The Promise of Rescheduling

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The False Promise of Rescheduling

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For the past 50 years, marijuana advocates have invested considerable effort trying to reschedule the drug under the Controlled Substances Act (CSA). Multiple times, they have petitioned the Drug Enforcement Administration (DEA) to take marijuana off the highly restrictive Schedule I and move it to one of the statute's less tightly regulated Schedules (II-V) or even deschedule the drug altogether.[1] Along the way, they have waged protracted legal battles with the agency over the tests and processes it uses for making scheduling decisions.[2]

To date, however, advocates have had very little to show for all their efforts. The DEA has rejected every prior petition to reschedule marijuana.[3] Although advocates have won some minor victories against the agency in court,[4] courts have upheld the two agency requirements that have posed the biggest obstacle to

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[1] For a very brief history of petitions to reschedule marijuana, see National Organization for the Reform of Marijuana Laws (undated), https://norml.org/marijuana/fact-sheets/a-brief-history-of-cannabis-rescheduling-petitions-in-the-united-states/.

[2] *E.g.*, *Nat'l Org. for Reform of Marijuana L. (NORML) v. Drug Enf't Admin.*, 559 F.2d 735 (D.C. Cir. 1977) (ordering DEA to obtain HHS evaluation of rescheduling petition before making final decision); *All. for Cannabis Therapeutics v. Drug Enf't Admin.*, 930 F.2d 936 (D.C. Cir. 1991) (ordering DEA to drop elements of its rescheduling test that were impossible to satisfy).

[3] *See* Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499-02 (1992); Notice of Denial of Petition, 66 Fed. Reg. 20038-01 (2001); Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40552-01 (2011); and Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016)..

[4] *See* sources cited *supra*, note 2.

rescheduling. First, the DEA has insisted that marijuana must have a "currently accepted medical use" (CAMU) to be moved off Schedule I. Second, the DEA has insisted that the only way to demonstrate that marijuana has a CAMU is by completing Randomized Controlled Trials (RCTs) that prove the drug is effective at treating some medical condition.[5] In past scheduling decisions, the Department of Health and Human Services (HHS) has applied these same requirements and advised the DEA that marijuana had to remain on Schedule I because there were as yet no scientific studies that met the agency's standards for RCTs.[6] Perhaps more worrisome, there is no guarantee advocates would ever be able to meet the agency's demands.

The string of setbacks involving past petitions suggested that marijuana would remain stuck on Schedule I unless and until Congress passed new legislation directing otherwise. But in August 2023, the Department of Health and Human Services (HHS) suddenly revived hopes for rescheduling marijuana administratively. At the request of President Biden himself, HHS had just completed a new review of marijuana's scheduling.[7] For the first time since the CSA was passed in 1970, the agency concluded that marijuana did not belong on Schedule I.[8] Instead, HHS advised the DEA that marijuana should be moved to Schedule III, alongside drugs like ketamine and Tylenol with codeine.[9]

[5] The CAMU and RCT requirements are discussed below in Part I.B. The requirements were upheld by the D.C. Circuit in *Alliance for Cannabis Therapeutics v. Drug Enf't Admin.*, 15 F.3d 1131 (D.C. Cir. 1994).

[6] *See infra*, Part I.B.

[7] In October 2022, President Biden announced he was "asking the Secretary of Health and Human Services and the Attorney General to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law." Statement from President Biden on Marijuana Reform (Oct. 6, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/. HHS's role in the administrative scheduling process is discussed below in Part I.A.

[8] *See infra*, Part I.C.

[9] *Id.*

The health agency's recommendation has generated a lot of buzz. It has been widely heralded as "historic"[10] and "momentous".[11] It has even been touted as "the most significant federal marijuana reform in modern history."[12] The recommendation has created expectations the DEA will reschedule marijuana very soon and thereby markedly improve the fortunes of the state-licensed marijuana industry.[13] Firms in the industry have languished under federal prohibition, struggling to secure basic business and legal services like banking,[14] trademark protection,[15] bankruptcy reorganization,[16] and contract enforcement.[17] While no panacea, rescheduling is expected to improve access to such services and thereby give the industry a much-needed shot in the arm.

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[10] Caroline D. Kessler et al., *Cannabis in 2024: HHS Rescheduling Recommendation and SAFER Banking* (Feb. 23, 2024), https://www.akingump.com/en/insights/alerts/cannabis-in-2024-hhs-rescheduling-recommendation-and-safer-banking; *id.* (remarking that the recommendation "represents a significant shift in the agency's perception of both the safety and available medical uses of cannabis").

[11] Joshua Weiss & Osiris Morel, *HHS Recommends Rescheduling Cannabis, Surprising an Entire Industry* (Sept. 13, 2023), https://cannabisindustryjournal.com/feature_article/hhs-recommends-rescheduling-cannabis-surprising-an-entire-industry/.

[12] Kylie Murdock, *The Most Significant Federal Marijuana Reform in Modern History* (Sept. 26, 2023), https://www.thirdway.org/memo/the-most-significant-federal-marijuana-reform-in-modern-history. *See also* Chris Roberts, *'Biggest thing, ever': Marijuana rescheduling recommendation hailed* (Aug. 30, 2023), https://mjbizdaily.com/biden-health-officials-say-marijuana-should-be-rescheduled/ (declaring that HHS recommendation is the "biggest development in marijuana policy reform in more than 50 years"); *id.* ("It's the biggest thing that's happened in cannabis reform at the federal level, ever.") (quoting attorney Shane Pennington).

[13] *See, e.g.*, Murdock, *supra* (suggesting rescheduling will have "major implications for the marijuana industry"); Kessler, *supra* note 10 (suggesting rescheduling will have "significant implications" for the state-licensed marijuana industry).

[14] Julie Andersen Hill, *Banks, Marijuana, and Federalism*, 65 CASE W. RES. L. REV. 597 (2015).

[15] Sam Kamin & Viva R. Moffat, *Trademark Laundering, Useless Patents, and Other IP Challenges for the Marijuana Industry*, 73 WASH. & LEE L. REV. 217 (2016); Robert A. Mikos, *Unauthorized and Unwise: The Lawful Use Requirement in Trademark Law*, 75 VAND. L. REV. 161 (2022).

[16] *E.g.*, Clifford J. White, III & John Sheahan, *Why Marijuana Assets May Not Be Administered in Bankruptcy*, Executive Office for U.S. Trustees (undated), https://www.justice.gov/archives/ust/file/abi_201712.pdf/dl.

[17] Luke Scheuer, *Are "Legal" Marijuana Contracts "Illegal"?*, 16 U.C. DAVIS BUS. L. J. 31 (2015).

This Essay serves as a reality check. Marshaling my familiarity with the complex web of federal drug law (of which the CSA is only part), I show that the expectations surrounding the HHS recommendation and rescheduling more generally are greatly inflated, for two reasons.

First, the DEA might yet refuse to reschedule marijuana.[18] To enable rescheduling, HHS had to reject the DEA's longstanding insistence that RCTs were the only way to demonstrate CAMU under the CSA.[19] (HHS had to make this move because it discovered there were still no RCTs demonstrating marijuana's medical efficacy when it conducted its latest review in 2023.[20]) In particular, HHS claimed that CAMU could also be demonstrated by the fact that large numbers of physicians were recommending marijuana to patients pursuant to state medical marijuana laws.[21] It is easy to see why the DEA would strongly disagree with HHS's change of standards for CAMU.[22] But just as importantly, the change could give the DEA the legal grounds it needs to reject rescheduling now or to rescind rescheduling later, if there is a change of Administrations following the fall 2024 election.[23]

Second, even assuming marijuana is rescheduled and stays off Schedule I, the change still will not significantly improve the fortunes of the marijuana industry.[24] Even after rescheduling, the CSA will impose a litany of restrictions on the manufacture and sale of marijuana.[25] What is more, the Food Drug and

[18] *See infra*, Part II.

[19] *Id.* I provide an in-depth analysis of the novel reasoning behind HHS's scheduling recommendation in Robert A. Mikos, *The Tyrannies of Scheduling*, __ FORDHAM L. REV. __ (forthcoming 2024).

[20] *See infra*, Part II.

[21] *Id.*

[22] *Id.* To be clear, I think the Biden DEA will probably follow the recommendation. But I was far more confident of that outcome before HHS disclosed its reasoning in January 2024.

[23] *Id.*

[24] *See infra*, Part III.

