MARIJUANA AND THE TYRANNIES OF SCHEDULING

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INTRODUCTION

The Drug Enforcement Administration (DEA) is poised to make the biggest change to federal marijuana policy in decades.[1] In May 2024, the agency announced that it would move marijuana from Schedule I to Schedule

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1. *See, e.g.*, Chris Roberts, *'Biggest Thing, Ever': Marijuana Rescheduling Recommendation Hailed*, MJ BIZ DAILY (Aug. 30, 2023), https://mjbizdaily.com/biden-health-officials-say-marijuana-should-be-rescheduled/ [https://perma.cc/XWZ2-YETZ] (declaring that rescheduling would be the "biggest development in [marijuana] policy reform in more than 50 years").

III under the Controlled Substances Act[2] (CSA). Although rescheduling will not fulfill every wish of marijuana advocates,[3] it will grant a welcome reprieve from the draconian restrictions the CSA imposes upon activities involving Schedule I drugs.

This Essay provides the first in-depth examination of the reasoning behind the marijuana rescheduling decision and its implications for *other* Schedule I drugs. In that vein, it makes three key contributions.

First, this Essay elucidates how an agency reinterpretation of a key statutory scheduling criterion—"currently accepted medical use" (CAMU)—suddenly paved the way for rescheduling marijuana after fifty-plus years of failed attempts. The DEA has long claimed that drugs that have no CAMU must be placed on Schedule I, even if they do not also have a "high potential for abuse," as seemingly required by the CSA.[4] In the past, however, the agency has insisted that only rigorous scientific proof of medical efficacy could demonstrate that a drug has a CAMU.[5] Because the research on marijuana's medical efficacy was never quite good enough, the DEA always found that marijuana had no CAMU and thus had to remain on Schedule I.[6]

But in 2023, the U.S. Department of Health and Human Services (HHS) quietly introduced a new CAMU test that marijuana could finally satisfy.[7] HHS claimed that widespread clinical experience with a drug could demonstrate a CAMU even if there was no rigorous scientific proof showing that the drug works as intended.[8] Because more than 30,000 health care practitioners (HCPs) had already recommended the drug to their patients in the thirty-eight states with medical marijuana laws, the agency concluded there was enough clinical experience to demonstrate that marijuana has a

2. 21 U.S.C. §§ 801–904; *see* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597 (proposed May 16, 2024) (to be codified at 21 C.F.R. pt. 1308).

3. *See generally* Robert A. Mikos, *The False Promise of Rescheduling*, 60 TULSA L. REV. (forthcoming 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4814284 [https://perma.cc/53QY-9DZP] (demonstrating that rescheduling will have a small impact on the fortunes of the state-licensed marijuana industry).

4. *See infra* notes 32–35 and accompanying text.

5. *See infra* Part I.B.

6. *See* Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499 (Mar. 26, 1992) [hereinafter 1992 Scheduling Decision]; Notice of Denial of Petition, 66 Fed. Reg. 20038 (Apr. 18, 2001) [hereinafter 2001 Scheduling Decision]; Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40552 (July 8, 2011) [hereinafter 2011 Scheduling Decision]; Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53688 (Aug. 12, 2016) [hereinafter 2016 Scheduling Decision]. The DEA's CAMU test is discussed in Part I.B.

7. *See generally* DEP'T OF HEALTH & HUM. SERVS., BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT (2023), https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf [https://perma.cc/7FE9-PRGK]. HHS advises the DEA on scientific and medical matters pertinent to scheduling decisions. 21 U.S.C. § 811(b). It introduced the new test after President Joseph R. Biden requested an expeditious review of marijuana's scheduling. *See* Presidential Statement on Marijuana Reform, 2022 DAILY COMP. PRES. DOC. 883 (Oct. 6, 2022).

8. *See infra* Part I.C.

CAMU and thus could be rescheduled.[9] Under prodding from the Office of Legal Counsel (OLC), the DEA accepted the health agency's reinterpretation and analysis, thereby paving the way for the rescheduling of marijuana and establishing an alternative CAMU test that advocates could use to seek the rescheduling of other Schedule I drugs.[10]

In short, new CAMU test, new scheduling result for marijuana.

Second, this Essay evaluates the implications of HHS's new CAMU test for the 150 *other* controlled substances now on Schedule I.[11] Like marijuana, several of these other drugs have shown some promise as medicine, including psilocybin, lysergic acid diethylamide (LSD), and 3,4-methylenedioxymethamphetamine (MDMA).[12] However, this Essay suggests none of these other drugs are likely to be removed from Schedule I anytime soon.

