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A (LOPER) BRIGHT FUTURE?: HOW THE SUPREME COURT OPENED A PATH FOR DRUG REFORM

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Jack Malich*

We are witnessing a sweeping transformation of administrative law. The Supreme Court has taken aim at what it believes is a constitutional error: the power of the administrative state. All parts of the so-called "fourth branch of government" are undergoing shifts in the legal doctrines governing their structure. For those in favor of a strong administrative state, most of the Court's new approach to agency action may represent a sinister effort to prevent the making of disfavored policy by the Executive. However, advocates of agency power would do well to remember that the administrative state can be oppressive. No agency may better represent how the "fourth branch" can harm disadvantaged populations than the Drug Enforcement Administration and its harsh regulation and punishment of psychoactive substance use in the United States. The Biden Administration decided to reevaluate the DEA's approach to the regulation of marijuana, but the problem runs deeper than any one substance, and the Biden Administration's efforts could easily be reversed. The Court's remaking of administrative law offers a more permanent solution. This revolution in administrative law comes at a time when constitutional challenges to the war on drugs are unlikely to succeed. The current Supreme Court is unlikely to rule in favor of plaintiffs bringing innovative constitutional challenges to the current drug regime using the Equal Protection Clause, Free Speech Clause, or a newly unearthed freedom-of-thought. Religious liberty claims offer a promising alternative but are unlikely to provide the widespread reform that is needed. The right to use drugs is unlikely to be "deeply rooted in tradition and history" in a way the current makeup of the Court would recognize. If there is any judicial path to weakening

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the current drug regime, the best way forward appears to be through administrative law.

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I. INTRODUCTION

Over the last decade, the Supreme Court has challenged what it sees as a constitutional overreach: the expanding power of the administrative state.[1] All parts of the so-called "fourth branch of government" have

1. Timothy Noah, *The Supreme Court Sounds Eager to Break the Government for Good*, THE NEW REPUBLIC (Jan. 18, 2024), https://newrepublic.com/article/178210/supreme-court-chevron-administrative-state; City of Arlington, Tex. v. F.C.C., 569 U.S. 290, 315 (2013) (Roberts, C.J., dissenting) ("It would be a bit much to describe the result as "the very definition of tyranny," but the danger posed by the growing power of the administrative state cannot be dismissed."); NEIL GORSUCH & JANIE NITZE, OVERRULED: THE HUMAN TOLL OF TOO MUCH LAW (2024) (describing the administrative state's danger to the average American citizen).

been weakened by various judicial decisions passed down by the Roberts Court.[2]

The list of wounds inflicted by the Court is long. In three decisions striking down agency action, the Court heightened its arbitrary and capricious standard of review.[3] The newly introduced major questions doctrine outlined in *West Virginia v. EPA*, the COVID cases, and *Biden v. Nebraska* reduces the ability of the executive to make major policy changes through interpretations of statutes.[4] Deference to agency interpretations of their own regulations has been limited.[5] In a final blow, the Court overruled perhaps the most important precedent in administrative law, *Chevron v. Natural Resources Defense Council*, and in doing so removed a long standing doctrine of federal court deference towards agencies' interpretations of their governing statutes.[6] These dramatic changes are already having an effect on lower court analysis of the lawfulness of agency decision-making.[7]

For those in favor of a strong administrative state, most of the Court's new approach to agency action represents an ideologically motivated and partisan effort to weaken the executive branch in favor of the judiciary.[8] However, advocates of agency power would do well to remember that the administrative state can be oppressive, especially

2. *See, e.g.*, W. Va. v. EPA, 597 U.S. 697 (2022); Seila Law LLC v. Consumer Fin. Prot. Bureau, 591 U.S. 197, 240 (2020); Sec. & Exch. Comm'n v. Jarkesy, 603 U.S. 109 (2024).

3. Dep't of Com. v. New York, 588 U.S. 752 (2019); Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 591 U.S. 1 (2020).

4. *W. Va. v. EPA,* 597 U.S. at 724 (2022); Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin., 595 U.S. 109 (2022) (Gorsuch, J., concurring); Ala. Ass'n of Realtors v. Dep't of Health and Hum. Servs., 594 U.S. 758, 764 (2021); Biden v. Neb., 143 S. Ct. 2355, 2374 (2023).

5. *See, e.g.*, Kisor v. Wilkie, 588 U.S. 588, 575–76 (2019).

6. Loper Bright Enterprises v. Raimondo, 609 U.S. 369, 412 (2024).

7. Eli Sanders, *A Supreme Court Justice Warned That a Ruling Would Cause "Large-Scale Disruption." The Effects Are Already Being Felt*, PROPUBLICA (Sep. 23, 2024), https://www.propublica.org/article/supreme-court-chevron-deference-loper-bright-guns-abortion-pending-cases.

8. *Biden*, 143 S. Ct. at 2400 (Kagan, J., dissenting) ("So the majority applies a rule specially crafted to kill significant regulatory action, by requiring Congress to delegate not just clearly but also micro-specifically. The question, the majority maintains, is 'who has the authority' to decide whether such a significant action should go forward. The right answer is the political branches. . . . The majority instead says that it is theirs to decide."); Kate Shaw, *The Imperial Supreme Court*, N.Y. TIMES (June 29, 2024), https://www.nytimes.com/2024/06/29/opinion/supreme-court-chevron-loper.html ("Loper Bright and Dobbs have a great deal in common. They grow out of the same ideological project of conservative legal transformation and reflect similar hubris, recklessness and retrograde constitutional vision. And they both involve overturning precedents and shifting the law in undemocratic directions while perversely claiming the mantle of democracy.").

towards those of little means and unpopular minorities.[9] No agency may better represent how the "fourth branch" can harm disadvantaged populations than the Drug Enforcement Administration ("DEA") and its interpretation and application of the Controlled Substances Act ("CSA"), the statute at the center of drug regulation, restriction, and prohibition in the United States.[10] The DEA, in both scheduling substances and enforcing drug law, too often acts as judge, jury, and executioner.[11] The agency's often irrational and overly restrictive scheduling decisions have played a substantial role in the failure of the war on drugs.[12] The Biden administration decided to reevaluate the DEA's approach to the regulation of marijuana, but the problem runs deeper than any one substance, and that administration's efforts could

9. Buffington v. McDonough, 143 S. Ct. 14, 14 (2022) (Gorsuch, J. dissenting from the denial of cert) ("Relying on its own internal regulations, the agency denied Mr. Buffington disability benefits that Congress promised him by statute. . . . Making matters worse, the lower courts in this case turned aside Mr. Buffington's petition asking them to set aside the agency's regulations and apply Congress's statutory instructions as written. Instead, the courts invoked '*Chevron deference*,' bypassed any independent review of the relevant statutes, and allowed the agency to continue to employ its rules to the detriment of veterans."); Alina Das, *Unshackling Habeas Review: Chevron Deference and Statutory Interpretation in Immigration Detention Cases*, 90 N.Y.U. L. REV. 143, 205–06 (2015) ("As administrative agencies have begun to play an increasingly important role in the immigration detention context, one might assume that federal courts would respond with greater vigilance, not less. Yet through the application of Chevron deference, federal courts have subjugated themselves to the agency in reviewing the lawfulness of immigrants' detention.").

10. *See generally* Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332 (2013) (recounting the abuse and irrationality rife in the DEA's scheduling regime); MICHELLE ALEXANDER, THE NEW JIM CROW 60–61 (2012) (recounting the mass incarceration of racial minorities due to the war on drugs).

11. Professor David Pozen argues the Attorney General, HHS, and the DEA acted according to their institutional roles and incentives, and Congress is truly to blame. *See* David Pozen, *Reading the Tea Leaves on Marijuana Rescheduling*, BALKANIZATION (May 20, 2024). I generally agree with Professor Pozen's argument that the structure of the CSA, its ambiguous language, and the politics of drug enforcement have led the agencies and relevant actors down a somewhat deterministic path. However, regardless of whether it was inevitable or not, the DEA's unbridled authority has caused harm, and the most likely short-term solution to reducing such harm is through the federal judiciary and administrative law, not congressional change. *See* Derek Willis and Paul Kane, *How Congress Stopped Working*, PROPUBLICA (Nov. 5, 2018) ("While few of these changes made headlines, taken together they have fundamentally altered the way Congress operates — and morphed this equally powerful branch of government into one that functions more as a junior partner to the executive, or doesn't function at all when it comes to the country's pressing priorities.").

12. Troy Farah, *Thanks for Nothing, DEA. Fifty Years Later, Drugs Are Deadlier and More Abundant than Ever*, SALON.COM (July 9, 2023), https://www.salon.com/2023/07/09/thanks-for-nothing-dea-fifty-years-later-are-deadlier-and-more-abundant-than-ever/.

easily be reversed.[13] The Court's remaking of administrative law offers a more permanent solution.[14]

This revolution in administrative law comes at a time when constitutional challenges to the war on drugs are unlikely to succeed.[15] The current Supreme Court is unlikely to rule in favor of plaintiffs bringing innovative constitutional challenges to the current drug regime using the Equal Protection Clause, Free Speech Clause, or a newly unearthed freedom-of-thought rationale.[16] Religious liberty claims offer a promising alternative, but are unlikely to provide the widespread reform that is needed.[17] The right to use drugs is unlikely to be "deeply rooted in tradition and history" in a way the current makeup of the Court would recognize.[18] If there is any judicial path to weakening the current drug regime, the best way forward appears to be through administrative law.

Part II of this Article recounts the history of the DEA's scheduling regime with a focus on the agency's interpretation of the CSA, and its application of its interpretation in the scheduling of substances.

In Part III this Article analyzes the effect recent administrative law decisions and changes in executive policy will have on potential legal challenges to the DEA's scheduling regime and its scheduling decisions, discussing the flaws in the DEA's approach under current administrative

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13. Julie Tsirkin & Monica Alba, *Biden Administration Plans to Reclassify Marijuana, Easing Restrictions Nationwide*, NBC NEWS (Apr. 30, 2024, 3:47 PM), https://www.nbcnews.com/politics/joe-biden/biden-administration-plans-reclassify-marijuana-easing-restrictions-na-rcna149424 ("The Biden administration will take a historic step toward easing federal restrictions on cannabis, with plans to announce an interim rule soon reclassifying the drug for the first time since the Controlled Substances Act was enacted more than 50 years ago."); Sarah N. Lynch, *Trump Administration Drops Obama-Era Easing of Marijuana Prosecutions*, REUTERS (Jan. 4, 2018), https://www.reuters.com/article/world/trump-administration-drops-obama-era-easing-of-marijuana-prosecutions-idUSKBN1ET2J6/ ("The U.S. Justice Department on Thursday rescinded an Obama administration policy that had eased enforcement of federal marijuana laws in states that legalized the drug, instead giving federal prosecutors wide latitude to pursue criminal charges.").

14. Nabil Al-Khaled, *MDMA And Psilocybin for Mental Health: Deconstructing the Controlled Substances Act's Usage of "Currently Accepted Medical Use*," 99 WA. U. L. R. 1023, 1039 (2021) (noting the effect of the decline of *Chevron* on the tenability of DEA interpretations of the CSA).

15. *See* DAVID POZEN, THE CONSTITUTION OF THE WAR ON DRUGS 9 (2024).

16. *See generally id.*

17. *Id.* at 116–36 (recounting the narrow scope of success for religious liberty claims involving illicit substances).

18. Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 257 (2022) ("These attempts to justify abortion through appeals to a broader right to autonomy and to define one's 'concept of existence' prove too much. Those criteria, at a high level of generality, could license ***fundamental rights to illicit drug use***, prostitution, and the like.") (citing Compassion in Dying v. Washington, 85 F.3d 1440, 1445 (9th Cir. 1996) (O'Scannlain, J., dissenting from denial of rehearing en banc)); POZEN, *supra* note 15, at 9.

law doctrine and presenting a new framework for drug scheduling aligned with the doctrine.

Part IV of this Article analyzes the potential rescheduling of Psilocybin, MDMA, and LSD using the new framework put forward in Part III.

II. AN OVERVIEW OF SCHEDULING UNDER THE CSA

The CSA, passed overwhelmingly by Congress in 1970, was first considered a relatively uncontroversial piece of legislation.[19] Many felt that a unified standard for drug policy was necessary given the patchwork of legislation that was in place prior to the Act's adoption.[20] The CSA was successful in establishing a national program of drug regulation, and essentially no psychoactive substance (other than alcohol, tobacco, and caffeine) escapes regulation under the statute.[21] However, the CSA turned out to be significantly more punitive than many of those who supported it originally expected.[22] This Article will briefly discuss the CSA's scheduling provisions and the DEA's application of those provisions relevant to possible administrative law challenges.

The DEA, delegated scheduling power by the Attorney General in 1973, schedules substances mainly based on findings regarding two factors outlined in the CSA: the given substance's "currently accepted medical use" and its "potential for abuse."[23] A third factor—the substance's safety and risk of dependence—essentially restates the first two factors.[24] Additionally, before the DEA takes action, the Secretary of the Department of Health and Human Services ("HHS") is required to complete a scientific and medical analysis on the substance that is binding on the DEA as to the scientific and medical data.[25] Substances are put on schedules from I to V, with I being the most restrictive and—

19. David T Courtwright, *The Controlled Substances Act: How a "Big Tent" Reform Became a Punitive Drug Law*, 76 DRUG AND ALCOHOL DEPENDENCE 10 (2004) (recounting the origin of the CSA); Kreit, *supra* note 10.

20. Kreit, *supra* note 10, at 334–35.

21. *Id.*

22. Courtwright, *supra* note 19, at 11.

23. Kreit, *supra* note 10, at 335–345.

24. *See* 21 U.S.C. §§ 811–12; Scott Bloomberg, Alexandra Harriman & Shane Pennington, *Rescheduling Marijuana Through Administrative Action*, 76 OK. L. REV., 526–27 (2024); Kreit, *supra* note 10, at 336–37.