[25] *Id.*

Cosmetic Act (FDCA) will still ban *all* interstate commerce in the drug.[26] (Marijuana has not been approved for sale by the Food and Drug Administration (FDA), and HHS made it abundantly clear that its rescheduling recommendation did not confer such approval.[27]) If firms in the industry fail to comply scrupulously with all of these rules–as seems almost inevitable–they could be denied banking, trademark protection, bankruptcy reorganization, contract enforcement, and so on, just as they are today.

The Essay proceeds as follows. Part I describes the CSA's administrative scheduling process, explains why the DEA and HHS previously concluded they could not (yet) reschedule marijuana through that process, and explains how HHS found a way to recommend rescheduling in 2023. Part II then explains why the Biden Administration DEA might not follow the health agency's scheduling recommendation. It also explains how a new Administration could quickly undo rescheduling. Part III explains why rescheduling will not provide much relief for the state-licensed marijuana industry, even if it lasts. The Essay concludes by offering some thoughts on the path forward. It suggests that marijuana reform advocates may have achieved all they can realistically hope to accomplish working through the administrative state. To secure further reform to federal marijuana law, they will need to convince Congress to pass new legislation.

I. Background

In this Part, I discuss the purpose behind drug scheduling and how the DEA and HHS together make scheduling decisions under the CSA. I then explain why those agencies have kept marijuana on Schedule I in the past, and why HHS now recommends moving the drug to a lower schedule.

[26] Sean M. O'Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 823 (2019). The issues posed by the FDCA are discussed infra, Part III.B.

[27] *See infra* notes 128-129 and accompanying text.

A. The CSA's Administrative Scheduling Process

The CSA was enacted to combat drug abuse.[28] To that end, the statute sorts all drugs of abuse into five distinct schedules (I-V) based on three core criteria: (1) their potential for abuse; (2) their dependence liability; and (3) whether they have recognized therapeutic value (a "currently accepted medical use", or CAMU, in the lingo of the statute).[29] Table 1 lists the specific criteria Congress provided for placing a drug on each of the statute's five schedules.

Table 1: The CSA's Scheduling Criteria[30]

	Schedule I	**Schedule II**	**Schedule III**	**Schedule IV**	**Schedule V**
CAMU	"no currently accepted medical use in treatment"	"has a currently accepted medical use in treatment" or "currently accepted medical use with severe restrictions"	"has a currently accepted medical use in treatment"	"has a currently accepted medical use in treatment"	"has a currently accepted medical use in treatment"

[28] *See* 21 U.S.C. § 801. Although the statute does not expressly define "drug abuse", federal agencies have interpreted drug abuse to mean the non-medical use of a drug in quantities sufficient to pose a hazard to the health of the user or to the safety of other individuals. Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016).

[29] 21 U.S.C. § 812(b).

[30] *Id.* at § 812(b). The statute also lists eight factors HHS and the DEA are to use to evaluate the three core scheduling criteria:

> "(1) [The drug's] actual or relative potential for abuse.
>
> (2) Scientific evidence of its pharmacological effect, if known.
>
> (3) The state of current scientific knowledge regarding the drug or other substance.
>
> (4) Its history and current pattern of abuse.
>
> (5) The scope, duration, and significance of abuse.
>
> (6) What, if any, risk there is to the public health.
>
> (7) Its psychic or physiological dependence liability.
>
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter."

Id. at § 811(c).

Abuse potential	"high potential for abuse"	"high potential for abuse"	"potential for abuse less than the drugs or other substances in schedules I and II"	"low potential for abuse relative to the drugs or other substances in schedule III"	"low potential for abuse relative to the drugs or other substances in schedule IV"
Dependence liability (or safety)[31]	"lack of accepted safety for use . . . under medical supervision"	"Abuse . . . may lead to severe psychological or physical dependence"	"Abuse . . . may lead to moderate or low physical dependent or high psychological dependence"	"Abuse . . . may lead to limited physical or psychological dependence relative to the drugs or other substances in Schedule III"	"Abuse . . . may lead to limited low physical or psychological dependence relative to the drugs or other substances in Schedule IV"

Scheduling determines how a drug is regulated under the statute. Reflecting their high potential for abuse and lack of recognized therapeutic value, Schedule I drugs are subject to the tightest possible controls. The CSA bans the manufacture, sale, and even possession of Schedule I drugs, except for use in scientific research.[32] The controls imposed on drugs on the other schedules become increasingly less restrictive as one moves down the schedules from II-V.[33]

Congress made all the initial scheduling decisions when it passed the CSA, including the decision to place marijuana on Schedule I–right alongside heroin, lysergic acid diethylamide (LSD), and Phencyclidine (PCP). At the same time, however, Congress created an administrative process to revise those scheduling decisions. In particular, the CSA authorizes the Drug Enforcement Administration

[31] Oddly, the statute does not make dependence liability one of the considerations for inclusion on Schedule I. Instead, it specifies that Schedule I drugs must have a "lack of accepted safety for use . . . under medical supervision." *Id.* at § 812(b)(1)(c). But the DEA has effectively written this criterion out of the statute by equating "lack of accepted safety for use" with "no currently accepted medical use in treatment." *See* Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499-02 (1992) ("[T]he ultimate determination of whether a drug is safe for a specific use is not a distinct issue. Safety and effectiveness are inextricably linked in a risks-benefits calculation. A determination that a drug is ineffective is tantamount to a determination that it is unsafe.").

[32] The bans on these activities are found in 21 U.S.C. §841 (trafficking) & §844 (possession).

[33] I discuss some of the controls applicable to the lower schedules below in Part III.A.

(DEA) to reschedule a drug when the agency determines that the criteria for placement on a different schedule have been satisfied.[34]

The CSA permits "any interested party" to petition the DEA to reschedule a drug.[35] (The DEA appears to have treated President Biden's October 2022 request for review of marijuana's scheduling as such a petition.) Once a petition is made, HHS is supposed to provide the DEA with a scientific and medical evaluation of the drug, as well as a recommendation for where the drug should be scheduled.[36] While the DEA makes the final decision, the CSA stipulates that HHS's evaluation and recommendation "shall be binding" on the DEA as to "scientific and medical matters."[37] Indeed, I am aware of no prior scheduling decision where the DEA has departed from HHS's scheduling recommendation.

B. Why the DEA Rejected Previous Petitions to Reschedule Marijuana

In the half-century before President Biden asked the DEA and HHS to review marijuana's scheduling, marijuana advocates had filed at least four petitions seeking to reschedule the drug through the administrative process just described.[38] In response to each of those petitions, HHS conducted a thorough scientific and medical evaluation of the drug, only to conclude that marijuana had to remain on

[34] 21 U.S.C. § 811. Technically, the CSA delegates scheduling authority to the Attorney General, but the Attorney General has re-delegated that authority to the Administrator of the DEA. *See* 28 C.F.R. § 0.100(b).

[35] 21 U.S.C. § 811(a)(2).

[36] *Id.* at § 811(b).

[37] *Id.* I explain why this language may not require the DEA to follow HHS's 2023 recommendation to reschedule marijuana below in Part II.B.

[38] *See supra* notes 1-2 and accompanying text. The four petitions I speak of were filed in 1972 (just after the CSA became effective), 1995 (just after the DEA denied the first petition), 2002 (just after the DEA denied the second petition), and 2011 (just after the DEA denied the third petition). There have been other petitions to reschedule marijuana, but the four I mention are the only petitions that have elicited lengthy published responses from the agencies.

Schedule I.[39] The DEA has invariably shared HHS's assessment and has heretofore refused to initiate rulemaking proceedings to reschedule marijuana.[40]

The refusal of all prior petitions to reschedule marijuana can be traced to a single factor: the CSA's CAMU scheduling criterion, or more accurately, the DEA's interpretation of that criterion. Although Congress enumerated three criteria for each of the CSA's five schedules (see Table 1 above), the DEA has claimed that Congress made CAMU *the only relevant criterion* for Schedule I. As the agency explained in its most recent (2016) marijuana scheduling decision,

> "Congress established only one schedule, schedule I, for drugs of abuse with 'no currently accepted medical use in treatment in the United States.' . . . Thus, any attempt to compare the relative abuse potential of schedule I substance to that of a substance in another schedule is inconsequential since a schedule I substance must remain in schedule I until it has been found to have a currently accepted medical use in treatment in the United States."[41]

[39] *See* Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499-02 (1992); Notice of Denial of Petition, 66 Fed. Reg. 20038-01 (2001); Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40552-01 (2011); and Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016).

