HOW MARIJUANA RESCHEDULING COULD TRANSFORM THE CONTROLLED SUBSTANCES ACT

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After fifty-five years, the federal government is on the verge of moving marijuana out of Schedule I, the most restrictive category in the federal Controlled Substances Act (CSA). In May 2024, then-Attorney General Merrick Garland issued a notice of proposed rulemaking to move marijuana to Schedule III—a change now making its way through the administrative process.

Underlying the proposal is a significant divide within the federal government over how to interpret the CSA's scheduling provisions. Under the CSA, Schedule I substances are those with a "high potential for abuse," "no currently accepted medical use," and "a lack of accepted safety for use." But the CSA does not define these terms, and the Drug Enforcement Administration (DEA) has long interpreted them strictly. In the lead-up to the Attorney General's rescheduling notice, the Department of Health and Human Services (HHS)—tasked by the CSA with conducting a scientific and medical evaluation in scheduling proceedings—abandoned the DEA's tests for assessing medical use and abuse potential. HHS's analysis, under this new and more lenient approach, formed the basis for the rescheduling proposal.

This Article examines the proposed transfer of marijuana from Schedule I to Schedule III of the CSA. In it, I argue that the split between the DEA and HHS—combined with the Supreme Court's 2024 reversal of Chevron *deference—sets the stage for a process likely to transform the CSA by requiring the DEA to abandon its longstanding approach to*

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interpreting and applying the scheduling criteria. In support of this analysis, the Article unearths two pieces of evidence from the history of the CSA and the Food, Drug, and Cosmetic Act (FDCA) that have gone overlooked by both courts and commentators, but that I argue significantly undermine the DEA's definition of "currently accepted medical use." Finally, the Article explains why the factual findings in HHS's recommendation to transfer marijuana to Schedule III could give marijuana reform advocates ammunition to press for an even lower CSA classification.

TABLE OF CONTENTS

INTRODUCTION

When Congress enacted the federal Controlled Substances Act (CSA)[1] in 1970, it placed marijuana[2] in the CSA's most restrictive category—Schedule I.[3] Ever since, drug policy reform advocates have sought for marijuana either to be moved from Schedule I to a less restrictive classification or to be placed outside of the CSA's

1. 21 U.S.C. §§ 801–904. The Controlled Substances Act was enacted as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1284.

2. The CSA defines marijuana to mean "all parts of the plant Cannabis sativa L.," excluding hemp and hemp-derived products. 21 U.S.C. § 802(16).

3. 21 C.F.R. § 1308.11(d)(23) (2026).

regulatory scheme entirely.[4] Now, after fifty-five years, advocates appear to be on the verge of getting their wish. In May 2024, then-Attorney General Merrick Garland issued a notice of proposed rulemaking, in which he concluded that there is "substantial evidence that marijuana does not warrant control under schedule I of the CSA" and proposed "to reschedule marijuana in schedule III."[5] The proposed rulemaking was the culmination of an October 2022 presidential directive instructing "the Secretary of Health and Human Services and the Attorney General to . . . review expeditiously how marijuana is scheduled under federal law."[6] The proposed rescheduling order is now making its way through the administrative process.[7]

At least to those who are unfamiliar with the ins and outs of the CSA, marijuana's placement in the same federal regulatory category as heroin has always seemed a bit "bizarre."[8]

Federal officials have been known to back themselves into making almost laughable claims while defending the placement of marijuana in Schedule I to lay audiences. In 2015, the former Drug Enforcement Administration (DEA) head Chuck Rosenberg said of marijuana, "Do I think it's as dangerous as heroin? Probably not. I'm not an expert."[9] Perhaps to avoid saying something equally silly,

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4. The National Organization for the Reform of Marijuana Laws (NORML) filed the first petition to remove marijuana from Schedule I in 1972. All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1133 (D.C. Cir. 1994). The proceedings on the petition did not come to an end until twenty-two years later, when—after a history that included four federal appellate opinions—the D.C. Circuit upheld the DEA's final denial of the petition. *Id.* at 1137. The DEA has denied multiple petitions to reschedule marijuana since then. *See* Grace Wallack & John Hudak, *Marijuana Rescheduling: A Partial Prescription for Policy Change*, 14 OHIO ST. J. CRIM. L. 207, 210 (2016).

5. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44619–20 (proposed May 16, 2024) (to be codified at 21 C.F.R. pt. 1308). The Attorney General's plan to propose the rescheduling marijuana to Schedule III was announced a few weeks before issuance of the formal notice in the federal register. *See* Alicia Wallace et al., *Justice Dept Plans to Reschedule Marijuana as a Lower-Risk Drug*, CNN (Apr. 30, 2024), https://perma.cc/W9TC-DKVB.

6. Statement from President Biden on Marijuana Reform, WHITE HOUSE (Oct. 6, 2022), https://perma.cc/P3WS-DQTA.

7. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 91 Fed. Reg. 22777 (Apr. 28, 2026) (providing notice that the DEA will hold a hearing on the proposed rescheduling of marijuana beginning June 29, 2026).

8. German Lopez & Javier Zarracina, *Poll: Americans Have No Idea Marijuana is in the Same Legal Category as Heroin and LSD*, VOX (Mar. 15, 2016), https://www.vox.com/2016/3/15/11224746/marijuana-drug-schedules-survey.

9. German Lopez, *The DEA Chief Finally Admitted the Truth About Marijuana Versus Heroin*, VOX (Aug. 6, 2015), https://www.vox.com/2015/7/30/9073215/marijuana-schedule-drug-heroin. One

Rosenberg's predecessor Michele Leonhart once chose simply to repeat the statement, "I believe all illegal drugs are bad," in response to questioning about the comparative dangers of marijuana and crack cocaine.[10]

To most observers, a look at the scheduling criteria as they are stated in the text of the CSA would, if anything, add to the confusion over marijuana's Schedule I status. The CSA classifies substances based primarily on three findings: first, the relative "potential for abuse" of the substance (the lower the abuse potential, the lower the schedule); second, whether the substance has a "currently accepted medical use in treatment in the United States"; and, third, the substance's safety and dependence profile.[11] Under this classification system, Schedule I drugs are defined as those with a "high potential for abuse," "no currently accepted medical use," and "a lack of accepted safety for use . . . under medical supervision."[12]

Based on these criteria, one might imagine that moving marijuana to a lower schedule would be an easy lift. After all, an overwhelming majority of states have adopted medical marijuana laws[13] (arguably, a signal of widespread acceptance), and there is a good deal of evidence that marijuana has medical uses.[14] Likewise, to those uninitiated in the DEA's scheduling decisions, the relative potential for abuse criterion might seem like a slam dunk in favor of rescheduling. The fact that marijuana is less dangerous to users—

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week later, after "criticism and mockery from the media," Rosenberg stated that "heroin is clearly more dangerous than marijuana." *Id.*

10. William Bergstrom, *DEA Chief Deflects Pot Questions*, POLITICO (June 21, 2012), https://perma.cc/SY83-DNNC.

11. *See* Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 336–51 (2013) (providing an overview of the CSA's scheduling system); 21 U.S.C. § 812(b)(1)(A)–(B). *Compare id.* § 812(b)(1)(C) (requiring a finding under Schedule I that "[t]here is a lack of accepted safety for use of the drug or other substance under medical supervision"), *with id.* § 812(b)(2)(C) (requiring a finding under Schedule II that "[a]buse of the drug or other substance may lead to severe psychological or physical dependence"). In addition to the three findings that expressly govern scheduling under the CSA, the statute separately lists eight additional "[f]actors determinative of control or removal from schedules." 21 U.S.C. § 811(c). For a discussion of the relationship between the eight factors and the scheduling findings, see Kreit, *supra*, at 344–46.

12. 21 U.S.C. § 812(b)(1).

13. Forty states had adopted medical marijuana laws as of June 26, 2025. *State Medical Cannabis Laws*, NAT'L CONF. STATE LEGISLATURES (June 27, 2025), https://perma.cc/7B9E-A4ES.

14. *See generally* NAT'L ACADS. OF SCIS., ENG'G & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF THE EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 85–128 (2017), https://perma.cc/2KV6-KC5F (reviewing the literature and concluding that there "is conclusive or substantial evidence that cannabis or cannabinoids are effective" in treating chronic pain and chemotherapy-induced nausea and for improving patient-reported spasticity symptoms in multiple sclerosis patients).

much less addicting, much less likely to result in overdose and other serious adverse outcomes—than, say, heroin seems self-evident. Even Chuck Rosenberg ultimately acknowledged that heroin is "clearly," not just "probably," "more dangerous than marijuana."[15] And yet, despite the widespread medical use of marijuana in the United States and its comparative lack of dangerousness, it has remained in Schedule I.[16]

The explanation for this lies in the fact that the CSA did not define any of the scheduling criteria.[17] And, in the absence of a statutory definition, the DEA—who was delegated regulatory authority over the CSA by the Attorney General—has interpreted the scheduling criteria quite strictly, some would say idiosyncratically.[18] The DEA's definition of the term, "currently accepted medical use in treatment in the United States" does not take state laws into account and does not make scientific studies, standing alone, controlling.[19] Instead, the DEA applies a five-factor test to determine whether a substance has an accepted medical use.[20] For a substance to have a medical use, all five factors must be met, and the first factor is that "a drug's chemistry must be known and reproducible."[21] This requirement alone has spelled doom for rescheduling marijuana because the chemistry of the marijuana plant (as opposed to specific strains) is *not* reproducible—it varies widely from strain to strain.[22] The DEA's test also requires a very specific kind of evidence to prove medical use: randomized controlled trials of the sort that are needed for FDA approval.[23] These trials are incredibly expensive to conduct,

15. Lopez, *supra* note 9.

16. 21 C.F.R. § 1308.11(d)(23) (2026).

17. Grinspoon v. DEA, 828 F.2d 881, 885 (1st Cir. 1987) (observing that the term "United States" in the medical use criterion "is the only portion of the Schedule I criteria that Congress has expressly defined in the CSA").

18. *See* Exec. Order No. 11,727, 38 Fed. Reg. 18357 (July 10, 1973); *see also* 28 C.F.R. § 0.1 (2026).

19. 21 U.S.C. § 812(b).

20. *See* All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 938, 940 (D.C. Cir. 1991).

21. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504 (Mar. 26, 1992).

22. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688, 53700 (proposed Aug. 12, 2016) (to be codified at 21 C.F.R. pt. 1301) ("[T]he chemistry of marijuana, as defined in the petition, is not reproducible in terms of creating a standardized dose."); *see also* Alex Kreit, *Federal Marijuana Reform and the Controlled Substances Act*, 101 B.U. L. REV. 1231, 1242 (2021) (arguing that because the marijuana plant's chemistry will never be reproducible, "it is difficult to see how the DEA could ever move marijuana from Schedule I to a different schedule under the agency's prevailing five-factor test").

23. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53688.

and the lack of them has served as an additional barrier to marijuana rescheduling.

The DEA's approach to assessing relative abuse potential is, if anything, even less intuitive than its definition of the medical use criterion. The DEA's definition of potential for abuse places great weight on the number of people who use the drug "on their own initiative."[24] Citing this factor, the DEA has found that because a lot of people use marijuana, it has a "high potential for abuse."[25] Specifically, the DEA has repeatedly pointed to "[t]he large number of individuals using marijuana on a regular basis, its widespread use, and the vast amount of marijuana that is available for illicit use" as being "indicative of the high abuse potential for marijuana."[26] Because marijuana has been the most commonly used illegal intoxicant for decades, it has seemed that it would continue to be stuck with the "high potential for abuse" classification under the CSA.[27]

So, what explains the federal government's about-face and proposal to move marijuana to Schedule III? Did marijuana use rates plummet and its chemistry suddenly become reproducible? No, the Department of Health and Human Services (HHS)—whose role in the rescheduling process is discussed later in this Article[28]—decided to abandon the DEA's tests for assessing medical use and abuse potential.[29] And, after seeking and receiving guidance from the Office of Legal Counsel (OLC),[30] the Attorney General (though, conspicuously, *not* the DEA) signed onto HHS's definitions and issued the notice of proposed rescheduling of marijuana.[31]

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24. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40552, 40553 (proposed July 8, 2011) (to be codified at 21 C.F.R. Chapter II).

25. *Id.* at 40562.

26. *Id.*; *see also* Notice of Denial of Petition, 66 Fed. Reg. 20038, 20051 (Apr. 18, 2001) (same); Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53706 ("A number of factors indicate marijuana's high abuse potential, including the large number of individuals regularly using marijuana, marijuana's widespread use, and the vast amount of marijuana available for illicit use.").

27. *See, e.g.*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES 15–16 (2020), https://perma.cc/9FYG-NPAU.

28. *See infra* Part I (discussing the role of HHS in making scheduling findings under 21 U.S.C. § 811(b)).

29. Memorandum from Rachel L. Levine, Assistant Sec'y for Health, U.S. Dep't of Health & Hum. Servs., to Anne Milgram, Adm'r, DEA (Aug. 29, 2023) [hereinafter *2023 HHS Recommendation*], https://perma.cc/Z387-R26W.

30. Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. (Apr. 11, 2024) (slip op. at 4) [hereinafter *OLC Rescheduling Opinion*].

31. Since its birth in 1973, the DEA has been delegated scheduling authority by the Attorney General. *See* Exec. Order No. 11,727, 38 Fed. Reg. 18357 (July

Perhaps because the marijuana rescheduling petition is still making its way through the administrative process, with its ultimate fate uncertain, it has thus far received limited scholarly attention.[32] The election of Donald Trump has added another layer of doubt to a process that already had an element of uncertainty because of the lack of buy-in from the DEA. After some signs early in Trump's term that appeared to "not bode well for the immediate future of federal

10, 1973). But in this case, the Attorney General submitted the notice of proposed rulemaking directly, without the DEA's sign-on. Indeed, the rulemaking stated that the "DEA has not yet made a determination as to its views of the appropriate schedule for marijuana." Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44601 (proposed May 21, 2024) (to be codified at 21 C.F.R. pt. 1308); *see also* David Pozen, *Reading the Tea Leaves on Marijuana Rescheduling,* BALKINIZATION (May 20, 2024), https://perma.cc/XVR2-D5WP (arguing that the available evidence suggests "OLC sided with HHS rather than DEA on the relevant legal standard and that Attorney General Merrick Garland—former prosecutor and federal judge, lawyer's lawyer par excellence, and just about the least likely countercultural icon one could imagine—then effectively overruled DEA and withdrew its scheduling authority with respect to marijuana").

32. In the time since the Attorney General's proposed marijuana rescheduling order was issued, it has been a central focus of just five law review articles. *See* Jack Malich, *A (Loper) Bright Future?: How the Supreme Court Opened a Path for Drug Reform*, 65 SANTA CLARA L. REV. 405, 417 (2025) (analyzing 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" and proposing a new framework for classifying substances); Robert A. Mikos, *Marijuana and the Tyrannies of Scheduling*, 93 FORDHAM L. REV. 473, 475 (2024) [hereinafter Mikos, *Tyrannies of Scheduling*] (arguing that there are flaws in both the DEA's test, and HHS's test, for determining whether a drug has a currently accepted medical use and proposing that "the DEA should stop insisting that a drug must be placed on Schedule I if it has no [currently accepted medical use] (however defined)"); Robert A. Mikos, *The False Promise of Rescheduling*, 60 TULSA L. REV. 1, 4 (2024) [hereinafter Mikos, *False Promise*] (discussing reasons why marijuana rescheduling could be stymied, despite the Attorney General's proposed rulemaking, and why marijuana rescheduling will not provide meaningful benefits to the marijuana industry); Jennifer D. Oliva, *Decriminalizing Cannabis*, 134 YALE L.J.F. 942, 975 (2025) (discussing the rescheduling proposal and arguing that "the federal government go beyond rescheduling" and "decriminalize and deregulate cannabis"); Melvin L. Otey, *Christian Faith and Marijuana Use After Federal Rescheduling*, 22 IND. HEALTH L. REV. 351, 355 (2025) (arguing that "consistent with both federal law and Christian moral principles, law-abiding persons might potentially use marijuana medicinally once it is rescheduled"). In addition to these, Mason Marks analyzed aspects of the marijuana rescheduling recommendation in the context of a study of the separation of scheduling authority between the DEA and HHS in *Separation of Drug Scheduling Powers*, 134 YALE L.J.F. 976 (2025), and Matthew B. Lawrence and David E. Pozen discussed the pending marijuana rescheduling proposal within their broader examination of the CSA's scheduling system in *Drug Scheduling as Institutional Design*, 139 HARV. L. REV. 849 (2026).

cannabis rescheduling,"[33] the administration issued an executive order in December 2025 that directed the Attorney General to "complete the rulemaking process related to rescheduling marijuana to Schedule III of the CSA in the most expeditious manner" permitted by law.[34]

The executive order did not result in immediate action to expedite the administrative process.[35] But as this Article was going to press, Acting Attorney General Todd Blanche announced that the DEA "will hold a hearing with respect to the proposed rescheduling of marijuana into schedule III" that will begin on June 29, 2026, and "will conclude not later than July 15, 2026."[36]

On the same day as that announcement, the Acting Attorney General also issued an order to place marijuana that is "in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license" into Schedule III.[37] The order was limited to marijuana in those categories—it left all other marijuana in

33. Laura I. Appleman, *Drug Decriminalization and Recriminalization: Predicting the Future in Uncertain Times*, 38 FED. SENT'G REP. 3, 7 (2026).