25. 21 U.S.C. § 811(b); Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C., 1, 4 (2024); Dep't of Health & Hum. Services, Basis For The Recommendation To Reschedule Marijuana Into Schedule I of The Controlled Substances Act at *4 (2024) (hereinafter "2024 HHS Marijuana Analysis"). The DEA is not bound by HHS's ultimate scheduling recommendation. *See* Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C., 1, 4 (2024).

at least according to the CSA's text—reserved for substances with no medical use and a high potential for abuse.[26] Schedule I is particularly restrictive. Research and production are harshly limited, and the substance cannot be prescribed or administered for any medical purpose.[27]

Under the DEA's interpretation of the CSA, substances with medical uses are scheduled between I and V based on their level of potential for abuse and risk of dependence.[28] Congress made initial scheduling decisions in 1970, but provided the DEA with authority to both schedule newly discovered substances and to reschedule substances based on changes to the factors listed in the CSA.[29] The process for rescheduling a substance can be initiated by the DEA, HHS, or a petition from any interested party.[30] Once initiated, the process includes an analysis of scientific and medical data by HHS, a scheduling recommendation by HHS, and a final decision on rescheduling by the DEA.[31]

It is unclear exactly how the DEA should evaluate substances based on these three findings. Currently, the DEA claims that any substance without an accepted medical use should be on Schedule I, the most restrictive schedule.[32] However, substances without a medical use have (coincidentally) always been found to have a "high potential for abuse" under the scheduling regime.[33]

In addition to the three findings above, the relevant text of the CSA holds that the Attorney General, in evaluating where to schedule a drug, should consider the following eight factors:

> (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)

26. *See* 21 U.S.C. §§ 812(b); Bloomberg et al., *supra* note 24, at 526–527; Kreit, *supra* note 10, at 335–345.

27. Kreit, *supra* note 10, at 350–354.

28. 21 U.S.C. §§ 812(b); Bloomberg et al., *supra* note 24, at 526.

29. 21 U.S.C. §§ 811(a); Bloomberg et al., *supra* note 24, at 525–26.

30. *See* 21 U.S.C. § 811.

31. Bloomberg et al., *supra* note 24, at 526.

32. Kreit, *supra* note 10, at 341.

33. *Id.* at 342 ("Strangely, forty-three years into the CSA's existence, this problem has yet to be tested in any judicial or administrative opinion. This is so only because the DEA appears never to have found a substance without an accepted medical use to have a low abuse potential.").

> Whether the substance is an immediate precursor of a substance already controlled under this subchapter.[34]

The interplay between the eight-factor test and the required findings is far from clear.[35]

Using this panoply of factors and findings, the DEA places a substance in Schedules I through V. Many substances with questionable potential for harm and in-depth clinical data behind medical use have been placed into Schedule I, while more deadly and addictive substances have been put on schedules II–V.[36] This inconsistency has been criticized.[37]

To be fair to Congress, there is nothing inherently wrong with the findings required or the eight outlined factors, other than the lack of guidance on how to balance the sum of the eleven scheduling components listed. Most would agree that the use of unsafe, addictive, and hazardous substances without a medical use should be limited. The eight factors on their own do not strike one as irrational. The DEA's interpretation and application of the text is where the problem lies.

Prior to 2024, the DEA determined whether a drug had an "accepted medical use" by applying a five-factor test:[38] (1) the drug's chemistry is known and reproducible, (2) there are adequate safety studies, (3) there are adequate and well-controlled studies showing efficacy, (4) the drug is accepted by qualified experts, and (5) the scientific evidence is widely available.[39] The DEA only turned to this interpretation after two much more restrictive tests were rejected by circuit courts.[40] This test has thus

34. 21 U.S.C. § 811(c).

35. Kreit, *supra* note 10, at 344 ("The exact relationship between these eight 'factors' and the three 'findings required for each of the schedules' remains somewhat mysterious . . . The list exhibits circular reasoning and lack of parallelism, particularly when viewed together with the definitions of the schedules. The first factor 'actual or relative potential for abuse' appears to duplicate the first scheduling finding, which also measures potential for abuse.").

36. POZEN, *supra* note 15, 53–54 ("Whatever unholy mix of forces lay behind it, the CSA's classification matrix struck critics at the time as a kind of Bizarro World of drug regulation: not merely outdated or overbroad but, in important respects, the opposite of what rational risk assessment called for. And so, it still seems to many.").

37. *Id.*

38. FDA approval of a substance is another path for a "medical use" finding, but FDA approval is more difficult than even the DEA's restrictive five-part test. *See*, Robert A. Mikos, *Marijuana and the Tyrannies of Scheduling*, 93 FORDHAM L. REV 473, 482 (2024).

39. Denial of Pet. to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688, 53714 (Aug. 12, 2016) [hereinafter "2016 Denial"].

40. *See* Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 884 (1st Cir. 1987) (rejecting a DEA interpretation of medical use as meaning approved for interstate marketing by the FDA under the FDCA.); Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., 930 F.2d 936, 940 (D.C. Cir. 1991) [hereinafter *Alliance I*] (rejecting an eight-factor test for medical use as arbitrary and capricious where three of the factors in the Administrator's eight-factor test appeared impossible to fulfill.).

far been upheld as a reasonable interpretation of the CSA, but only where a court has invoked *Chevron* deference.[41]

The DEA has construed the test such that several of the requirements are extremely difficult, if not impossible, for a substance that has been placed on Schedule I to fulfill.[42] The agency heavily restricts research on Schedule 1 substances to prevent "leakage" of the substance to unauthorized and illicit use.[43] The DEA then requires safety studies and scientific data similar in scientific rigor to what the FDA requires for a New Drug Application (NDA), a high bar to reach when research is limited.[44] Application of the test seems to suggest a substance needs to pass each of the five factors for the DEA to find an "accepted medical use," further restricting the ability of petitioners to prove a substance is medically useful.[45] The end result is a system that makes it nearly impossible to reschedule a substance without executive branch assent because the DEA has many paths to restricting or excluding scientific evidence that a substance does in fact have a medical use.[46]

However, on April 11, 2024, the Biden Administration's Office of Legal Counsel ("OLC") released an opinion calling the DEA's interpretation of the "accepted medical use" provision of the CSA "impermissibly narrow."[47] Instead of the five-part test currently used, OLC communicated that the DEA must use a new two-part test

41. Alliance for Cannabis Therapeutics v. Drug Enf't Admin., 15 F.3d 1131, 1134 (D.C. Cir. 1994) [hereinafter *Alliance II*] (citing to *Chevron* and accepting the DEA's interpretation of "accepted medical use" put forward in *Alliance I* excluding the three factors that made the test impossible to fulfill because the interpretation was "reasonable").

42. Kreit, *supra* note 10, at 351–57; Craker v. Drug Enf't Admin., 714 F.3d 17, 28 (1st Cir. 2013) (upholding the DEA's interpretation of § 823(a)(1) that the number of manufacturers of marijuana for research purposes should be limited to the minimum amount possible).

43. Kreit, *supra* note 10, at 351–57.

44. 2016 Denial, 81 Fed. Reg. at 53701 ("Currently, no published studies conducted with marijuana meet the criteria of an adequate and well-controlled efficacy study. The criteria for an adequate and well-controlled study for purposes of determining the safety and efficacy of a human drug are defined under the Code of Federal Regulations (CFR) in 21 CFR 314.126."); 21 CFR 314.126 (this is the FDA's definition of adequate and well controlled study used in its review of a substance pursuant to a New Drug Application under the FDCA).

45. Denial of Pet. to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40552, 40579 (Dep't of Justice July 8, 2011).

46. *See*, *e.g.*, 2016 Denial, 81 Fed. Reg. at 53701; Mikos, *supra* note 38, at 474 ("In the past, however, the agency has insisted that only rigorous scientific proof of medical efficacy could demonstrate that a drug has a CAMU. Because the research on marijuana's medical efficacy was never quite good enough, the DEA always found that marijuana had no CAMU and thus had to remain on Schedule I."); *Id.* at 489 ("It should come as no surprise, then, that very few Schedule I drugs have ever been able to satisfy the DEA's demanding CAMU test. GW Pharmaceutical's Epidiolex is the most recent example.").

47. Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C., 1, 12 (2024) (hereinafter "2024 Marijuana Rescheduling Opinion").

developed by HHS based on two inquiries: (1) "whether licensed health care providers have widespread current experience with the drug in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine," and if the answer is yes, then (2) whether there is "some credible scientific support for at least one of the medical uses."[48]

In guiding the first inquiry, HHS relies on three factors: whether (1) "a substantial number of . . . practitioners have gained clinical experience with [a] medical use . . . under . . . state-authorized programs," (2) "a substantial number of entities that regulate the practice of medicine recognize . . . [a] medical use of the substance," and (3) "licensed health care practitioners' clinical experience with the medical use of the substance is of sufficient extent and duration to . . . evaluate potential clinical uses . . . and . . . harms."[49] To guide the second inquiry, HHS evaluates whether (1) "favorable clinical studies of the medical use" have been published, (2) [q]ualified expert organizations have opined in favor of the use, (3) data indicates that "medical use of the substance poses unacceptably high safety risks for the likely patient population," (4) "clinical studies with negative efficacy findings for the medical use have been published," and (5) "qualified expert organizations . . . have recommended against the medical use of the substance."[50]

In its May 16, 2024 notice of proposed rulemaking, the DEA used this interpretation as part of its proposal to reschedule marijuana (the "DEA Marijuana Rescheduling Notice").[51] Under this interpretation it should be far easier for the DEA and HHS to find a substance has an accepted medical use.[52] This new interpretation has not yet led to the rescheduling of a substance (although the rescheduling of marijuana seems imminent), nor has this interpretation been upheld by a court.[53]

The DEA continues to use a four-factor test for "potential for abuse": (1) individuals are taking the substance in amounts sufficient to

48. *Id.* at *3.

49. *Id.* at *10–11.

50. *Id.* at *11.

51. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44617 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

52. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *17 ("nothing in the text of the CSA suggests that establishing that a drug has a CAMU requires the medical community to believe that the drug is the best way to treat a condition. So long as there is widespread understanding in the medical community that a drug is a permissible and reasonable way to treat a condition, it has a CAMU. That reflects a basic reality about the medical profession: that 'in medicine there is often a range of reasonable treatments[.]' ") (citation omitted).

53. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

create a hazard to their health or to the safety of other individuals or to the community, (2) there is a significant diversion from legitimate drug channels, (3) individuals are taking the substance on their own initiative, and (4) the substance is so related in its action to a substance already scheduled, thus making it reasonable to assume that the first three factors will also weigh in favor of the same "potential for abuse" finding.[54] This test in its application essentially boils down to a finding on the drug's recreational popularity, rather than its per-capita harm.[55]

Like the provisions of the CSA, the issue with these tests is not solely or even primarily their text, but rather the DEA's unbridled discretion in interpreting and applying the tests. In summary, the DEA, at least until 2024, made it extraordinarily difficult for a substance to be found to have a medical use unless the Food and Drug Administration ("FDA") approved of the substance, even if it was being prescribed for medical treatment by medical professionals. If a substance does not have a medical use, the DEA automatically placed the substance on Schedule I, which heavily restricts research into the substance that could lead to a scheduling change. Then, even if a medical use was found, the DEA's contra-textual and subjective "potential for abuse" test further allowed the agency to make scheduling decisions based on subjective preferences of the agency and the executive branch rather than on objective fact.[56] Although drug reformers could petition the DEA to reschedule a substance under this regime, no petition could be successful on the factors that should have been dispositive: clinical research, testaments from medical professionals, and scientific data. The only relevant factor under this system was the DEA's agenda.

A common sense understanding of the plain meaning of the CSA's text and the various tests that the DEA employs should have led to the rescheduling of some of the most popular and medically useful substances. This regime is ripe for administrative law challenges in a political and legal environment where such challenges continue to be successful. Part III will explore the challenges that are likely to be successful given recent developments in administrative law.

54. 2016 Denial, 81 Fed. Reg. at 53690; Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44601–03 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

55. Bloomberg et al., *supra* note 24, at 543 ("The current stance equates any recreational marijuana use with abuse, but the 'potential for abuse' inquiry could focus instead on harm.").

56. *See supra* notes 38–47 and accompanying text.

III. A NEW PLAYING FIELD: THE EFFECT OF THE ROBERTS COURT'S RESTRUCTURING OF ADMINISTRATIVE LAW AND THE BIDEN ADMINISTRATION'S MARIJUANA APPROACH

While the DEA's scheduling process has remained mostly static until recently, the Roberts Court has made significant changes to the law governing agencies throughout the Chief Justice's tenure.[57] Agencies no longer receive judicial deference in their interpretation of the given agency's governing statutes or in their interpretation of their own regulations, a drastic change from the state of the law as recently as 2018.[58] The Court has also taken a closer look at agencies' factual and policy conclusions while also signaling an increased appetite for declaring such conclusions "arbitrary and capricious," and thus unlawful.[59] The end result of these changes is a new understanding of the balance of power between agencies and courts. The federal judiciary has taken back power it had voluntarily relinquished, and has been readied by this Supreme Court to check agency action. This new system will have consequences for the DEA and its implementation of the CSA's scheduling provisions. The following sections of this Article analyze the changes in administrative law that will have a substantial effect on the ability of the DEA to prohibit, limit, or otherwise restrict the use of psychoactive substances.

A. The End of Deference: Will the Demise of Chevron *and the Rise of the Major Questions Doctrine Change Drug Policy for the Better?*

Chevron is no longer the law of the land.[60] At its most basic level, *Chevron* deference required courts to defer to an agency's interpretation of its governing statute if the statute was ambiguous and the agency's interpretation was reasonable, nominally a far more forgiving standard of review than *de novo* textual analysis.[61] The DEA consistently received *Chevron* deference in interpreting the text of the CSA, and this is in large part a reason many legal challenges to the DEA's scheduling regime have failed.[62]

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57. *See, e.g.*, *supra* footnotes 1–7 and accompanying text.

58. Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024).

59. *See generally* Dep't of Com. v. New York, 139 S. Ct. 2551, 204 L. Ed. 2d 978 (2019); Dep't of Homeland Sec. v. Regents of the Univ. of California, 140 S. Ct. 1891 (2020); Ohio v. Env't Prot. Agency, 144 S. Ct. 2040, 2054 (2024).

60. *Loper*, 603 U.S. at 412.

61. THOMAS W. MERRILL, THE CHEVRON DOCTRINE 80–99 (2022).

62. *See, e.g.*, Alliance I, 930 F.2d 936, 939 (D.C. Cir. 1991); Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 884–85 (1st Cir. 1987); Craker v. Drug Enf't Admin., 714 F.3d 17, 28 (1st Cir. 2013).

Now *Chevron* is gone.[63] In *Loper Bright v. Raimondo* the Court condemned *Chevron's* requirement that federal courts defer to "reasonable" agency interpretation of statutes and reasoned that such a requirement "defie[d] the command of the [Administrative Procedure Act]"[64] and is "fundamentally misguided . . . [and] unworkable."[65] Although the Court did not lay out the exact test lower courts should use when reviewing statutory interpretation by agencies, the Court cited favorably to a *Skidmore* style review where the statute's text, the agency's persuasiveness, and the long standing historical practice of the agency will play a role.[66] Courts are still obligated to "accor[d] due respect to executive branch interpretations of federal statutes," but are no longer under an obligation to defer to those interpretations.[67] Additionally, courts will now determine the best reading of a statute, instead of allowing different interpretations that fall within a range of "reasonableness," preventing drastic changes in policy from administration to administration.[68]

Chevron had already been hobbled by a previous Roberts' Court decision before it was officially overturned. In *West Virginia v. EPA*, the Court introduced the major questions doctrine and held that an agency action that was "politically or economically" significant would require "clear authorization" to be lawful, a complete reversal from the normal procedure of deference to agency action that existed before 2024.[69] The Court listed several factors that would lead to a finding an agency

63. *Loper*, 603 U.S. at 412; *see generally* W. Va. v. EPA, 597 U.S. 697 (2022).

64. *Loper*, 603 U.S. at 372.

65. *Id.* at 375.

66. *Id.* at 402; Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) ("We consider that the rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."); Thomas Merrill, *The Demise of Deference — and the Rise of Delegation to Interpret?*, 138 HARV. L. REV. 227, 260 (2024) ("Independent judgment does not preclude courts from drawing upon the expertise and insights of the agency, as a matter of respect, or from considering
whether the agency's explication is persuasive. The traditional canons and Skidmore are reaffirmed as general canons of interpretation.").

67. *Loper*, 603 U.S. at 385.

68. *Id.* at 438 (Gorsuch, J., concurring) ("Under Chevron, executive officials can replace one 'reasonable' interpretation with another at any time, all without any change in the law itself.").

69. W. Va. v. EPA, 597 U.S. 697, 766 (2022) (Kagan, J., dissenting) ("First, a court must decide, by looking at some panoply of factors, whether agency action presents an 'extraordinary case.' If it does, the agency 'must point to clear congressional authorization for the power it claims,' someplace over and above the normal statutory basis we require.").

interpretation is a major question with an emphasis on the economic effect, political controversy, and novelty of the interpretation.[70] Thus far, the Court has not described what "clear authorization" entails, but many scholars believe the Court may require something more than the best reading of the statute for an agency's interpretation to pass muster under judicial review.[71]

Regardless of whether the DEA's interpretation of the primary provisions of the CSA were reviewed under either a *Skidmore* or major questions style of analysis, litigants may have a real chance of success under the new non-deferential regime. For example, the meanings of the critical CSA terms "accepted medical use" and "potential for abuse" have never been cemented by courts.[72]

As discussed in Part II, after substantial litigation, the DEA recently had used a five-factor test to determine what is an "accepted medical use," but this formulation of the test has only survived judicial review because the DEA received *Chevron* deference, and an earlier interpretation of "accepted medical use" was struck down even under *Chevron*.[73] Recently, executive pressure forced the DEA to adopt a new two-part test developed by HHS, but a reviewing court may invalidate this interpretation as well.[74] The four-factor "potential for abuse" test has not been challenged in court, but would-be challengers may have been hesitant to pursue a case because it was unlikely that a court would find the DEA's interpretation "unreasonable."[75] It is worth asking if the DEA's current interpretation of "accepted medical use" and "potential for abuse" could survive without *Chevron* deference.[76]

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70. *Id.* at 724–28.

71. *See, e.g.*, Mila Sohoni, *The Major Questions Quartet*, 136 HARV. L. REV 262, 274 (2022); Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009, 1039 (2023).

72. *See supra* text accompanying notes 36–55.

73. *See supra* text accompanying notes 39–41; Bloomberg et al., *supra* note 24, at 542 ("Indeed, had the D.C. Circuit not originally reviewed the five-part test 'during an era of reflexive Chevron deference' it may well not have survived judicial review in the first place.").

74. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *10–12; Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44617 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

75. Kreit, *supra* note 10, at 347 (noting the "potential for abuse" has been untested in courts).

76. Additionally, it is worth noting that the DEA's interpretation of the CSA, that a substance with no "accepted medical use" should be placed on Schedule I even if the "potential for abuse" is low, should fail either a *Skidmore* analysis or a major question analysis. A reviewing court, in dicta, said as much when stating, "placement in Schedule I does not appear to flow inevitably from a lack of currently accepted medical use." *See* Nat'l Org. Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d at 748–49. If this interpretation were to be litigated, it would be near certain to fail under a proper reading of the text and structure of the statute. *See* Mikos, *supra* note 38, at 497–98 ("In other words, the

1. Accepted Medical Use

a. Pre-2023 Interpretation

As discussed in Part II, *supra*, up until 2024 the DEA used a five-part test to determine if a drug has a "currently accepted medical use": (1) the drug's chemistry is known and reproducible, (2) there are adequate safety studies, (3) there are adequate and well-controlled studies showing efficacy, (4) the drug is accepted by qualified experts, and (5) the scientific evidence is widely available.[77] This test has been upheld as reasonable by a reviewing court, but only after *Chevron* deference was granted to the DEA.[78] This interpretation is vulnerable to several textualist attacks after the Supreme Court's ruling in *Loper Bright*.

The DEA's five-part test for "accepted medical use" is a result of defeats in court, rather than agency's expertise, a reasonable policy determination, or the statute's text.[79] In *Grinspoon v. DEA*, the First Circuit rejected the DEA's conclusion that a substance only had an "accepted medical use" if had been approved by the FDA for interstate marketing under the Food, Drug, and Cosmetic Act ("FDCA"). The First Circuit found this interpretation contrary to both the text of the CSA and legislative intent, even while giving the DEA *Chevron* deference.[80] The DEA then retreated to an eight-factor test which was also struck down.[81] In *Alliance I*, the DC Circuit found the eight-factor test to be arbitrary and capricious because three of the eight factors made it impossible for a Schedule I substance to ever be found to have a medical use and thus be rescheduled.[82] On remand, the DEA disclaimed use of the three

agency has combined 'lack of accepted safety for use' and 'no currently accepted medical use' into a single inquiry, arguably making it unnecessary to consider each of them separately. More troublingly, however, the agency has claimed that the other finding Congress required for Schedule I—that a drug has a 'high potential for abuse'—is simply irrelevant. In other words, the agency does not claim that the lack of a 'currently accepted medical use' also necessarily implies that a drug has a 'high potential for abuse.' Instead, the agency claims that Congress simply did not care about the abuse potential of drugs that have no CAMU—it wanted all such drugs to be subject to the strictest possible controls under the CSA, notwithstanding its declaration in § 812(b) that Schedule I drugs must exhibit a 'high potential for abuse.' The DEA has no authority to disregard the terms of the CSA in this way."

77. *See supra* notes 38–41 and accompanying text.

78. *See supra* notes 38–41 and accompanying text.

79. W. Va. v. EPA, 597 U.S. 697, 729 (quoting Kisor v. Wilkie, 588 U.S. 558, 577–78 (2019)) (discussing the importance of agency expertise in upholding an agency's interpretation of its governing statute).

80. Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 884–90 (1st Cir. 1987) (rejecting the DEA's interpretation of accepted medical use).

81. Alliance I, 930 F.2d 936, 940 (D.C. Cir. 1991).

82. *Id.* ("Which brings us to the most troubling part of the Administrator's decision—the part which we think obliges us to order a remand. Petitioners, almost in passing, point out that

"impossible" factors and, from then on, used the five-part test described above, which was found "reasonable" by a reviewing court.[83]

OLC presented compelling arguments that the DEA's interpretation was *ultra vires*—beyond its legal authority.[84] OLC faulted the test on textual grounds, claiming that the DEA's test does not comport with the plain meaning of "accepted" and "medical use" because those terms require observation and analysis of the on-the-ground decision-making of medical professionals and their use of the substance in treatment, which the DEA's test does not account for.[85]

OLC's argument should carry the day. According to Webster's Third New International Dictionary, at the time of the CSA's passage, (1) "current" meant "in genuine knowledge, acceptance use or practice"; (2) "accepted" meant "generally approved, widely used, or found"; (3) "medical" meant "of, relating to, or concerned with physicians or with the practice of medicine"; and (4) "use" meant "the act or practice of using something."[86] Put simply, a substance meets this definition if the medical community acknowledges that the substance has some utility in medical treatment. The DEA's definition places conditions far beyond the test's scope in finding a medical use for substances, requiring near-flawless, rather than adequate, evidence that a substance is safe and useful.[87]

Additionally, OLC criticized the DEA's test for misconstruing the CSA's requirements for finding a medical use with FDA approval under the FDCA.[88] All five parts of the DEA's test were based on FDA standards for their approval of drugs, and four of the five factors were expressly borrowed from FDA regulations even though the FDCA's text does not mention "medical use" and the FDCA contains requirements

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three of the factors in the Administrator's eight-factor test appear impossible to fulfill and thus must be regarded as arbitrary and capricious. Impossible requirements imposed by an agency are perforce unreasonable: 'Conditions imposed by [the] order are . . . unreasonable by virtue of being impossible to meet.' ") (quoting D. C. Transit Sys., Inc. v. Washington Metro. Area Transit Comm'n, 466 F.2d 394 (D.C. Cir. 1972)).

83. *Alliance II*, 15 F.3d 1131, 1134 (D.C. Cir. 1994); Marijuana Scheduling Pet., 57 Fed. Reg. 10499, 10507 (Dep't of Just. Mar. 26, 1992) (denial of petition and remand).

84. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *13 ("It is hard to square DEA's exclusive reliance on FDA approval and its five-part test with this language. To begin, DEA's approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard.").

85. *Id* at *13–14.

86. Al-Khaled, *supra* note 14, at 1041–42; WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (Philip Babcock Gove et al. eds., 1969).

87. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *17 ("Relatedly, nothing in the text of the CSA suggests that establishing that a drug has a CAMU requires the medical community to believe that the drug is the best way to treat a condition.").

88. *Id.* at *14.

for approval like patent information and manufacturing process requirements that are nowhere to be found in the CSA.[89]

The other strong argument against the DEA's interpretation of the statute is that—contrary to the text and intent of the CSA—the test makes it overly difficult to find a substance has an accepted medical use.[90] This five-part test only survived DC Circuit review because it was technically possible to fulfill the requirements and because the text is ambiguous and the interpretation was "reasonable" under *Chevron*.[91] The DEA's current test is nothing more than the strictest interpretation they could get away with.

However, this history does not mean a reviewing court would simply invalidate this interpretation if the court did not have to defer to the agency's interpretation. It is difficult to say that the DEA's test contradicts the simple phrase "currently accepted medical use."[92] The text is genuinely ambiguous.[93] Additionally, the Roberts Court seems to particularly value historical consistency in interpretation.[94] In both the *West Virginia* and *Loper Bright* majority opinions, the Chief Justice noted that the long-standing use of an interpretation by an agency should

89. *Id.*

90. Mikos, *supra* note 38, at 488–89 ("The DEA's CAMU test is tyrannical because it requires a very specific type of evidence [randomized controlled trials] (RCTs) that is almost impossible to generate, especially when a drug is already on Schedule I. Conducting successful RCTs is difficult enough even without considering the research barriers the CSA imposes on Schedule I drugs. Among other things, RCTs must include large numbers of subjects, they must be well-controlled (e.g., double-blinded, with standardized dosage), and they must be well-executed. Due to these requirements, the process of completing even a single RCT takes several years.").

91. *Alliance II*, 5 F.3d 1131, 1134–35 (D.C. Cir. 1994) ("On reviewing the Administrator's decision [in *Alliance I*], we found the eight-factor test… to be 'in the main acceptable.' We noted the ambiguity of the phrase and the dearth of legislative history on point and deferred to the Administrator's interpretation as **reasonable**… None of these criteria is impossible for a Schedule I drug to meet; in fact, petitioners concede in their briefs that the new standard has corrected the flaws we identified in ACT [1]").

92. Kreit, *supra* note 10, at 350 ("Without a definition from Congress, the DEA has been free to come to its own conclusion, with very little to constrain its discretion.").