[40] *Id.*

[41] Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016). The DEA employed similar reasoning in earlier marijuana's scheduling decisions as well. See, e.g., Notice of Denial of Petition, 66 Fed. Reg. 20038-01 (2001) ("[W]hen it comes to a drug that is currently listed in schedule I, if it is undisputed that such drug has no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision, and it is further undisputed that the drug has at least some potential for abuse sufficient to warrant control under the CSA, the drug must remain in schedule I. In such circumstances, placement of the drug in schedules II through V would conflict with the CSA since such drug would not meet the criterion of 'a currently accepted medical use in treatment in the United States.'") (quoting 21 USC § 812(b)).

In another paper, I criticize the DEA's reasoning for reading the CSA's "potential for abuse" criterion out of the statute.[42] But ever since the DEA has insisted that CAMU is paramount, petitioners have needed to demonstrate that marijuana has a CAMU to get the drug rescheduled.

At the same time, the DEA has made it very challenging to demonstrate that a drug has a CAMU. Since the early 1990s, the agency has insisted there are only two ways for petitioners to make this critical demonstration:[43] 1) obtain FDA approval for the drug under the Food Drug and Cosmetic Act (FDCA);[44] or, if the drug has not yet been approved by the FDA, 2) satisfy a five-part test that closely resembles the test the FDA uses for approving new drugs under the FDCA.[45] In past scheduling decisions, HHS applied the same two tests for determining whether a drug has a CAMU (though as discussed below, the agency has recently recognized a third pathway).[46]

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[42] Mikos, *The Tyrannies of Scheduling*, *supra* note 19. The DEA has effectively written the other criterion ("accepted safety for use") out of the statute as well. *See supra*, note 31.

[43] *See* Mikos, *The Tyrannies of Scheduling*, supra note 19 (detailing the origins of the two pathways).

[44] The requirements for new drug approval under the FDCA can be found at 21 C.F.R. § 314.125.

[45] The DEA's full five-part test for unapproved drugs requires:

> "(1) The drug's chemistry must be known and reproducible;
>
> (2) there must be adequate safety studies;
>
> (3) there must be adequate and well-controlled studies proving efficacy;
>
> (4) the drug must be accepted by qualified experts; and
>
> (5) the scientific evidence must be widely available."

Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53767-01 (2016). The DEA based its test on FDCA's requirements for new drug approval by reasoning that "it seems likely that the core standards developed under the FDCA represent a long-term consensus of expert medical and scientific opinion concerning when a drug should be accepted by anyone as safe and effective for medical use." Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499-02 (1992). Part II.A infra discusses the perceived link between the two statutes in greater depth.

[46] *See* sources cited *supra*, note 3.

Although the two pathways differ in some respects not relevant here,[47] they share a common requirement that has repeatedly stymied marijuana advocates. Namely, both pathways require conducting Randomized Controlled Trials (RCTs) that demonstrate marijuana is effective at treating a medical condition.[48] RCTs are notoriously expensive and time-consuming,[49] especially when they involve drugs (like marijuana) that are already on Schedule I.[50] Among other things, RCTs must include large numbers of subjects, measures to minimize bias (e.g., double-blinding), "well-defined and reliable" methods of assessing treatment effects, and standardized dosing.[51]

In past scheduling decisions, HHS has reviewed hundreds of scientific studies on marijuana's therapeutic benefits and concluded that not a single one met all the criteria of a RCT.[52] In its evaluation of the most recent petition, completed in 2015, the agency advised the DEA that the research relied on by petitioners only amounted to "preliminary evidence" of marijuana's therapeutic value and was thus "not sufficient to prove efficacy" of the drug under the prevailing CAMU test.[53] Just as importantly, the DEA and HHS have previously refused to provide petitioners any other way to demonstrate CAMU. The agencies have warned that

[47] For a discussion of the differences between the tests and an explanation for why the DEA did not simply make CAMU contingent on FDA approval, see Mikos, *The Tyrannies of Scheduling*, *supra* note 19, at __ (discussing Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 884 (1st Cir. 1987)).

[48] *See* sources cited *supra*, note 3.

[49] *E.g.*, John P. A. Ioannidis, Effect of the Statistical Significance of Results on the Time to Completion and Publication of Randomized Efficacy Trials, 279 JAMA 281 (January 1998) (reporting that median RCT takes 5.5 years from enrollment to publication).

[50] In the past, the federal government imposed tight controls on marijuana research because of the drug's Schedule I status. *See* Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 352-58 (2013). In 2022, Congress passed and President Biden signed into law the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 117-215, 136 Stat. 2257, which promises to expand research on marijuana's therapeutic benefits by relaxing some of those controls.

[51] *See* 21 C.F.R. § 314.126.

[52] Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016) ("[N]o published studies meet the criteria of an adequate and well-controlled efficacy study.").

[53] Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016).

other types of evidence cited by petitioners – including the opinions and actions of practicing physicians and state lawmakers – could not establish CAMU.[54]

In short, no RCTs, no CAMU; and no CAMU, no rescheduling.

C. Why HHS Endorsed Rescheduling in 2023

In October 2022, President Biden asked the DEA and HHS to conduct another review of marijuana's scheduling under the CSA. Just eleven months later (quick by historical standards[55]), HHS completed its evaluation and concluded – for the first time – that marijuana has a CAMU.[56]

Notably, HHS reached this conclusion even while acknowledging there were still no RCTs convincingly demonstrating marijuana's medical efficacy.[57] The agency rattled off an all-too-familiar list of shortcomings in the studies that had been completed in the eight years since its last evaluation.[58] However, rather than slam the door shut on rescheduling, HHS quietly introduced a new pathway to demonstrate CAMU that no longer requires completing expensive and time-consuming RCTs. In particular, HHS indicated it was now satisfied marijuana has a CAMU because 1) there was already widespread physician- and state-approved therapeutic use of the drug for a wide variety of indications and 2) there was "some credible scientific support" that such therapeutic use actually works for at least some of those indications (pain, nausea and vomiting, and anorexia).[59] In other

[54] *See* Mikos, Tyrannies of Scheduling, *supra* note 19 (detailing past agency critiques of such evidence). *See also infra*, Part II.A.

[55] For example, it took HHS two years to complete its last marijuana scheduling evaluation. Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01, 53689 (noting request for review was received from the DEA in June 2013, and completed review was returned to the DEA in June 2015).

[56] *See* Dep't of Health & Hum. Svcs., Basis for the Recommendation to Reschedule Marijuana Into Schedule III of the Controlled Substances Act (Aug. 29, 2023) [hereinafter HHS Basis for Recommendation]. The HHS evaluation and recommendation are available at https://www.dropbox.com/scl/fi/pw3rfs9gm6lg80ij9tja6/2023-01171-Supplemental-Release-1.pdf?rlkey=v5atj0tcnhxhnszyyzcwdcvvt&dl=0.

[57] *Id.*

[58] *Id.*

[59] *Id.*

words, no RCTs, no problem. (I unpack and critically analyze HHS's shortcut in another paper.[60])

Because HHS found that marijuana has a CAMU, it also had to assess marijuana's relative potential for abuse and dependence liability to determine where the drug best fit on the CSA's remaining schedules (II-V). To be sure, the agency had discussed those harms in recent scheduling evaluations.[61] But 2023 marked the first time consideration of those other scheduling criteria had any influence on the agency's scheduling recommendation.

To that end, HHS identified a variety of other substances to serve as comparators, including heroin (Schedule I), fentanyl (Schedule II), ketamine (Schedule III), tramadol (Schedule IV), and even alcohol (unscheduled).[62] Analyzing epidemiological data on adverse outcomes like emergency room visits, it determined that "although abuse of marijuana produces clear evidence of harmful consequences, these appear to be relatively less common and less severe than some other comparator drugs."[63] Put more simply, marijuana is dangerous, but it is not as dangerous as many other controlled (and uncontrolled) substances. Accordingly, HHS concluded that marijuana belonged on Schedule III.[64]

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Since HHS delivered its scheduling recommendation to the DEA in August 2023, the ball has been in the DEA's court. In the following three Parts, I prognosticate on what is likely to happen next and what it will mean for the state-licensed marijuana industry.

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[60] *See* Mikos, *The Tyrannies of Scheduling*, *supra* note 19.

[61] *See* Notice of Denial of Petition, 66 Fed. Reg. 20038-01 (2001); Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40552-01 (2011); and Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016).