This Essay explains that both agency CAMU tests impose challenges that are virtually impossible for any drug already on Schedule I to meet.[13] This Essay labels these challenges the "Tyrannies of Scheduling." The DEA test imposes the "Tyranny of the Scientists" because it requires rigorous scientific evidence that is nearly impossible to assemble, especially for drugs that are already subject to the restrictions the CSA imposes on Schedule I drugs.[14] Although the HHS CAMU test drops the DEA's demand for such evidence, it imposes a different form of tyranny: "the Tyranny of the Majority."[15] I show that the HHS test, in effect, first requires advocates to convince a majority of voters in a substantial number of states to authorize the medical use of a drug. That is the only way to accumulate the widespread clinical experience HHS requires in lieu of rigorous scientific evidence. Although advocates were eventually able to win over majority support for the legalization of medical marijuana in a sufficiently large number of states, I suggest that no other drug is likely to repeat that feat anytime soon (if ever).

In short, new CAMU test, but same scheduling result for all other Schedule I drugs.

Third, this Essay proposes a novel way to soften the Tyrannies of Scheduling and enable rescheduling more Schedule I drugs. I propose that the DEA should stop insisting that a drug must be placed on Schedule I if it has no CAMU (however defined), at least when the drug lacks the "high potential for abuse" that is supposed to be characteristic of the drugs on that

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9. *See* BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7, at 24, 30.

10. *See infra* notes 52–53 and accompanying text.

11. A complete list of the substances controlled under the CSA can be found at DRUG ENF'T ADMIN., CONTROLLED SUBSTANCES - ALPHABETICAL ORDER (2024), https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf [https://perma.cc/V98M-9D69].

12. *See generally* Danilo De Gregorio, Argel Aguilar-Valles, Katrin H. Preller, Boris Dov Heifets, Meghan Hibicke, Jennifer Mitchell & Gabriella Gobbi, *Hallucinogens in Mental Health: Preclinical and Clinical Studies on LSD, Psilocybin, MDMA, and Ketamine*, 41 J. NEUROSCIENCE 891 (2021).

13. *See infra* Part II.

14. *See infra* Part II.A.

15. *See infra* Part II.B.

schedule.[16] This Essay demonstrates that the DEA's myopic focus on CAMU is contrary to the text of the CSA and serves no useful purpose.[17] Although this proposal would not make either agency CAMU test any easier to satisfy, it would reduce the influence those tests now wield over scheduling and thereby foster more rational scheduling decisions.[18]

In short, no CAMU, no problem.

This Essay proceeds as follows. Part I surveys the CSA's three core scheduling criteria and explains how the DEA made one of them (CAMU) paramount for Schedule I decisions. It then details the competing science-focused and experience-focused tests that the DEA and HHS have devised for determining whether a drug has a CAMU.

Part II illuminates the Tyrannies of Scheduling imposed by the two CAMU tests. It explains how each test effectively traps all Schedule I drugs besides marijuana on that tightly controlled schedule.

Finally, Part III proposes a more flexible approach for determining whether a drug belongs on Schedule I. It demonstrates that the DEA's single-minded focus on CAMU conflicts with the text of the CSA and fosters irrational scheduling decisions that are difficult to reconcile with any statutory purpose. Part III outlines how the agencies could apply the CAMU criteria in a more sensible way intended by Congress and why that change would prove beneficial, even if the agencies continued to apply their tyrannical CAMU tests.

I. SCIENCE VERSUS EXPERIENCE

In this part, I elucidate the new CAMU test that enabled marijuana to be rescheduled. Part I.A introduces the scheduling system created by the CSA and explains how the DEA made CAMU findings pivotal for determining whether a drug is placed on Schedule I under that system. Part I.B then explains how the DEA proceeded to equate "currently accepted medical use" under the CSA with the standards for new drug approval under the Federal Food, Drug, and Cosmetic Act[19] (FDCA). Based on that interpretation, the DEA devised a CAMU test that requires the same rigorous scientific evidence needed for new drug approval—multiple randomized controlled trials (RCTs) showing that the drug is safe and effective at treating some medical condition. Because the scientific support for marijuana's medical efficacy has fallen short of the lofty standards for RCTs, the RCT requirement has precluded rescheduling the drug in the past. But as discussed in Part I.C, HHS devised a new CAMU test in 2023. The new test allows real-world experience gleaned from state medical marijuana programs to substitute for the RCTs the DEA CAMU test requires. The adoption of this new test allowed HHS to conclude for the first time that marijuana has a CAMU and thus could be moved off Schedule I.