93. *Id.*

94. W. Va. v. EPA, 597 U.S. 697, 724 (2022); Loper Bright Enterprises v. Raimondo, 603 U.S. 369, 394 (2024)("And interpretations issued contemporaneously with the statute at issue, and which have remained consistent over time, may be especially useful in determining the statute's meaning"); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) ("its consistency with earlier and later pronouncements"); Merrill, *supra* note 66, at 272 ("Finally, the Court's remixing of elements points toward a strong preference for the regulatory status quo. Its reaffirmation of the traditional contemporaneous and longstanding canons, combined with Skidmore's inquiry about the consistency of the agency interpretation, will discourage agencies from revising their initial interpretations. And Loper Bright's declaration that courts will independently determine the scope of agency authority will tend to confine the agency to the problems that were salient when it was initially created. These factors may increase the stability and predictability of administrative law. But they will also reduce the opportunities for innovation and regulatory change.").

be a substantial factor in a court finding an agency's interpretation is the correct reading of a statute.[95] The DEA, for all its faults, has been consistent in its interpretation of the CSA's text.

Other interpretations have been put forward, such as HHS's new two-part approach or finding a medical use when a "significant minority" of doctors find it useful in treatment.[96] Although these are appealing interpretations from a policy perspective, it is hard to say with certainty a court will find them more persuasive readings of the CSA.[97] Courts could be a hindrance in this instance by invalidating a new and more flexible interpretation, like the one put forward by OLC and HHS in 2024.

b. HHS's 2024 Interpretation

If a court rejected the DEA's prior interpretation of "accepted medical use" under *Skidmore*, it is not guaranteed that HHS's new two-part inquiry would be upheld. As discussed in Part II, HHS and OLC's test finds a substance has an "accepted medical use" if (1) health care providers have experience with the drug "in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine," and if so then (2) if there is "some credible scientific support for at least one of the medical uses."[98] If the answers to both questions are yes using a variety of guiding factors, the substance has an accepted medical use and is eligible to be placed in a schedule other than Schedule I.[99]

In the same memo in which OLC criticized the DEA's test, it also defended the legality of this new two-part test.[100] OLC reasoned the better reading of the phrase "accepted medical use" requires an analysis of the practices of physicians and other medical professionals throughout the country.[101] This analysis of the reality of medical treatment is the

95. *W. Va. v. EPA*, 597 U.S. at 724; *Loper*, 603 U.S. at 394 ("And interpretations issued contemporaneously with the statute at issue, and which have remained consistent over time, may be especially useful in determining the statute's meaning").

96. In the Matter of Marijuana Rescheduling Pet., Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge (1988); 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *10–12; HHS 2024 Marijuana Analysis at *24.

97. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *10–12; HHS 2024 Marijuana Analysis at *24.

98. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *3; HHS 2024 Marijuana Analysis at *24.

99. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *10–12; HHS 2024 Marijuana Analysis at *24.

100. 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. at *16–18.

101. *Id.*

core of the HHS test and ignored in the DEA test.[102] OLC also correctly recognized that the experience and expertise of state regulatory regimes should be considered, as statewide medical use of a substance certainly is evidence of an accepted medical use.[103] Simply put, whether a substance has an "accepted medical use" is much more likely to be accurately answered by HHS's analysis than the DEA's.

As previously discussed, it is not clear that a court would necessarily agree with this interpretation due to the inherent vagueness of the phrase "accepted medical use."[104] If courts after *Loper Bright* are required to find a statute's "single, best meaning," it is impossible to say HHS's test—or any test one could come up with— is the perfect interpretation of the meaning of "accepted medical use" as those words were understood in 1970. It could be that a court, hard pressed to come up with a single, best interpretation, would simply revert back to the DEA's test because of its long-standing nature.

There is also a strong argument that HHS's interpretation, although a marked improvement, is still an invalid reading of the CSA because the test imposes overly strict requirements that the statutory text does not support.[105] Prong 1 of HHS's test requires that health care professionals and state governments ***violate federal law*** by facilitating the use of a Schedule I substance currently held to have no medical use.[106] The text of the CSA certainly does not require that states and doctors violate federal law in order for a substance to be rescheduled. Neither HHS nor the DEA acknowledged this paradox in their published analysis

102. *Id.* at *12–18.

103. *Id.* at *18–20.

104. Kreit, *supra* note 10, at 350; Al-Khaled, *supra* note 14, at 1042.

105. Mikos, *supra* note 38, at 475 ("[T]he [new] HHS test, in effect, first requires advocates to convince a majority of voters in a substantial number of states to authorize the medical use of a drug. That is the only way to accumulate the widespread clinical experience HHS requires in lieu of rigorous scientific evidence. Although advocates were eventually able to win over majority support for the legalization of medical marijuana in a sufficiently large number of states . . . no other drug is likely to repeat that feat anytime soon (if ever)."). Professor Mikos makes strong arguments but is likely overly pessimistic about the chances of state governments legalizing Schedule I substances, *See New National Poll: More Than 60 Percent of U.S. Voters Support Legalizing Psychedelic Therapy*, UC BERKELEY CENT. FOR THE SCI. OF PSYCHEDELICS (June 20, 2023), https://psychedelics.berkeley.edu/berkeley-psychedelics-survey-2023; *see generally* NORML v. DEA, 559 F.2d 735 (D.C. Cir. 1977). Mikos also does not analyze the effect decisions like *Loper Bright* and *Kisor* may have on the tenability of the new "medical use" definition. It is also unclear that the new test requires a majority of states to legalize a substance before a finding of "accepted medical use" can be made, especially given that courts will no longer accord the DEA significant deference in its interpretation of the text of its own test.

106. Kreit, *supra* note 10, at 335; JOSEPH T. RANNAZZISI & MARK W. CAVERLY, DRUG ENFORCEMENT ADMIN., PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 5 (2006), http://www.deadiversion.usdoj.gov/pubs/manuals /prac t/pract_manual012508.pdf.

regarding the rescheduling of marijuana, even while acknowledging thirty-eight states and territories and thousands of medical professionals have enabled marijuana's use—ostensibly in violation of the CSA. To resolve this interpretive issue, prong one should be understood that for Schedule I substances, a foreign jurisdiction's legalization, regulation, and its medical professionals' administration of the substance for medical treatment allows for a finding of a medical use.

If a court took its *Loper Bright* role seriously—to say "what the law is"—the DEA's interpretation would certainly be invalidated.[107] A closer look should also invalidate the first prong of HHS's analysis. A "correct" interpretation of the "accepted medical use" provision of the CSA should simply require that petitioners show that the medical community has acknowledged scientific evidence a substance has utility in medical treatment. At the very least, a court should modify prong one of HHS's interpretation such that evidence of the medicinal use of a substance outside the United States could allow for a finding of an "accepted medical use."

2. Potential for Abuse

Somewhat ironically given recent changes to the interpretation of "currently accepted medical use," the DEA's interpretation of "potential for abuse" is far more likely to be overturned by a court based solely on a plain reading of the text. The DEA uses a four-factor test for "potential for abuse": (1) individuals are taking the 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 a significant diversion from legitimate drug channels, (3) individuals are taking the substance on their own initiative, and (4) the substance is so related in its action to a substance already listed.[108]

This interpretation is vulnerable on several fronts and should fall to a *de novo* textual analysis required by *Loper Bright*. The first issue with the interpretation is that the definition of "abuse," according to the Oxford Dictionary, is "[t]he use of something in a way that is wrong or harmful."[109] The plain meaning of the term "potential for abuse" thus calls for an analysis of the substance's ability to cause harm to the

107. Loper Bright Enterprises v. Raimondo, 603 U.S. 369, 385 (2024).

108. 2016 Denial, 81 Fed. Reg. at 53690; Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44601–03 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

109. *Abuse*, Oxford Learner's Dictionaries, https://www.oxfordlearnersdictionaries.com/us/definition/american_english/abuse (last visited Apr. 14, 2024).

general public.[110] Only the first factor of the DEA's test implicates the actual harm the substance causes, and when the DEA reviews a substance under that factor it often ignores the empirical evidence of "harm" and focuses on evidence of use.[111] Use is not abuse, and real health or societal hazards should have to be empirically studied and found for the agency to make a determination a substance has a "potential for abuse."[112]

It is unclear why the fact that individuals take the substance on their own initiative without a medical purpose should factor into a finding of "potential for abuse" given that plenty of non-scheduled substances can be taken at one's own initiative without issue. The DEA's interpretation is circular in that a scheduled substance (or a substance similar to a scheduled substance) causes harm if it is used, so if it is used, it justifies such substance's scheduling.[113] This reasoning cannot be squared with a statutory requirement to analyze a substance's potential for abuse and the "[t]he scope, duration, and significance of abuse; [w]hat, if any, risk there is to the public health; [and] [i]ts psychic or physiological dependence liability."[114] The factors point towards a finding of relative harm, not use.

The second issue is that this test is entirely crafted from the legislative history of the CSA.[115] Such use of legislative history has been a disfavored interpretive activity for decades, especially without support in the statute's text.[116] Again, a test more clearly in line with statutory text—what textualists on the Court say is all that should matter—would emphasize the empirical harm of a substance's use.

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110. One could also determine that the phrase might also allow for the banning of substances the DEA determines are morally "wrong" to use. The structure and textual context of the phrase in the CSA, with its focus on scientific and objective data, forecloses this interpretation.

111. *See* 2016 Denial, 81 Fed. Reg. at 53691 ("Evidence shows that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. **A large number of individuals use marijuana**."); *Id.* at 53694 ("The abuse potential of a substance is associated with the repeated or sporadic use of a substance in nonmedical situations for the psychoactive effects the substance produces.").

112. Bloomberg et al., *supra* note 24, at 535, 543(discussing the DEA's mistaken application of use as abuse).

113. Kreit, *supra* note 10, at 347.

114. 21 U.S.C.A. § 811(c)(5)–(7).

115. U. S. v. Pastor, 419 F. Supp. 1318, 1339 (S.D.N.Y. 1975); Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 893 (1st Cir. 1987).

116. Conroy v. Aniskoff, 507 U.S. 511, 519 (1993) (Scalia, J., concurring) ("The greatest defect of legislative history is its illegitimacy. We are governed by laws, not by the intentions of legislators."); Harvard Law School, *The Antonin Scalia Lecture Series: A Dialogue with Justice Elena Kagan on the Reading of Statutes*, YOUTUBE (Nov. 25, 2015), https://www.youtube.com/watch?v=dpEtszFT0Tg ("[w]e're all textualists now.").

A court would be hard-pressed to call the DEA's test the "single, best meaning" of the term "potential for abuse" given the above. A reformulated test is required. A good guess as to what such "best reading" could look like is the following: (1) the substance's harm potential when used without the guidance of a physician, (2) the substance's potential for psychological and physical dependence, (3) the substance's risk of being used in such a way that causes empirically measurable harm or dependency, and (4) the substance's per capita relative harm compared to other similarly scheduled substances.

Such a test would require a balancing of data regarding the substance's harm and the risk of the substance actually causing the harm from on-the-ground data and would avoid conflating the widespread use of a substance with a public-health crisis. Given the harmful nature of substances in Schedule II like cocaine, meth, and fentanyl, such a test would likely lead to the rescheduling of many relatively benign substances to Schedules III–V.[117] As noted above, it is unclear whether a court would find this test to be the "best meaning" of the CSA, but it is far more in tune with the structure and text of the CSA then the current test and is useful for predicting what the future may hold for rescheduling.

3. Major Questions Doctrine

Current interpretations of the definitions of "accepted medical use" and "potential for abuse" in §811(c) of the CSA are almost certain to be considered major questions under the standard outlined in *West Virginia v. EPA* and applied in the COVID cases and *Biden v. Nebraska*.[118] This (debatably) novel legal doctrine requires courts strike down agency action that addresses matters of great "economic or political significance" unless a statute provides "clear authorization" for the agency action.[119] The interpretation of the "medical use" and "potential for abuse" provisions of the CSA and their relation to the scheduling of commonly used psychoactive substances is certainly of "economic and political significance." The sale of federally illegal drugs brings in a multitude of billions of dollars of revenue and employs hundreds of

117. *See generally* David J. Nutt et al., *Drug Harms in the UK: A Multicriteria Decision Analysis*, 376 LANCET 1558 (2010) (analyzing the harms of various substances and finding several Schedule II substances among the most harmful).

118. W. Va. v. EPA, 597 U.S. 697 (2022); Biden v. Neb., 143 S. Ct. 2355 (2023); Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs., 594 U.S. 758 (2021); Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety and Health Admin., 595 U.S. 109 (2022).

119. Thomas Merrill, *The Major Questions Doctrine: Right Diagnosis, Wrong Remedy*, HOOVER INST. PRESS, 1 (2023); Jack Malich, *My Unfair Lady*, 2023 COLUM. BUS. L. REV. 937, 944–46 (2024).

thousands, if not millions, of Americans.[120] Americans are engaged in a "profound debate" about the issue, and dozens of state legislatures have discussed bills decriminalizing or legalizing substances on the CSA's schedules.[121]

The "clear authorization" prong of the major questions test has not yet been articulated in a comprehensible manner.[122] Its applications in *West Virginia*, *Nebraska v. Biden*, and the COVID cases fail to provide a clear standard by which a statute can "clearly authorize" an agency action.[123] It is likely that this prong requires *more* than the best reading of a statute to authorize the action.[124]

However, the CSA's text unambiguously authorizes the Attorney General and DEA, to whom the Attorney General delegated its power, to classify drugs, and the DEA did not, in interpreting the CSA as strictly as possible, "claim to discover in a long-extant statute an unheralded power."[125] The DEA claimed the power very soon after the passage of the CSA and received little pushback.[126] Although there is an argument the DEA's interpretations of the CSA had the effect of essentially allowing the DEA to pick and choose which substances to restrict based on political will, a "sweeping and consequential authority," the major

120. Rachel Soloveichik, *Including Illegal Activity in the U.S. National Economic Accounts*, BUR. OF ECON. ANALY. 1, 34 (2019).