[62] *See* HHS Basis for Recommendation, *supra* note 56. Although alcohol is plainly abused, Congress expressly exempted it (and tobacco) from the CSA. 21 U.S.C. § 802(6) ("The term [controlled substance] does not include distilled spirits, wine, malt beverages, or tobacco[.]").

[63] HHS Basis for Recommendation, *supra* note 56.

[64] *Id.*

II. Why Rescheduling Still Might Not Happen

The most pressing question at this point in time is whether the DEA will accept the HHS recommendation and issue a rule moving marijuana onto Schedule III.

Not necessarily. In this Part, I explain why rescheduling still might not happen. Section A explains why we should not be surprised if the DEA strongly disagrees with the reasoning behind HHS's recommendation. Section B then explains why the DEA might have leeway to reject the recommendation and keep marijuana on Schedule I (or just move it to Schedule II), notwithstanding the CSA's instruction that the DEA must defer to HHS on "scientific and medical" matters. Finally, Section C explains how a new Administration could quickly undo rescheduling even if the Biden Administration moves the drug off Schedule I.

A. The DEA has Strong Reasons to Disagree with HHS

The DEA has not yet revealed what it thinks of the HHS recommendation.[65] But I suspect the DEA may strongly disagree with the reasoning behind the recommendation, and, as a result, may be reluctant to follow the recommendation.

Recall that in 2023, HHS dropped the DEA's longstanding five-part test for CAMU and replaced it with a brand new two-part CAMU test of its own creation.[66] The new test diverges from the DEA's old test (and the FDCA's drug approval process) in several ways. Most importantly, the new test eliminates the requirement to conduct Randomized Controlled Trials demonstrating medical efficacy.[67] HHS suggested that CAMU could be established instead by 1) widespread physician-

[65] It is worth noting, however, that five former DEA Administrators and five former federal drug czars – from across multiple Presidential Administrations – have emphatically urged the current DEA Administrator (Anne Milgram) to reject rescheduling. Michele Leonhart et al., *Letter to United States Attorney General Merrick Garland & Administrator Anne Milgram* (Oct. 2023), https://learnaboutsam.org/wp-content/uploads/2023/10/Former-DEA-Admins-and-White-House-Drug-Czars-Rescheduling-Letter.pdf.

[66] *See supra* Part I.C.

[67] *See* Mikos, *The Tyrannies of Scheduling*, *supra* note 19.

and state-approved therapeutic use of marijuana combined with 2) "some credible scientific support" showing such therapeutic use actually works.[68]

The change of tests was pivotal to the HHS recommendation. As noted above, HHS acknowledged that there were still no RCTs demonstrating the drug is effective at treating even a single medical condition.[69] Hence, to accept HHS's recommendation, the DEA likely must accept HHS's new two-part CAMU test as a valid alternative to its own five-part CAMU test.[70]

I think accepting HHS's novel CAMU reasoning will be a difficult pill for the DEA to swallow. Although the CSA does not expressly specify the requirements for CAMU, the DEA has claimed its five-part test reflects Congress's intentions, and thus cannot be amended by the agencies. In particular, the agency has suggested 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."[71] For this reason, DEA modeled its five-part CAMU test on the FDCA's requirements for new drug approval. In its 1992 scheduling decision, the DEA explained the link between the two statutory regimes:

> "A century before the Controlled Substances Act was enacted, the determination of what drugs to accept as medicine was totally democratic and totally standardless. Each patient and each physician was free to decide for himself, often based on no more than anecdotal evidence. This state of affairs became unsatisfactory to a majority of the American people. In 1906, Congress intervened with the passage of the Food, Drug and Cosmetic Act (FDCA). A shift began away from anecdotal evidence to objectively conducted scientific research, away from uninformed opinions of lay

[68] *See supra* Part I.C.

[69] *Id.*

[70] I have suggested a way for the DEA to accept HHS's recommendation without also accepting the agency's new two-part test for CAMU. Mikos, *The Tyrannies of Scheduling*, *supra* note 19 (explaining that the DEA could reschedule marijuana without finding the drug has a CAMU by dropping its misguided insistence that CAMU is required for removal from Schedule I in the first instance).

[71] Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499-02 (1992).

> persons and local doctors to expert opinions of specialists trained to evaluate the safety and effectiveness of drugs, and away from totally democratic decision-making to oversight by the Federal Government.
>
> By 1969, Congress had developed detailed Federal statutory criteria under the FDCA to determine whether drugs are acceptable for medical use. . . .
>
> In enacting the Controlled Substances Act in 1970, could Congress have intended to create a totally new Federal standard for determining whether drugs have accepted medical uses? Or did Congress intend to rely on standards it had developed over the prior 64 years under the FDCA? There is nothing in the Controlled Substances Act, its legislative history, or its purposes that would indicate Congress intended to depart radically from existing Federal law. Indeed, it seems likely that the core standards developed under the FDCA represent a long-term consensus of expert medical and scientific opinion concerning when a drug should be accepted by anyone as safe and effective for medical use."[72]

Consistent with this depiction of Congressional intent, the DEA has previously dismissed as irrelevant the factors that comprise part 1 of HHS's new CAMU test. In its 1992 scheduling decision, for example, the DEA declared that even if "a substantial segment of the medical practitioners in the United States" recognized the therapeutic value of marijuana and / or advised their patients to use the drug, those facts were simply "*irrelevant to whether marijuana has a currently accepted medical use*."[73] In similar fashion, in its 2011 scheduling decision, the DEA dismissed the notion that the passage of medical marijuana laws by states could somehow help establish that the drug has a CAMU.[74] The basic idea is that

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[72] *Id.*

[73] *Id*. (emphasis added).

[74] Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40552-01 (2011) ("The CSA does not assign to the states the authority to make findings relevant to CSA scheduling determinations. Rather, the CSA expressly delegates the task of making such findings—including whether a substance has any currently accepted medical use in treatment in the United States—to the Attorney General. . . . The CSA also expressly tasks the Secretary of DHHS to provide a scientific and medical evaluation and scheduling recommendations to inform the Attorney General's findings. . . . That Congress explicitly provided scheduling authority to these two federal entities in this comprehensive and exclusive statutory scheme precludes the argument

because practicing physicians and state lawmakers "are not qualified to determine whether a drug is generally recognized as safe and effective or meets NDA requirements" under the FDCA, they are also not qualified to determine whether a drug has an accepted medical use under the CSA.[75]

In similar fashion, the DEA has previously dismissed the notion that scientific research less than that required for new drug approval under the FDCA could nonetheless be adequate for establishing CAMU under the CSA. In its 1992 marijuana scheduling decision, for example, the DEA intoned that:

> "Incomplete studies are insufficient. . . . Uncontrolled studies are insufficient. . . . Statistically insignificant studies are insufficient. . . . Poorly designed studies are insufficient. . . . Poorly conducted studies are insufficient. . . . Poorly documented studies are insufficient. . . . Studies by investigators who are not qualified, both to conduct and to evaluate them are insufficient. . . . Moreover, since scientific reliability requires a double examination with similar results, one valid study is insufficient. There must be two or more valid studies which corroborate each other. . . ."[76]

Given that courts have previously upheld the DEA's five-part CAMU test,[77] that agency has no obvious incentive to accept HHS's very different CAMU test. HHS has not helped its case. In its 2023 scheduling evaluation, it failed to offer any defense of the new test it was introducing. Indeed, as I have remarked elsewhere, HHS failed even to acknowledge that its two-part test was new.[78]

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that state legislative action can establish accepted medical use under the CSA.") (internal citations omitted).

[75] Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688-01 (2016).

[76] Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499-02 (1992). *See also id*. at __ (noting that "[s]ince 1962, Congress has prohibited the FDA to approve an NDA unless the applicant submits adequate, well-controlled, well-designed, well-conducted, and well-documented studies, performed by qualified investigators, which prove the efficacy of a drug for its intended use").

[77] *E.g.*, *All. for Cannabis Therapeutics v. Drug Enf't Admin.*, 15 F.3d 1131 (D.C. Cir. 1994).

[78] Mikos, *The Tyrannies of Scheduling*, *supra* note 19, at __.

For all of these reasons (and more), I would not be surprised if the DEA disagreed with HHS's CAMU analysis, and thus, its conclusion that marijuana may be rescheduled.[79]

B. The DEA is Not Required to Follow HHS's Recommendation

Recall that the CSA instructs the DEA to defer to HHS on certain issues. In particular, Section 811(b) of the CSA declares that the Secretary of HHS is supposed to provide the Attorney General with a "scientific and medical evaluation" as well as a recommendation for where the drug should be scheduled, based on the "scientific and medical considerations" pertinent to scheduling.[80] The same Section then stipulates that "[t]he recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters."[81] (As noted earlier, the DEA now sits in the shoes of the Attorney General in the administrative scheduling process.) For this reason, it would appear the DEA has no choice but to accept HHS's conclusion that marijuana has a CAMU, and thus, may be moved to a lower schedule.