16. *See infra* Part III.
17. *See infra* Parts III.A–B.
18. *See infra* Part III.C.
19. 21 U.S.C. §§ 301–399i.

A. Scheduling Criteria and the Primacy of CAMU

The CSA was enacted to combat drug abuse, commonly defined as the use of hazardous drugs for nonmedical purposes.[20] To that end, the CSA regulates the manufacture, sale, and possession of all drugs of abuse. Roughly 400 different drugs of abuse are presently controlled under the statute.[21]

The specific regulations applicable to any given drug depend on the schedule to which it is assigned. The statute creates five Schedules (I through V), each with its own set of regulations that vary in their strictness.[22] The regulations applicable to Schedule I drugs are the strictest, arguably reflecting the notion that Schedule I drugs are the most hazardous of all controlled substances (heroin is a paradigmatic example). The CSA bans the manufacture, sale, and even possession of all Schedule I drugs, except when they are used in federally approved research studies, which are themselves tightly regulated.[23] The sets of controls imposed on the remaining schedules become steadily less strict as one moves down the Schedules from I to V.[24]

Congress made all the initial scheduling decisions when it passed the CSA in 1970, including the decision to place marijuana alongside heroin on Schedule I. At the same time, however, Congress gave the DEA the authority to reschedule a drug when the agency acquires new information indicating the drug belongs on a different schedule.[25] Any interested party may petition the DEA to reschedule a drug.[26] Once the DEA receives a petition, HHS must conduct an evaluation of "scientific and medical matters" that inform scheduling and provide the DEA with a scheduling recommendation.[27] After reviewing the HHS evaluation and recommendation, the DEA makes the final decision where the drug will be scheduled.[28]

Congress instructed the agencies to use three criteria to decide where to schedule a drug of abuse. Broadly speaking, these criteria relate to the harms and benefits attributable to use of the drug, including:

(1) the drug's relative potential for abuse;

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20. *See id.* § 801 (stating congressional purposes). Although the CSA does not expressly define "drug abuse," the DEA and HHS have interpreted the term to mean the nonmedical use of a drug that poses a hazard to safety of the user or other parties. *See, e.g.*, 2016 Scheduling Decision, *supra* note 6, at 53690.

21. *See* DRUG ENF'T ADMIN., *supra* note 11.

22. 21 U.S.C. §§ 822–832.

23. *Id.* §§ 841, 844. For a discussion of the special restrictions imposed on research involving Schedule I drugs, see *infra* Part II.A.

24. For a discussion of the controls applicable to Schedule III drugs see Mikos, *supra* note 3 (manuscript at 28–29).

25. 21 U.S.C. § 811(a). The statute also authorizes the DEA to schedule drugs of abuse that Congress did not schedule (say, because they were not yet developed when the CSA was passed). *Id.*

26. *Id.*

27. *Id.* § 811(b).

28. Although not pertinent here, the CSA requires the DEA to defer to HHS on scientific and medical matters. *Id.* Section 811(b) raises thorny interpretive questions, which the OLC addressed in its 2024 slip opinion. *See generally infra* note 53.

(2) whether the drug has a "currently accepted medical use" (CAMU); and

(3) the drug's relative dependence liability.[29]

Congress delineated the specific findings the agencies must make regarding each of these criteria to place a drug on each of the CSA's five schedules as displayed in Table 1 below.[30]

29. 21 U.S.C. § 812(b).

30. *Id.* Congress also instructed the agencies to consider eight factors when making the findings that drive scheduling:

(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. § 811(c).

Table 1: The Specific Findings Required for Placement on Each of the CSA's Five Schedules[31]

	Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
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"
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"
Dependence liability (or safety)	"lack of accepted safety for use . . . under medical supervision"[32]	"Abuse . . . may lead to severe psychological or physical dependence"	"Abuse . . . may lead to moderate or low physical dependence or high psychological dependence"	"Abuse . . . may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III"	"Abuse . . . may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV"

31. *Id.* § 812(b).