121. *See, e.g.*, Oriana Zill & Lowell Bergam, *Do the Math: Why the Illegal Drug Business is Thriving*, PBS (2017), https://www.pbs.org/wgbh/pages/frontline/shows/drugs/special/math.html; Rachel Soloveichik, *Including Illegal Activity in the US National Economic Accounts*, IMF (Nov. 15, 2019); *Drug Law Reform*, NAT'L ASS. OF CRIM. DEF. LAWYERS (2024), https://www.nacdl.org/Landing/DrugLaw#:~:text=State%20Drug%20Law%20Reform&text=As%20of%20October%202023%2C%20thirty,legalized%20recreational%20marijuana%20for%20adults (listing the number of states where marijuana is legalized); Sam Levin, *Oregon Becomes First US State to Decriminalize Possession of Hard Drugs*, THE GUARDIAN (Nov. 4, 2020), https://www.theguardian.com/us-news/2020/nov/03/oregon-drugs-decriminalize-arizona-new-jersey-marijuana; W. Va. v. EPA, 597 U.S. 697, 732 (2022) (quoting Gonzales v. Oregon, 546 U.S. 243, 268 (2006).

122. *See, e.g.*, Mila Sohoni, *The Major Questions Quartet*, 136 HARV. L. REV 262, 274 (2022); Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009, 1039 (2023); Malich, *supra* note 119, at 968; Merrill, *supra* note 119, at 14 ("Instead, the opinions for the Court speak of the requirement of 'clear authorization' by Congress. Clear statement connotes a demand for express authorization in the text of a statute. Clear authorization is less precise. It might include, for example, implicit ratification of the agency position by subsequent legislative action or (heaven forbid!) authorization found in persuasive legislative history.").

123. *See, e.g.*, Sohoni, *supra* note 122, at 274; Deacon & Litman, *supra* note 122, at 1039.

124. *See, e.g.*, Sohoni, *supra* note 122, at 274; Deacon & Litman, *supra* note 122, at 1039.

125. 21 U.S.C. § 811; W. Va. v. EPA, 597 U.S. 697, 724 (2022) (quoting Util. Air Regul. Grp. v. EPA, 573 U.S. 302, 324 (2014)).

126. Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 885–88, 892–94 (1st Cir. 1987) (stating the DEA's interpretations of "potential for abuse" and "accepted medical use").

questions doctrine is not the best avenue forward for drug reformers.[127] For better or worse, the Roberts Court's major questions doctrine is focused on novel interpretations of statutes, not long-standing interpretative abuses.[128]

B. What About Auer*? The Effect of* Kisor v. Wilkie

Finally, regardless of the way the statutory interpretation question comes out, another recent Supreme Court decision, *Kisor v. Wilkie*, should restrain the way the DEA construes its own interpretations of the CSA.[129] Before the *Kisor* decision, *Auer* deference called for reviewing courts to give administrative agencies almost reflexive deference to the agency's interpretation of its own regulations, based on the agency's interpretation of its governing statute.[130] *Kisor* substantially narrowed

127. *W. Va. v. EPA*, 597 U.S. at 721. It is also unlikely that a major questions analysis would prevent rescheduling to a lower schedule. *See* Bloomberg, *supra* note 24, at 568 ("We need not wade into the debate around the source or soundness of the major questions doctrine to safely conclude that it does not apply here. To be sure, re/descheduling marijuana may well have 'vast economic and political significance'; it may arguably be a major action for the President to take. But re/descheduling marijuana would not bear any of the other hallmarks that the Court has identified for invoking the doctrine. Here, the delegation of authority to re/deschedule drugs is not 'vague' or 'cryptic.' Congress laid out that authority in painstaking detail throughout an entire section of the CSA. Nor is there a 'mismatch' between the scope of the President's claimed authority and the scope of the provision purportedly granting that authority. Section 811 creates a procedure for the Executive Branch to re/deschedule drugs, and that is the exact authority the President would be exercising. Finally, this would not be a case where the relevant agencies are regulating outside of their areas of expertise."). Additionally, there is an argument that the overturn of *Chevron* in *Loper* has reduced the need for, or implicitly done away with the major questions doctrine. *See*, Merrill, *supra* note 66, at 270 ("Armed with the *Loper Bright* regime, it is at least plausible that the Court could have reached all the judgments it entered in the major questions cases without having to announce a novel doctrine applicable only to major questions. If this is plausible, then it is conceivable that the Loper Bright regime could, in time, supersede the major questions doctrine."); *Id.* at 240 ("The major questions doctrine has no analog in pre-APA decisional law, which would suggest, on the majority's reasoning in *Loper Bright*, that the major questions doctrine violates the APA.").

128. Biden v Neb., 143 S. Ct. 2355, 2369 (2023) ("The Secretary's new 'modifications' of these provisions were not 'moderate' or 'minor.' Instead, they created a novel and fundamentally different loan forgiveness program.").

129. Kisor v. Wilkie, 588 U.S. 558 (2019).

130. *Id.* at 568 ("In each case, interpreting the regulation involves a choice between (or among) more than one reasonable reading. To apply the rule to some unanticipated or unresolved situation, the court must make a judgment call. How should it do so? In answering that question, we have often thought that a court should defer to the agency's construction of its own regulation."); *Id.* at 599 (Gorsuch, J., concurring in judgment) ("*Auer* represents the apotheosis of this line of cases [establishing deference]. In the name of what some now call the *Auer* doctrine, courts have in recent years 'mechanically applied and reflexively treated' *Seminole Rock's* dictum 'as a constraint upon the careful inquiry that one might ordinarily expect of courts engaged in textual analysis.' Under *Auer*, judges are forced to subordinate their own views about what the law means to those of a political actor, one who may even be a party to the litigation before the court.").

Auer such that an agency only receives judicial deference in interpreting its own regulations when the regulation is generally ambiguous after the court uses all "traditional tools" of construction.[131] Additionally, the regulation has to be reasonable, be based on the agency's expertise, come from an "authoritative" action, and must not be a "convenient litigation position" advanced "to defend past agency action against attack."[132]

If all else fails, *Kisor* should allow petitioners to push back on the DEA's currently unbridled authority. For example, in *Americans for Safe Access v. DEA*, the DEA interpreted the "adequate and well-controlled studies" prong of its medical use test to mean studies reached a level of scientific rigor such that they would be accepted by the FDA in a New Drug Application.[133] The DC Circuit went through a cursory review of the DEA's regulations and the plaintiffs' arguments without using any traditional tools of construction.[134] Instead, the court simply decided that the DEA's construction was "eminently reasonable," and thus it was "obliged to defer," even though other federal courts have rejected the idea that the DEA can use FDA standards in drug scheduling.[135]

Under *Kisor*, a federal court would be obligated to at least do more than simply write the word reasonable before deferring to the agency. Based on reasoning from other courts, and the many textual differences between the CSA and FDCA, it is very likely a *Kisor* style review of the

131. *Id.* at 591 (Roberts, J., concurring) ("The majority catalogs the prerequisites for, and limitations on, Auer deference: The underlying regulation must be genuinely ambiguous; the agency's interpretation must be reasonable and must reflect its authoritative, expertise-based, and fair and considered judgment; and the agency must take account of reliance interests and avoid unfair surprise."); Paul J. Larkin, Jr., *Agency Deference after Kisor v. Wilkie*, 18 GEO. J.L. & PUB. POL'Y 105, 119 (2020) ("The bottom line, then, is this: Under the Kagan opinion, an agency will receive deference for its interpretation of one of its own rules only if all the following stars align: (1) the rule must be unclear and (2) the agency's interpretation must be reasonable, fore-seeable, official, and reflect its particular knowledge and skill-set.").

132. *Id.* at 572–79 (describing the limitations on *Auer* deference).

133. Americans for Safe Access v. Drug Enf't Admin., 706 F.3d 438, 451 (D.C. Cir. 2013) ("At bottom, the parties' dispute in this case turns on the agency's interpretation of its own regulations. Petitioners construe 'adequate and well-controlled studies' to mean peer-reviewed, published studies suggesting marijuana's medical efficacy . . . The DEA interprets 'adequate and well-controlled studies' to mean studies similar to what the Food and Drug Administration ('FDA') requires for a New Drug Application ('NDA').").

134. *Id.* at 451–52.

135. *Id.* at 452 ("The DEA's construction of its regulation is eminently reasonable. Therefore, we are obliged to defer to the agency's interpretation of 'adequate and well-controlled studies.' "); Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 884 (1st Cir. 1987) (rejecting a DEA interpretation of medical use as meaning approved for interstate marketing by the FDA under the FDCA.).

DEA's regulations would find that medical use studies *do not* need to be as rigorous as those required by the FDA.[136]

This exemplifies a broader pattern: the DEA routinely expands its authority by interpreting its regulations in ways that stretch beyond its already questionable statutory interpretations. Other examples include the DEA's previous determination that medical use of a Schedule I substance was "abuse" or that severe research restrictions on Schedule I substances are appropriate even with positive preliminary data regarding their use in medical treatment.[137]

Kisor's more stringent form of judicial review should also prevent future regulatory abuse by the DEA. HHS's new "medical use" test is vulnerable to an overly restrictive interpretation by the DEA. Prong one of HHS's new test finds a substance has an "accepted medical use" if "health care providers have . . . experience with the drug in accordance with implemented state-authorized programs."[138] In guiding analysis under this factor, HHS looks at whether a "substantial number of practitioners have experience prescribing the drug under state authorized programs" and whether a "substantial number of entities . . . recognize . . . [a] medical use of the substance."[139] The DEA (or HHS) could interpret "substantial number" of either entities or practitioners to require a majority of states to legalize a substance before a medical use can be found even though the plain meaning of "substantial number" should be read to only require one state to legalize a substance, as any state legalization regime will govern hundreds if not thousands of practitioners.[140] *Kisor* should prevent the worst of these potential downstream interpretative abuses.

C. The Incompatibility of the DEA's Rescheduling Decisions with A&C Review after DHS v. Regents and Department of Commerce v. New York

Given the breadth of the CSA's statutory grant of power, DEA scheduling decisions are most directly reviewable under the "arbitrary and capricious" ("A&C") standard of review found in the text of the Administrative Procedure Act ("the APA") and refined through case

136. *Grinspoon*, 828 F.2d at 886–87 (discussing the differences between the FDCA and CSA); Larkin, *supra* note 131, at 118 ("The Kagan opinion lowers the reader's expectation as to the amount of deference an agency's rule-interpretation should receive.").

137. Denial of Pet. to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40552, 40579–81 (Dep't of Just. July 18, 2011).

138. *See supra* notes 48–50 and accompanying text.

139. *See supra* notes 48–50 and accompanying text.

140. *Substantial*, Merriam Webster Dict., https://www.merriam-webster.com/dictionary/substantial (last visited Oct. 25, 2024).

law.[141] The APA governs all agency action unless the agency's governing statute expressly replaces it with another framework.[142] In the CSA, the APA governs except that "[f]indings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive."[143] This text however, essentially mirrors §706(e)(2) of the APA, which requires that agency action be set aside if it is "unsupported by substantial evidence."[144]

The relevant text of the APA requires courts to set aside agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[145] The A&C standard of review was most clearly laid out in *State Farm*, which held that courts should strike down agency action as arbitrary and capricious when the agency has

> relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[146]

However, the Court made sure to say that the standard of review is deferential to agencies, as they need flexibility to change policies and adopt new rules.[147] More recent case law has fleshed out this standard, but its basic form has remained the same.

The Roberts Court's has tweaked arbitrary and capricious review in three high-profile cases. In *Department of Commerce v. New York*, the Court invalidated the agency's decision to add a question on immigration status to the census as "arbitrary and capricious" because the agency's decision was based on "pretextual rationale."[148] In *Ohio v. EPA*, the Court enjoined an EPA rule restricting air downwind air pollution because the EPA did not "reasonably explain[ ]" objections to the rule.[149]

More importantly, in *DHS v. Board of Regents*, the Court found the Department of Homeland Security did not consider reliance interests or alternatives "within the ambit of the existing policy" when the head of DHS rescinded the DACA program.[150] Although such language derives

141. 5 U.S.C. § 706(2)(a).
142. 5 U.S.C. § 704.
143. 21 U.S.C. § 877.
144. 5 U.S.C. § 706(2)(e).
145. 5 U.S.C. § 706(2)(a).
146. Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).
147. *Id.*
148. Dep't of Com. v. N. Y., 588 U.S. 752, 766 (2019).
149. Ohio v. Env't Prot. Agency, 603 U.S. 279, 294 (2024).
150. Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 591 U.S. 1, 30 (2020).

from *State Farm*, it was sparsely used by courts.[151] In the *DHS* case, the Court invalidated the Trump Administration's recission of the DACA program because the agency's only stated rationale was that DACA was illegal, it did not discuss the reliance interests of those who received deferred removal, and the agency did not discuss the possible alternative of only rescinding DACA's benefits conferral.[152] As the primary dissent pointed out, this was a departure from ordinary *State Farm* A&C review.[153] This reasoning may be fruitful in A&C challenges to DEA scheduling, which will be evaluated below.

Arbitrary and capricious review has been successful in combating the excesses of DEA discretion before.[154] The DEA has failed A&C review because their interpretation of "accepted medical use" seemingly made it impossible for substances on Schedule I to be rescheduled.[155] On remand, the DEA denied it used factors that made rescheduling impossible and argued the initial rescheduling petition misstated the DEA's position.[156] It then revised the test as narrowly as possible to survive future review.[157] More recently, the Ninth Circuit held that the DEA's rejection of a petition to reschedule psilocybin was arbitrary and capricious because the DEA "failed to provide analysis sufficient to allow its 'path' to 'reasonably be discerned.' "[158] Setting aside challenges to the issue of research restrictions making rescheduling impossible (which have been better explored elsewhere), other A&C challenges to the DEA scheduling process could and should be successful.[159]

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151. *State Farm*, 463 U.S. at 51; A Westlaw search found fewer than a dozen cites to the "within the ambit of the existing policy" language from *State Farm* before the *DHS* case was decided in 2019.

152. *DHS v. Regents of Univ. of Cal.*, 591 U.S. at 29.

153. *Id.* at 57 (Thomas, J., dissenting).