But the DEA is not bound to follow HHS's CAMU conclusion for a subtle and previously overlooked reason. HHS's 2023 determination that marijuana has a CAMU arguably rests on a *legal* consideration, rather than a scientific or medical one (such as the methodological rigor of a given clinical study). Without acknowledging it was doing so, HHS appeared to reinterpret the meaning of "currently accepted medical use" under the CSA. It appeared to claim that Congress did not equate "currently accepted medical use" with "approved under the FDCA", as the DEA has long contended. Instead, HHS appeared to claim (again, implicitly) that "currently accepted medical use" could also mean 'currently approved by large numbers of practicing physicians and large numbers of states.'[82] As explained

[79] HHS omitted all five requirements of the DEA's CAMU test from its evaluation. Although I have focused on the RCT requirement, the DEA could object to HHS's decision to drop the other four requirements as well.

[80] 21 U.S.C. § 811(b).

[81] *Id.*

[82] *See* Mikos, *The Tyrannies of Scheduling*, *supra* note 19.

above, this re-interpretation of CAMU was pivotal to the agency's recommendation.

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. On its face, Section 811(b) only requires the DEA to defer to HHS on "*scientific and medical matters*", not legal ones.[83] Had HHS concluded the scientific evidence for marijuana's medical efficacy was strong enough to satisfy the DEA's five-part test, the DEA likely would have been stuck with that conclusion, even if it thought HHS had misjudged the quality of the scientific research. But that is not what happened here. HHS acknowledged the scientific evidence for marijuana's therapeutic value was still limited; it only concluded that marijuana has a CAMU by claiming that science was not the only touchstone for that statutory scheduling criterion–i.e., that Congress wanted the agencies to consider physician practices and state laws instead of or in addition to scientific research.

Pursuant to this argument, the DEA could refuse to accept HHS's conclusion that marijuana has a CAMU. It could then request HHS conduct another evaluation, this time using its (the DEA's) five-part CAMU test. But it might be able to skip this step and rely on HHS's recent (2023 evaluation). Citing HHS's (tacit) concession there are still no RCTs demonstrating efficacy, the DEA could conclude for itself that marijuana still cannot pass its five-part test and thus, cannot be moved off Schedule I.

In the alternative, the DEA could invoke another provision of the CSA to reject the HHS recommendation. Section 811(d) provides that "If control is required by United States obligations under international treaties . . . 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

[83] The CSA's division of authority appears to track each agency's comparative expertise. HHS has the edge on scientific matters – for example, we should expect that agency to do a better job of assessing the methodological strengths and weaknesses of clinical studies. But the Attorney General (and the Attorney General's designee, the DEA) has the edge when it comes to legal matters – for example, we should expect the Attorney General to do a better job of divining the meaning of ambiguous statutory language.

normally required for placing a drug on that schedule.[84] In effect, Section 811(d) makes international law trump all other scheduling considerations (CAMU, abuse potential, etc.).[85] In so doing, it empowers the DEA (qua Attorney General) to disregard HHS's recommendation to the extent it would put the United States out of compliance with treaty obligations.

The provision is relevant now because the DEA has previously argued that the controls the CSA imposes on Schedule III (or lower) cannot satisfy our obligations under international drug control conventions. For example, the agency noted that those conventions require the United States to impose quotas on the production of marijuana, but the CSA only imposes such quotas on Schedule I and II drugs (and not Schedule III-V drugs).[86] To avoid creating a breach, the agency thus concluded that marijuana could be placed no lower than Schedule II under the CSA, even if the agency thought the drug met the statute's criteria for placement on a lower schedule.[87]

International law has not changed in any legally relevant sense since the DEA first announced that international law effectively set a floor (Schedule II) for any marijuana scheduling decision. The DEA could cite the same argument today to reject HHS's recommendation to move marijuana to Schedule III. However, the DEA probably could not keep marijuana on Schedule I either, given its prior concession that Schedule II controls would meet our obligations under international law. So the agency would probably have to move marijuana to Schedule II, alongside cocaine and fentanyl. Although that would constitute rescheduling, it would be even less impactful than the change HHS has recommended (for reasons discussed below in Part III.A).

[84] 21 U.S.C. § 811(d)(1).

[85] I discuss the constraints imposed by Section 811(d)(1) on the agencies in Robert A. Mikos, *POTUS and Pot: Why the President Could Not Legalize Marijuana Through Executive Action*, 89 U. CIN. L. REV. 668, 677-78 (2021).

[86] *Nat'l Org. for the Reform of Marijuana Laws (NORML) v. Drug Enforcement Admin.*, 559 F.2d 735, 757 (D.C. Cir. 1977).

[87] *Id.*

C. A Future Administration Could Undo Rescheduling

Now suppose the Biden Administration DEA accepts the recommendation and issues a proposed final rule moving marijuana to Schedule III. Notwithstanding my contention that the DEA likely disagrees with HHS, the DEA might follow the recommendation anyway, for several reasons. It might disagree with my assessment of Section 811(b) and conclude that provision does require it to follow HHS. It might determine that there is another path to rescheduling that does not require it to follow HHS's reasoning (elsewhere, I have laid out such a path for the agency[88]). Or, most likely, Attorney General Merrick Garland might simply pressure (order?) the agency to put aside its misgivings and accept rescheduling for the good of the Administration, which is under political pressure to make rescheduling happen.

Nevertheless, I want to suggest that even if the Biden Administration issues a rule rescheduling marijuana, that move could be undone very quickly—not by the courts, but by a new DEA Administrator. Namely, if President Biden loses reelection in fall 2024, a new Trump Administration could quickly move marijuana back on to Schedule I.

At the outset, I want to note that I doubt the courts would stop the Biden Administration DEA from moving marijuana to a lower schedule. For one thing, it is difficult to imagine anyone who would have standing to bring a legal challenge in the first instance. To be sure, parties have been able to wage challenges against DEA marijuana scheduling decisions in the past.[89] But in each of those cases, the plaintiffs were challenging the DEA's decision to maintain tight Schedule I controls on marijuana. Those decisions injured the plaintiffs in a very direct way: they claimed they wanted to use marijuana for therapeutic purposes, but Schedule I controls were making that very difficult (that was the point).[90]

[88] Mikos, *The Tyrannies of Scheduling*, *supra* note 19.

[89] *See, e.g.*, cases cited *supra* note 2.

[90] *See, e.g.*, *Americans for Safe Access v. Drug Enf't Admin.*, 706 F.3d 438 (D.C. Cir. 2013) (finding that patient of Veterans Administration hospital had standing to challenge DEA rule keeping marijuana on Schedule I, where veteran claimed that agency's decision prevented him from obtaining medical marijuana through the VA).

By contrast, if the DEA were to move marijuana to Schedule III, the agency would be making it easier to use marijuana (though not by much, for reasons explained below). Opponents of rescheduling would not be injured by that decision, at least in a constitutionally cognizable sense.[91] Even assuming that more people used marijuana post-rescheduling, and even assuming there were more car accidents, emergency room visits, cases of psychoses, etc. that resulted from that additional usage, those injuries would not be directly caused by the DEA–they would be caused by the individuals who choose to use marijuana after the agency rescheduled the drug.[92]

(The Supreme Court's pending decision in a lawsuit challenging the FDA's decision to relax controls on the abortion pill mifepristone should shed light on whether anyone would have standing to challenge a DEA decision to relax controls on marijuana as well.[93] If the Court rules as expected and dismisses the mifepristone lawsuit for want of standing,[94] it should quell any concerns that rescheduling could be derailed by litigation.)

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[91] Of course, advocates of rescheduling might have standing to challenge the DEA's decision on the grounds it did not go far enough (i.e., the controls imposed by Schedule III might still prevent them from using the drug). But they would not be asking the court to set aside rescheduling. Instead, they would be asking the court to order the agency to move marijuana to an even lower schedule (or deschedule the drug altogether), which is not the relief opponents of rescheduling want.

