provision.²¹⁶ Between the 1992 Test, which essentially synonymizes the four words of a provision—"currently accepted medical use"—into five distinct and unrelated factors,²¹⁷ and this author's interpretation—a drug or substance has "no currently accepted medical use" only if HHS has made a determination within the past year that the drug or substance has no legitimate or valid use in the United States—the latter is certainly more lenient. It vindicates the principles that only Congress may define federal crimes and determine punishments, and that Congress "cannot, through ambiguity, effectively leave that function to the courts—much less to [an] administrative bureaucracy"²¹⁸ such as the DEA.

Practical considerations militate in favor of the proposed interpretation. Applied here, this test compels the DEA to remove MDMA and psilocybin from Schedule I because HHS has not determined that either drug has no legitimate or valid use in the United States. This does not mean that, under the proposed interpretation, the drugs would need to be removed entirely from CSA control because the DEA could properly find them to be suitable to a less restrictive schedule.²¹⁹ For example, alprazolam (commonly known as Xanax) is a Schedule IV drug,²²⁰ and was prescribed over twenty-five million times in 2019 for the treatment of panic and anxiety disorders.²²¹ Thus, under a proper interpretation of "currently accepted medical use," the DEA would retain a suitable level of control, in tandem with wider researcher and patient access to MDMA and psilocybin. Equally, it would incentivize more communication and coordination between HHS and the DEA (since the DEA would effectively require an HHS determination *before* classifying a drug in Schedule I). This in turn may favor the prioritization of public health considerations going forward as opposed to predilections of bureaucrats, which in turn would promote a more rational and coherent national drug policy that better comports with the CSA's purpose.

The only plausible alternative to a federal solution—a patchwork of discontinuous state and local laws—would unnecessarily impede safe, equitable, and urgent patient access to MDMA and psilocybin. MDMA and

216. See *McNally v. United States*, 483 U.S. 350, 359–60 (1987).

217. See *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 Fed. Reg. 10,499, 10,506 (Mar. 26, 1992).

218. *Whitman*, 574 U.S. at 1005 (Scalia, J., concurring in denial of certiorari).

219. See 21 U.S.C. § 812(b)(1)–(b)(5) (setting forth the criteria for Schedules II–V).

220. *Controlled Substances*, *supra* note 30.

221. *The 50 Most Commonly Prescribed Drugs in America and Their Average Price*, DRUG REP. (Mar. 23, 2020), <https://www.drugreport.com/50-commonly-prescribed-drugs-in-america/#sources-links> [<https://perma.cc/J65K-2WCA>].

psilocybin were historic “causalities” of the war on drugs,²²² and the “psychedelic renaissance” demonstrates that cities and states are quickly beginning to recognize their untapped potential by taking measures to ensure those who need these types of treatments can legally access them.²²³ Such a clash between federal and state law in the drug regulation context is not new:²²⁴ the disparate regulation of marijuana between the state and federal levels illustrates this phenomenon.²²⁵ As of 2021, forty-seven states and the District of Columbia have legalized marijuana or cannabidiol, for either medical or recreational use, or both.²²⁶ Yet, like MDMA and psilocybin, marijuana remains on Schedule I of the CSA, and congressional efforts to change that fact are still largely falling on deaf ears.²²⁷ Moreover, the state deregulation of marijuana occurred discontinuously over twenty years.²²⁸ This disjointed approach lays bare the pitfalls of a federalism-based, state-led solution to drug deregulation: it can take decades and requires patients to assume the risk of federal prosecution, notwithstanding their compliance with state law.²²⁹

These pitfalls need not be repeated here. As Professor Marks aptly tweeted, “What might have happened if the psychedelics research of the 1950s and 60s had been allowed to continue? How many lives could have been saved?”²³⁰ These questions underscore both the urgency and ultimate conclusion: only a federal rescheduling of MDMA and psilocybin would ensure immediate, uniform, and equitable access in all U.S. states and territories to millions of Americans living with the debilitating disorders of severe depression and PTSD, whose suffering has only been exacerbated by the COVID-19 pandemic.²³¹ Rescheduling would also stimulate further

222. See Marks, *supra* note 17, at 666.

223. See discussion *supra* Introduction.

224. Joëlle Anne Moreno, *Half-Baked: The Science and Politics of Legal Pot*, 123 PENN ST. L. REV. 401, 406–07 (2019).

225. *Id.*

226. Christian Nunley, *Democratic Senators Will Push to Pass Pot Reform Bill This Year*, CNBC (Feb. 1, 2021, 6:58 PM), <https://www.cnbc.com/2021/02/01/cannabis-reform-senators-say-they-will-push-pot-bill-in-2021.html> [<https://perma.cc/S7Q8-MNY5>]; Michael Hartman, *Cannabis Overview*, NAT’L CONF. ST. LEGISLATORS (July 6, 2021), <https://www.ncsl.org/research/civil-and-criminal-justice/marijuana-overview.aspx> [<https://perma.cc/P7SE-2Z2S>].