154. Alliance I, 930 F.2d 936, 940 (D.C. Cir. 1991).

155. *Id.*

156. Marijuana Scheduling Petition, 57 Fed. Reg. 10,499, 10,507 (Dep't of Justice Mar. 26, 1992) (denial of petition and remand) ("I have found no evidence indicating initial factors (4)(a) or (8)(b) played any role in my predecessor's decision. In light of my understanding of the legal standard involved, these factors are irrelevant to whether marijuana has a currently accepted medical use.").

157. *Id.* at 10504–07.

158. Aggarwal v. U. S. Drug Enf't Admin., No. 22-1718, 2023 WL 7101927, at *1 (9th Cir. Oct. 27, 2023) (quoting Gill v. U.S. Dep't of Just., 913 F.3d 1179, 1187–88 (9th Cir. 2019)).

159. In the *Alliance II* case, Plaintiffs conceded, and the DC Circuit held that the definition of accepted medical use, the scheduling of marijuana, and the related research restrictions did not make it impossible for those pushing for marijuana rescheduling to fail to do the necessary research. Alliance II, 5 F.3d 1131, 1135 (D.C. Cir. 1994) ("None of these criteria is impossible for a Schedule I drug to meet; in fact, petitioners concede in their briefs that the new standard has corrected the flaws we identified in ACT."); *see also* Craker v. Drug Enf't Admin., 714 F.3d 17, 29 (1st Cir. 2013) ("Instead, he argues that the adequacy of supply must not be measured against NIDA-approved research, but by whether the supply is adequate to supply

There are strong arguments to be made that the DEA's (and HHS's) ordinary course of analysis fails to satisfy the arbitrary and capricious standard of review outlined above and applied in previous cases against the DEA. The DEA's last published long-form denial of a petition of rescheduling was its denial of a petition to reschedule marijuana in 2016.[160] Although this denial may soon be overturned, it is the best and most recent available evidence of how the DEA analyzes high profile drug rescheduling petitions. The DEA's ordinary form of petition denial should be held arbitrary and capricious because it (1) runs counter to the evidence presented before the DEA and the conclusions in the petition are completely implausible and (2) fails to consider reasonable alternatives.

1. The DEA's Ordinary Course of Petition Denial Often Runs Counter to the Evidence

The DEA made several conclusions in its 2016 denial that could not be drawn from the evidence evaluated. The DEA, in conjunction with HHS, contended that marijuana has no accepted medical use while simultaneously acknowledging a majority of states had legalized marijuana for medical use.[161] The DEA simply hand-waved away the millions of Americans who are prescribed medical marijuana in states where such practice is legalized, stating that no scientific evidence has come from such states. If this is not implausible, it is at the very least ignorance of "an important aspect of the problem."[162]

Worse, the DEA went through the available scientific research, looking at hundreds of abstracts and narrowing down the list to eleven studies that met their minimum scientific criteria (double-blinded,

projects approved by the FDA. But even if we were to accept his premise—which we don't—Dr. Craker fails to demonstrate that the supply is inadequate for those needs, either. He merely states that certain projects were rejected as 'not bonafide' by NIDA, a claim which does not address the adequacy of supply. The fact that Dr. Craker disagrees with the method by which marijuana research is approved does not undermine the substantial evidence that supports the Administrator's conclusion or render that conclusion arbitrary or capricious.").

160. 2016 Denial, 81 Fed. Reg. 53714.

161. *Id.* at 53741 ("The HHS noted that there are several states as well as the District of Columbia which have passed laws allowing for individuals to use marijuana for purported 'medical' use under certain circumstances, but data are not available yet to determine the number of individuals using marijuana under these state laws. Nonetheless, according to 2014 NSDUH data, 22.2 million American adults currently use marijuana. Based on the large number of individuals who use marijuana and the lack of an FDA-approved drug product, the HHS concluded that the majority of individuals using marijuana do so on their own initiative rather than by following medical advice from a licensed practitioner.").

162. Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

placebo-controlled).[163] ***Every single one*** of the eleven studies showed that the use of marijuana was found to successfully treat symptoms for a variety of medical conditions.[164] In response, the DEA said "all 11 studies that examined effects of inhaled marijuana do not currently prove efficacy of marijuana in any therapeutic indication based on a number of limitations in their study design."[165] Even if the conclusion of the DEA was upheld on judicial review, proper A&C review should require the DEA to at least provide substantiated reasoning as to why these studies fail to prove a medical use beyond just stating there are methodological limitations. At least, the DEA should have addressed the unanimity in positive results because it runs directly counter to the DEA's ultimate decision to find no medical use for marijuana.

Then, in finding marijuana "unsafe," the DEA claimed that safety is an abstract concept that can only be measured by a risk-benefit analysis, and since the agency found that because there was no showing of medical efficacy under factor three of the "medical use" test, nothing could be weighed against marijuana's risk.[166] Essentially, the DEA found that there were no adequate safety studies, because such studies could not exist![167] Thus, a failure under factor three (requiring studies that show medical efficacy) automatically leads to a failure under factor two, ***even though such studies did show efficacy***, just not according to the scientific rigor the DEA requires. This type of circular reasoning cannot stand as reasoned agency decision-making.

2. The Denial Ignores Reasonable Alternatives in Its Scheduling Decisions

There are instances in the petition where the DEA could have considered alternatives that were "within the ambit of the existing

163. 2016 Denial, 81 Fed. Reg. at 53713.

164. *Id.* ("The eleven clinical studies that met the criteria and were evaluated in this review **showed positive signals** that marijuana may produce a desirable therapeutic outcome, under the specific experimental conditions tested. Notably, it is beyond the scope of this review to determine whether these data demonstrate that marijuana has a currently accepted medical use in the United States.").

165. *Id.* at 53701.

166. *Id.* ("When determining whether a drug product is safe and effective for any indication, FDA performs an extensive risk-benefit analysis to determine whether the risks posed by the drug product's side effects are outweighed by the drug product's potential benefits for a particular indication. Thus, contrary to the petitioner's assertion that marijuana has accepted safety, **in the absence of an accepted therapeutic indication which can be weighed against marijuana's risks, marijuana does not satisfy the element for having adequate safety studies** such that experts may conclude that it is safe for treating a specific, recognized disorder.").

167. *Id.*

policy."[168] Here, the alternative the DEA should have considered is clear; the DEA could have put marijuana on a schedule other than Schedule I.[169] The DEA needed to consider that option in a reasonable way in their petition, and at least according to the Court's analysis in *DHS v. The Board of Regents*, it did not. The alternative here is far more discernable than the alternative of splitting up rather than total recission of the DACA program's deferred deportation and benefits conferral.[170] Here, the main defense of marijuana's Schedule I status is that it currently has no acceptable medical use.[171] As shown in Part II.C.1, the conclusion that there is no medical use is implausible.

Furthermore, the CSA's text does not support automatically placing substances on Schedule I merely because they lack medical use, regardless of their potential for harm.[172] The determination that a substance belongs on Schedule I—solely because one finding out of three required—is very similar to the DHS's invalidated determination that a finding of illegality was enough to rescind DACA in *DHS v. Regents*.[173] Like the DHS's decision to only focus on DACA's illegality in that case, the DEA in 2016 made a decision to keep marijuana on Schedule I almost entirely based on one factor ("no accepted medical use") without seriously looking into any alternatives, like that marijuana might have a "potential for abuse" more fit for Schedule II or III.[174]

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168. Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 591 U.S. 1, 30 (2020).

169. *Id.* at 59 n.14 (Thomas, J., dissenting) ("The majority's interpretation of the Fifth Circuit's opinion is highly questionable. Because a grant of deferred action renders DACA recipients eligible for certain benefits and work authorization, it is far from clear that the Department could separate DACA's 'forbearance component' from the major benefits it conferred without running into yet another APA problem.").

170. *Id.* at 28–31.

171. 2016 Denial, 81 Fed. Reg. at 53689 ("As explained below, the medical and scientific evaluation and scheduling recommendation issued by the Secretary of Health and Human Services concludes that marijuana has no currently accepted medical use in treatment in the United States, and the DEA Administrator likewise so concludes. For the reasons just indicated, **no further analysis beyond this consideration is required** [in placing Marijuana on Schedule I].").

172. Kreit, *supra* note 10, at 340–41.

173. *Id.*; *DHS v. Regents of Univ. of Cal.*, 591 U.S. at 28.

174. 2016 Denial, 81 Fed. Reg. at 53689 ("Accordingly, in view of section 811(d)(1), this scheduling petition turns on whether marijuana has a currently accepted medical use in treatment in the United States. If it does not, DEA must, pursuant to section 811(d), deny the petition and keep marijuana in schedule I."); The DEA did complete an analysis of marijuana's potential for abuse but focused mostly on the popularity of the drug rather than its harm (especially its relative harm) and such analysis was clearly secondary to the "medical use" analysis. The denial was decided based on the medical use prong according to the DEA's own words. *See id.* ("As explained below, the medical and scientific evaluation and scheduling recommendation issued by the Secretary of Health and Human Services concludes that marijuana has no currently accepted medical use in treatment in the United States, and the DEA Administrator likewise so concludes. For the reasons just indicated, no further analysis beyond this consideration is required.").

The DEA's analysis laid out above is illustrative of the approach it takes to rescheduling petitions and scheduling substances generally.[175] The DEA does not properly analyze alternatives to its chosen schedule and it ignores or fails to respond to clear evidence contrary to its position.[176] A&C review after the DACA recission case, if applied seriously by courts, should provide an avenue for rescheduling petitions to succeed for substances currently misclassified.

D. The New Marijuana Approach

As mentioned in Part I, the Biden Administration pushed for the rescheduling of marijuana, which has already resulted in major change to the status quo.[177] HHS, at the request of the Biden Administration, analyzed the scientific and medical data, and the agency's conclusion drastically differed from the 2016 analysis.[178] Afterwards, the DEA initiated a Notice of Rulemaking for the Rescheduling in which the DEA reviewed HHS's analysis—which the DEA considered binding—and requested input from interested parties on marijuana's rescheduling.[179] At this point, the DEA has not taken a position on marijuana rescheduling, but most experts assume the agency will follow the Biden Administration and HHS's recommendation to reschedule marijuana from Schedule I to Schedule III.[180] Analysis of the HHS and the DEA's response to the Biden Administration's prodding on marijuana rescheduling in comparison to their previous obstinance on the subject provides an insight into how a new legal framework would be applied, especially when contrasting the 2024 Marijuana Rescheduling Notice analysis with the 2016 Petition Denial discussed in Part III.C.

1. Accepted Medical Use

As discussed, HHS put forward a new interpretation of "accepted medical use" which, after consulting with OLC, the DEA accepted.[181] Under part one of this new interpretation, evaluating medical use in

175. *See, e.g.*, Denial of Pet. to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40552, 40566 (Dep't of Just. July 8, 2011); Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act, 51 FR 36552-01 (1986).

176. *See supra* Part III.

177. *See, e.g.*, Tsirkin & Alba, *supra* note 13; 2024 Marijuana Rescheduling Opinion, 48 Op. O.L.C. 1; HHS 2024 Marijuana Analysis.

178. HHS 2024 Marijuana Analysis.

179. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597, 44601 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

180. *Id.* at 44601 ("DEA has not yet made a determination as to its views of the appropriate schedule for marijuana.").

181. *See supra* footnotes 47–52 and accompanying text.

states where the substance is legalized, HHS found marijuana has an accepted medical use because thousands of health care professionals and millions of their patients have been using the substance in accordance with the laws of a "substantial number of jurisdictions" for a number of years.[182] In part two of the analysis, weighing credible scientific data, the HHS analyzed data gathered by universities, the FDA, and national surveys and found such evidence credible and conclusive.[183]

2. Potential for Abuse

Although the DEA, for the moment, is continuing to use the four-part "potential for abuse" test, the test was applied in a completely different manner by HHS in 2024. In 2016, HHS determined marijuana had a high potential for abuse primarily because marijuana was the most commonly used illicit substance in the United States.[184] Although HHS did look at the rate of emergency room visits related to marijuana use and the rate of use by minors in 2016, the bulk of HHS and the DEA's analysis was focused on use.[185] Both HHS and the DEA refused to consider the fact that many Americans were using marijuana to treat medical conditions (and thus not abusing the substance) because the agencies took the view that medical professionals could only "legitimately" prescribe the substance through an FDA research process.[186]

182. CTR. FOR DRUG EVALUATION & RSCH., U.S. FOOD & DRUG ADMIN., CONSIDERATIONS FOR WHETHER MARIJUANA HAS A CURRENTLY ACCEPTED MEDICAL USE IN THE U.S. FOR PURPOSES OF SECTION 202(B) OF THE CONTROLLED SUBSTANCES ACT at 10 (Aug. 28, 2023), *in* RACHEL L. LEVINE, DEP'T OF HEALTH & HUM. SERVICES, BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT (Aug. 29, 2023) ("OASH conducted the evaluation and assessment of marijuana under Part 1 of the CAMU test and has confirmed that more than 30,000 HCPs across 43 U.S. jurisdictions are authorized to recommend the medical use of marijuana for more than six million legally registered patients for at least 15 medical conditions. Taken together, the data support that a substantial number of HCPs have gained clinical experience with marijuana, and a substantial number of regulatory entities recognize at least one specific medical use of marijuana under authorized programs.").

183. *Id.* at 90 ("Based on the totality of the available data described in Section II.4 of this document, we conclude that there exists some credible scientific support for the use of marijuana in at least one of the indications for which there is widespread current experience with its medical use in the United States, as identified under Part 1 of the CAMU test.").

184. 2016 Denial, 81 Fed. Reg. at 53691 ("Evidence shows that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. **A large number of individuals use marijuana**.").

185. 2016 Denial, 81 Fed. Reg. at 53691–93.