[92] In legal terms, the users would be an intervening cause that breaks the agency's legal responsibility for the alleged injury. I discuss a similar standing issue surrounding civil RICO claims against the marijuana industry. *See* Robert A. Mikos, *A Critical Appraisal of the Department of Justice's New Approach to Medical Marijuana*, 22 STAN. L. & POL'Y REV. 633, 651-53 (2011) .

[93] *Danco Lab'ys, L.L.C. v. All. for Hippocratic Med.*, 144 S. Ct. 537, 217 L. Ed. 2d 285 (2023). In the lawsuit, emergency room physicians are challenging FDA decisions to expand the pool of health care practitioners (HCPs) who may prescribe mifepristone; lengthen the period of time during which the drug may be prescribed (from the seventh to the tenth week of pregnancy); and repeal an agency imposed requirement that all patients first undergo an in-person visit with a HCP. The physicians have asked the court to block those (and other) regulatory changes. They claim that mifepristone is unsafe, and that if the agency relaxes its controls on that drug they might have to treat more patients who suffer (rare) side effects from the drug. For excellent coverage of all the issues posed by the case, see Amy Howe, *Abortion access again before Supreme Court*, SCOTUSblog (Mar. 25, 2024, 3:39 PM), https://www.scotusblog.com/2024/03/abortion-access-again-before-supreme-court/.

[94] Howe, *supra*.

Of course, standing is not the only obstacle plaintiffs would face in any suit against the DEA. Plaintiffs would also struggle to persuade a court that the agency had acted unlawfully by moving marijuana to Schedule III. The agency's interpretation of the CSA and findings of fact would be reviewed under very deferential standards.[95] Although I think the reasoning behind HHS's scheduling recommendation is problematic (for reasons just explained), I do not think it would be unreasonable for the DEA to follow that recommendation.[96]

Nonetheless, even if rescheduling might be litigation-proof, it still might not last for long. The reason is that President Biden might lose reelection in fall 2024. If that happens, a new Trump Administration could quickly move marijuana back on to Schedule I.

Earlier, I explained why the Biden Administration DEA might oppose rescheduling. It is even easier to imagine that a new Trump Administration would do so. Recall that the first Trump Administration renounced an internal DOJ policy discouraging enforcement of the federal marijuana ban; it also stonewalled an Obama-Administration policy designed to facilitate medical research on the drug.[97]

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[95] *See* Congressional Research Service, *The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress* (Jan. 19, 2023), https://sgp.fas.org/crs/misc/R45948.pdf (noting that "courts accept DEA's interpretation of the CSA as long as the interpretation of ambiguous statutory text is reasonable, and the CSA provides that the DEA Administrator's findings of fact are 'conclusive' on judicial review if the findings are supported by substantial evidence.") (quoting 21 U.S.C. § 877).

[96] Before promulgating any rescheduling rule, the DEA could also develop additional arguments to support rescheduling and thereby further insulate its decision from legal challenge. *See* Mikos, *The Tyrannies of Scheduling*, supra note 19 (outlining different ways the DEA could follow the HHS recommendation without necessarily adopting its reasoning).

[97] *See* Robert A. Mikos, *Risky Business? The Trump Administration and the State-Licensed Marijuana Industry*, 2017 U. ILL. L. REV. ONLINE: TRUMP 100 DAYS (April 29, 2017), https://illinoislawreview.org/symposium/first-100-days/risky-business/ (discussing enforcement policy); Robert A. Mikos, *Using One Dying Regime to Save Another: The Influence of International Drug Conventions on United States' Cannabis Research Policy*, 114 AM. J. INT'L L. UNBOUND 296 (2020) https://www.researchgate.net/publication/346190027_Using_One_Dying_Regime_to_Save_Another_The_Influence_of_International_Drug_Conventions_on_United_States'_Cannabis_Research_Policy (discussing research policy).

What is more, many Republican leaders have openly criticized the HHS recommendation and urged the DEA to refuse to follow it.[98]

Just as importantly, there is nothing that would prevent the DEA under a new Trump Administration from moving marijuana back onto Schedule I. Agencies like the DEA are allowed to change their minds. In *FCC v. Fox Television*, the Supreme Court made clear that an agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; [instead] it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better . . . ."[99] Indeed, when the Presidency changes hands, it is not uncommon for the new Administration to undo the rulemaking of its predecessor.[100]

Under *Fox Television*, the Trump Administration could re-initiate the CSA's administrative scheduling process, conclude that marijuana belongs (back) on Schedule I, and promulgate a new administrative rule to that effect. The Administration might not even need to complete a new HHS evaluation of the drug. Instead, the Trump DEA could argue that the Biden DEA / HHS had employed the wrong legal test for rescheduling, and that under the correct test (the DEA's old five-part test), it was clear from HHS's 2023 evaluation that marijuana lacked a CAMU and should never have been rescheduled.

The Trump DEA might be able to move even more quickly (Day 1?) by issuing an Order moving marijuana back to Schedule I (or at least, move it up to Schedule II). The Trump Administration set a precedent for expedited scheduling via Order (versus rulemaking) in 2018, when the Acting DEA Administrator placed all FDA-approved CBD drugs on Schedule V, without waiting for HHS's input.[101]

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[98] *See, e.g.*, Sen. Mitt Romney et al., *Letter to DEA Administrator Anne Milgram*, https://www.romney.senate.gov/wp-content/uploads/2024/03/3.27.24_Letter-to-DEA-Final.pdf (Mar. 27, 2024).

[99] *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

[100] *See, e.g.*, Congressional Res. Svc., *Responses to Midnight Rulemaking: Legal Issues* (Jan. 21, 2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10566.

[101] Drug Enforcement Administration, Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements, 83 Fed. Reg. 48950 (Sept. 28, 2018),

The Administrator claimed that Section 811(d)--the international law provision discussed above–gave the agency that power:

> "[S]ection 811(d)(1) expressly requires that this type of scheduling action [involving international treaties] not proceed through the notice-and-comment rulemaking procedures governed by the Administrative Procedure Act (APA), which generally apply to scheduling actions; it instead requires that such scheduling action occur through the issuance of an 'order.'"[102]

Pursuant to this reasoning, the new Trump-appointed DEA Administrator could argue that the decision to place marijuana on Schedule III had put the United States out of compliance with its treaty obligations and was thus in violation of Section 811(d)(1)'s command to heed those obligations. To rectify that breach, the Administrator could issue an Order placing marijuana on Schedule II. The Administrator might even try to move it back to Schedule I, though as discussed above, international law does not appear require the United States to keep marijuana on Schedule I, so Section 811(d)(1) arguably would not justify moving the drug all the way back to that (even more restrictive) schedule.

For reasons explained above, any DEA decision moving marijuana back to Schedule I (or moving it from Schedule III to Schedule II) could be challenged in court. Standing would pose no real obstacle. But given judicial precedent upholding past agency scheduling decisions, it seems likely any new legal challenge would fail as well.

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In short, the DEA is likely to have serious concerns with the reasoning behind HHS's scheduling recommendation. If it does, the agency has the discretion under the CSA to reject that recommendation and keep marijuana on Schedule I (or at least, move it no lower than Schedule II). Even if the Biden Administration DEA decides to suppress any misgivings and move marijuana to Schedule III, the drug's stay on that schedule could be short-lived. If President Biden loses the fall 2024 election, a new Trump Administration DEA could quickly undo the change and

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https://www.govinfo.gov/content/pkg/FR-2018-09-28/pdf/2018-21121.pdf.

[102] *Id*.

place marijuana back on Schedule I. The possibility that rescheduling still might not happen—or might not last for long, if there is a sudden change of Administrations, constitutes the first reason why I think the expectations regarding HHS's 2023 scheduling recommendation are inflated.

III. Why Rescheduling Will Not Significantly Improve the Fortunes of the Marijuana Industry

Now, put aside the doubts raised in the last Part. Assume for sake of argument that the Biden Administration DEA moves marijuana to Schedule III and the agency does not later change its mind.[103] What would be the ramifications of the change in scheduling? In particular, how might rescheduling benefit state-licensed marijuana suppliers?

Up to now, those suppliers have faced a litany of well-known legal and business challenges because federal law bans the production and sale of marijuana. These challenges include:

- The threat of criminal sanctions;[104]
- Limited access to basic banking services;[105]

[103] If President Biden wins reelection, for example, it seems highly unlikely the DEA would suddenly reverse its decision on rescheduling. Even if Donald Trump wins the election, his Administration might decide moving marijuana back to Schedule I is not a high priority or would be too costly, politically speaking.