34. Exec. Order No. 14,370, 90 Fed. Reg. 60541, 60542 (Dec. 18, 2025).

35. *See* Kyle Jaeger, *Congressman Demands Marijuana Rescheduling Update From DOJ, Three Months After Trump's Executive Order*, MARIJUANA MOMENT (Mar. 27, 2026), https://perma.cc/993B-MHDG (reporting on a letter from Congressman Steve Cohen to the Attorney General inquiring about the marijuana rescheduling timeline, particularly in light of the fact that the administrative law judge who had been overseeing the proceedings "is now retired and has not been replaced"); Kyle Jaeger, *DEA Says Marijuana Rescheduling Appeal Process 'Remains Pending' Despite Trump's Executive Order*, MARIJUANA MOMENT (Jan. 5, 2026), https://perma.cc/Z4SU-2KDU (reporting that an interlocutory appeal concerning "allegations of agency bias and improper communications with anti-rescheduling parties during the rescheduling review process" remains pending).

36. Schedules of Controlled Substances: Rescheduling of Marijuana, 91 Fed. Reg. 22777, 22777 (Apr. 28, 2026). At the same time as the Acting Attorney General announced this expedited hearing, he terminated a hearing process on the rescheduling petition that had stalled in the face of an interlocutory appeal by two parties and the retirement of the presiding ALJ. *See* Schedules of Controlled Substances: Rescheduling of Marijuana; Withdrawal, 91 Fed. Reg. 22778, 22778–79 (Apr. 28, 2026) (summarizing the status of the initial hearing process on the marijuana rescheduling petition). Citing the December 2025 executive order, the Acting Attorney General explained these actions by noting that "DEA has determined that the most expeditious manner of completing the rulemaking process in accordance with Federal law is to terminate the pending hearing proceedings and initiate new hearing proceedings." *Id.* at 22778.

37. Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana From Schedule I to Schedule III; Corresponding Change to Permit Requirements, 91 Fed. Reg. 22714, 22722 (Apr. 28, 2026).

Schedule I, pending resolution of the 2024 rescheduling petition.[38] The order to move state-licensed medical marijuana into Schedule III did not rely on or even apply the CSA's scheduling criteria. Instead, the legal basis for the order was a provision of the CSA regarding drugs that are subject to control under international drug treaties.[39] Indeed, in the order, the Acting Attorney General took the position that the CSA's treaty provision relieved him from the obligation to consider the statute's scheduling criteria or to follow the standard scheduling procedures.[40]

The Acting Attorney General's order raises a host of interesting questions, beginning with the fact that its reliance on the CSA's treaty provision to circumvent the CSA's standard rescheduling provisions appears to conflict with a 1977 D.C. Circuit Court decision.[41] But examination of issues raised by the order to reschedule

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38. *Id.* at 22718 (noting that "unlicensed bulk marijuana" is maintained in Schedule I under the order). The order also rescheduled marijuana extract and naturally derived delta-9 THC on the same limited basis as marijuana. *Id.* at 22722–23 (placing marijuana extract and naturally derived delta-9 THC into Schedule III if they are "in a U.S. Food and Drug Administration approved product or subject to a state medical marijuana license").

39. *Id.* at 22715 (citing 21 U.S.C. § 811(d)(1)). The CSA's treaty provision states: "If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section." 21 U.S.C. § 811(d)(1).

40. Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana From Schedule I to Schedule III; Corresponding Change to Permit Requirements, 91 Fed. Reg. at 22717 (concluding that when "control of a drug is required by" international drug treaties, "the plain and unambiguous statutory language [of 21 U.S.C. § 811(d)(1)] does not require the Administrator to request a medical and scientific evaluation or scheduling recommendation from" HHS); *id.* at 22721 (explaining that the rescheduling action was issued by order, rather than by rule, and that the "DEA believes that the notice-and-comment requirements of the Administrative Procedure Act . . . do not apply to this scheduling action").

41. Nat'l Org. for Reform of Marijuana L. v. DEA, 559 F.2d 735 (D.C. Cir. 1977). In that case, the D.C. Circuit considered 21 U.S.C. § 811(d)(1) and held that "it enables him to place a substance in a CSA schedule without regard to medical and scientific findings only to the extent that placement in that schedule is necessary to satisfy United States international obligations." *Id.* at 746. In other words, the provision "directs the Attorney General" to identify the "minimum schedule or level of control below which placement of the substance may not fall" as a result of United States treaty obligations. *Id.* at 747. But "once that minimum schedule is established by the Attorney General, the decision whether to impose controls more restrictive than required by treaty implicates the same medical and scientific considerations as do scheduling decisions regarding those few substances not controlled by treaty." *Id*; *see also id.* at 746

state-licensed medical marijuana will have to wait for another day. Because the order did not apply the CSA's rescheduling criteria or halt the pending proceedings to reschedule all marijuana based on the 2024 notice of proposed rulemaking, it does not directly affect the topics discussed in this Article.

As to the 2024 notice of proposed rulemaking that is the focus of this Article, even though it is now on an administrative fast track, if history is any guide, it could be years before the rescheduling petition and any resulting litigation is complete.[42] The prospects for marijuana rescheduling will depend in part on the outcome of the administrative process, and the impact of the rescheduling proceedings will depend on the outcome of litigation. But a close examination of the proposed rescheduling at this relatively early stage is nevertheless capable of yielding important insights.

This Article analyzes the basis for the proposed transfer of marijuana from Schedule I to Schedule III of the CSA. I argue that the proposed rescheduling is likely to result in a transformed CSA, under which the DEA's longstanding approach to interpreting and applying the two major scheduling criteria—accepted medical use and relative abuse potential—could be upended. HHS's decision to part ways with the DEA on these criteria, in combination with the Supreme Court's recent reversal of the *Chevron* doctrine, which had required courts to defer to agency interpretations of ambiguous statutory provisions,[43] helps create the conditions for the current rescheduling process to bring about this change. Without *Chevron* deference for the DEA's interpretation of the scheduling criteria, or cover from HHS with respect to factual findings regarding potential for abuse, the DEA's past practices become difficult to reconcile with the CSA. In the course of this analysis, I unearth two pieces of evidence from the history of the CSA and the Food, Drug, and Cosmetic Act (FDCA) that have gone overlooked by both courts and commentators, but that I argue significantly undermine the DEA's definition of "currently accepted medical use."

The Article proceeds in four parts. Part I provides an overview of the CSA and past and present marijuana rescheduling petitions and describes why the current rescheduling process, in combination with

("Congress never intended to allow the Attorney General to displace the Secretary whenever any international obligations attach to a particular drug especially in view of the fact that the vast majority of substances listed in the CSA are controlled by treaty.").

42. The first petition to reschedule marijuana was filed in 1972 by the National Organization for the Reform of Marijuana Laws and was not finally resolved until 1994. *See* Wallack & Hudak, *supra* note 4, at 210 (discussing this history).

43. Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2273 (2024) (overruling Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984)).

the reversal of *Chevron*, sets the stage for significant changes to the CSA. Part II engages in a close analysis of the CSA's medical use criterion and explains how it could be transformed by the conclusion of the pending marijuana rescheduling process. Part III undertakes a similar analysis for the CSA's potential for abuse criterion. Part IV concludes.

I. SCHEDULING UNDER THE CONTROLLED SUBSTANCES ACT AND SETTING THE STAGE FOR CHANGE

A. Controlled Substances Act 101

Federal drug prohibition did not begin with passage of the CSA in 1970.[44] Federal law has effectively criminalized marijuana since 1937, when Congress passed the Marijuana Tax Act.[45] The federal prohibition of opiates and cocaine dates back even further, to the 1914 Harrison Narcotics Act.[46] When Congress enacted these early federal drug prohibition laws, the "commerce clause was still read rather restrictively by the courts."[47] As a result, both the Marijuana Tax Act and the Harrison Narcotics Act were technically billed as revenue measures, but "taxation was only a guise for law enforcement and regulation."[48]

In the decades leading up to adoption of the CSA, Congress continued with a piecemeal approach to drug prohibition by enacting "'more than 50 pieces of legislation' relating to the regulation of dangerous drugs."[49] Especially notable among the pre-CSA laws were the Drug Abuse Control Amendments of 1965 to the Food, Drug, and Cosmetic Act (1965 Amendments), which gave the Secretary of Health, Education, and Welfare (HEW)—HHS's predecessor agency—the "administrative discretion to place drugs under [federal] control without having to return to Congress each time a new drug capable of abuse was discovered or presented a problem."[50] Mirroring

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44. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1284.

45. Marihuana Tax Act of 1937, Pub. L. No. 75-238, 50 Stat. 551.

46. *See* Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 CATH. U. L. REV. 586, 593 (1973) (recounting the history of federal drug laws).

47. *Id.* at 593.

48. ROBERT L. BOGOMOLNY ET AL., A HANDBOOK ON THE 1970 FEDERAL DRUG ACT: SHIFTING THE PERSPECTIVE 7 (1975); *see also* ALFRED R. LINDESMITH, THE ADDICT AND THE LAW 3 (2d prtg. 1965) ("Another unusual feature of the federal narcotic laws is that, while they are in legal theory revenue measures, they contain penalty provisions that are among the harshest and most inflexible in our legal code.").

49. Ams. for Safe Access v. DEA, 706 F.3d 438, 447 (D.C. Cir. 2013) (quoting H.R. REP. NO. 91-1444, pt. 1, at 6 (1970)).

50. BOGOMOLNY ET AL., *supra* note 48, at 14. Regulatory "authority to designate drugs for control was transferred to the Attorney General" in 1968, as

the language in one of the CSA's scheduling criteria,[51] the power to control drugs under the 1965 Amendments depended upon a finding that a drug had "a potential for abuse."[52] But administrative control authority under the 1965 Amendments was limited to drugs with a hallucinogenic, "depressant[,] or stimulant effect on the central nervous system," and expressly excluded opiates, cocaine, and marijuana.[53]

The result was an unwieldy system. By the time the CSA was drafted, opiates and cocaine were controlled by one law (the 1914 Harrison Act), marijuana by another (the 1937 Marihuana Tax Act), and hallucinogens, stimulants and depressants by a third (the Food, Drug and Cosmetic Act, under the 1965 Amendments).[54] These "separate bodies of statutory law, one based on the taxing power, and the other upon the commerce clause . . . [i]n many cases [were] inconsistent with each other and [could not] easily be made to coalesce in either logic or practice."[55]

The CSA, enacted as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, was designed to "synthesize the existing controls into one body of organic law."[56] Congress tasked the Attorney General with administering the CSA, but, as noted in the introduction to this Article, the Attorney General has delegated that authority to the head of the DEA.[57] Because the DEA has historically

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part of a plan to reorganize and combine previously separate agencies, the Federal Bureau of Narcotics and the Bureau (housed in the Treasury Department) of Drug Abuse Control (housed in the Food and Drug Administration), in order "to form the Bureau of Narcotics and Dangerous Drugs (BNDD)." *Id.*

51. 21 U.S.C. § 812(b)(1)(A), (b)(3)(A) (providing that a Schedule I drug is one that "has a high potential for abuse" and that a Schedule III drug is one that "has a potential for abuse less than the drugs or other substances in schedules I and II").

52. Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, § 3, 79 Stat. 226, 227 (1965) (repealed 1970).

53. *Id.* At the time of passage of the Drug Abuse Control Amendments, the Harrison Narcotic Act granted the Secretary of the Treasury the administrative power to, "after considering the technical advice of the Secretary of Health, Education, and Welfare, or his delegate on the subject," add substances to regulation under the act that were found "to have an addiction-forming or addiction-sustaining liability similar to morphine or cocaine." 26 U.S.C. § 4731(g)(1) (1964) (repealed 1970).

54. *See* Quinn & McLaughlin, *supra* note 46, at 593, 600, 603.

55. BOGOMOLNY ET AL., *supra* note 48, at 18 (quoting Letter from John N. Mitchell to the Speaker of the House of Representatives (July 15, 1969)).

56. *Id.* The CSA was Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, although the entire Act is also sometimes "referred to as the Controlled Substances Act." Kenneth C. Baumgartner & Michael X. Morrell, *Pharmaceutical Industry Regulation by the Department of Justice*, 23 SYRACUSE L. REV. 785, 785 & n.2 (1972).

57. 21 U.S.C. § 811(a); 28 C.F.R. § 0.1(b) (2026).

overseen scheduling decisions, I will refer to the DEA as the agency responsible for administering the CSA throughout this Article, except when referring to actions taken by the Attorney General directly.

At the heart of the CSA is a five-tier system—referred to by the law as schedules—for classifying drugs that are found to have "a potential for abuse."[58] (Alcohol and tobacco are statutorily exempt from control.)[59] In order to add a drug to the list ("scheduling"), or move an already-controlled drug to a different schedule ("rescheduling"), the DEA must make findings related to three different criteria: the substance's relative "potential for abuse"; whether it has a "currently accepted medical use in treatment in the United States"; and the substance's safety or relative potential for physical or psychological dependence.[60]

With respect to the first scheduling criterion, Schedules I and II both require a finding that the substance has a "high potential for abuse"; a progressively lower relative abuse potential is required for Schedules III through V.[61] The second scheduling criterion has historically been a "major dividing line."[62] Schedule I drugs have "no currently accepted medical use in treatment in the United States,"[63] whereas drugs in Schedules II and below all have a currently accepted medical use.[64] The CSA's third scheduling criterion concerns safety for Schedule I and dependence for Schedules II and lower. Schedule I requires a finding that "[t]here is a lack of accepted safety for use of the drug or other substance under medical supervision."[65] By contrast, Schedule II's third finding is that "[a]buse of the drug or

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58. 21 U.S.C. § 811(a)(1) (providing that the threshold for adding a substance to one of the CSA's schedules is a finding that the "drug or other substance has a potential for abuse" and that it meets the criteria "for the schedule in which such drug is to be placed").

59. 21 U.S.C. § 802(6) ("The term 'controlled substance' means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.").

60. 21 U.S.C. § 812(b)(1)(A)–(B). *Compare* 21 U.S.C. § 812(b)(1)(C) (stating Schedule I's third criterion requires a finding regarding safety), *with* 21 U.S.C. § 812(b)(2)(C) (stating the parallel finding for Schedules II and below concerns the extent to which "[a]buse of the drug" might lead to physical or psychological dependence).

61. *Id.* § 812(b)(1)(A), (2)(A), (3)–(5).

62. BOGOMOLNY ET AL., *supra* note 48, at 73–74.

63. 21 U.S.C. § 812(b)(1)(B).

64. The second finding for Schedule II is that the "drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." *Id.* § 812(b)(2)(B). Schedules III through V all require only that the "drug or other substance has a currently accepted medical use in treatment in the United States" for their second finding. *Id.* § (b)(3)–(5).

65. *Id.* § 812(b)(1)(C).

other substances may lead to severe psychological or physical dependence," with a progressively lower risk of dependence for Schedules III and below.[66]

66. *Id.* § 812(b)(2)(C), (3)–(5).

TABLE 1. THE CSA SCHEDULING CRITERIA[67]

	ABUSE POTENTIAL	**MEDICAL USE**	**SAFETY AND DEPENDENCE**
Schedule I	High potential for abuse	No currently accepted medical use in treatment in the United States	Lack of accepted safety for use of the drug or other substance under medical supervision
Schedule II	High potential for abuse	Has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions	Abuse may lead to severe psychological or physical dependence
Schedule III	Potential for abuse less than the substances in Schedules I and II	Has a currently accepted medical use in treatment in the United States	Abuse may lead to moderate or low physical dependence or high psychological dependence
Schedule IV	Low potential for abuse relative to the substances in Schedule III	Has a currently accepted medical use in treatment in the United States	Abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III
Schedule V	Low potential for abuse relative to the substances in Schedule IV	Has a currently accepted medical use in treatment in the United States	Abuse may lead to limited physical or psychological dependence relative to Schedule IV

67. *See id.* § 812(b).

The CSA does not state exactly how the scheduling criteria fit together.[68] For present purposes, it is enough to know two things. First, the DEA has interpreted the CSA to require all substances that have no currently accepted medical use and *any* potential for abuse sufficient to warrant control—high or low—to be placed in Schedule I.[69] Under this interpretation, a finding that a scheduled substance has no currently accepted medical use "is paramount and must trump all other considerations in cases of conflict."[70] Second, the courts and the DEA have interpreted the CSA to make the third criterion—the safety/dependence criterion—less important than the first two. Indeed, in the case of Schedule I, the DEA has treated the third finding as not just insignificant but irrelevant.[71] The CSA's text seems to place all three findings on equal footing. But, as one court has put it, "the potential for abuse and the medical applications of a drug are the major bases for classification."[72] This view appears to be grounded in large part on the legislative history of the CSA, which included statements in reports and from individual members suggesting that scheduling would be based primarily on the potential for abuse and medical use findings.[73] As a result of these two facts, the medical use finding has been first among equals when it comes to

68. *See* Kreit, *supra* note 11, at 338–42 (providing an overview of this issue).

69. Notice of Denial of Petition, 66 Fed. Reg. 20038, 20038 (April 18, 2001) ("Congress established only one schedule—schedule I—for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.'" (quoting 21 U.S.C. § 812(b))).

70. Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 480. For an argument that the DEA's position on this point is mistaken, see *id.* at 496.

71. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504 (Mar. 26, 1992) (concluding that although "[t]he scheduling criteria of the Controlled Substances Act appear to treat the lack of medical use and lack of safety as separate considerations . . . . [s]afety cannot be treated as a separate analytical question" because "[s]afety and effectiveness are inextricably linked in a risks-benefits calculation"). The D.C. Circuit appeared to bless this position in a short footnote, in which it rejected an argument that the DEA's finding "that marijuana lacks 'accepted safety for use'" was flawed on the ground that, because the DEA "Administrator based this determination on his decision that no medical uses are possible (and thus any use lacks 'accepted safety'), we do not see that 'safety' issue as raising a separate analytical question." All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 940 n.4 (D.C. Cir. 1991).