227. Nathalie Bougenies, *Is 2021 the Year Marijuana Becomes Federally Legal? Probably Not.*, ABOVE THE L. (June 22, 2021, 5:01 PM), <https://abovethelaw.com/2021/06/is-2021-the-year-marijuana-becomes-federally-legal-probably-not/> [<https://perma.cc/5TFR-JJCV>].

228. Moreno, *supra* note 224, at 406–07.

229. See Moreno, *supra* note 224, at 442 (discussing “whether, in jurisdictions where marijuana is now legal, it is physically impossible to comply with both state and federal law”).

230. Mason Marks (@MasonMarksMD), TWITTER (Oct. 24, 2021, 4:48 PM), <https://twitter.com/MasonMarksMD/status/1452391529205559296> [<https://perma.cc/E8MS-SGC6>].

231. Marks, *supra* note 17, at 651. See also Marks, *supra* note 27 (opining that the judicial path to rescheduling psilocybin (as opposed to Congressional or DEA action), is likely the “most effective” path).

medical research and innovation.²³² But for that to happen, federal courts must recognize the “regulatory black hole” they enabled in their broad deference to the DEA’s interpretation of “currently accepted medical use,”²³³ deference that is no longer warranted under current Supreme Court jurisprudence.

IV. CONCLUSION

This Note has presented the primary legal challenge that is restricting nationwide access to MDMA and psilocybin qualifying patients. It has also illustrated the limitations of a state-based approach by reviewing the drawbacks of the limited and staggered deregulation of another Schedule I substance (marijuana). The statutory interpretation analysis has demonstrated that Congressional amendments to the CSA may not be necessary because proper interpretation of “currently accepted medical use” for purposes of Schedule I classification forecloses the DEA from continuing to classify MDMA and psilocybin in Schedule I of the CSA.

There are several additional legal, social, and practical obstacles that may hinder patient access to MDMA and psilocybin, notwithstanding their Schedule I status. First, the United States is a party to the United Nations Convention of Psychotropic Substances,²³⁴ a treaty that imposes certain control obligations on its parties relating to particular psychoactive drugs that may hinder a federal rescheduling of MDMA and psilocybin.²³⁵ Second, the negative social stigma associated with MDMA and psilocybin among patients and medical professionals still exists, although it has waned significantly in recent years.²³⁶ Although these are considerable challenges, they are arguably subordinate to the federal regulatory framework governing the interpretation of “currently accepted medical use” under the CSA. Resolving these obstacles would not result in any meaningful impact

232. See Marks, *supra* note 27.

233. See *id.* at 677.

234. The International Drug Control Conventions, *Schedules of the Convention on Psychotropic Substances of 1971*, U.N. Doc. ST/CND/1/Add.2/Rev.7 (Dec. 7, 2021).

235. The International Drug Control Conventions, *Single Convention on Narcotic Drugs of 1961* as amended by the 1972 Protocol art. 2, Mar. 30, 1961, 18 U.S.T. 407, 520 U.N.T.S. 151.

236. Mason Marks, *Drug Regulation for the COVID-19 Mental Health Crisis*, HARV. L. & POL’Y REV. BLOG (May 30, 2020), <https://harvardlpr.com/2020/05/30/drug-regulation-for-the-covid-19-mental-health-crisis/> [https://perma.cc/N97M-Z8MD].

* J.D. Candidate (2022), Washington University School of Law; M.B.A. (2018), Columbia University; B.S. (2006), Northwestern University. I would like to thank my fellow editors at the *Washington University Law Review* for their invaluable contributions, most especially Frank Cascone, Sara Hubaishi, Maya Kieffer, Clare Martin, and Robert Neel. Equally, a special thanks to my dear brother Fahad and devoted friend Fay Al-Tukhaim for their engagement and support throughout the writing process.

to struggling patients until “currently accepted medical use” is properly interpreted by the federal courts.

*Nabil Al-Khaled**