[104] *See* Robert A. Mikos, *On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power to Legalize Federal Crime*, 62 VAND. L. REV. 1419 (2009) (detailing sanctions applicable to marijuana offenses under the CSA). Of course, the threat of criminal sanctions has receded in recent years, due to congressionally-imposed and self-imposed limits on DOJ enforcement actions against state-licensed marijuana suppliers. *See* Robert A. Mikos, *The Evolving Federal Response to State Marijuana Reforms*, 26 WIDENER L. REV. 1 (2020) (discussing shift in federal enforcement policy).

[105] Banks have been reluctant to deal with the industry because its money is "dirty", i.e., it constitutes the proceeds of "specified unlawful activity" under federal money laundering statutes. 18 U.S.C. § 1956.

- Punitive tax accounting rules under Section 280E of the Internal Revenue Code;[106]
- Limited protection for their intellectual property rights;[107]
- Lack of access to bankruptcy reorganization;[108]
- Sporadic assistance in the enforcement of contracts;[109]

The list goes on and on.

The hope (the expectation?) is that these challenges will disappear once marijuana is moved to Schedule III. But the impact of rescheduling is likely to be far more limited. While rescheduling would make it possible for firms to comply with the CSA, such compliance is far from guaranteed. What is more, rescheduling will have no effect on the FDCA. That statute will continue to ban the sale of marijuana, even after rescheduling.

To the extent firms are unable to comply with either the CSA or the FDCA (or both), the challenges now facing them will persist post-rescheduling, with only one exception–Section 280E. Unlike the other sanctions listed above, Section 280E only applies to offenses involving Schedule I and II drugs.[110] Thus, even if firms continue to run afoul of the CSA or the FDCA post-rescheduling, they will no longer need to worry about the federal government's punitive tax accounting rules. (Indeed, for this reason, even unlicensed marijuana dealers will reap this benefit.)

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[106] 26 U.S.C. § 280E. Section 280E bars marijuana suppliers from deducting certain expenses when calculating their federal tax liability. *See also* Benjamin Moses Leff, *Tax Planning for Marijuana Dealers*, 99 IOWA L. REV. 523 (2014).

[107] For example, the United States Patent and Trademark Office (PTO) has refused to allow anyone to register a trademark used on a marijuana product because the sale of marijuana is unlawful. *See* Mikos, *Unauthorized and Unwise*, *supra* note 15.

[108] *See supra*, note 16.

[109] *See* Scheuer, *supra* note 17.

[110] 26 U.S.C. § 280E ("No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in *controlled substances (within the meaning of schedule I and II of the Controlled Substances Act*) which is prohibited by Federal law or the law of any State in which such trade or business is conducted.") (emphasis added).

The following Sections explain more fully why firms in the industry will struggle to comply with the CSA and FDCA post-rescheduling, thereby limiting the practical benefits of rescheduling.

A. The Lingering Compliance Challenges Posed by the CSA

Even after rescheduling, marijuana would remain subject to a litany of regulations under the CSA. Although the regulations applicable to Schedule III drugs are less onerous than the ones that apply to Schedule I drugs, they will still pose compliance challenges for firms in the marijuana industry. Indeed, I suspect that few (if any) of the more than 12,000 firms now licensed by the states to produce and / or sell marijuana will be able and willing to scrupulously comply with all the new regulations the CSA will throw at them.[111]

To begin, the CSA requires every producer and distributor of a Schedule III controlled substance to obtain a registration (e.g., a license) from the DEA before engaging in those activities.[112] Many state-licensed firms will struggle to meet this threshold requirement even though (by definition) they were able to obtain a license from the state. For one thing, the DEA is likely to refuse registration to any firm that operates in the recreational (i.e., adult-use) marijuana market, because the CSA bans the production and sale of controlled substances for non-medical purposes.[113] Such refusal will deny the benefits of rescheduling (limited as they are) to firms in the largest and most quickly growing segment of the marijuana market. (In Colorado, for example, recreational marijuana now accounts for more than eight-five percent (85%) of all marijuana sales.[114]) The DEA could also refuse

[111] Dispense, *Total Cannabis Dispensaries by State in 2024* (Jan. 1, 2024), https://www.dispenseapp.com/blog/cannabis-dispensaries-by-state (reporting there were 12,156 licensed marijuana suppliers in the United States as of January 1, 2024).

[112] 21 U.S.C. § 822.

[113] *Id*. at § 829.

[114] Colorado MED Dashboard, *Q1 2024 Colorado Marijuana Market Update: Sales*, https://public.tableau.com/app/profile/cu.business.research.division/viz/ColoradoMEDDashboard/Overview.

registration to any firm controlled by an individual with a prior drug conviction.[115] Such refusal would likely have a disproportionate impact on social equity licensees, many of whom obtained their state licenses precisely because they had previously been convicted of a marijuana offense.[116]

Even if a firm obtains registration, it must also comply with sundry other rules the CSA imposes on the production and sale of Schedule III drugs. Among other things, registrants will have to stop buying marijuana from or selling marijuana to firms that are not also DEA registered.[117] This prohibition could disrupt many long-term business relationships in the industry, especially if only a small percentage of firms in the market are able to obtain registration. Registrants must also comply with CSA rules governing the handling, labeling, packaging, and tracking of Schedule III drugs.[118] While firms are intimately familiar with state rules governing those same matters, the federal requirements are likely to differ from state requirements.[119] Registrants will need to invest time and money adjusting their operations to ensure they comply with both.[120]

Firms that fail to comply with all of these new rules under the CSA will likely gain nothing from rescheduling, apart from the reprieve from Section 280E mentioned above. Even if marijuana is rescheduled, offenses involving the drug

[115] 21 U.S.C. § 823 (listing prior drug convictions among the factors the DEA is supposed to consider in reviewing registration applications).

[116] In an effort to make amends for targeting minority communities during the War on Drugs, some states have granted special marijuana business licenses (commonly called social equity licenses) to individuals who were previously convicted of marijuana offenses. *E.g.*, Washington State Liq. & Cannabis Bd., Cannabis Social Equity (undated), https://lcb.wa.gov/se/cannabis-social-equity. If the DEA refuses to register applicants with past convictions, it could severely damage these social equity licensing programs.

[117] *See* 21 U.S.C § 823.

[118] E.g., id. at §§ 825-829.

[119] *See* ROBERT A. MIKOS, MARIJUANA LAW, POLICY, AND AUTHORITY 413- 481 (2017) (discussing wide variety of state regulations imposed on the marijuana industry).

[120] Adding to the difficulty, many of the specific rules that will apply to marijuana as a Schedule III drug have yet to be written. For example, once marijuana is rescheduled, the FDA will need to draft labeling requirements for marijuana products. 21 U.S.C. § 825.

will trigger the same harsh criminal sanctions they always have under the CSA.[121] Money derived from those offenses will still constitute "the proceeds of specified unlawful activity" under federal money laundering statutes, keeping banks reluctant to deal with non-compliant firms.[122] Trademarks used in those offenses will remain unregistrable under the USPTO's lawful use requirement.[123] Non-compliant firms that cannot cure their violations still will not be able to file a Chapter 13 reorganization plan that is "in good faith and not by means forbidden by law."[124] Contracts involved in marijuana offenses would still be unenforceable as against public policy. And so on.

B. The Even More Daunting Compliance Challenge Posed by the FDCA

But even if firms find a way to comply with the CSA, they will still need to worry about a second statute: the Food Drug and Cosmetic Act (FDCA). The FDCA regulates the sale and marketing of drugs across state lines. Most relevantly, for present purposes, the statute bans the interstate sale of unapproved drugs–i.e., drugs the FDA has not (yet) found to be safe and effective.[125] Marijuana is an unapproved

[121] The sanctions for many offenses involving marijuana are specified by the CSA, and would not change upon rescheduling unless Congress amends the statute. For example, Congress specified that the unauthorized distribution of more than fifty marijuana plants is subject to a mandatory minimum five year term of imprisonment. 21 U.S.C. § 841(b)(1)(B). It is worth noting, however, that some relatively minor violations (e.g., sale of improperly labeled marijuana by a registrant) would only be subject to modest civil sanctions post-rescheduling. *Id.* at § 842.

[122] 18 U.S.C. § 1956(c)(7). To be sure, post-rescheduling, there may be some minor CSA violations involving marijuana that do not constitute "specified unlawful activity" under Section 1956(c).

[123] *See* Mikos, *Unlawful and Unwise*, *supra* note 15 (describing the stunningly broad reach of the agency's lawful use requirement).