72. Nat'l Org. for Reform of Marijuana L. v. Bell, 488 F. Supp. 123, 126–127 (D.D.C. 1980).

73. *See id.* at 140 n.40 (noting that the House Report indicated that a substance's potential for abuse would be a "key criterion . . . and the one which will be used most often"; that a Senator stated "the existence of an accepted medical use was the primary factor in a drug's classification"; and that "[o]ther members of Congress indicated the two criteria were equally important" (first quoting H.R. REP. NO. 91-1444, pt. 1, at 34 (1970); and then citing 116 CONG. REC. 36882 (1970) (statement of Sen. Harold Hughes))).

scheduling under the CSA, with relative potential for abuse a close second.

The procedural provisions of the CSA are, for the most part, unconnected to the focus of this Article with one very important exception: the Secretary of Health and Human Services' role in the rescheduling process. Although the CSA places the ultimate scheduling decision in the hands of the Attorney General (who has in turned delegated it to the DEA), the statute requires the DEA to, "before initiating [a scheduling proceeding] . . . , request from the Secretary [of HHS] a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance."[74] Significantly, HHS's role is much more than advisory; the CSA provides that its recommendations "shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance."[75]

The controls over a drug regulated by the CSA depend on the schedule in which it is placed. The legal market for Schedule I drugs is limited to authorized research.[76] By contrast, substances in Schedules II and below can be manufactured and distributed for both research and medical uses,[77] although marketing a substance as a medicine in interstate commerce requires separate approval under the Food, Drug, and Cosmetic Act.[78] No substance that is scheduled under the CSA can be distributed for recreational use.[79]

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74. 21 U.S.C. § 811(b).

75. *Id.* The FDA plays a "lead" role in the process of preparing "the scientific and medical evaluations and recommendations." Memorandum of Understanding with the National Institute on Drug Abuse, 50 Fed. Reg. 9518, 9519 (Mar. 8, 1985); *see also* JOANNA R. LAMPE, CONG. RSCH. SERV., R45948, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 118TH CONGRESS 10 (2023).

76. 21 U.S.C. § 823(g)(2)(a).

77. 21 U.S.C. § 823(g)(1).

78. *See* Rebecca S. Eisenberg & Deborah B. Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 FOOD & DRUG L.J. 246, 254 (2019) (providing an overview of the FDA's authority to approve drugs under the FDCA before they are introduced into interstate commerce and the relationship between that authority).

79. *See* 21 U.S.C. § 829(c) (providing that even Schedule V substances may not "be distributed or dispensed other than for a medical purpose"). I will use the term recreational in this Article to distinguish between permitted and nonpermitted uses under the CSA, although it bears noting that the line between medical and nonmedical use is not always a bright one. *See* Matt Lamkin, *Legitimate Medicine in the Age of Consumerism*, 53 U.C. DAVIS L. REV. 385, 421 (2019) (arguing that "[a]s doctors increasingly prescribe psychotropic drugs to healthy people to relieve stress, enhance performance, and otherwise obtain desired mental states, it becomes harder to distinguish these uses from 'recreational' drug-taking").

Beyond these core provisions is a relatively complex web of regulatory distinctions related to a variety of "control mechanisms imposed on the manufacturing, obtaining, and selling of" controlled substances.[80] The CSA's control mechanisms include registration requirements for "[e]very person who desires to handle a controlled substance,"[81] restrictions on manufacturing and distribution (e.g., through rules about order forms and, for Schedule I and II substances, quotas), and recordkeeping and reporting requirements.[82] The controls are targeted at preventing diversion of drugs for use outside of research or medicine and "[t]he degree of regulatory control imposed over a given drug depends upon the schedule in which the drug is listed."[83] The lower the schedule, the more relaxed the controls.

The controls applicable to Schedule I substances can be especially onerous. Although Schedule I substances can be manufactured and distributed for research purposes, "[t]he CSA subjects research on Schedule I drugs to a litany of regulations it does not apply to (1) new drugs developed in a laboratory that have not yet been scheduled, or (2) existing drugs on any of the statute's lower schedules (II through V)."[84] These Schedule I "obstacles" involve

> mandatory FDA approval of research involving Schedule I substances; mandatory special registration with the DEA; mandatory reporting and security procedures beyond those required for drugs placed in Schedules II through V; unavoidable bureaucratic delays; and other adverse impacts due to the grave concern caused by a substance's placement in Schedule I, such as difficulty in obtaining volunteers for clinical studies and, for academic researchers, difficulty in securing approval from institutional review boards.[85]

The CSA also criminalizes certain conduct involving controlled substances including the unauthorized manufacture, distribution, and possession of controlled substances.[86] When the CSA was enacted, the criminal penalties "depend[ed] upon the schedule in which the drug is placed and whether it is classified as a narcotic or

80. William W. Vodra, *The Controlled Substances Act*, 2 DRUG ENF'T 2, 2 (1975); *see also* Lawrence & Pozen, *supra* note 32, at 857–63 (providing an overview of the CSA's framework "with an eye toward the key institutional design choices it embeds").

81. Vodra, *supra* note 80, at 3; *see also* 21 U.S.C. §§ 822–823 (outlining the CSA's registration requirements).

82. 21 U.S.C. §§ 826–828.

83. BOGOMOLNY ET AL., *supra* note 48, at 75.

84. Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 489.

85. Grinspoon v. DEA, 828 F.2d 881, 896 (1st Cir. 1987) (citations omitted).

86. 21 U.S.C. § 841(a).

a nonnarcotic."[87] The importance of drug scheduling to federal drug sentencing was significantly diminished in the 1980s as a result of the passage of mandatory minimum drug penalties for certain drugs and offenses and the Federal Sentencing Guidelines.[88] These mandatory minimum drug penalty provisions tied minimum sentences to drug type and quantity, rather than drug schedule, for most of the most widely used illegal drugs.[89] In the case of marijuana, for example, the manufacture, distribution, or possession with the intent to distribute of 100 kilograms (or 100 plants) or more triggers a five-year mandatory minimum sentence; 1,000 kilograms (or 1,000 plants) or more results in a ten-year mandatory minimum sentence.[90] Although the 1980s amendments now govern minimum sentencing for some drug types and quantities, the CSA continues to link the statutory maximum for drug trafficking offenses for which there is not a mandatory minimum sentence to drug scheduling, with a twenty-year maximum for Schedule I and II drugs, a ten-year maximum for Schedule III drugs, a five-year maximum for Schedule IV drugs, and a one-year maximum for Schedule V drugs.[91]

B. The Conditions for a Transformed Controlled Substances Act

As noted in the previous Section, two of the CSA's three scheduling criteria—medical use and potential for abuse—are the primary drivers of most scheduling decisions. Each will be examined in detail in the Sections below. Before getting there, this Section sets the stage for the remainder of the Article. It provides a brief overview of the basis for the DEA's previous denials of marijuana rescheduling petitions, and of the basis for the proposed rescheduling. It also explains why the proposed rescheduling order helps to create the conditions for a court battle that could end with a version of the CSA's scheduling provisions that looks very different than it has to date.

The idea that the meaning of the CSA's core scheduling provisions might change dramatically fifty-five years after its enactment, and as the result of an administrative rescheduling proceeding, might at first seem a bit strange. Although litigants have attempted to challenge the DEA's interpretation of the scheduling criteria, these efforts have historically been made more difficult by two facts.

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87. BOGOMOLNY ET AL., *supra* note 48, at 75; *see also* Vodra, *supra* note 80, at 5 (describing the CSA's penalty structure at the time of enactment).

88. *See* Alex Kreit, *Drug Truce*, 77 OHIO ST. L.J. 1323, 1332–33 (2016) (providing an overview of the enactment of federal mandatory minimum drug sentencing laws and their influence on drug sentencing under the Federal Sentencing Guidelines).

89. *Id.*

90. 21 U.S.C. § 841(b)(1)(A)–(B).

91. *Id.* § 841(b)(1)(C)–(E). The statute provides a number of exceptions and alterations to these basis maximums based on additional factors. *Id.*

First, the DEA and HHS have almost always marched in lockstep with respect to scheduling.[92] Yet, in the case of the proposed marijuana rescheduling petition, the agencies have parted ways. The divide is made possible in large part by the fact that Congress did not include definitions for *any* of the scheduling criteria in the CSA's long list of defined terms.[93] The only term connected to the scheduling findings defined in the CSA is "United States," which appears in the findings regarding "currently accepted medical use in treatment in the United States."[94] Beyond that, the statute is silent as to the definitions of the scheduling criteria. Nor did Congress delegate the power to define the scheduling criteria administratively in the CSA.[95] It simply left the matter unaddressed.

In the absence of definitions from Congress, the DEA has historically filled the void. With respect to the CSA's medical use finding, the DEA has employed a five-characteristic test, all five of which must be met for the DEA to find that a drug has a currently accepted medical use. The DEA's test is based on core requirements from the FDCA, the law that governs the approval of medicines for interstate marketing.[96] Since 1962, the FDCA has included a provision that requires substantial evidence of a drug's efficacy through adequate and well-controlled investigations for it to win FDA approval.[97] Drawing on the FDCA's drug approval regime, the DEA's medical use test includes requirements that the drug's chemistry be "known and reproducible" and that there are "adequate and well-controlled studies proving efficacy."[98] These twin requirements have proved to be particularly stubborn barriers to marijuana rescheduling. Although there is scientific support that marijuana has some medical uses, there are no randomized controlled trials demonstrating its efficacy[99] and there are significant legal and

92. An early analysis of the CSA went so far as to call the compromise that gave HHS's scientific and medical recommendations binding authority "a hollow concession to the scientific community" because "[t]hrough 1972, no request for control initiated by the Department of Justice has been denied by the Secretary." BOGOMOLNY ET AL., *supra* note 48, at 25.

93. *See* 21 U.S.C. § 802 (providing definitions for various terms used in the CSA).

94. Grinspoon v. DEA, 828 F.2d 881, 885 (1st Cir. 1987) (observing that the term "United States" in the medical use criterion "is the only portion of the Schedule I criteria that Congress has expressly defined in the CSA"); 21 U.S.C. § 812(b)(1)(B).

95. *Grinspoon*, 828 F.2d at 885 n.5.

96. *See infra* Part II.

97. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(c), 76 Stat. 780, 781 (codified as amended at 21 U.S.C. § 355(d)).

98. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504–07 (Mar. 26, 1992).

99. Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 482–83 (explaining how "advocates have yet to complete even a single study demonstrating

practical impediments to conducting such trials.[100] And, even if there were randomized controlled trials, the chemistry of the marijuana plant, as defined by the CSA, is not and never will be reproducible.[101] For this reason, the reproducibility requirement, in particular, seemed to effectively foreclose the prospect of *ever* rescheduling marijuana under the DEA's accepted medical use test.[102]

The DEA's approach to analyzing a drug's relative potential for abuse under the CSA has likewise consistently resulted in the agency finding that marijuana has a "high potential for abuse."[103] The DEA applies a four-factor test for determining whether a drug has the minimum potential for abuse necessary to warrant control under the CSA, one of which is whether people are taking the drug on their own initiative.[104] However, the agency has never adopted a generally applicable method for measuring and comparing the *relative* potential for abuse of different drugs. This approach has left the DEA with a great deal of flexibility in its potential for abuse findings. In the case of marijuana, the DEA has consistently emphasized the large number of people using the drug on their own initiative in its potential for abuse assessment.[105] Because marijuana is the most widely used illegal drug, the DEA's approach has led it to conclude that it has a high potential for abuse.[106]

The Attorney General's proposal to transfer marijuana to Schedule III hinges primarily on two fundamental shifts away from the DEA's past practices, both of which came from HHS's statutorily required scientific and medical evaluation. The first is that HHS declined to apply the DEA's five-part definition of accepted medical

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marijuana's medical efficacy that satisfies the [DEA's] lofty standards for [randomized control trials]").

100. *See* Eisenberg & Leiderman, *supra* note 78, 261–68 (discussing the obstacles to FDA approval of marijuana, including the completion of randomized controlled trials).

101. *Id.* at 263 (noting that "cannabis is a plant with many active and inactive constituents that exhibits biological variability rather than an isolated or synthetic chemical entity that can be reliably reproduced").

102. Kreit, *supra* note 22, at 1242 (arguing that because the marijuana plant's chemistry will never be reproducible, "it is difficult to see how the DEA could ever move marijuana from Schedule I to a different schedule under the agency's prevailing five-factor test"). *But see* Scott Bloomberg, Alexandra Harriman & Shane Pennington, *Re/Descheduling Marijuana Through Administrative Action*, 76 OKLA. L. REV. 517, 548–51 (2024) (arguing that the DEA could reschedule marijuana without modifying its five-factor test by conducting "a more holistic analysis" that relies more heavily on eight additional scheduling criteria contained in a different statutory provision of the CSA).

103. *See infra* Part III.

104. *See infra* Part III.

105. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44602 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

106. *Id.* at 44610.

use.[107] Instead, HHS adopted a new test, under which an accepted medical use can be proven by a showing that there is (1) "widespread medical use of a drug under the supervision of licensed health care practitioners under State-authorized programs" and (2) "credible scientific evidence supporting such medical use."[108] Although more subtle, HHS also broke significantly from past practice with respect to assessing relative potential for abuse. Instead of determining relative abuse based primarily on the number of users, HHS emphasized "the profile of and propensity for serious outcomes related to that abuse" in its assessment.[109] The result was a finding that marijuana has a currently accepted medical use and a potential for abuse less than drugs in Schedules I and II, thus warranting a proposal to transfer marijuana to Schedule III.

The DEA has not publicly taken a position on HHS's recommendation or the basis for it. But the fact that the proposal to reschedule marijuana was issued by the Attorney General, and not the DEA, makes it clear enough that the DEA was not in agreement with HHS. Prior to HHS's recommendation to reschedule marijuana, HHS had consistently applied the DEA's definitions of the scheduling criteria in making its assessments.[110] HHS's break from the DEA's past practices (which, by all appearances, are consistent with its current views as well), will give the losing side of the marijuana rescheduling petition at the end of the administration process a strong basis for challenging the outcome in court.

The second fact that sets the stage for litigation that could transform the CSA's scheduling criteria, is the death of *Chevron* deference. Because Congress failed to define the CSA's scheduling criteria, "the DEA's interpretation of the CSA's provisions governing the scheduling of controlled substances" have always been reviewed deferentially by courts under the two-step *Chevron* doctrine.[111] Under *Chevron*, a court interpreting a statute administered by a federal agency would "first assess 'whether Congress has directly spoken to the precise question at issue'" and, if not, "defer to the agency's interpretation if it 'is based on a permissible construction of the statute.'"[112] Although *Chevron* review was not entirely toothless—as discussed further below, the DEA's first attempt at defining currently

107. *Id.* at 44617.
108. *Id.*
109. *Id.* at 44616.
110. *See id.* at 44616–17.
111. John Doe, Inc. v. DEA, 484 F.3d 561, 570 (D.C. Cir. 2007) (DEA's interpretation of CSA scheduling provisions are subject to *Chevron* deference).
112. Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2254 (2024) (quoting Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984)).

accepted medical use was rejected in court[113]—it has insulated the DEA's current definitions from close review.[114]

But now, any litigation over the outcome of the current marijuana rescheduling proceedings will play out in a remade landscape of administrative law. That is because in 2024, the Supreme Court's overruled the doctrine of *Chevron* deference in *Loper Bright Enterprises v. Raimondo*.[115] As others have explained in greater detail, now that the Supreme Court has overruled *Chevron*, courts will no longer defer to the DEA's interpretation of the scheduling criteria.[116] Instead, it will be up to the courts to define the scheduling criteria.[117]

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113. *See infra* Part II.

114. *See* All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991) (finding that "neither the statute nor its legislative history precisely defines the term 'currently accepted medical use'; therefore, we are obliged to defer to the Administrator's interpretation of that phrase if reasonable" (citing *Chevron*, 467 U.S. at 843–45)); Grinspoon v. DEA, 828 F.2d 881, 884 (1st Cir. 1987) ("The Administrator argues correctly that we must review his interpretation of the CSA in light of the guidelines set forth by the Supreme Court in [*Chevron*]."). Although lower courts applied *Chevron* deference to the DEA's interpretations, the United States Supreme Court has never addressed a case that raised the meaning of the CSA's scheduling criteria. The Supreme Court declined to apply *Chevron* deference to an interpretive rule issued by the Attorney General that "determine[d] that using controlled substances to assist suicide is not a legitimate medical practice and that dispensing or prescribing them for this purpose is unlawful under the CSA." Gonzales v. Oregon, 546 U.S. 243, 249 (2006). In so holding, the Court distinguished the interpretive rule from a CSA scheduling order, which it implied would be accorded *Chevron* deference. *Id.* at 260 (rejecting the argument that *Chevron* deference applied to the Attorney General's interpretation of what constitutes a legitimate medical purpose for distributing a controlled substance in part because the Interpretive Rule "does not concern the scheduling of substances and was not issued after the required procedures for rules regarding scheduling, so it cannot fall under the Attorney General's 'control' authority").

115. 144 S. Ct. 2244 (2024).

116. *E.g.*, Malich, *supra* note 32; Matthew C. Zorn, *Chevron's Demise Vis-a-Vis Cannabis Rescheduling*, ON DRUGS (July 2, 2024), https://perma.cc/GT6M-Q9DV; Saumya Sinha, *Regulating the Psychedelic Renaissance: FDA's Critical Role in the Push for Scheduling Reform to Expand Research into Psychedelic Medicines*, 76 ADMIN. L. REV. 731, 754 (2024) ("Though the implications of *Loper Bright* on judicial review of the denial of rescheduling petitions are yet to be seen, courts will now have more latitude to dictate the outcome of these situations."); *Loper Bright*, 144 S. Ct. at 2273 ("*Chevron* is overruled.").