186. *Id.* at 53691 ("Because the FDA has not approved an NDA or BLA for a marijuana drug product for any therapeutic indication, the only way an individual can take marijuana on the basis of medical advice through legitimate channels at the federal level is by participating in research under an IND application.").

In 2023, HHS took a very different view of what "abuse" meant than it did previously while continuing to superficially use the DEA interpretation of "potential for abuse." HHS found that marijuana had a relatively low potential for abuse even though it was commonly used.[187] Absent was the previous equivalence—seemingly required by the DEA's interpretation of the CSA—of use with abuse.[188] In 2024, HHS focused on the relative harm of marijuana compared to other substances, finding marijuana less dangerous—using markers like overdose deaths, hospitalizations, and accidental poisoning—than other similarly scheduled substances.[189] This represents a departure from the 2016 denial where the DEA found such analysis of relative harm "inconsequential," and there was no mention of the complete absence of overdose or accidental deaths from marijuana use.[190]

Essentially, without a change in the underlying facts, HHS's 2024 scientific and medical analysis completely contradicted its 2016 conclusion. This disagreement boils down to new interpretations of the CSA's scheduling criteria and new application of the criteria to the evidence HHS reviewed. It is unclear if the DEA will agree with HHS's marijuana analysis. The DEA, based on OLC's analysis, understood the CSA's text to mean that HHS's scientific and medical analysis is binding only until after the DEA puts forward a notice of proposed rulemaking, a fact the DEA makes very clear throughout the notice.[191] Although the DEA is required to give HHS's analysis "significant deference" in making the ultimate scheduling decision, based on the current

187. CTR. FOR DRUG EVALUATION & RSCH., *supra* note 182, at 6 ("Evidence shows that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. However, evidence also exists showing that the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others.").

188. *Id.*

189. *Id.* at 8 ("The risks to the public health posed by marijuana are lower compared to other drugs of abuse (e.g., heroin, oxycodone, cocaine), based on an evaluation of various epidemiological databases for emergency department (ED) visits, hospitalizations, unintentional exposures, and most importantly, for overdose deaths. The rank order of the comparators in terms of greatest adverse consequences typically places heroin, benzodiazepines and/or cocaine in the first or immediately subsequent positions, with marijuana in a lower place in the ranking, especially when a utilization adjustment is calculated. For overdose deaths, marijuana is always in the lowest ranking among comparator drugs. These evaluations demonstrate that there is consistency across databases, across substances, and over time that although abuse of marijuana produces clear evidence of a risk to public health, that risk is relatively lower than that posed by most other comparator drugs.").

190. 2016 Denial, 81 Fed. Reg. at 53747 ("Thus, any attempt to compare the relative abuse potential of schedule I substance to that of a substance in another schedule is inconsequential since a schedule I substance must remain in schedule I until it has been found to have a currently accepted medical use in treatment in the United States.").

191. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44599 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

interpretation of "potential for abuse," the DEA would still have a basis for placing marijuana on Schedule I.[192] It is even less clear if HHS's analysis would carry over to other, less politically popular substances, but in conjunction with changes in administrative law, the analysis provides a potential framework for scheduling substances while complying with current administrative law doctrine.

E. Putting It All Together: A Revised Framework for Classifying Substances

The end result of the various administrative law decisions and recent changes in executive policy is that the DEA will be forced to overhaul their procedure for scheduling drugs. It is worth examining what a new scheduling process might entail in comparison to the process described in Part I.

Findings of an accepted medical use will become much more common if HHS's interpretation of "accepted medical use" is validated by courts, especially if the first prong of the test is tailored to accept evidence from foreign governments for Schedule I substances as laid out in Part III.A.1.[193] If a substance is legalized for medicinal purposes and medical professionals prescribe it, HHS and the DEA will likely be ***forced*** to find a medical use unless there is a lack of credible evidence that the substance is effective in treating medical conditions.[194] Once a state (or a foreign government)[195] has gone through the process of regulating the substance and a substantial number of doctors are prescribing the substance in order to treat conditions, there will almost certainly be credible evidence as to a medical use given the reality that medical professionals prescribe effective substances. Without the backdrop of strong-form *Auer* deference, the DEA will be unable to bend the interpretation of its new test to exclude relevant medical data as it did in the past.[196]

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192. *Id.*

193. *See supra* notes 98–107 and accompanying text.

194. This assumes HHS and the DEA apply their tests evenly across substances, or that courts force them to do so.

195. HHS and OLC used the phrase "substantial number of jurisdictions" in their guidance factors as to prongs 1 and 2 but did not offer any further clarity. Even legalization by one state should suffice because there is a vast number "of jurisdictions," medical providers, and patients within any given state. In order to better fit the definition of "accepted medical use," HHS's test should only require legalization by one (or a small number) of states.

196. 2016 Denial, 81 Fed. Reg. at 53701 ("Currently, no published studies conducted with marijuana meet the criteria of an adequate and well-controlled efficacy study. The criteria for an adequate and well-controlled study for purposes of determining the safety and efficacy of a human drug are defined under the Code of Federal Regulations (CFR) in 21 CFR 314.126."); Americans for Safe Access v. Drug Enf't Admin., 706 F.3d 438, 451 (D.C. Cir. 2013).

Under a textually acceptable definition of "potential for abuse" like the one put forward in Part IV.B, the DEA will have to prove both actual and relative harm rather than simply finding that a substance is used recreationally.[197] Given that substances like fentanyl, cocaine, and methamphetamine are on Schedule II, this new approach, consistent with the text, should ease restrictions on less harmful substances currently in Schedule I.[198] In conjunction with the new interpretation of "accepted medical use," the DEA will be forced, either through litigation or through institutional acquiescence, to reclassify a variety of substances.

A more demanding form of A&C review will require the DEA to apply these new interpretations logically, objectively, and fairly across a wide variety of substances, not just those that are politically advantageous to reclassify.[199] The DEA should have to evaluate alternative schedules for a substance due to *DHS v. Regents* decision, and other Roberts Court decisions provide legal support for stronger federal court oversight over agency decision-making.[200]

Finally, without *Chevron* or strong-form *Auer* deference, these drug reform wins will be made permanent, free of the winds of executive change.[201] An anti-drug administration will not be able to re-interpret either the CSA or its own regulations in order to restrict substances

197. *See supra* Part III.A.2.

198. CTR. FOR DRUG EVALUATION & RSCH., *supra* note 182, at 8 ("The risks to the public health posed by marijuana are lower compared to other drugs of abuse (e.g., heroin, oxycodone, cocaine), based on an evaluation of various epidemiological databases for emergency department (ED) visits, hospitalizations, unintentional exposures, and most importantly, for overdose deaths. The rank order of the comparators in terms of greatest adverse consequences typically places heroin, benzodiazepines and/or cocaine in the first or immediately subsequent positions, with marijuana in a lower place in the ranking, especially when a utilization adjustment is calculated. For overdose deaths, marijuana is always in the lowest ranking among comparator drugs. These evaluations demonstrate that there is consistency across databases, across substances, and over time that although abuse of marijuana produces clear evidence of a risk to public health, that risk is relatively lower than that posed by most other comparator drugs.").

199. Carrie Rosenbaum, *Arbitrary Arbitrariness Review*, 100 DENV. L. REV 775, 778 ("The *Regents* brand of hard look review can foster rule of law principles by requiring agency transparency in reason-giving.").

200. *See, e.g.*, Dep't of Com. v. N. Y., 588 U.S. 752 (2019); Ohio v. Env't Prot. Agency, 603 U.S. 279 (2024); Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 591 U.S. 1 (2020).

201. Buffington v. McDonough, 143 S. Ct. 14, 20 (2022) (Gorsuch, J., dissenting) ("When the law's meaning is never liquidated by a final independent judicial decision, when executive agents can at any time replace one reasonable interpretation with another, individuals can never be sure of their legal rights and duties. Instead, they are left to guess what some executive official might 'reasonably' decree the law to be today, tomorrow, next year, or after the next election. '[E]very relevant actor may agree' that the agency's latest pronouncement does not represent best interpretation of the law, yet all the same each new iteration 'carries the force of law.' Fair notice gives way to vast uncertainty.").

simply because it is in their political interest.[202] Scientific data and the reality of the substance's use will drive classification, rather than prohibitionist sentiment that has driven the DEA to abuse its power since 1970. Before the path to rescheduling was murky, biased, and based almost entirely on the whims of the executive branch. Now drug reformers have a clear path for successful rescheduling petitions, facilitated by new administrative law doctrines.

Under this new legal framework, a substance that (1) is legalized and regulated in at least one state or foreign country for medical use, (2) is being used by medical professionals for medical treatment, (3) has credible evidence backing its medical use (and thus can pass HHS's two-part test), and (4) is less harmful than substances on the same or lower schedule should be removed from Schedule I if a valid petition is brought before the DEA.[203] Once such a substance is rescheduled, changes to *Auer* and *Chevron* should "lock-in" these wins, assuming no change to either the scientific facts underlying the medical use and harm potential or the legal status of the substance at the state level. Part IV of this Article will analyze the potential rescheduling of several popular and relatively safe Schedule I substances that appear ripe for reclassification under the new framework: Psilocybin, LSD, and MDMA.

IV. THE NEW FRONTIER: CHALLENGING THE SCHEDULING OF PSILOCYBIN, MDMA, AND LSD UNDER THE NEW REGIME ADMINISTRATIVE LAW REGIME

The Roberts Court's restructuring of administrative law has provided a basis for the rescheduling of a variety of substances. At the same time, both the American public and state governments have become more amenable to the potential decriminalization and legalization of a variety of substances.[204] Major research efforts have

202. Loper Bright Enterprises v. Raimondo, 603 U.S. 369, 411 (2024) ("Chevron thus allows agencies to change course even when Congress has given them no power to do so. By its sheer breadth, Chevron fosters unwarranted instability in the law, leaving those attempting to plan around agency action in an eternal fog of uncertainty." [citation omitted]); *Id.* at 434 (Gorsuch, J., concurring) ("And because the reasonable bureaucrat may change his mind year-to-year and election-to-election, the people can never know with certainty what new 'interpretations' might be used against them. This 'fluid' approach to statutory interpretation is 'as much a trap for the innocent as the ancient laws of Caligula,' which were posted so high up on the walls and in print so small that ordinary people could never be sure what they required.").

203. *See supra* Part III.

204. *New National Poll: More Than 60 Percent of U.S. Voters Support Legalizing Psychedelic Therapy*, UC BERKELEY CENT. FOR THE SCI. OF PSYCHEDELICS (June 20, 2023), https://psychedelics.berkeley.edu/berkeley-psychedelics-survey-2023/ (finding more than 60% of Americans support legalizing medical use of psychedelics); Deborah Samenow et al., *State Psychedelic Regulation: Oregon and Colorado Taking the Lead*, DLA PIPER (Jan. 11,

gone into the therapeutic uses of various psychedelics, including psilocybin, MDMA, and LSD in recent years.[205] Colorado and Oregon have already taken the step of partially legalizing psilocybin, and California looks likely to follow.[206] Outside the United States, Australia and the Canadian province of Alberta have recently put in place legalization regimes for psychedelics.[207] The shift has also reached the federal government, as the FDA released guidance for the research of psychedelic substances in June of 2023, noting that "psychedelic drugs show initial promise as potential treatments for mood, anxiety, and substance abuse disorders."[208] The time is ripe, both politically and legally, for petitioners to push for the reclassification of the most promising and popular psychoactive substances.

Drug reformers should aim to petition for the rescheduling of psilocybin, MDMA, or LSD. To be successful reformers will need to prove the substances (1) are legalized and regulated in at least one state (or foreign country) for medical use, (2) are being used by medical professionals for medical treatment, (3) have credible evidence backing its medical use (and thus can pass HHS's two-part test), and (4) are less harmful than substances on the same or lower schedule. Under the new framework, a well-written petition including those four factors should cause the substance to be moved from Schedule I to a less restrictive schedule.[209]

A. Psylocibin

Psilocybin is the most likely of the three substances to be successfully rescheduled through petitioning and judicial review under the new framework. Psilocybin is currently a Schedule I substance, even though studies have found it useful in treating a wide variety of mental

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2023), https://www.dlapiper.com/en/insights/publications/2023/01/state-psychedelic-regulation-oregon-and-colorado-taking-the-lead (detailing Colorado and Oregon's legalization of psilocybin).

205. Heather Stringer, *The Emergence of Psychedelics as Medicine*, 55 AM. PSYCH. ASS'N 4, 50–55 (2024) (detailing research).

206. *See* Samenow et al., *supra* note 204; Sydney Johnson, *California Drops Psychedelic Therapy Legalization Bill, Again*, PBS NEWS (June 25, 2024), https://www.kqed.org/news/11991959/california-drops-psychedelic-therapy-legalization-bill-again.

207. Jennifer Chesak, *What Psychedelics Legalisation and Decriminalisation Looks Like Around the World*, BBC (Mar. 21, 2024), https://www.bbc.com/future/article/20240320-legal-status-of-psychedelics-around-the-world (detailing the legal status of psychedelics around the world, noting the changes in Australia and Alberta).

208. *FDA Issues First Draft Guidance on Clinical Trials with Psychedelic Drugs*, FDA, June 23, 2023.