[124] 11 U.S.C. § 1325(a)(3) (stipulating that a reorganization plan must be "in good faith and not by any means forbidden by law"). *See also*, *e.g.*, *In re McGinnis*, 453 B.R. 770 (Bankr. D. Ore. 2011) (refusing to confirm Chapter 13 reorganization plan filed by medical marijuana dispensary because it would have been funded through the unlawful sale of marijuana).

[125] 21 U.S.C. § 355(a).

drug, and, as Professors Sean O'Connor and Erica Lietzan have astutely observed, it would remain so even if it were descheduled under the CSA.[126]

To be sure, in the past, one might have reasonably expected drug approval to follow on the heels of rescheduling, because the requirements for both were nearly identical.[127] By definition, the RCTs that would demonstrate marijuana has a "currently accepted medical use" under the CSA would also serve to demonstrate the drug is safe and effective under the FDCA (and vice versa). But as discussed above, HHS severed the link between the two statutes in its latest scheduling evaluation. It dropped the RCT requirement for rescheduling under the CSA, but at the same time, the agency left that requirement intact for the new drug approval process under the FDCA.[128] Indeed, HHS emphasized that its CAMU determination was "not meant to imply that safety and effectiveness have been established for marijuana that would support FDA approval of marijuana for a particular indication."[129] In other words, FDA approval of marijuana remains a long way off because the drug approval process remains as demanding as ever.

The lack of FDA approval poses a daunting challenge for the industry. Until the FDA approves marijuana, it will be virtually impossible for state-licensed marijuana firms to comply with the FDCA.[130] While some firms might think they can escape the statute by not selling their wares across state lines, that strategy is unlikely to work.[131] The FDA has interpreted the FDCA's jurisdictional provision very broadly. For example, the agency has claimed the statute applies to the intrastate sale of a drug if a component of the drug is sourced from out-of-state.[132]

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[126] O'Connor & Lietzan, *supra* note 26.

[127] *See supra* note Part I.B.

[128] *See* Mikos, *The Tyrannies of Scheduling*, supra note 19.

[129] HHS Basis for Recommendation, *supra* note 56, at 63.

[130] *See* O'Connor & Lietzan, *supra* note 26.

[131] All states currently ban their licensees from shipping marijuana across state lines, so all licensed marijuana firms could (in theory) claim they are not subject to the FDCA. *See* Robert A. Mikos, *Interstate Commerce in Cannabis*, 101 B.U. L. REV. 857 (2021) (surveying state restrictions on interstate commerce in marijuana).

[132] O'Connor & Lietzan, *supra* note 26, at 860 (noting that the FDA "takes the position that it may regulate products containing components (such as ingredients) previously shipped in interstate commerce, and the courts have generally deferred to the agency on this point").

I suspect most finished marijuana products now on the market include some component that was sourced out of state, even if the marijuana itself was grown locally–think of rolling papers, glass vape cartridges, ethanol used to extract hash oil, containers used for packaging, and so on. For this reason, and others, marijuana products in the licensed market are likely subject to the FDCA.

Because the sale of marijuana would remain unlawful under the FDCA post-rescheduling, the legal and business challenges I mentioned earlier would persist. Violations of the FDCA, like violations of the CSA, are subject to a variety of legal sanctions, including criminal sanctions.[133] Even if the FDA did not enforce those sanctions, violations would still constitute grounds for refusing to bank the industry, register its trademarks, entertain its bankruptcy petitions, and enforce its contracts. I will note, however, that violations of the FDCA might not deter banks from serving marijuana firms. In other words, banks might not refuse to serve a marijuana firm just because it is violating the FDCA. Unlike violations of the CSA, violations of the FDCA do not constitute "specified unlawful activity" under federal money laundering statutes.[134] In simpler terms, the money earned from the sale of an unapproved drug is not (necessarily) tainted. This gives banks one less reason to shun marijuana firms (at least the CSA compliant ones), though they still may not welcome such firms post-scheduling.[135]

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In short, because the marijuana industry will continue to struggle to comply with the CSA and FDCA even after rescheduling, firms in that industry will continue to face many of the same vexing challenges they do today. Ultimately, rescheduling may amount to no more than a tax cut for marijuana suppliers (licensed or otherwise)—far short of the (inflated) expectations advocates have

[133] 21 U.S.C. § 333 (listing penalties for violations of the FDCA).

[134] 18 U.S.C. § 1956 (defining "specified unlawful activity").

[135] Banks will still have other reasons to refuse to deal with the marijuana industry. *See* Hill, *supra* note 14. For example, lending money to a marijuana supplier might constitute aiding and abetting the firm's FDCA violations, even if it would not also constitute money laundering. 18 U.S.C. § 2 (defining aiding and abetting under federal law).

attached to this "historic" and "momentous" development in federal marijuana policy.

IV. Meaningful Reform Takes Congress

The HHS recommendation has been heralded as "historic" and "momentous", but its practical impact will be limited at best. The slim payoff from the five-decade effort to reschedule marijuana should be a lesson for marijuana advocates. The power of agencies to reshape federal marijuana policy – to untangle the complicated web of federal law governing marijuana - is highly circumscribed. The implication – the key takeaway – is that if you want more meaningful reform of federal marijuana policy, you really need Congress to act.

I realize that getting Congress to pass new legislation seems like a tall task. But for too long, advocates may have fooled themselves into believing they could avoid that task and reshape federal marijuana policy by working through administrative agencies (or the courts) instead. Even after bumping up against obstacles (like the DEA's tough five-part CAMU test), advocates persisted with rescheduling efforts, seemingly fueled by inflated expectations about what such efforts could ultimately accomplish.

Congress has been happy to play along and feed expectations about what Executive Branch administrative agencies could accomplish on their own without further help from Congress. For example, some members of Congress have suggested the DEA could (and should) go beyond what HHS just recommended and deschedule marijuana.[136] Some have even hinted that administrative rescheduling was "necessary" to ending the federal government's prohibition on marijuana.[137] All the while, legislative reform proposals quietly gather dust.

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[136] *Letter from 10 United States Senators to Attorney General Garland and DEA Administrator Milgram* (Jan. 29, 2024), https://www.booker.senate.gov/imo/media/doc/2024.01.29%20Letter%20to%20DEA%20on%20descheduling%20marijuana.pdf ("We write to urge the Drug Enforcement Administration (DEA) to swiftly deschedule marijuana from the Controlled Substances Act (CSA).").

[137] *E.g.*, Kyle Jaeger, *Congressman Demands Answers from Biden Admin on Marijuana Rescheduling*, MARIJUANA MOMENT (Mar. 21, 2024), https://www.marijuanamoment.net/congressman-demands-answers-from-biden-admin-on-

While administrative agencies do share some of responsibility for our current federal marijuana policy, we must not forget it was Congress that Congress passed the CSA; it was Congress that placed marijuana on Schedule I; it was Congress that designed the cumbersome administrative scheduling process; it was Congress that incorporated international law into that process; it was Congress that demanded scientific proof of safety and efficacy for all drugs; and it was Congress that passed amendments to sundry other statutes – like the federal tax code – to bolster its war on taboo drugs. No agency has the power to dismantle the tangled web of federal drug laws that Congress has spun. Only Congress can do that.

Let me end on a more hopeful note. If there is any issue on which Congress should be able to reach consensus and pass new legislation, marijuana reform should be it. Seventy percent (70%) of American adults now support full (adult use) legalization.[138] I can think of few other policy proposals that command such overwhelming and bi-partisan support. When the CSA was first passed, only twelve percent (12%) of adults supported legalization,[139] making the administrative rescheduling process and its emphasis on science (not public opinion) look relatively more promising to marijuana advocates than the Article I lawmaking process. But now that marijuana advocates have won over the hearts and minds of the vast majority of American voters, continuing to push for administrative rescheduling may simply distract from the unavoidable if inconvenient truth: Meaningful reform takes Congress.

marijuana-rescheduling-legal-opinion-request-for-doj/ ("The [DEA's] formal review of the scheduling of marijuana is a *necessary step* in the work to end the federal government's failed and discriminatory prohibition of cannabis.") (quoting Rep. Earl Blumenauer) (emphasis added).

[138] Lydia Saad, *Grassroots Support for Legalizing Marijuana Hits Record 70%*, GALLUP (Nov. 8, 2023), https://news.gallup.com/poll/514007/grassroots-support-legalizing-marijuana-hits-record.aspx.

[139] *Id.*