117. *Loper Bright*, 144 S. Ct. at 2273 ("Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires."). The CSA did not "expressly vest[] the [DEA] with authority to define general statutory criteria by issuing regulations." *Grinspoon*, 828 F.2d at 885 n.5. Instead, the statute "expressly delegates to the Attorney General only the authority to make 'the *findings* prescribed by subsection (b) of section 812 of this title for the schedule in which [a] drug is to be placed.' This

Together, the death of *Chevron* and HHS's decision to break from the DEA's longstanding scheduling definitions create the conditions for litigation over the marijuana rescheduling petition that could significantly alter the core provisions of the CSA, more than fifty years after its enactment. Of course, just because *Chevron* deference no longer applies, it does not mean that courts will reject the DEA's past definitions and practices.[118] The death of *Chevron* deference means only that whichever side prevails on marijuana rescheduling in the administrative process will not enjoy *Chevron* deference in the litigation that is very likely to follow.[119] With these background points in mind, the remainder of this Article examines the two CSA scheduling criteria at issue in the pending proposal to reschedule marijuana in greater depth. I argue that the rescheduling process is likely to result in significant changes to the CSA, as it has been interpreted and applied by the DEA.

II. RESCHEDULING AND THE FUTURE OF CURRENTLY ACCEPTED MEDICAL USE

A. The DEA's Test

Of the scheduling findings, the definition of "currently accepted medical use in treatment in the United States"[120] has been by far the most litigated. This is almost certainly a product of the DEA's position that all substances without an accepted medical use must be placed

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explicit delegation of authority to *apply* prescribed statutory criteria is not equivalent to an explicit delegation of authority to *define* those criteria." *Id.* (alteration in original) (citations omitted) (quoting 21 U.S.C. § 811(a)(1)(B)).

118. Indeed, some commentors have expressed concern that *Chevron*'s reversal could prove harmful to rescheduling, on the theory that if the proposed rulemaking to move marijuana to Schedule III is ultimately adopted, the decision will not receive *Chevron* deference. Zorn, *supra* note 116 (quoting an attorney that has worked on cannabis rescheduling issues as saying, in response to *Loper Bright*, that, "[a]long with *Chevron*, I think rescheduling is gone").

119. The contentiousness over the administrative process thus far suggests that litigation over the outcome is inevitable, regardless of whichever side loses. *See, e.g.*, Kyle Jaeger, *DEA Judge Won't Remove Agency from Marijuana Rescheduling Hearing, But Raises Concerns About Alleged Unlawful Contact with Prohibitionists*, MARIJUANA MOMENT (Nov. 27, 2024), https://perma.cc/583X-V382 (reporting that an administrative filing by advocates in favor of rescheduling "alleged [the] DEA effectively conspired with Smart Approaches to Marijuana (SAM), an anti-cannabis group that was selected to serve as a witness" in the rescheduling proceedings). *But see* Mikos, *False Promise*, *supra* note 32, at 15–17 (arguing that "it is difficult to see how any opponent [of marijuana rescheduling] could establish standing to challenge" an order moving marijuana to Schedule III).

120. 21 U.S.C. § 812(b).

in Schedule I.[121] Because courts to date have applied *Chevron* deference to the DEA's interpretation, none has offered its own definition of the term based on first principles. Courts did, however, reject the DEA's initial definition of currently accepted medical use. A review of that history is helpful to fully appreciating the DEA's current definition, as well as the implications of HHS's decision to depart from it in its 2024 rescheduling recommendation.

The DEA's first attempt at a definition of accepted medical use to be tested in court was that it "mean[t], in essence, 'approved for interstate marketing by the FDA under the FDCA.'"[122] The definition was litigated in the context of an order placing MDMA (also known as "ecstasy" or "molly") in Schedule I issued in the mid-1980s.[123] The stated rationale for the definition was twofold, "[f]irst, if use of the drug is unlawful whenever interstate commerce is involved, medical use of the drug cannot be classified as accepted."[124] And, second, without "the data necessary for approval of [a new drug application under the FDCA], the agency has no basis for concluding that medical

121. Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 481 (observing that "ever since the DEA has made [currently accepted medical use] the paramount criteria for Schedule I . . . . scheduling decisions have focused an inordinate amount of attention on deciphering the meaning of" the term).

122. *Grinspoon*, 828 F.2d at 884.

123. *Id.* Although litigated in the context of the scheduling of MDMA, the definition appears to have been first proposed by the FDA as part of its review of the scheduling of THC. *See* Proposed Recommendations to the Drug Enforcement Administration Regarding the Scheduling Status of Marihuana and Its Components and Notice of a Public Hearing, 47 Fed. Reg. 28141, 28150–51 (June 29, 1982) ("FDA interprets the term 'accepted medical use' to mean lawfully marketed under the Federal Food, Drug, and Cosmetic Act.") The agency stated this interpretation previously in the Federal Register document dealing with THC. *See* Proposed Recommendation to the Drug Enforcement Administration Regarding the Scheduling Status of Tetrahydrocannabinol, 47 Fed. Reg. 10080, 10084 (Mar. 9, 1982); *see also* Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act, 51 Fed. Reg. 36552, 36554 (Oct. 14, 1986) (discussing reliance on this definition in the MDMA scheduling proceedings). The DEA had previously argued in the D.C. Circuit that the lack of FDA approval of marijuana "mandated" its placement in Schedule I, but the argument arose in the context of a challenge to the DEA's failure to seek and receive a full medical and scientific evaluation from HHS's predecessor agency, and so it was only addressed in a footnote by the court. Nat'l Org. for Reform of Marijuana L. v. DEA, 559 F.2d 735, 750 n.65 (D.C. Cir. 1977). The D.C. Circuit's brief analysis concluded that it was "not inappropriate for NORML to apply first for rescheduling under the CSA" despite a lack of FDA approval. *Id.*

124. Proposed Recommendations to the Drug Enforcement Administration Regarding the Scheduling Status of Marihuana and Its Components and Notice of a Public Hearing, 47 Fed. Reg. 28141, 28151 (June 29, 1982).

use of the drug in treatment can be considered acceptable by medical standards."[125]

Defining accepted medical use for purposes of drug scheduling under the CSA "to mean lawfully marketed in this country under the Federal Food, Drug, and Cosmetic Act"[126]—and, conversely, for no currently accepted medical use to mean not "lawfully marketed"[127]—had the appeal of regulatory simplicity. But the First Circuit found that the DEA's FDA-approval-based-test was impermissible, even viewed through the forgiving lens of *Chevron*.[128] The central flaw in the DEA's position was this: A drug might "fail to obtain FDA interstate marketing approval" for reasons that have nothing to do with its medical value.[129] For example, a substance may "be disapproved for interstate marketing because it . . . fails to contain relevant patent information, or even because the labeling proposed for the drug 'is false or misleading in any particular.'"[130] Likewise, for some substances—namely, those that "cannot be patented and exploited commercially"[131]—a lack of FDA approval might simply be a product of a lack of economic incentive to apply for approval. In both scenarios, "it is plainly possible that a substance may fail to obtain interstate marketing approval even if it has an accepted medical use."[132] The First Circuit concluded that Congress therefore could not

125. *Id.*

126. Proposed Recommendation to the Drug Enforcement Administration Regarding the Scheduling Status of Tetrahydrocannabinol, 47 Fed. Reg. at 10084.

127. *Id.*

128. *Grinspoon*, 828 F.2d at 884 ("The Administrator argues correctly that we must review his interpretation of the CSA in light of the guidelines set forth by the Supreme Court in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*"); *see id.* at 891 (finding that the DEA's interpretation it "directly conflict[ed] with congressional intent").

129. *Id.* at 887.

130. *Id.* (citation omitted).

131. *Id.*

132. *Id.* The court cited two additional reasons in support of its conclusion. First, it found that subsequent legislation amending the CSA—including legislation that created a temporary emergency drug scheduling process that could not be applied to FDA-approved drugs—"buttress[ed] our conclusion that the Administrator's construction of the CSA conflicts with congressional intent." *Id.* at 889. This was because Congress's decision to rely on FDA approval for purposes of scheduling "only in temporary emergency situations suggests to us that these shorthand methods are not appropriate in routine (i.e., nonemergency) situations such as the one before us in the instant case." *Id.* Second, the Court pointed to the CSA's provision "for a meaningful hearing *after* receipt of the HHS report" to the Attorney General in the scheduling process. *Id.* at 890. The DEA's definition would render these hearings "an empty formality" for substances that did not yet have FDA approval. *Id.*

have intended for accepted medical use under the CSA to mean approval for marketing under the FDCA.[133]

Although the First Circuit rejected the DEA's attempt to require FDA approval under the FDCA in order to demonstrate accepted medical use under the CSA, it left the agency with a significant amount of flexibility. The court declined to adopt its own definition to replace the DEA's because it found itself "unable to ascertain with any certainty what Congress intended to be the proper interpretation" of the scheduling finding.[134] Accordingly, it remanded the matter to the DEA to come up with a substitute definition.[135]

That process led the DEA to replace the test rejected by the First Circuit with a five-requirement test for medical use that "tracks the 'core standards developed under the FDCA,'" without requiring FDCA approval itself.[136] Under the test, a drug that does not have FDA approval[137] must meet the following requirements in order to be found to have a currently accepted medical use:

1. "The Drug's Chemistry Must Be Known and Reproducible"[138]
2. "There Must Be Adequate Safety Studies"[139]
3. "There Must Be Adequate and Well-Controlled Studies Proving Efficacy"[140]
4. "The Drug Must Be Accepted by Qualified Experts"[141]
5. "The Scientific Evidence Must Be Widely Available"[142]

The DEA has applied this five-requirement test to non-FDA-approved drugs ever since, and it has made it all but impossible for a drug that does not have FDA approval to be placed anywhere other than Schedule I. (The test originally had eight requirements, but the D.C.

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133. *Id.* at 886.

134. *Id.* at 892.

135. *Id.*

136. *OLC Rescheduling Opinion*, *supra* note 30, at 2 (quoting Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10503–04 (Mar. 26, 1992)).

137. The DEA deems a drug that "has been approved by FDA for marketing under the FDCA, either through the NDA process or by meeting the criteria to be recognized as a 'Generally Recognized As Safe and Effective' ('GRASE') drug" to have a currently accepted medical use under the CSA, without having to conduct a separate application of the five-requirement test. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44616 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

138. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10506 (Mar. 26, 1992).

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

Circuit found that three were fatally flawed because they appeared to be "impossible" for any substance currently on Schedule I to fulfill.)[143]

All five requirements were based on the DEA's "understanding of FDA standards and practices"[144] and "four were expressly derived from the FDCA or FDA regulations setting forth requirements that a drug must meet before receiving FDA approval."[145] The test reflected the DEA's view that the First Circuit's rejection of the FDA-approval-based test did not "mean that CSA standards differ from FDCA standards."[146] Instead, the agency's approach proceeded from the premise that if it excluded those FDCA requirements that were not "pertinent"[147] to assessing medical utility from its analysis, mirroring the other requirements for FDA approval would be acceptable.[148]

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143. All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 937 (D.C. Cir. 1991). The original test required:

> (1) Scientifically determined and accepted knowledge of [the substance's] chemistry; (2) The toxicology and pharmacology of the substance in animals; (3) Establishment of its effectiveness in humans through scientifically designed clinical trials; (4) General availability of the substance and information regarding the substance and its use; (5) Recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks; (6) Specific indications for the treatment of recognized disorders; (7) Recognition of the use of the substance by organizations or associations of physicians; and (8) Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.

Id. at 938. The three flawed requirements were numbers (4), (5), and (8). Because "[o]ne of the very purposes in placing a drug in Schedule I is to raise significant barriers to prevent doctors from obtaining the drug too easily," the court reasoned, "[w]e are . . . hard-pressed to understand how one could show that *any* Schedule I drug was in general use or generally available." *Id.* at 940. Although the D.C. Circuit found these three requirements to be arbitrary and capricious, it wrote that the test "was in the main acceptable," signaling to the DEA that significant revision would not be required on remand. *Id.* at 937. The remaining five factors closely aligned with, although did not exactly mirror the five-requirement test that the DEA adopted after remand from the D.C. Circuit.

144. Eisenberg & Leiderman, *supra* note 78, at 259.

145. *OLC Rescheduling Opinion*, *supra* note 30, at 9.

146. Eisenberg & Leiderman, *supra* note 78, at 259; *see* Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504 (Mar. 26, 1992) ("The pattern of initial scheduling of drugs in the Controlled Substance Act, viewed in light of the prior legal status of these drugs under the FDCA, convinces me that Congress equated the term 'currently accepted medical use in treatment in the United States' as used in the Controlled Substances Act with the core FDCA standards for acceptance of drugs for medical use.").

147. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504 (Mar. 26, 1992).

148. *Cf. id.* at 10503–04 ("The Court of Appeals for the First Circuit was correct when it decided in *Grinspoon v. DEA*, 828 F.2d 881 (1987) that NDA approval is not the only method by which drugs can achieve Federal recognition

Reviewing the DEA's test in the context of the denial of a petition to reschedule marijuana, the D.C. Circuit agreed that nothing in the First Circuit's MDMA scheduling opinion "suggested the DEA Administrator was foreclosed from incorporating and relying on those standards employed by the FDA that are relevant to the pharmaceutical qualities of the drug" in assessing medical use.[149] The court "deferred to the Administrator's interpretation as reasonable" under *Chevron* and upheld the DEA's five-requirement test.[150]

The result is a definition of accepted medical use under the CSA that effectively requires FDA approval in practice, even if not in name. This is because the DEA test's third and fourth factors—adequate safety studies and adequate and well-controlled studies proving efficacy, respectively—effectively import the FDCA's requirement of a particular kind of scientific proof into the CSA's medical use finding. Specifically, to demonstrate safety and efficacy under the DEA's test, the agency demands randomized-controlled trials of the sort that would be necessary to gain FDA approval.[151] Under this test, evidence of medical use that is based on studies that do not meet the FDA-level standard is not sufficient, regardless of the quantity or quality of that evidence.[152]

Practical and legal hurdles make it exceedingly difficult to generate these kinds of studies for substances that are already in Schedule I under the CSA like marijuana, even in the case of substances for which there is strong evidence of medical promise. For starters, producing randomized-controlled trials that meet FDA

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as having medical uses. Congress put both GRASE drugs and pre-1938-grandfathered drugs into Schedules II, III, IV and V of the CSA.").

149. All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991).

150. All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1134 (D.C. Cir. 1994).

151. Mikos, *False Promise*, *supra* note 32, at 2 ("[T]he DEA has insisted that the only way to demonstrate that marijuana has a [currently accepted medical use] is by completing Randomized Controlled Trials . . . ."); *see* Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. at 10505 ("There must be adequate, well-controlled, well-designed, well-conducted and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could fairly and responsibly be concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder."). For a description of the kind of scientific trials required for FDA approval, see Sean M. O'Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis Even After Descheduling*, 68 AM. U. L. REV. 823, 873–78 (2019).

152. *See* Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 481–83; *see also* Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. at 10504–05.

standards is expensive and time consuming—"the process of completing even a single RCT takes several years."[153] Academic researchers are unlikely to be able to fund these kinds of studies through grants, and private companies will only have an incentive to undertake them in the case of patented products.[154] As to legal barriers, as described in the previous Section, the CSA's regulations and restrictions add to the regulatory burden for researching scheduled substances, particularly in the case of substances in Schedule I.

Tellingly, only a handful of drugs have ever been moved from Schedule I to a lower schedule, and in most cases, it was only a specific patented pharmaceutical formulation of the drug—not the drug as whole—that was down-scheduled.[155] In 1986, for example, the DEA "conducted a product-specific rescheduling"[156] of dronabinol, a version of synthetic THC (the main psychoactive constituent in marijuana), from Schedule I to Schedule II after it received FDA approval.[157] But the transfer was limited to "dronabinol in sesame oil and encapsulated in soft gelatin capsules in a FDA approved drug product";[158] it did not extend to "THC itself,"[159] which remains in Schedule I to this day.[160]

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153. Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 488–89.

154. Eisenberg & Leiderman, *supra* note 78, at 276 ("Large pharmaceutical firms that expect to sell patent-protected molecules for many years can afford to amortize large premarket R&D burdens over the life cycles of the products, while manufacturers of medical devices . . . and sellers of unpatented dietary supplements . . . may find similar regulatory burdens unsustainable.").

155. *See* Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 490 n.89 and accompanying text.

156. U.S. FOOD & DRUG ADMIN., BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT (2023), *enclosed in 2023 HHS Recommendation*, *supra* note 29, at 4 [hereinafter *FDA Evaluation*].

157. Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule I to Schedule II; Statement of Policy, 51 Fed. Reg. 17476, 17476 (May 13, 1986) (to be codified at 21 C.F.R pt. 1308).

158. *Id.* at 17476.

159. Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol (Martinol®[sic]; (-)-Δ^9-(trans)-Tetrahydrocannabinol in Sesame oil and Encapsulated in Soft Gelatin Capsules) From Schedule II to Schedule III., 63 Fed. Reg. 59751, 59752 (Nov. 5, 1998) (to be codified at 21 C.F.R. pts. 1308, 1312).