32. Confusingly, the statute does not specify the dependence liability for Schedule I drugs. Instead, it states that such drugs must have a "lack of accepted safety for use . . . under medical supervision." *Id.* § 812(b)(1)(C). As discussed in Part III.A, the DEA has made this criterion redundant with the schedule's "no CAMU" criterion. For that reason, the agency seldom discusses "lack of accepted safety for use" in its scheduling decisions.

When the findings for a drug all point to the same schedule, the task of scheduling that drug is straightforward. But scheduling findings do not necessarily align so neatly, because the criteria the findings measure do not necessarily move in lockstep. In other words, a drug's abuse potential, accepted medical use, and dependence liability are not perfectly correlated to one another, and thus, the findings for each of these three criteria could suggest placing the same drug on a different schedule. To illustrate, suppose the DEA makes the following three findings for a drug under review:

> (1) The drug's potential for abuse is "less than the drugs or other substances in schedules I and II,"
>
> (2) The drug has "no currently accepted medical use," and
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> (3) Abuse of the drug "may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV."[33]

Per Table 1 above, the first finding (abuse potential) indicates the drug belongs on Schedule III, the second finding (CAMU) indicates the drug belongs on Schedule I, and the third finding (dependence liability) indicates the drug belongs on Schedule V.

Unfortunately, the CSA does not expressly instruct the DEA how to proceed when its scheduling findings do not neatly align, as in the illustration above. But since the 1970s, the DEA has insisted that one finding is paramount and must trump all other considerations in cases of conflict. In particular, the DEA has claimed that any drug it finds to have "no currently accepted medical use" *must* be placed on Schedule I, regardless of its abuse potential and dependence liability.[34] Pursuant to this approach, a drug must have a CAMU to be placed on any other schedule.[35] For this reason, I label the agency's approach the "CAMU requirement."

The agency has based this CAMU requirement on the language of § 812(b) of the CSA. In its 2016 marijuana scheduling decision, the agency reasoned that

> 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." . . . 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.[36]

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33. *Id.* § 812(b).

34. *See, e.g.*, 2016 Scheduling Decision, *supra* note 6, at 53740 ("If a controlled substance has no such currently accepted medical use, it must be placed in schedule I.").

35. *See id.*

36. *Id.* at 53688, 53747. The DEA employed nearly identical reasoning in its earlier marijuana scheduling decisions as well. *See* 2001 Scheduling Decision, *supra* note 6, at 20039 ("[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

Notably, this textualist argument is the only justification the DEA has ever given for its requirement.

In Part III.B below, I illuminate the flaws in the DEA's reasoning. But ever since the DEA has made CAMU the paramount criterion for Schedule I, it has been necessary to demonstrate that a drug has a CAMU to get it removed from (or keep it off) that schedule. As a result, scheduling decisions have focused an inordinate amount of attention on deciphering the meaning of this single scheduling criterion, which Congress did not expressly define.[37] As discussed in Parts I.B and I.C, the DEA and HHS have championed two starkly different conceptions of CAMU, each demanding a very different type of evidence.

B. CAMU Based on Science

For its part, the DEA has suggested that "Congress equated the term 'currently accepted medical use in treatment in the United States' as used in the CSA with the core FDCA standards for acceptance of drugs for medical use."[38] On this view, the drugs that have a "currently accepted medical use" under the CSA are the drugs that have been (or could be) approved as safe and effective under the FDCA, i.e., those that are FDCA compliant.

In its 1992 marijuana scheduling decision, the DEA explained the supposed linkage between the two statutes:

> 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 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.
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> By 1969, Congress had developed detailed Federal statutory criteria under the FDCA to determine whether drugs are acceptable for medical use. . . .

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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 U.S.C. § 812(b))); 2011 Scheduling Decision, *supra* note 6, at 40552 ("The statutory mandate of 21 U.S.C. 812(b) is dispositive. 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.'").

37. *See* All. for Cannabis Therapeutics v. Drug Enf't Admin., 930 F.2d 936, 939 (D.C. Cir. 1991) (observing that "neither the statute nor its legislative history precisely defines the term 'currently accepted medical use'").

38. 1992 Scheduling Decision, *supra* note 6, at 10504.

> 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.
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> 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.[39]

Pursuant to this interpretation, the DEA insisted that demonstrating CAMU required (1) obtaining FDA approval for the drug, or (2) if the drug was not yet approved, satisfying a five-part test modeled on the test the FDA uses for the new drug approval process.[40] Collectively, I refer to these two tests as the "DEA's CAMU test."