209. *See supra* Part III.D.

illnesses, and most objective data finds the substance relatively harmless.[210]

Psilocybin satisfies parts three and four of the new framework. A wealth of new scientific research is uncovering an array of possible mental health treatments involving the use of psilocybin.[211] Researchers concluded, after reviewing numerous medical studies, that "psilocybin offers a wide range of possible medical applications."[212] It would be nearly impossible for the DEA to justifiably determine there is not credible evidence of medical use for psilocybin. Additionally, psilocybin is relatively benign compared to Schedule II substances like fentanyl and meth.[213] A study found that only 0.2% of psilocybin users sought emergency medical treatment, and there has only been three recorded deaths due to excess intake of psilocybin.[214]

Prongs one and two of the new framework are more challenging, but with a push by drug reformers to update state regulatory schemes, psilocybin could be rescheduled relatively quickly. As of 2024, two states, Oregon and Colorado, have legalized psilocybin for quasi-medical use.[215] Oregon legalized the substance through a ballot measure in November 2020, and the state has authorized twenty-seven "service centers" and over 300 "facilitators" to dispense psilocybin to over 3,500

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210. Emma I Kopra et al., *Adverse Experiences Resulting in Emergency Medical Treatment Seeking Following the Use of Magic Mushrooms*, SAGE 971 (Apr. 7, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9353971/ ("Magic mushrooms are relatively innocuous substances and rarely cause harm to the individual consuming them nor to other people. Most adverse reactions are short-lived, and their risk can be minimized with certain safety precautions."); Shawn Ziff et al., *Analysis of Psilocybin-Assisted Therapy in Medicine: A Narrative Review*, CUREUS 10 (Feb. 5, 2022) ("Psilocybin offers a wide range of possible medical applications, according to clinical studies. Addiction medicine, depression, and end-of-life mood disorders are among the areas with the most evidence of benefit. The traditional treatments for these disorders are frequently ineffective, and psilocybin-assisted therapy might provide a new treatment option for millions of patients.").

211. *Psychedelic Treatment with Psilocybin Relieves Major Depression, Study Shows*, JOHN HOPKINS MED. NEWSROOM (Nov. 4, 2020), https://www.hopkinsmedicine.org/news/newsroom/news-releases/2020/11/psychedelic-treatment-with-psilocybin-relieves-major-depression-study-shows; Dan Vahaba, *Duke Researchers Probe the Magic of Psychedelics as Medicine*, DUKE UNI. SCH. OF MED. (Oct. 25, 2023), https://medschool.duke.edu/stories/duke-researchers-probe-magic-psychedelics-medicine.

212. Ziff et al., *supra* note 210.

213. Matthew W. Johnson, Roland R. Griffiths, Peter S. Hendricks, Jack E. Henningfield, *The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act*, 142 NEUROPHARMACOLOGY 143, 160–61 (2018) (analyzing all eight of the CSA's scheduling factors and finding that psilocybin belongs on Schedule IV or V).

214. Kopra et al., *supra* note 210.

215. Samenow et al., *supra* note 204; Andrew Kenney, *What to Know About Colorado's Psychedelic Law*, CPR NEWS (July 21, 2023, 4:00 AM), https://www.cpr.org/2023/06/21/colorado-psychedelic-law-for-psilocybin-mushrooms/; Deena Prichep, *In Oregon, Psilocybin Treatment is an Experiment in Real Time*, NPR (Feb. 28, 2024, 5:30 AM), https://www.npr.org/2024/02/28/1234012939/in-oregon-psilocybin-treatment-is-an-experiment-in-real.

patients.[216] Facilitators are not required to be licensed medical professionals (although many are), nor are patients required to obtain a medical referral or prescription before treatment.[217] Colorado is in the process of implementing a similar system, allowing "healing centers" to distribute psilocybin as a "natural medicine service" after a ballot referendum in 2022.[218] Outside the U.S., Alberta and Australia began allowing psychiatrists to prescribe the substance after a finding by the respective governments that the substance was safe and medically effective.[219]

Although early treatment results have been promising in the two states, the current regulatory structure is unlikely to pass the first prong of HHS's current test. State governments allowed doctors and other medical professionals to prescribe or administer marijuana as a medical treatment, but no state has regulated psilocybin in the same way.[220] Licensed medical professionals are not treating patients with psilocybin nor are they prescribing the substance in the ordinary course of medical treatment.[221]

There are possible solutions. The first is to challenge HHS's test in federal court as illogical as applied to Schedule I substances for the reason that it requires states and doctors to violate the CSA as discussed in Part III.A. The other solution is persuasion. Colorado, Oregon, and other states considering psilocybin regimes should be convinced to allow psilocybin to be prescribed by medical professionals in the state. Given the wealth of new evidence showing the effectiveness of the treatment,

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216. Jane Vaughan, *A Year Later, Psilocybin-Assisted Therapy is More Accessible in Oregon, but Remains Costly*, OPB (May 28, 2024, 3:24 PM), https://www.opb.org/article/2024/05/28/a-year-later-psilocybin-assisted-therapy-is-more-accessible-in-oregon-but-remains-costly/.

217. *See generally* ORS §475A Psilocybin Regulation; OAR §333.333; Prichep, *supra* note 215.

218. Kenney, *supra* note 215; Chryss Cada, *Colorado Decriminalized Psilocybin. Here's Your Guided Trip Through What Happens Next*, THE COLORADO SUN (June 18, 2023), https://coloradosun.com/2023/06/18/colorado-decriminalized-psilocybin-whats-next/.

219. *Change to Classification of Psilocybin and MDMA to Enable Prescribing by Authorised Psychiatrists*, THERAPEUTIC GOODS ADMIN. (Feb. 3, 2023), https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists; A.J. Herrington, *Alberta to Be First Canadian Province to Regulate Psychedelics for Therapeutic Use*, FORBES (Oct. 6, 2022), https://www.forbes.com/sites/ajherrington/2022/10/06/alberta-to-be-first-canadian-province-to-regulate-psychedelics-for-therapeutic-use/.

220. *State Medical Cannabis Laws*, NAT. CONF. OF STATE LEGIS. (last updated July 12, 2024), https://www.ncsl.org/health/state-medical-cannabis-laws (listing state marijuana regimes); *see generally* ORS §475A Psilocybin Regulation; OAR §333.333; Pricep, *supra* note 215; Samenow et al., *supra* note 204.

221. *See generally* ORS §475A Psilocybin Regulation; OAR §333.333; Prichep, *supra* note 215; Samenow et al., *supra* note 204.

the safety of the substance, and preliminary results of successful treatment within and outside the U.S., a green light from a state for medical prescription would force the DEA to take psilocybin off of Schedule I.[222]

B. MDMA

MDMA, like psilocybin, is recreationally popular, less harmful than many Schedule II substances, and shows promise in treating a number of psychiatric disorders.[223] A recent scientifically rigorous study by *Nature Magazine* found evidence that MDMA is effective at combating Post-Traumatic Stress Disorder ("PTSD"), and the Australian government, in addition to psilocybin, has permitted doctors to prescribe MDMA as treatment for PTSD, finding MDMA was effective at reducing anxiety and improving mood after reviewing the results of a number of clinical trials.[224]

Research shows that while MDMA is not risk-free, it is less harmful than substances currently on Schedule II.[225] Overdose deaths are rare.[226] MDMA has a significantly lower mortality rate than Schedule II substances like fentanyl and methamphetamine, which cause tens of thousands of deaths annually.[227] MDMA should pass prongs three and four of the new scheduling framework.

The problem for MDMA, like with psilocybin, lies in prongs one and two of the new framework (prong one of HHS's medical use test). Unlike psilocybin, no state has currently crafted a decriminalization/quasi-legalization regime for MDMA, and as of now no state is currently discussing the substance's legalization. Australia and Alberta have developed a medical MDMA regimes, but under the current HHS/DEA interpretation of the CSA, this is irrelevant.[228] In a

222. *See* footnotes 207–221 and accompanying text.

223. Rachel Nuwer, *MDMA Is One of the Safer Illegal Drugs. But There Are Risks*, N.Y. TIMES (Aug. 18, 2023), https://www.nytimes.com/2023/08/18/well/mind/mdma-ecstasy-risk.html; Victoria Colliver, *MDMA's Latest Trial Results Offer Hope for Patients with PTSD*, UCSF (Sept. 18, 2023), https://www.ucsf.edu/news/2023/09/426116/mdmas-latest-trial-results-offer-hope-for-patients-ptsd.

224. Jennifer M. Mitchell et al., *MDMA-Assisted Therapy for Moderate to Severe PTSD: A Randomized, Placebo-Controlled Phase 3 Trial*, 29 Nat. Med. 2473, 2473 (2023); Chesak, *supra* note 207.

225. Nutt et al., *supra* note 117.

226. Nuwer, *supra* note 223.

227. *Drug Overdose Deaths: Facts and Figures*, NAT. INST. ON DRUG ABUSE, https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Download (last visited Sept. 24, 2024).

228. *Change to Classification of Psilocybin and MDMA to Enable Prescribing by Authorised Psychiatrists*, THERAPEUTIC GOODS ADMIN. (Feb. 3, 2023), https://www.tga.gov

promising moment, the FDA considered approving MDMA as a treatment for PTSD, but decided against approval in a contested vote.[229] Without any state regulatory regime, the current rescheduling of MDMA is unlikely to occur absent a change in CSA interpretation.

C. LSD

LSD is currently the furthest away from fulfilling rescheduling conditions as no state has instituted a regulatory regime nor foreign jurisdiction has allowed its medical use. However, there is credible evidence of LSD's effectiveness in treatment for anxiety, depression, and alcoholism.[230] Dying of an LSD overdose is essentially impossible, with only two known cases in history, and emergency room visits are also rare.[231] Compared to the high level of danger many Schedule II substances present, LSD is relatively safe.[232] However, no jurisdiction has yet permitted the use of LSD for medical purposes. Even under a realistic, permissive interpretation of the CSA, the DEA will not be forced to reschedule LSD. Without further research and legal advances, is unlikely to be rescheduled in the near future.

.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists; Herrington, *supra* note 219.

229. Kai Kupferschmidt, *FDA Rejected MDMA-Assisted PTSD Therapy. Other Psychedelics Firms Intend to Avoid That Fate*, SCIENCE.ORG (Aug. 12, 2024, 9:00 AM), https://www.science.org/content/article/fda-rejected-mdma-assisted-ptsd-therapy-other-psychedelics-firms-intend-avoid-fate; Will Stone, *FDA Advisers Reject MDMA Therapy for PTSD, Amid Concerns Over Research*, NPR (June 4, 2024, 8:10 PM), https://www.npr.org/sections/shots-health-news/2024/06/04/nx-s1-4991112/mdma-therapy-ptsd-fda-advisors. FDA approval would also have led to a finding of "accepted medical use" for MDMA, as FDA approval is a sufficient but not necessary condition to such a finding according to the DEA (and now OLC).

230. Juan José Fuentes et. al., *Therapeutic Use of LSD in Psychiatry: A Systematic Review of Randomized-Controlled Clinical Trials*, FRONTIERS IN PSYCHIATRY 1 (Jan. 21, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6985449/ ("LSD is revealed as a potential therapeutic agent in psychiatry; the evidence to date is strongest for the use of LSD in the treatment of alcoholism."); Matthias E. Liechti, *Modern Clinical Research on LSD*, NEUROPSYCHOPHARMACOLOGY 2124 (June 14, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5603820/.

231. Emma I Kopra et al., *Adverse Experiences Resulting in Emergency Medical Treatment Seeking Following the Use of Lysergic Acid Diethylamide (LSD)*, SAGE 957 (June 7, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9353972/ ("LSD has low toxicity relative to other psychoactive drugs and in normal doses induces only minor physiological effects including slight increases in heart rate and blood pressure. Only two known cases exist where massive LSD overdose appears to have been directly responsible for death. Based on these case reports and evidence from animal studies, the lethal dose of LSD has been estimated as roughly a thousand times or more the usual recreational dose.").

232. Nutt et al., *supra* note 117, at 1561.

V. CONCLUSION

The purpose of this Article is not to disparage the previous administrative law regime. Agencies had the flexibility to tackle new problems, and despite some criticism, they had been successful in using reasoned analysis and empirical data to protect the environment, improve public health, and increase the average American's standard of living. The Court's precedents facilitated this flexibility by allowing Congress to delegate power to agencies, by giving agencies deference in their interpretations of their own regulations and their governing statutes, and by deferring to agency fact-finding and reasoned analysis, all within limits of various standard of reviews that center on "reasonableness."

One cannot discuss the benefits of that regime without a discussion of the costs. As the analysis in this Article shows, the flexibility was taken advantage of by the DEA to institute draconian anti-drug policies with thin empirical and statutory backing. If there is an area in which criticism of the administrative state appears strongest, it is in the area of drug control.

It is worth summarizing how the Court's administrative law precedents have altered the balance in favor of the DEA. The Court's permissive non-delegation regime allowed Congress to delegate the DEA power to schedule any "substance." Then, *Chevron* deference required courts to accept the DEA's interpretation of the provisions of the CSA as long as the provision is ambiguous, and the DEA's interpretation is "reasonable," which was especially problematic in the case of the CSA because the statute is full of ambiguous and overlapping terms and provisions. *Auer* deference further required courts to defer to the agency's interpretation of its own regulations, and the regulations were based on statutory interpretations that only were acceptable because of *Chevron*. Finally, relatively lax A&C review allowed the DEA to make scheduling decisions based on illogical analysis and political will rather than scientific data.

The Court's administrative law decisions from 2019 onward provide a path to altering this balance of power. The overturn of *Chevron* removes judicial deference from agency interpretations of the law. *Kisor* empowers courts to police agencies when they interpret their own regulations. *DHS v. Board of Regents* requires that agencies give alternative policies real attention.

If the Court applies new doctrine in an objective and neutral way, at least some less harmful and medically promising substances should soon be moved off Schedule I, and the worst excesses of DEA authority would be reduced. Prison sentences and related punishment for the possession and distribution of the most popular recreational substances

would be reduced given the tie-in between CSA scheduling and sentencing. Americans would have access to substances that may provide relief to some of the country's most severe public health crises. The new process would incentive innovative federalism, as states could lead the way in gathering data and on-the-ground evidence of substances' medical effectiveness. These wins would not be reversible. The new administrative law regime would prevent backsliding if a less drug-friendly presidential administration is elected.

Some observers contend that the Court's changes to administrative law are politically motivated and potentially unwise as a matter of policy. In the context of the drug war, it may offer something different. A judicially enforced truce is possible.

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