160. 21 C.F.R. § 1308.11(d)(31); *FDA Evaluation*, *supra* note 156, at 4 ("Dronabinol is a Schedule I substance under the CSA unless it is contained in an FDA-approved drug product."). Marinol was transferred to Schedule III in 1999 and, in 2017, the DEA moved "'FDA-approved products containing dronabinol in an oral solution' from Schedule I into Schedule II" following FDA approval of a 5 mg/ml oral solution called Syndros. *Id.*

The DEA's requirement of randomized-controlled trials to demonstrate medical use under the CSA has consistently thwarted past petitions to reschedule marijuana. Although there is scientific evidence in support of some medical uses of marijuana, there are not randomized-controlled trials of the kind that would be required to win FDA approval.[161] Moreover, even if there were such studies, one of the other five requirements in the DEA's test has posed an independent barrier. As discussed above, the requirement that the drug's chemistry "be known and reproducible" has doomed the prospect for rescheduling marijuana the plant (as opposed to a specific formulation of it) because the chemistry of the marijuana plant, as defined by the CSA, is not and never will be reproducible.[162]

B. HHS's New Approach

The Attorney General's proposal to reschedule marijuana got around this seemingly insurmountable medical-use roadblock by declining to apply the DEA's accepted medical use test and, instead, adopting and applying a new two-step test. The new test in the Attorney General's proposed rescheduling came from HHS's evaluation of marijuana's status under the CSA. HHS's test asks "(1) whether there is widespread medical use of a drug under the supervision of licensed health care practitioners under State-authorized programs and, (2) if so, whether there is credible scientific evidence supporting such medical use."[163] The HHS test is not meant to replace the DEA's five-requirement test. Instead, HHS adopted it as an "independently sufficient approach for determining whether a substance has a [currently accepted medical use] under the CSA."[164]

The first part of HHS's test can be satisfied by evidence of three factors, none of which is dispositive: first, whether "a substantial number of [healthcare practitioners] have gained clinical experience with at least one specific medical use of the substance" under a state program; second, "[w]hether a substantial number of entities that regulate the practice of medicine recognize at least one specific use of the substance"; and, third, whether "clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses" and safety.[165]

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161. *See* Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 482–83.

162. Kreit, *supra* note 22, at 1242; *see also* Eisenberg & Leiderman, *supra* note 78, at 263 ("[C]annabis is a plant with many active and inactive constituents that exhibits biological variability rather than an isolated or synthetic chemical entity that can be reliably reproduced.").

163. 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).

164. *Id.*

165. Memorandum from Rachel L. Levine, Assistant Sec'y for Health, U.S. Dep't Health & Hum. Servs., to Commissioner, Food & Drug Admin. (July 17,

If the first part of the test is met, then the second step "evaluates whether there exists some credible scientific support for at least one of the medical conditions for which the Part 1 test is satisfied."[166] The "credible scientific support" standard is much more forgiving than the FDCA-inspired requirement of randomized controlled trials that the DEA has previously employed. Indeed, HHS emphasized in its analysis that the "evaluation in Part 2 is not meant to be, nor is it, a determination of safety and efficacy that meets the Federal Food, Drug, and Cosmetic Act's (FD&C Act's) drug approval standard for new human or animal drugs."[167] Rather than require the kind of randomized controlled trials needed to earn FDA approval for interstate marketing, the "credible scientific support" standard takes account of five different kinds of evidence—two that support a finding of accepted medical use, and three that can weigh against it.[168] Credible scientific support for medical use of a substance can be demonstrated by "favorable clinical studies [that], although not necessarily adequate and well-controlled clinical studies that would support [FDA] approval . . . , have been published in peer-reviewed academic journals" and/or favorable assessment by "qualified expert organizations" such as professional medical societies.[169]

Applying its new test to marijuana, HHS's analysis of Part 1 pointed to evidence that more than 30,000 healthcare practitioners "are authorized to recommend the use of marijuana for more than six million patients";[170] that "a substantial number of [state] regulatory entities recognize at least one specific medical use" of marijuana;[171] and that the large number of people using medical marijuana under

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2023), *enclosed in 2023 HHS Recommendation*, *supra* note 29, at 2 [hereinafter *HHS Part 1 Analysis Memo*].

166. CTR. FOR DRUG EVALUATION & RSCH., FOOD & DRUG ADMIN., CONSIDERATIONS FOR WHETHER MARIJUANA HAS A CURRENTLY ACCEPTED MEDICAL USE IN THE UNITED STATES FOR PURPOSES OF SECTION 202(B) OF THE CONTROLLED SUBSTANCES ACT 3 (2023), *enclosed in 2023 HHS Recommendation*, *supra* note 29, at 3.

167. *Id.*

168. *Id.* at 4–5.

169. *Id.* at 4. The factors that can weigh against a finding of credible scientific support of a medical use are: (1) evidence "that medical use of the substance is associated with unacceptably high safety risks"; (2) clinical studies with negative efficacy findings published in peer reviewed journals; and (3) recommendations against the use of the substance by qualified expert organizations. *Id.* at 4–5. Although HHS describes the test as considering two factors that can weigh in favor of a finding of medical use and three that can weigh against, it would be more succinct to say that the test considers a total of three factors. The first two—clinical studies and expert organization opinions—can weigh either for or against a finding of credible scientific support, while the third—information that there are "unacceptably high safety risks"—can weigh against a finding. *Id.* at 4.

170. *HHS Part 1 Analysis Memo*, *supra* note 165, at 3.

171. *Id.* at 5.

these state regimes meant that the "clinical experience with the use of marijuana for various medical conditions is of sufficient extent and duration to help evaluate potential clinical uses."[172] The agency concluded that this evidence, taken together, was sufficient to satisfy Part 1 and to therefore "warrant an FDA assessment under Part 2" of the test.[173]

In its Part 2 analysis, the FDA evaluated evidence of the medical efficacy of marijuana in the treatment of seven different medical conditions: anorexia due to a medical condition (e.g., HIV/AIDS), anxiety, epilepsy, inflammatory bowel disease, nausea and vomiting, pain, and post-traumatic stress disorder.[174] For each condition, the FDA considered "data from peer-reviewed publications included in a systematic review of the medical literature on marijuana" conducted by the University of Florida, the agency's own review of "published systemic reviews," position statements from professional organizations, the "FDA's findings for approved drug products related to marijuana," such as Marinol, and an analysis of safety data.[175] The agency's determination of whether there is credible scientific support for the use of marijuana to treat a condition was "based on the totality of the available evidence" considered in the evaluation.[176] But, the analysis indicated that "peer-reviewed clinical studies reporting evidence of benefit, or a reputable medical/scientific organization recommending treatment with marijuana for an indication within their area of expertise" would be the kind of evidence that would "meet[] the requirement for demonstrating some credible scientific support" for medical use.[177]

The scope of the FDA's assessment makes it impossible to capture every aspect of its review of the relevant evidence for any single medical indication, let alone all of them, in a short summary. For purposes of this Article, the key point is that at the end of its evaluation, the FDA found that the Part 2 test had been met for three of the seven conditions it evaluated: "pain; anorexia related to certain medical conditions; and nausea and vomiting (e.g., chemotherapy-induced), with varying degrees of support and consistency of

172. *Id.*

173. *Id.* at 6.

174. CTR. FOR DRUG EVALUATION & RSCH., *supra* note 166, at 4. HHS's Part 1 analysis identified "at least 15 medical conditions where there is widespread current experience with medical use" of marijuana in accordance with a state-authorized program. *Id.* n.2. The FDA selected the seven conditions that it believed "were likely to have the most robust evidence available for review" to evaluate. *Id.* Because the FDA "concluded that the Part 2 test has been met" in its evaluation of the seven conditions that it initially selected for review, it found that "there was no need to analyze" the other conditions. *Id.*

175. *Id.* at 11.

176. *Id.*

177. *Id.*

findings."[178] Combining the analysis from Parts 1 and 2 of its test, HHS concluded that "marijuana has a currently accepted medical use in the United States, specifically for the treatment of anorexia related to a medical condition, nausea and vomiting (e.g., chemotherapy-induced), and pain."[179] The Attorney General adopted HHS's conclusion in his marijuana rescheduling notice.[180] In contrast, the DEA did not sign onto HHS's new test, or to its conclusion that marijuana has a currently accepted use.[181] Indeed, the DEA appears to have objected to HHS's test, in an interagency dispute that was resolved in HHS's favor.[182]

C. Accepted Medical Use After Rescheduling

The DEA's apparent disagreement with HHS's test prior to the initiation of rescheduling raises the prospect that the agency might ultimately decline to apply it in the pending rescheduling

178. *Id.* at 92. For the FDA's full evaluation, see *id.* at 11–92. The FDA did not make an express overall finding for the other four conditions it evaluated—anxiety disorders, PTSD, inflammatory bowel disease, and epilepsy—although its discussion of the evidence for each suggests that data was inconclusive (rather than, for example, that the data indicated a lack of efficacy for these indications). *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44618 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308) ("FDA's review of the available information identified mixed findings of effectiveness across indications, ranging from data showing inconclusive findings to considerable evidence in favor of effectiveness, depending on the source.").

179. *FDA Evaluation*, *supra* note 156, at 64.

180. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. at 44619 ("Applying HHS's two-part test, and in light of OLC's legal opinion that HHS's test is sufficient under the CSA, the Attorney General concurs with HHS's conclusion, for purposes of the initiation of these rulemaking proceedings, that there is a CAMU for marijuana.").

181. *See supra* note 31 and accompanying text.

182. Although the DEA's exact position during the administrative review that preceded the proposed rescheduling rulemaking has not yet been made public, the OLC opinion memo issued during that process strongly suggests that the DEA objected to HHS's test. The OLC memo notes that it "solicited and received written views from HHS and DEA" on the three questions that it was asked to address, including the definition of currently accepted medical use. *OLC Rescheduling Opinion*, *supra* note 30, at 3 n.3. The OLC memo does not describe DEA or HHS's views in detail, and neither the DEA's nor HHS's written submissions to OLC have been released. But the OLC memo notes that the "DEA's main concern with HHS's two-part inquiry is that it places too much emphasis on state regulatory decisions," and—quoting from the DEA's written submission to OLC—that the DEA believed this "emphasis on states is 'misplaced' because, in DEA's view, the process states follow for enacting legislation 'are generally less rigorous than the requirements placed on federal agencies when they act pursuant to the APA.'" *Id.* at 19. This passage reveals that the DEA, at the very least, had doubts about HHS's two-part test, although the OLC memo does not state directly that the DEA expressly objected to the test.

proceedings.[183] As discussed above, regardless of the outcome of the administrative process for marijuana rescheduling, courts will no longer apply *Chevron* deference to whatever definition of currently accepted medical use the DEA uses to resolve the marijuana rescheduling proposal.[184] Instead, for the first time, a reviewing court will independently determine the best reading of the CSA's medical use scheduling criterion.[185]

In this Section, I argue that without *Chevron* deference, courts are likely to reject the DEA's existing five-factor test in favor of a less demanding standard. My focus here will be on two previously overlooked pieces of history from the drafting of the CSA and the implementation of the FDCA's efficacy provisions, that I argue significantly undercut the case for the DEA's five-factor test or anything close to it. Before turning to this original contribution, it is helpful to begin with a short summary of the analysis of the CSA's medical use criterion in the OLC opinion memo that was issued prior to the Attorney General's proposal to reschedule marijuana.

As noted in the introduction to this Article, prior to issuing the notice of proposed rulemaking to reschedule marijuana, the Attorney General asked for OLC's opinion on the DEA's and HHS's conflicting tests for determining whether a drug has a currently accepted medical use. OLC found "that limiting the [currently accepted medical use] analysis to whether a drug has been approved by FDA or meets DEA's five-part test is an impermissibly narrow interpretation of" the CSA.[186]

OLC cited three reasons in support of its conclusion. First, OLC found that the DEA's test conflicted with the text of the CSA "by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard"[187] of having a "currently accepted medical use in treatment in the United States."[188] The phrase accepted medical use "suggests that the relevant inquiry is whether the medical community has accepted that a drug has a 'use in treatment,'" but "neither FDA approval nor the DEA's five-part test examines whether health care practitioners are actually using a drug to treat a condition or whether the entities regulating those practitioners allow the drug to be so used."[189] Next, OLC pointed to

183. *See* Mikos, *False Promise*, *supra* note 32, at 13 ("Even if HHS is correct—i.e., even if its interpretation of the statutory language better reflects Congress's intentions—the DEA has no obligation to accept HHS's interpretation in lieu of its own.").

184. *See supra* pp. 354–56.

185. *See* Malich, *supra* note 32, at 418–19.

186. *OLC Rescheduling Opinion*, *supra* note 30, at 12.

187. *Id.* at 13.

188. 21 U.S.C. § 812(b)(1)(B).

189. *OLC Rescheduling Opinion*, *supra* note 30, at 13 (quoting 21 U.S.C. § 812(b)(1)(B)). OLC similarly found that by equating "an 'accepted' medical use

other provisions in the CSA that "refer[] to, and in some places explicitly rel[y] on, the FDCA" as evidence that Congress "did not mean to equate [currently accepted medical use] with the standards necessary for FDA approval."[190] Finally, the OLC memo concluded that mid-1980s amendments to the CSA, which created an emergency scheduling process and criminalized controlled substance analogues, reinforced the distinction between the CSA's accepted medical use scheduling criterion and FDA approval, as both amendments expressly exempted FDA approved drugs.[191]

OLC's reasoning—which focused on the CSA's text and subsequent history—provides a strong basis for rejecting the DEA's three-decades-old test for determining whether a drug has a currently accepted medical use as "impermissibly narrow."[192] In the two Sections that follow, I discuss two points from the regulatory and legislative history of the CSA and FDCA that I argue add additional support for this conclusion.

1. The Forgotten "Well Documented and Approved" Criterion

As the OLC noted, the phrase "currently accepted medical use" suggests a less demanding standard than FDA approval based on well-controlled studies.[193] The text of the bill that became the CSA further underscores the distinction between acceptance and approval. As first proposed by the Nixon administration and initially passed by the Senate, the CSA would have required a substance to have a "well documented and approved medical use in the United States"—and *not* a "currently accepted medical use in treatment in the United States"—for Schedule III drugs.[194] This feature of the CSA's legislative history appears to have been overlooked entirely by courts and academics to date. None of the court opinions addressing the CSA

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under the CSA with the 'approval,' or potential approvability, of the drug under the FDCA," the DEA's test appeared to be at odds with the CSA's text. *Id.* at 14 (citing Grinspoon v. DEA, 828 F.2d 881, 887 (1st Cir. 1987)). For an additional argument that the DEA's test is inconsistent with the plain meaning of the term currently accepted medical use in treatment, see Nabil Al-Khaled, *MDMA and Psilocybin for Mental Health: Deconstructing the Controlled Substance's Act's Usage of "Currently Accepted Medical Use*," 99 WASH. U. L. REV. 1023, 1041–42 (2021); *see also* Malich, *supra* note 32, at 424.

190. *OLC Rescheduling Opinion*, *supra* note 30, at 14.

191. *Id.* at 15.

192. *Id.* at 35.

193. *Id.* at 35–36.

194. 21 U.S.C. § 812(b)(3)(B); STAFF OF THE H.R. COMM. ON WAYS AND MEANS, 91ST CONG., MATERIALS PREPARED BY THE ADMINISTRATION RELATING TO PROPOSED LEGISLATION TO REGULATE CONTROLLED DANGEROUS SUBSTANCES AND AMEND NARCOTICS AND DRUG LAWS 50 (Comm. Print 1970); *see also id.* at 229 n.3 (noting that in in the House version of the bill, "the words 'currently accepted' were substituted for the words 'well documented and approved,'" which were in "S. 3246, the Senate-passed Controlled Dangerous Substances Act").

have mentioned this provision, nor have any academic articles.[195] But Congress's consideration, and apparent rejection, of it provides strong evidence that Congress meant for the CSA's medical use criterion to encompass a broader group of substances than those that have, or could receive, FDA approval.

The CSA's legislative history does not reveal much about the "well documented and approved medical use" provision. There do not appear to be any materials that directly shed light on the reasons for its inclusion in the original draft of the CSA, introduced in Congress as the Controlled Dangerous Substances Act,[196] or why it was removed as the proposal made its way through Congress.[197] The most that the legislative history shows is this: The "well documented and approved medical use" criterion for Schedule III substances was included in the version of the CSA initially passed by the Senate in January 1970,[198] and it was still in the version of the CSA considered by a House subcommittee in hearings held in February through early March.[199] Then, in an April 1970 memorandum of proposed changes to the Senate-passed bill, a Nixon administration official who was involved in drafting the CSA and shepherding it through Congress listed replacing the "well documented and approved" language in Schedule III with "currently accepted" as one of twenty-five

195. A Westlaw search for the phrase "well documented and approved" returns two court opinions and nine secondary sources, none of which discuss the federal CSA's legislative history. A brief filed in 2020 before the Ninth Circuit included a short discussion of the "well documented and approved" provision. *See* Petitioners' Brief at 60 in Sisley v. DEA, 11 F.4th 1029 (9th Cir. 2021) (No. 20-71433). But the Court dismissed the case on administrative exhaustion grounds and did not address the "well documented and approved" provision. *Sisley*, 11 F.4th at 1036. Interestingly, although the "well documented and approved" scheduling criterion was removed from the CSA's text relatively early in the legislative process, it found its way into two state Controlled Substances Act statutes. The National Conference of Commissioners on Uniform State Laws promulgated a Uniform Controlled Substances Act based on the federal act, and nearly every state reformed its drug laws based on the model law. Richard L. Braun, *Uniform Controlled Substances Act of 1990*, 13 CAMPBELL L. REV. 365, 365 (1991). Most of these states closely track the federal CSA's scheduling criteria. But Maryland and South Dakota each adopted, and still require, proof of a "well documented and approved medical use in the United States" as one of their Schedule III findings. MD. CODE ANN., CRIM. LAW § 5-404(b)(2) (2025); S.D. CODIFIED LAWS § 34-20B-18(2) (2025).

196. S. 3246, 91st Cong. (1970).

197. *See* 21 U.S.C. § 812(b).

198. S. 3246, 91st Cong. (1970).

199. *Drug Abuse Control Amendments—1970: Hearings on H.R. 11701 and H.R. 13743 Before the Subcomm. on Pub. Health & Welfare of the H. Comm. on Interstate & Foreign Com.*, 91st Cong. 11 (1970). The scheduling criteria were not a major focus of those hearings, and the "well documented and approved" criterion was mentioned only twice in the record of the hearings *Id.* at 195, 280.

contemplated changes to the bill that had passed the Senate.[200] The memorandum did not provide a reason for its proposed changes, but the next version of the legislation, introduced in the House in May 1970, appears to have adopted them.[201] The new bill omitted the "well documented and approved medical use" criterion in favor of the now-familiar "currently accepted medical use in the United States" language.[202]

The presence of the "well documented and approved" scheduling criterion for Schedule III substances in the original proposed bill, and the bill initially passed by the Senate, is significant in two respects. First, the fact that Congress considered, but did not adopt, a scheduling criterion that would have required both an "approved" and "well documented" use adds further support to the conclusion that the CSA's accepted medical use finding is not synonymous with FDA approval. To be sure, the notion that Congress meant to equate accepted medical use under the CSA with FDA approval has always suffered from a central flaw: If this is what Congress had intended, it could have easily achieved that goal directly by requiring FDA approval for drugs in Schedules II through V.[203] But the fact that the

200. Memorandum from Michael R. Sonnenreich, Deputy Chief Couns., Bureau of Narcotics & Dangerous Drugs, to John W. Dean III, Assoc. Deputy Att'y Gen. (Apr. 17, 1970) [hereinafter *April 17 Memorandum*] ("On page 20, line 23, delete the words 'well documented and approved' and insert in lieu thereof the words 'currently accepted.'"). Sonnenreich's April 17, 1970, memo began by noting that it was a "follow up to my memorandum of April 8, 1970." *Id.* Sonnenreich's April 8 memorandum did not state any reasons for the proposed change to the "well documented and approved" criterion, either. Memorandum from Michael R. Sonnenreich, Deputy Chief Couns., Bureau of Narcotics & Dangerous Drugs, to John W. Dean III, Assoc. Deputy Att'y Gen. (Apr. 8, 1970). The April 8 memo included the change in a group of "those changes which I feel should be made. Most of [which] are of a technical nature and should pose little or no problem with the members of the House Subcommittee on Health and Welfare." *Id.*

201. H.R. 17463, 91st Cong. (1970).

202. *Id.* § 202(b)(2), (d)(2). *Compare April 17 Memorandum*, *supra* note 200, *with Controlled Dangerous Substances, Narcotics and Drug Control Laws: Hearings on Legislation to Regulate Controlled Dangerous Substances and Amend Narcotics and Drug Laws Before the Comm. on Ways & Means*, 91st Cong. 214 n.3 (1970) (comparing provisions of H.R. 17463 with the earlier Senate-passed version of the CSA and noting changes that align with those proposed by Sonnenreich, including that, "[u]nder (c) schedule III (2), page 30, line 13, the words 'currently accepted' were substituted for the words 'well documented and approved'").

203. Courts are typically hesitant to conclude that Congress took a circuitous route to achieve a goal, when a direct one was available. *See* Designworks Homes, Inc. v. Columbia House of Brokers Realty, Inc., 9 F.4th 803, 811 (8th Cir. 2021) ("[W]e think using a hidden assumption in § 120(b) is too circuitous a route for Congress to have taken to include floorplans in § 120(a), especially when

version of the CSA's scheduling system that was initially passed by the Senate would have required an "approved" medical use for one of the schedules only underscores the point. Congress was not blind to the fact that it could have required an "approved" medical use in the CSA's scheduling criteria. That it ultimately chose not to is telling.

Second, the phrase "well documented and approved medical use in the United States" itself reads as though even *it* would not have demanded FDA or federal approval. Again, if that had been the goal, the most straightforward way to accomplish it would have been to simply require FDA approval. Although the phrase "well documented and approved use" bears some similarity to the FDCA's reference to "adequate and well-controlled investigations," the absence of a reference to the FDA (or any other federal body) seems to contemplate that state approval, if based on sufficient documentation, could also have satisfied it.[204]

To appreciate this possibility, it is important to recognize that when Congress considered and enacted the CSA, the concept of intrastate medicines, and the role of state regulators, was viewed differently than today. The FDCA's drug approval provisions only apply to medicines in interstate commerce.[205] Over time, experience

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Congress had a much more direct route—using better-fitting, alternative terms that it had employed elsewhere in the same and previous acts.").

204. 21 U.S.C. § 355(d).

205. *See id.* § 331(a)–(d) (providing penalties for violations in interstate commerce); *id.* § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [other sections of the FDCA] is effective with respect to such drug."). Other scholars have observed that this could, in theory, make it possible for state marijuana businesses to comply with the FDCA if marijuana were rescheduled under the CSA. *See* O'Connor & Lietzan, *supra* note 151, at 907–09 (identifying this as one of three possible "pathways forward under FDA law for medical cannabis"); Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 879 (2017) (explaining that FDA's jurisdiction would not cover the intrastate production and sale of marijuana). The FDA also recognized this possibility as early as the 1980s. In the course of making recommendations to the DEA regarding a marijuana rescheduling petition, the FDA observed that "[a] drug may also, theoretically, be legally marketed without violating the Federal Food, Drug, and Cosmetic Act if it is manufactured, processed, and used entirely within a single State without any connection at all with interstate commerce" and noted that it had "considered whether there is any basis to conclude that the substances at issue in this document have obtained 'accepted medical use' by virtue of totally intrastate production and use and has found no basis for a conclusion that these products have obtained acceptance of their medical use by that means." Proposed Recommendations to the Drug Enforcement Administration Regarding the Scheduling Status of Marihuana and Its Components and Notice of a Public Hearing, 47 Fed. Reg. 28141, 28150–51 (June 29, 1982). Of course, because "[m]ost finished marijuana products now on the market likely include some component that was sourced out of state, even if the marijuana itself was grown locally," avoiding FDA regulation via intrastate operation might not be a viable

and court decisions have reduced the significance of this limitation, which now does little to constrain the agency's regulatory reach in practice.[206] But the prospect of state-approved medicines was more than just theoretical in the 1970s. A drug called laetrile was the most prominent example of a non-FDA-approved drug that some states expressly allowed to be distributed as a medicine during this period.[207] The FDA's power to prohibit state-authorized laetrile was actively litigated in federal courts until a 1979 Supreme Court decision resolved the issue in the FDA's favor and effectively halted even the intrastate market for laetrile.[208] Around this same time, Congress considered—but did not adopt—proposed legislation that would have (among other things) extended the FDCA to cover intrastate drugs.[209]

In contrast to the FDCA, the CSA was drafted to expressly apply to wholly intrastate activity from the beginning.[210] Because of this, it

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option for marijuana businesses in practice. Mikos, *False Promise*, *supra* note 32, at 22–23; *see also* O'Connor & Lietzan, *supra* note 151, at 907 (arguing that "there are reasons to be cautious about this pathway").

206. *See* O'Connor & Lietzan, *supra* note 151, at 907 (noting that the FDA's interstate authority covers sales where "[a]ny inactive ingredient" of a substance traveled in interstate commerce and to "in-person sales if the purchasers cross state lines").

207. Laetrile is "a compound derived from apricot pits that was marketed as a cancer cure." Zettler, *supra* note 205, at 879; *see also* Thomas Ascik, *The Drug Regulation Reform Act*, HERITAGE FOUND.: ISSUE BULL., June 21, 1978, at 10, https://perma.cc/PVU7-6ET9 (stating that the "intention" of the bill's elimination of the distinction between interstate and intrastate drugs was "to bring all cures, such as laetrile, manufactured and sold completely within a state, under federal regulations").

208. United States v. Rutherford, 442 U.S. 544 (1979); *see* Catherine M. Sharkey & Daniel J. Kenny, *FDA Leads, States Must Follow,* 102 WASH. U. L. REV. 155, 180 (2024) (discussing *Rutherford* and noting that, although "[t]he Court did not expressly say that states cannot legalize drugs the FDA had not approved[,] . . . . the use of Laetrile dwindled after *Rutherford*, likely due to a combination of deference to the FDA's decision and the legal difficulties of disentangling intrastate from interstate distribution of Laetrile in a national market"); LEWIS A. GROSSMAN, CHOOSE YOUR MEDICINE: FREEDOM OF THERAPEUTIC CHOICE IN AMERICA 154–61 (2021) (discussing state laetrile laws and federal litigation).

209. The Drug Regulation Reform Act of 1978 was put forward by the Carter Administration. S. 2755, 95th Cong. (1978); H.R. 12980, 95th Cong. (1978). The proposed law would have enacted a range of significant changes to the review process for medicinal drugs, including "eliminate[ing] any distinctions between interstate and intrastate drugs" under the FDCA. U.S. DEP'T OF HEALTH, EDUC., & WELFARE, 95TH CONG., DRUG REGULATION REFORM ACT OF 1978 SECTION-BY-SECTION ANALYSIS 189 (1978).

210. *See* S. 3246, 91st Cong. § 101 (as passed by Senate, Feb. 5, 1970) ("The Congress finds and declares that Federal control of the primarily intrastate incidents of the traffic in controlled dangerous substances is essential to the effective control of the interstate incidents of such traffic."); *see also* 21 U.S.C.

may have made some sense for the CSA's drafters to have included a well documented and approved medical use scheduling provision that could have been satisfied by state approval. The significance of this point is that such a provision, which contemplated a more demanding standard (well documented and approved use) than the one ultimately adopted for Schedule III drugs (currently accepted use), would itself likely have been less restrictive than the current DEA medical use test.

In sum, this long-forgotten feature of the CSA's legislative history provides additional support for the conclusion that Congress meant for "currently accepted medical use in treatment in the United States" to be a less demanding standard than FDA approval. Congress considered the possibility of a scheduling finding that would have expressly required a "well documented and approved medical use in the United States."[211] It appears that this provision would have required a formally approved medical use of some kind, whether by the FDA or a state. Instead of retaining this language in the final version of the CSA, however, Congress elected to employ the less demanding standard of acceptance, as opposed to approval, and it did away with the requirement that the medical use be "well documented" entirely.[212]

2. The DEA's Misplaced Reliance on FDA's Controlled Trials Regulation

The CSA's structure and history both suggest that Congress did not intend for the currently accepted medical use criterion to be synonymous with FDA approval. But could it still be that Congress meant to "equate[] the term 'currently accepted medical use in treatment in the United States' as used in the Controlled Substances Act with the core FDCA standards for acceptance of medical use"?[213] As discussed above, the DEA's five-factor test is premised on this interpretation. In the DEA's view, it would have been unlikely for Congress to "create a totally new Federal standard for determining whether drugs have accepted medical uses" instead of "rely[ing] on standards it had developed over the prior 64 years under the

§ 801(5) ("Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate."). *See generally* Gonzales v. Raich, 545 U.S. 1 (2005) (upholding the application of the CSA to intrastate marijuana cultivation and possession).

211. S. 3246, 91 Cong. § 202 (as passed by Senate, Feb. 5, 1970).

212. *Id.*; *see* 21 U.S.C. § 812(b).

213. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504 (Mar. 26, 1992).

FDCA."[214] Thus, because the FDA has interpreted the FDCA to require multiple randomized controlled trials proving efficacy for a drug to win interstate marketing approval, the DEA has required the same as part of its five-requirement test.[215]

The DEA's rationale suffers from a critical flaw that appears to have gone overlooked to date. Contrary to the DEA's assumption, the FDA's position that there must be multiple randomized controlled trials to prove a drug's efficacy under the FDCA was *not* "existing Federal law" at the time Congress enacted the CSA.[216] Instead, the FDA's regulatory regime for proving efficacy was still very much unsettled during the period in which the CSA was drafted, debated, and enacted. A short review of the pertinent FDCA provisions and FDA regulations tells the story.

The FDCA was enacted in 1938 to replace the significantly less rigorous Pure Food and Drug Act of 1906.[217] The 1906 Act was centered around the principle of disclosure by requiring manufacturers to list "the presence and amount of certain drugs" for consumers.[218] The law did not require safety testing for new drugs and, instead, "assumed that people could use instrumental behavior to choose drugs if they had the correct information about the drugs' composition."[219] A tragedy involving an untested drug that killed over 100 people in 1937 led Congress to enact the FDCA.[220] In its original form, the FDCA forbade drug manufacturers from marketing "'unsafe' drugs at all."[221] The FDCA of 1938 did not, however, require efficacy testing.[222] And, even with respect to safety, the 1938 law did not require regulatory premarket approval.[223] Instead, "a new drug manufacturer only submitted premarket notice called a new drug application" and, "[i]f the FDA did not object within sixty days, the manufacturer was free to market the new drug immediately."[224]

In 1962, Congress amended the FDCA in the aftermath of another medical drug crisis (this time, a drug that was found to cause

214. *Id.* at 10503.

215. *See id.* at 10504–05.

216. *Id.* at 10503.

217. Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 224 (2009).

218. Kimani Paul-Emile, *Making Sense of Drug Regulation: A Theory of Law for Drug Control Policy*, 19 CORN. J.L. & PUB. POL'Y 691, 718 (2010).

219. PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 45 (1980).

220. See *id.* at 42–43.

221. *Id.* at 45.

222. Van Tassel, *supra* note 217, at 225 ("[U]ntil 1962, there was no obligation to test a product prior to distribution for efficacy.").

223. *Id.* at 223–24.

224. *Id.* at 224.

serious birth defects) to require drug manufacturers "to test all new drugs for both safety *and* effectiveness."[225] The 1962 amendments also moved from a system in which a new drug application allowed a manufacturer to market the drug unless the FDA objected, to one that "requires affirmative agency approval" of a new drug.[226] With respect to existing drugs, the 1962 amendments permitted the FDA "administratively to withdraw approval already granted to an NDA" if there was "a 'lack of substantial evidence' of effectiveness" for the drug.[227]

Although the 1962 FDCA amendments required evidence of a drug's efficacy for premarket approval, they did not specify in detail exactly what sort of evidence would suffice. Instead, the relevant provisions required "substantial evidence" of a drug's efficacy, and defined substantial evidence to mean

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.[228]

This definition is not nearly as open-ended as the CSA's scheduling criteria, but it still left many questions about the kind and amount of evidence manufacturers would have to produce for approval.[229]

The FDA had yet to clarify the meaning of the phrase "adequate and well-controlled studies," either through rulemaking or adjudication, at the time the bill that became the CSA was introduced in Congress in 1969.[230] In the mid-to late-1960s, the FDA began to

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225. *Id.* at 228–29 (emphasis added) (providing an overview of the Thalidomide crisis and discussing how, although the drug had been rejected by the FDA under its notification procedures, it "had already been provided to 20,000 patients in the United States as part of a[n] 'investigational study'" by the time its role in causing birth defects was discovered).

226. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 614 (1973).

227. TEMIN, *supra* note 219, at 125; *see also Weinberger*, 412 U.S. at 613–14 (noting that the 1962 amendments exempted drugs that were not defined as a "new drug" under the 1938 Act, and that met certain other requirements, from the effectiveness requirement and review through a grandfather clause).

228. 21 U.S.C. § 355(d).

229. TEMIN, *supra* note 219, at 130 (observing that it "was not clear" what "the law's call for 'adequate and well-controlled investigations'" required, "though it was clear that ordinary clinical experience did not qualify").

230. *Id.* at 134 (noting that at the time of an early 1970 court opinion over an FDA drug approval withdrawal, "neither the FDA's actions nor [its] Drug Efficacy Study had clarified [the] meaning" of the phrase "adequate and well-controlled

withdraw approval for some drugs that had been lawfully marketed under the pre-1962 regime on the grounds that there was a lack of substantial evidence of efficacy.[231] This resulted in litigation over the question of what constituted substantial evidence of drug effectiveness,[232] which in turn encouraged the FDA to issue a regulation defining the term "adequate and well-controlled investigations."[233] The final regulations were issued in May 1970,[234] but challenges to them along with "the issue of how closely the FDA could shape the [New Drug Application] process by regulation was not settled"[235] until a 1973 Supreme Court opinion.[236]

It was in these May 1970 regulations that the FDA first "demanded that a drug's sponsor submit the results of clinical trials that incorporated a control, presumptively a placebo control, and met other standards of scientific rigor."[237] To be sure, the FDA's interpretation of the phrase "adequate and well-controlled studies" was based on "the methodology broadly adopted by the field of clinical pharmacology during the 1950s"[238] and "reflected an emerging consensus on the essential features of trial design among academic clinicians."[239] The point here is not to suggest that the FDA's

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study"); *see* 115 CONG. REC. 39253, 39253–54 (1969) (introduction of the Controlled Dangerous Substances Act in the Senate).

231. TEMIN, *supra* note 219, at 133–34; *see id.* at 128 (noting that the FDA established a Drug Efficacy Study Group in 1966 to carry out the efficacy review for thousands of pre-1962 drugs; the process lasted three years); Upjohn Co. v. Finch, 422 F.2d 944, 948 (6th Cir. 1970).

232. *E.g.*, *Upjohn*, 422 F.2d at 951–54 (rejecting a drug manufacturer's argument "that the effectiveness of its combination drugs has been established by their use under prescription of physicians and their wide acceptance by the medical profession" and holding "that the record of commercial success of the drugs in question, and their widespread acceptance by the medical profession, do not, standing alone, meet the standards of substantial evidence prescribed by" the 1962 FDCA amendments).

233. TEMIN, *supra* note 219, at 134–35.

234. Hearing Regulations and Regulations Describing Scientific Content of Adequate and Well-controlled Clinical Investigations, 35 Fed. Reg. 7250, 7250–53 (May 8, 1970) (amending 21 C.F.R. §§ 130.12, 130.14, 146.1).

235. TEMIN, *supra* note 219, at 135.

236. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973).

237. Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1771 (1996). The FDA later issued additional guidance to address statistical questions in clinical trials and, since the guidance was issued in 1998, "two trials, each with a two-sided alpha level of 0.05, has remained the paradigm for FDA approval of drug efficacy." Lee Kennedy-Shaffer, *When the Alpha is the Omega: P-Values, "Substantial Evidence," and the 0.05 Standard at FDA*, 72 FOOD & DRUG L.J. 595, 619 (2017).

238. Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 AM. J.L. & MED. 687, 698 (2016).

239. Merrill, *supra* note 237, at 1771. Notably, some commentators have suggested that, although it is "difficult to dispute the reasonableness of" the

interpretation of the FDCA's substantial-evidence-of-efficacy requirement was unreasonable, but to highlight that the FDCA drug approval regime as we now know it was as much a creature of the 1970 regulations as the 1962 amendments. It was "only in 1970 [that] informal clinical evidence [was] definitively excluded from 'substantial evidence'"[240] under the FDCA, and it was only in 1970 that the now familiar and "famously rigorous"[241] requirement of randomized controlled trials was established. And, even then, the status of the FDA's regulations remained uncertain until the Supreme Court addressed them in 1973.[242]

Returning to the CSA's "currently accepted medical use" criterion with this history in mind, the DEA's justification for its five-factor, FDCA-based test becomes even more difficult to defend. The heart of the DEA's position is that it is unlikely that "Congress intended to depart radically from existing Federal law" with respect to the standards for "determining whether drugs have accepted medical uses."[243] But as the discussion above shows, the pertinent "core FDCA criteria" for assessing drug efficacy was *not*, in fact, "existing Federal law" at the time the CSA was drafted.[244] By the time the FDA issued its final regulations requiring randomized controlled trials in May 1970, Congress was well into the legislative process that led to the

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FDA's regulations interpreting the requirement of adequate and well-controlled studies, the "FDA's chief purpose in defining the 'substantial evidence' standard was to erect a hurdle so high that few sponsors of pre-1962 drugs whose effectiveness it had challenged would be entitled to a hearing on the agency's proposal to withdraw approval." *Id.* at 1771–72; *see also* STEPHEN BREYER, REGULATION AND ITS REFORM 141 (1982) (describing how the FDA's rule "that a drug company could show efficacy only through prospective, double-blind testing" allowed it to "circumvent[]" complicated procedural requirements for withdrawing approval for pre-1962 drugs).

240. TEMIN, *supra* note 219, at 137–38.

241. Adam I. Muchmore, *Marketing Authorization at the FDA: Paradigms and Alternatives*, 74 ADMIN. L. REV. 539, 578 n.143 (2022).

242. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629–31, 634 (1973). *Weinberger* concerned a procedural question, but the Court's decision in the case was perceived as having "sustained the regulation on procedural grounds and on its consistency with the 1962 act." TEMIN, *supra* note 219, at 136–37; *see also Weinberger*, 412 U.S. at 638 (Powell, J., concurring in part) (concurring in the result regarding the drug manufacturer's entitlement to a hearing on efficacy with the reservation that the content of the FDA's definition of adequate and well-controlled studies had "not been squarely presented" and that, had the issue been presented, "there might well be serious doubt whether the Commissioner's rigorous threshold specifications as to proof of 'adequate and well-controlled investigations' . . . go beyond the statutory requirements").

243. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10503 (Mar. 26, 1992).

244. *Id.* at 10503–04.

enactment of the CSA.[245] Although Congress did not pass the final version of the CSA until October 1970,[246] one or more drug schedules had included "currently accepted medical use in the United States" as a scheduling criterion since the beginning of the legislative process, including in the version of the bill passed by the Senate in January of 1970.[247] It was three years after that, in 1973, that litigation addressing the FDA's regulations defining adequate and well-controlled investigations was resolved by the Supreme Court.[248]

All this makes the notion that Congress intended for the CSA's "currently accepted medical use" criterion to incorporate a requirement of randomized controlled trials in order to be aligned with the FDCA's adequate and well-controlled studies provision particularly implausible. First, the FDA regulation requiring randomized controlled trials did not yet exist at the time the CSA was introduced in Congress and initially passed by the Senate. Second, the randomized control trial regulation was still in its infancy and was the subject of fierce litigation in court when the final version of the CSA was passed.[249] Finally, it is important to recall the DEA's contrary position requires not only overlooking this regulatory history but ignoring the fact that Congress could have easily incorporated FDCA standards into the CSA's scheduling criteria through cross-reference or the use of identical language. But rather than require "substantial evidence" of a drug's effectiveness "consisting of adequate and well-controlled investigations,"[250] as the FDCA does, Congress elected to make "a currently accepted medical use" the relevant CSA scheduling criterion.

As the discussion above reveals, there is good reason to think that the DEA's five-factor test's days are numbered. This is not to say that

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245. BOGOMOLNY ET AL., *supra* note 48, at 17–20 (providing an overview of the timeline of the CSA's progression through Congress).

246. *Id.* at 20.

247. 116 CONG. REC. 1587, 1674 (1970) (listing a "currently accepted medical use in the United States" as a criterion for Schedule IV drugs); S. 3246, 91st Cong. (1970).

248. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629–31, 634 (1973).

249. Notably, the FDA continued to take steps in the 1970s and into the 1980s to make the standard outlined in its 1970 regulation even more rigorous by "placing emphasis on placebo controls." DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 514 (2010). As a result of this effort, "drug sponsors began to regard the placebo control arm as an absolute requirement" for FDA approval. *Id.* At the same time, even as the FDA's view of what constitutes adequate and well-controlled investigations became more rigorous, Congress and the agency have "shift[ed] from reliance on rigorous enforcement of approval standards through premarket testing" toward alternative methods of initial approval for certain small subsets of drugs. Eisenberg & Leiderman, *supra* note 78, at 273; *see also id.* at 269–74.

250. 21 U.S.C. § 355(d).

a court is likely to find that HHS's test reflects the best interpretation of the currently accepted medical use requirement.[251] But the considerations identified in the OLC memo, along with the history of the proposed "well documented and approved" criterion and the FDCA's regulations regarding randomized and controlled trials, both counsel in favor of a standard more closely resembling the HHS test than one primarily focused on randomized controlled trials and other FDCA standards.

III. RESCHEDULING AND THE FUTURE OF RELATIVE POTENTIAL FOR ABUSE

A. The DEA's Test

When thinking about the CSA's potential for abuse criterion, it is important to first distinguish between the statute's threshold potential for abuse finding that is necessary for control, and the relative potential for abuse finding that varies between schedules. The relative finding contemplates four different levels of potential for abuse—a "high potential for abuse" in Schedules I and II, and then three lower levels of potential for abuse for Schedules III, IV, and V.[252] The threshold potential for abuse finding is the minimum that is required for a drug to be controlled under the statute.[253] The threshold finding is housed in a CSA provision that is separate from the scheduling findings, and it requires the DEA to determine that a "drug or other substance has a potential for abuse" to add it to any of the CSA's schedules—i.e., to classify the drug as a controlled substance.[254] (Presumably, this threshold finding is identical to the relative potential for abuse finding in Schedule V, the CSA's lowest schedule, although the CSA does not say so expressly.)

The CSA, of course, defines none of the scheduling criteria, nor does its text provide further guidance on the degree of potential for abuse necessary to meet the threshold for control. But one of the CSA's predecessor statutes, along with the CSA's legislative history, have pointed the way to a degree of clarity with respect to the threshold finding required for control. The CSA's "potential for abuse" requirement was imported from the Drug Abuse Control Amendments of 1965, which provided for administrative authority to control drugs that had "a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic

251. HHS's proposed test's reliance on state laws and widespread clinical experience makes it "unlikely any drug besides marijuana" could meet it. *See* Mikos, *Tyrannies of Scheduling*, *supra* note 32, at 495.

252. 21 U.S.C. § 812(b)(1)(A), (2)(A), (3)–(5).

253. *Id.* § 811(a)(1)(A).

254. *Id.*

effect."[255] Courts consistently held that the "potential for isolated or occasional non-therapeutic" use was not enough to meet this standard under the 1965 Amendments.[256] Instead, the 1965 Amendments required evidence of "a substantial potential for the occurrence of significant diversions from legitimate drug channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community."[257] Congress did not indicate that it intended to depart from that definition in any way when it repealed the 1965 Amendments and enacted the CSA; indeed, the CSA's legislative history suggests an intent to retain it.[258]

In addition to specifying the degree of abuse potential required to meet the threshold for control under the CSA, a regulation implementing the 1965 Amendments identified four paths to meeting that threshold. Under a final rule issued one year after passage of the 1965 Amendments by the FDA Commissioner (who had regulatory authority over the 1965 Amendments), a drug could be found to have a potential for abuse if:

> (1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or
>
> (2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or
>
> (3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to

255. Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74 § 3(a), 79 Stat. 226, 227.

256. Carter-Wallace, Inc. v. Gardner, 417 F.2d 1086, 1090 (4th Cir. 1969).

257. *Id.* (quoting H.R. REP. NO. 130, at 7 (1965)); *see also* Hoffmann-La Roche, Inc. v. Kleindienst, 478 F.2d 1, 6 (3d Cir. 1973) (adopting the holding in *Carter-Wallace*); Iske v. United States, 396 F.2d 28, 30 (10th Cir. 1968) (explaining that the potential for abuse finding requires "substantial potential for occurrence of significant diversions," not merely "isolated or occasional nontherapeutic" use); White v. United States, 395 F.2d 5, 9 (1st Cir. 1968).

258. *See* Placement of Carisoprodol Into Schedule IV, 76 Fed. Reg. 77330, 77336 (Dec. 12, 2011) (to be codified at 21 C.F.R. pt. 1308) ("The legislative history [of the CSA] also explains that a determination that a substance has 'potential for abuse' should not 'be determined on the basis of isolated or occasional nontherapeutic purposes.' Rather, 'there must exist a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community.'" (citations omitted)).

> administer such drugs in the course of his professional practice: or
>
> (4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.[259]

A House Committee report "accompanying the bill that eventually became the CSA"[260] quoted this language verbatim, and the DEA has consistently relied on these four factors throughout the CSA's history when assessing potential for abuse.[261]

This history has proven a helpful guide for the CSA's *threshold* potential for abuse requirement. But the considerations that should drive the evaluation of *relative* abuse potential under the CSA—and the line that distinguishes each of the CSA's four tiers of potential for abuse from one another—are a different matter. At the heart of the problem is the fact that, in contrast to the CSA, the 1965 Amendments had no relative potential for abuse finding; there was only an all-or-nothing threshold determination.[262] As a result, the factors identified in the 1965 Amendments, and that Congress seemed to have in mind when it drafted the CSA, were designed for making that threshold determination. The regulation said only that if any of four things are shown—that people are taking the drugs in amounts that create a health or safety hazard; that there is significant diversion from legitimate channels; that there is use on a person's own initiative rather than under medical supervision; or that the drug is so similar to an already-controlled-drug that it is reasonable to assume at least one of the first three things will be true—there is *a* potential for abuse.[263]

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259. *See* Regulations Implementing Drug Abuse Control Amendments of 1965, 31 Fed. Reg. 1071, 1072 (Jan. 25, 1966). The first three of these paths paralleled the definition of potential for abuse in the 1963 report of the President's Advisory Commission on Narcotics and Drug Abuse. *See Carter-Wallace*, 417 F.2d at 1091 n.9.

260. Grinspoon v. DEA, 828 F.2d 881, 893 (1st Cir. 1987) (quoting H.R. REP. NO. 91-1444 (1970)).

261. *E.g.*, Proposed Placement of Clortermine in Schedule III, 38 Fed. Reg. 12121, 12122 (May 9, 1973) (to be codified at 21 C.F.R. pt. 308) (quoting H.R. REP. NO. 91-1444); Placement of Carisoprodol Into Schedule IV, 76 Fed. Reg. at 77336.

262. Regulations Implementing Drug Abuse Control Amendments of 1965, 31 Fed. Reg. 1071, 1072 (Jan. 27, 1966).

263. *Id.*

Whether, and how, these threshold factors might help to inform an assessment of a drug's *relative* abuse potential beyond that threshold is far from clear. In an article published five years after the CSA's enactment, the DEA's former Assistant Chief Counsel and "principal author of [its] regulations,"[264] acknowledged this fact, observing that, "among Schedules II, III, IV, and V, Congress has not provided significant guidance in determining what weight should be given to individual factors of abuse."[265] He continued, explaining that

> [t]he statute and legislative history are silent . . . on such questions as: Is organic harm more serious than psychological harm? Is long-term physical deterioration more serious than acute toxicity? What weight should be given to mutagenic and teratogenic effects? Is task-related misuse (e.g., truck drivers using stimulants) less serious than recreational use (e.g., teenagers using drugs on weekends)?[266]

These kinds of questions "are at the heart of determining the relative potential for abuse and relative actual abuse of various drugs," and therefore should be central to "determining which level of control should be imposed on specific drugs."[267] But the DEA has never attempted to carefully examine, let alone answer, them. Nor has it ever articulated a methodology for assessing relative abuse potential, described what distinguishes the CSA's four potential for abuse tiers from one another, or even provided a comprehensive list of considerations to be used in analyzing a substance's abuse potential.

Instead, DEA scheduling opinions have generally focused on the four factors derived from the 1965 Amendments in their analysis of relative potential for abuse, with the occasional discussion of other factors.[268] The analysis always proceeds on a case-by-case basis, with no attempt to articulate a comprehensive list of factors that should be considered in assessing relative abuse potential, develop a method for how they should be weighed, or further define each of the four different CSA potential for abuse tiers. Indeed, the DEA has suggested that it does not believe there is a need to do any of these things, writing in one scheduling opinion that "there is no single test or assessment procedure that, by itself, provides a full and complete characterization of a substance's abuse potential, as this is a complex determination that is multidimensional."[269]

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264. Robert J. Rosthal, *Introduction* to Vodra, *supra* note 80, at 2.

265. Vodra, *supra* note 80, at 38.

266. *Id.* at 39.

267. *Id.*

268. *See* 1 GERALD F. UELMEN & ALEX KREIT, DRUG ABUSE AND THE LAW SOURCEBOOK § 1:10 (2025).

269. Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV, 76 Fed. Reg. 77330, 77336 (Dec. 12, 2011) (to be codified at 21 C.F.R.

In comparison to the CSA's medical use criterion, there has been little litigation regarding the question of relative potential for abuse.[270] This is likely due at least in part to the DEA's view of the primacy of the medical use finding in placing substances in Schedule I. Even in cases where litigants have pressed challenges to the DEA's finding of relative abuse potential, courts have not waded into the question of how to determine relative potential for abuse. In a particularly notable example, in the challenge to the DEA's placement of MDMA in Schedule I discussed in the previous Section, the petitioner argued that the agency's finding of high potential for abuse was flawed because "the Administrator articulated no standard for showing that MDMA had a *relative* potential for abuse sufficient to warrant placement in Schedule I."[271] The First Circuit "acknowledge[d] that the Administrator's final rule is silent with respect to the legal standard required for a finding of 'high' potential for abuse" relative to other schedules.[272] Nevertheless, it upheld the agency's finding on the ground that it was permissibly based on "evidence of close structural and pharmacological similarity between MDMA and other substances, such as MDA, which already have been found to have a high potential for abuse and have been placed in Schedule I or II."[273]

This dynamic has left the DEA with an inordinate amount of flexibility in its assessment of a substance's relative potential for abuse. It allows the DEA to emphasize a particular data point in the context of one drug, but to pay that same data point no attention in the context of a different drug. It also goes a long way toward explaining the agency's repeated findings that marijuana has a "high" potential for abuse, on par with that of heroin and cocaine.

In the marijuana setting, the DEA has relied in large part on the second and third factors from the threshold potential for abuse standard—the availability of the drug outside of legitimate channels and evidence that people are taking the substance on their own initiative—and placed a gloss on both, tying relative abuse potential to the sheer number of users.[274] In its 2016 marijuana rescheduling petition denial, for example, the DEA (following HHS's recommendation) "concluded that marijuana has a high potential for abuse based on a large number of people regularly using marijuana, its widespread use, and the vast amount of marijuana that is

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pt. 1308) (quoting Letter from Howard H. Koh, Assistant Sec'y for Health, U.S. Dep't Health & Hum. Servs., to Michele Leonhart, Adm'r, DEA 6 (Oct 6, 2009)).

270. UELMEN & KREIT, *supra* note 268, § 1:10.

271. Grinspoon v. DEA, 828 F.2d 881, 893 (1st Cir. 1987).

272. *Id.*

273. *Id.* at 893–94 (footnote omitted).

274. *See* Kreit, *supra* note 22, at 1243–44.

available through illicit channels."[275] The fact that "[m]arijuana is the most abused and trafficked illicit substance in the United States"—or, put another way, the most popular illegal intoxicant in the United States—has meant that it has a "high potential for abuse" in the DEA's eyes.[276]

B. HHS's New Approach

The finding that marijuana has a currently accepted medical use would be enough to require its removal from in Schedule I.[277] But if marijuana has a high potential for abuse, then it could be moved only to Schedule II.[278] The basis for HHS's change of course and finding that marijuana has a lower potential for abuse than Schedule I and II drugs is in some ways even more interesting than the basis for its medical use finding.

As discussed immediately above, the DEA has never adopted a standard or methodology for assessing relative abuse potential under the CSA.[279] Instead, the DEA's (and HHS's) potential for abuse assessments have generally been grounded in the four criteria—derived from the Drug Abuse Control Amendments of 1965—that were designed to measure whether a drug has the minimum potential for abuse to warrant that it be controlled at all.[280] HHS did not deviate from this general approach in its evaluation of marijuana's potential for abuse in the current rescheduling petition.

HHS began its assessment of marijuana's abuse potential by outlining the four criteria from the 1965 Amendments: that people are taking the drugs in amounts that create a health or safety hazard; that there is significant diversion from legitimate channels; that people are taking the drug on their own initiative rather than on the basis of medical advice; and that the drug is similar to an already-controlled-drug.[281] As it has in the past, the agency expressed its view that because of the complexity of determining potential for abuse "no single test or assessment provides a complete characterization. Thus, no single measure of abuse potential is ideal."[282] It then outlined a non-exclusive list of "elements" that can be considered in a potential for abuse evaluation (such as epidemiological data and behavioral

275. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688, 53761 (Aug. 12, 2016).

276. *Id.*

277. 21 U.S.C. § 812(b)(1)–(2).

278. *Id.* (Schedule I and II drugs both have "a high potential for abuse.").

279. *See supra* Section III.A.

280. *See* Schedules of Controlled Substances, 88 Fed. Reg. 86278, 86281 (Dec. 13, 2023) (to be codified at 21 C.F.R. pt. 1308).

281. *FDA Evaluation*, *supra* note 156, at 6.

282. *Id.*

effects) and proceeded to analyze each of the four factors from the 1965 Amendments one-by-one.[283]

Despite following the same basic approach to evaluating abuse potential as it and the DEA have in the past, HHS reached a different conclusion than it had in previous marijuana rescheduling petitions by deemphasizing the significance of the raw number of marijuana users and more closely comparing the relative risk of harmful outcomes for marijuana and other drugs.

The difference in approach is noticeable from the beginning of HHS's analysis. HHS's discussion of the first potential for abuse factor in its recent evaluation began with the same sentence—word-for-word—as the 2016 marijuana rescheduling denial: "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."[284] But, while the next sentence in the 2016 denial was, "A large number of individuals use marijuana,"[285] the next sentence in HHS's recent rescheduling recommendation was, "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."[286] The contrast between these two sentence captures the central difference between HHS's recent evaluation of marijuana's relative abuse potential and its previous evaluations. In past evaluations, the sheer number of marijuana users was the central factor in assessing relative abuse potential. But in this evaluation, relative risk of harm was the primary focus.

To the extent that previous marijuana rescheduling denials had discussed data beyond use rates, the focus was on raw numbers. The 2016 marijuana rescheduling denial found, for example, that in 2011 marijuana was involved in "36.4 percent of all illicit drug related [emergency department] visits."[287] The raw number of emergency department visits involving marijuana—455,668—was "higher than the number of [emergency department] visits involving heroin (258,482) and stimulants (*e.g.*, amphetamine, methamphetamine) (159,840)."[288] Of course, because marijuana is so much more widely

283. *Id.* at 6–9. In addition to its direct evaluation of actual or relative potential for abuse, which focused on the four 1965 Amendments factors, HHS separately considered evidence regarding other factors that bear on abuse potential, such as the scope, duration, and significance of abuse and the risk to public health, as required by 21 U.S.C. § 811(c)(5) and (6). *Id.* at 28–61.

284. *Id.* at 6; *see also* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688, 53691 (Aug. 12, 2016).

285. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53691.

286. *FDA Evaluation*, *supra* note 156, at 6–7.

287. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53704.

288. *Id.* at 53744.

used than other illegal drugs, these raw numbers tell us nothing about relative risks of harm.[289] But the 2016 rescheduling denial never attempted to adjust the raw data to account for differences in use rates.

By contrast, HHS's recent evaluation of marijuana's potential for abuse calculated a "utilization-adjusted rate" of emergency department visits by dividing the number of visits for a substance by the number of people reporting past-year use of that substance.[290] Not surprisingly, the comparison showed that marijuana use poses a much lower risk of resulting in an emergency room visit than other commonly used drugs. The utilization-adjusted rate for 100,000 past-year users showed a rate of 46,281 emergency department visits per 100,000 people for heroin, 7,119 visits per 100,000 people for cocaine, 1,715 visits for 100,000 people for alcohol, and 1,529 visits per 100,000 people for marijuana.[291]

Comparative data for other adverse outcomes likewise showed marijuana to be at or near the bottom of the list of relative risk. The National Poison Data System for 2019, for example, showed a utilization-adjusted rate of 7,201 cases per one million people for heroin, 227 cases per one million people for ketamine, 389 cases per one million people for cocaine, and 139 cases per one million people per benzodiazepines.[292] The rate for marijuana was 70 cases per one million people.[293] Regarding hospitalizations, utilization-adjusted rates "calculated per 100,000 individuals who reported any past-year use" showed that "heroin had the highest rate (757 hospitalizations per 100,000 individuals), followed by cocaine (145 hospitalizations per 100,000 individuals), and benzodiazepines (73 hospitalizations per 100,000 individuals)."[294] The rate for marijuana was just 11 hospitalizations per 100,000 individuals.[295] Finally, with respect to the risk of substance use disorder, "there was an 81% prevalence for meeting" at least 2 of the 11 criteria for a substance use disorder among past-year users of heroin, but only a 30% prevalence for past-year nonmedical users of marijuana (the rate for past-year users of cocaine was also 30%).[296]

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289. *See id.* at 53761.

290. *See FDA Evaluation*, *supra* note 156, at 42 (describing the utilization-adjusted rate calculation method use by HHS for various outcomes throughout its evaluation).

291. *Id.* at 53.

292. *Id.* at 39.

293. *Id.*

294. *Id.* at 47.

295. *Id.*

296. *Id.* at 40. Drug-specific data on substance use disorder prevalence among past-year users was only available for heroin, cocaine, marijuana, and alcohol. *Id.*

In its overall evaluation of this comparative evidence, HHS found that

> [t]he 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.[297]

Applying the CSA's scheduling criteria to its factual evaluation, HHS concluded that the "totality of the available data" concerning relative potential for abuse "supports the placement of marijuana in Schedule III."[298] Or, to put it in the terms of the CSA, HHS found, in effect, that marijuana has a potential for abuse that is "less than the drugs or other substances in schedules I and II" but more than the drugs in Schedule IV.[299] As with the currently accepted medical use finding, the Attorney General followed "HHS's recommendation, for purposes of initiation of these rulemaking proceedings, that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II."[300]

C. Relative Potential for Abuse After Rescheduling

In contrast to the medical use finding, HHS did not adopt a new definition of potential for abuse in support of its break with past marijuana rescheduling recommendations. As discussed above, Congress's intent to incorporate the 1965 Amendments' standard for the threshold potential for abuse determination seems to be on firm ground.[301] But, with respect to the relative potential for abuse

297. *Id.* at 8.

298. *Id.* at 63.

299. 21 U.S.C. § 812(b)(3)(A).

300. Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44616 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

301. For an argument that the DEA's four-factor threshold potential for abuse standard "is vulnerable on several fronts" after *Chevron*, see Malich, *supra* note 32, at 425–26 ("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."). Malich's argument rests on the premise that the DEA's test "is entirely crafted from the legislative history of the CSA," a "disfavored interpretive" method. *Id.* at 426. But that view ignores the fact that the DEA's test—however odd it may be as a matter of policy or language—was not merely a product of the CSA's legislative history. Instead, it derived from the

findings that divide Schedules III, IV, and V from each other and Schedules I and II, the DEA has never attempted to define the different categories or adopt a uniform method for assessing relative abuse potential. For this reason, HHS was able to make its finding that marijuana has a potential for abuse less than drugs in Schedules I and II without expressly questioning the DEA's past practices.[302] But, as the analysis above demonstrates, HHS's assessment is nevertheless impossible to reconcile with the DEA's past marijuana rescheduling denials. Nothing indicates that there has been a significant change in marijuana use rates or other markers related to abuse potential in recent years. Instead, what changed in HHS's assessment was its decision to focus more on data related to relative negative health outcomes and less on the number of marijuana users.[303]

At first glance, this would seem to suggest that the DEA will have more room to disregard HHS's potential for abuse assessment in the rescheduling proceedings, if it wishes. This is because the CSA provides that, on judicial review of scheduling decisions, "[f]indings of fact by the [DEA], if supported by substantial evidence, shall be conclusive."[304] And, as discussed, HHS's departure from the DEA's past practices was based primarily on a factual, not legal, analysis.

There are two significant impediments to the DEA's ability to disregard HHS's potential for abuse recommendation by reaching different factual conclusions, one legal and one evidentiary. First, although the CSA makes the DEA's factual findings conclusive, as noted in Section I, the CSA also provides that HHS's recommendations "shall be binding on the Attorney General as to . . . scientific and medical matters."[305] Precisely what it means for HHS's "recommendations" to "be binding on the Attorney General as

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standard for assessing potential for abuse under the CSA's predecessor law, the 1965 Drug Amendments. *See supra* Section III.B. Accordingly, at least with respect to the threshold potential for abuse analysis (as opposed to relative abuse potential), the DEA's approach is well supported by the "longstanding interpretive principle: When a statutory term is '"obviously transplanted from another legal source,"' it '"brings the old soil with it."'" Taggart v. Lorenzen, 139 S. Ct. 1795, 1801 (2019) (quoting Hall v. Hall, 138 S. Ct. 1118, 1128 (2018)).

302. *FDA Evaluation*, *supra* note 156, at 63.

303. *See* sources cited *supra* notes 296–302 and accompanying test.

304. 21 U.S.C. § 877. The statute refers to the Attorney General, but as noted above, the Attorney General has delegated his administrative authority over the CSA to the DEA. *See supra* note 57 and accompanying text.

305. 21 U.S.C. § 811(b). The FDA plays a "lead" role in the process of preparing "the scientific and medical evaluations and recommendations." Memorandum of Understanding With the National Institute on Drug Abuse, 50 Fed. Reg. 9518, 9519 (Mar. 8, 1985); *see also* LAMPE, *supra* note 75, at 10.

to . . . scientific and medical matters" is not entirely clear.[306] Does it mean that HHS's scheduling findings and/or its ultimate scheduling recommendation are binding on the DEA, or only its underlying medical and scientific conclusions? Do the recommendations bind the DEA throughout the rulemaking process, or does the binding effect end once the notice of a proposed scheduling order is issued?[307]

These questions have not been definitively addressed in litigation. In its opinion letter issued in relation to the pending proposal to move marijuana to Schedule III, the OLC concluded that only "the scientific and medical determinations that underlie HHS's" scheduling findings are binding; the agency's "overall [currently accepted medical use] recommendation is not binding on DEA."[308] The DEA's scientific and medical determinations are only binding

> until the initiation of formal rulemaking proceedings to schedule a drug. Once DEA initiates a formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.[309]

The OLC's guidance would thus make it very difficult for the DEA to make a factual finding that is at-odds with HHS's.

Second, even putting the binding nature of HHS's factual findings aside, any attempt by the DEA to disregard HHS's determinations would also encounter an evidentiary problem—namely, that the DEA would need an evidentiary basis for doing so.[310] HHS's factual conclusions regarding the relative harms of marijuana and other drugs rests on authoritative health reporting sources.[311] It is therefore exceedingly unlikely that HHS's factual determinations on any significant point regarding questions like overdose risk will be undermined by other evidence presented during the rulemaking process.

For these reasons, HHS's factual determinations and analysis would make it all but impossible for the DEA to reject its recommendation without expressly finding that high usage rates outweigh all other factors when it comes to relative potential for

306. 21 U.S.C. § 811(b); United States v. Pastor, 419 F. Supp. 1318, 1340 (S.D.N.Y. 1975) (observing that "the role of the Attorney General in considering the scientific and medical factors is somewhat ambiguous").

307. For a thorough examination of the division of scheduling authority between the DEA and HHS, and an argument that HHS has often abdicated its role in practice, see generally Marks, *supra* note 32.

308. *OLC Rescheduling Opinion*, *supra* note 30, at 4.

309. *Id.* at 1.

310. *Id.* at 25–26.

311. *Id.* at 18–19.

abuse. Put another way, if the DEA were to reject HHS's ultimate potential for abuse recommendation, it would almost certainly have to do so on legal grounds—such as whether relative potential for abuse should be tied to raw usage rates or comparative risks of harm—and not factual grounds. Doing this would surely require the DEA to, finally, break its "silen[ce] with respect to the legal standard required for a finding of 'high' potential for abuse"[312] relative to other schedules. And, any legal standard that disregarded relative risks of harm in assessing relative potential for abuse would seem likely to be on shaky ground under *Chevron*.[313]

Of course, the DEA would not necessarily have to disagree with HHS's recommendation to transfer marijuana to Schedule III to tee up the question of how to best interpret and apply the relative potential for abuse findings in the CSA. Even if the administrative rescheduling proceedings conclude with the transfer of marijuana to Schedule III, HHS's factual findings could give marijuana reform advocates an opening to press for an even more favorable outcome in any subsequent litigation.

This is because, in reading HHS's evaluation of the comparative risks posed by marijuana—particularly in contrast to the benzodiazepines in Schedule IV—one can't help but wonder why the agency did not find that marijuana has an even lower potential for abuse than it did.[314] After all, in its ranking of "greatest adverse consequences," marijuana was "in a lower place in the ranking" in comparison to benzodiazepines.[315] This would seem to suggest marijuana has a potential for abuse that should place it in Schedule V or, at a minimum, Schedule IV.[316]

HHS did not discuss why it found marijuana has a greater potential for abuse than drugs in Schedule IV—indeed, it did not even expressly make such a finding. The agency concluded only that the data "supports the placement of marijuana in Schedule III" and that "marijuana is most appropriately controlled" there.[317] The closest

312. Grinspoon v. DEA, 828 F.2d 881, 893 (1st Cir. 1987).

313. *See* Malich, *supra* note 32, at 425–27; *see also* LAMPE, *supra* note 75, at 10 (noting that under *Loper Bright*, "DEA scheduling decisions that rely on statutory interpretations" may no longer receive deferential review).

314. *FDA Evaluation*, *supra* note 156, at 63 (noting that HHS compared marijuana to benzodiazepines in Schedule IV as part of its evaluation).

315. *Id.* at 8.

316. 21 U.S.C. § 812(b)(4)(A), (5)(A) (Schedule V drugs have "a low potential for abuse relative to the drugs or other substances in schedule IV" and Schedule IV drugs have "a low potential for abuse relative to the drugs or other substances in schedule III").

317. *FDA Evaluation*, *supra* note 156, at 63; *see id.* at 37 (finding that "data show that use of marijuana for medical and nonmedical purposes is extensive in the United States, but that its prevalence of use is less than that of alcohol and significantly more than that of other drugs of abuse that are scheduled under the CSA").

HHS got to addressing the apparent discrepancy between its factual evaluation (which suggested that marijuana has a potential for abuse that is lower than benzodiazepines) and its recommendation (which implicitly found that marijuana has a higher potential for abuse than benzodiazepines) was to observe that "the ranking of relative harms . . . often do not align with the scheduling placement of [the comparator drugs considered in HHS's evaluation] under the CSA."[318] Shortly following this observation, HHS concluded that "*while marijuana is associated with a high prevalence of abuse*, the profile of and propensity for serious outcomes related to that abuse lead to a conclusion that marijuana is most appropriately controlled in Schedule III under the CSA."[319] The explanation suggests that the widespread use of marijuana—although not enough to warrant placement in Schedule I or II—may have tipped the scales in favor of a finding of a higher potential for abuse than the risk of adverse consequences would suggest. Even if the DEA ultimately finalizes the proposed transfer of marijuana to Schedule III, the facts underlying HHS's recommendation could provide ammunition to push for movement to an even lower schedule, which would require courts to consider how the factors that influence relative potential for abuse findings under the CSA fit together.

CONCLUSION

Fifty-five years after the passage of the CSA, marijuana rescheduling advocates appear to be on the verge of success. As the administrative process continues to play out, the implications of marijuana rescheduling for federal marijuana policy have understandably drawn the most attention from participants in the rulemaking process and outside observers. But the bigger impact may be on the CSA itself. This is because the marijuana rescheduling petition sets the stage for rejection of the DEA's longstanding approach to interpreting and applying the CSA's scheduling criteria.

In a post-*Chevron* world, the DEA's five-factor definition of "currently accepted medical use" is unlikely to withstand court scrutiny. And, with an administrative record from HHS that thoroughly compares the relative harms of marijuana use to those of other substances, the DEA's past practice of linking abuse potential to the number of users will be exceedingly difficult for the agency to defend.

Although this Article has argued that the DEA's narrow interpretation of the scheduling criteria is inconsistent with the CSA, even if the DEA's interpretation is jettisoned, the CSA remains a peculiar statute. As others have explained, marijuana rescheduling will not have much effect on federal marijuana policy on the ground,

318. *Id.* at 63.
319. *Id.* (emphasis added).

particularly with respect to the decades-long conflict between state marijuana legalization and federal law.[320] After all, FDA approval is required to market a drug as a medicine.[321] And, even after rescheduling, compliance with the CSA itself would still require navigating its cumbersome and costly registration requirements.[322] With respect to distribution for nonmedical purposes, the CSA does not allow scheduled substances—even those in Schedule V—to be distributed for recreational use.[323] In short, even if the CSA's scheduling criteria are transformed, the practical impact on marijuana and other controlled substances may be limited. Broader reform of federal drug policy will require rethinking the CSA at a fundamental level.[324]

320. *See* Mikos, *False Promise*, *supra* note 32, at 23 (arguing that "rescheduling may amount to no more than a tax cut for marijuana suppliers" in terms of its practical effect on the state-licensed marijuana industry).

321. *Id.* at 4.

322. *See id.* at 20–21.

323. 21 U.S.C. §§ 829, 841.

324. For a recent thought-provoking examination of the CSA and proposal to "retain[] the CSA's categorical scheduling approach" but with significant revisions, including "creating new schedules permitting but regulating non-medical use," see Lawrence & Pozen, *supra* note 32, at 855.