Although the two tests differ in some respects not relevant here, both share a common requirement that has repeatedly stymied the rescheduling of marijuana and other Schedule I drugs. As I have observed elsewhere, both the FDA's new drug approval process and the DEA's five-part CAMU test for unapproved drugs

> require successfully completing Randomized Controlled Trials (RCTs) demonstrating that [a drug] is effective at treating a medical condition. RCTs are notoriously expensive and time-consuming, especially when they involve drugs (like marijuana) that are already on Schedule I. 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.[41]

Crucially, the DEA insisted that no other evidence could take the place of RCTs under its CAMU test. Consistent with the FDCA's focus on science, the DEA dismissed the actions of HCPs and state regulators as being

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39. *Id.* at 10503.

40. Originally, the DEA suggested that a drug had to be approved by the FDA to demonstrate that it had a CAMU. But a court rejected that position because drug approval could be denied on grounds that had no obvious relevance to CAMU, e.g., because the applicant failed to claim a patent on the drug. *See* Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 887–88 (1st Cir. 1987). The court held that FDA approval would be sufficient to demonstrate CAMU, but it was not the only way to do so. *Id.* at 892. In response to that decision, the DEA developed a new five-part CAMU test for unapproved drugs. The DEA's test is modeled on the FDCA test for drug approval but omits the requirements that the court in *Grinspoon v. Drug Enforcement Administration* found extraneous. In full, the DEA's five-part test for unapproved drugs requires: (1) the chemistry of the drug is "Known and Reproducible," (2) "Adequate Safety Studies" are present, (3) there are "Adequate and Well-Controlled Studies Proving Efficacy," (4) "Qualified Experts" must accept the drug, and (5) scientific evidence is "Widely Available." 1992 Scheduling Decision, *supra* note 6, at 10504–06. The U.S. Court of Appeals for the District of Columbia Circuit subsequently found the five-part test to be reasonable in *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration* 15 F.3d 1131, 1134 (D.C. Cir. 1994).

41. Mikos, *supra* note 3 (manuscript at 10–11) (footnotes and citations omitted).

irrelevant to the CAMU inquiry. For one thing, the agency suggested that these actors "are not qualified by scientific training and experience to evaluate the safety and effectiveness of drugs."[42] In addition, neither HCPs nor state regulators were mentioned among the eight factors Congress instructed the DEA and HHS to consider when making scheduling findings under the CSA.[43] Those factors instead appear to emphasize scientific evidence.[44] Furthermore, regarding such evidence, the DEA has repeatedly intoned that research that is not good enough to demonstrate safety and efficacy under the FDCA is likewise not good enough to demonstrate CAMU under the CSA:

> 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.[45]

In conjunction with the DEA's CAMU requirement discussed above, the RCT requirement has stymied every past petition to reschedule marijuana because advocates have yet to complete even a single study demonstrating marijuana's medical efficacy that satisfies the lofty standards for RCTs.[46] As I have written elsewhere:

> In past scheduling decisions, HHS reviewed hundreds of scientific studies on marijuana's therapeutic benefits and concluded that not a single one met all the criteria of a RCT. 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.[47]

Simply put, no RCTs, no CAMU—and no CAMU, no rescheduling.

C. CAMU Based on Experience

In October 2022, President Joseph R. Biden asked the DEA and HHS to conduct another review of marijuana's scheduling under the CSA.[48] Eleven months later, HHS forwarded its scientific and medical evaluation to the DEA.

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42. 2016 Scheduling Decision, *supra* note 6, at 53701.
43. *See supra* note 30 (listing the factors).
44. *See supra* note 30.
45. 1992 Scheduling Decision, *supra* note 6, at 10505 (citations omitted).
46. *See, e.g.*, 2016 Scheduling Decision, *supra* note 6, at 53701 ("[N]o published studies conducted with marijuana meet the criteria of an adequate and well-controlled efficacy study."); 2011 Scheduling Decision, *supra* note 6, at 40579 (finding that "well-controlled, well-designed, well-conducted, and well-documented scientific studies" involving marijuana "have not been performed").
47. Mikos, *supra* note 3 (manuscript at 11) (footnotes and citations omitted).
48. *See* Presidential Statement on Marijuana Reform, *supra* note 7.

In a sharp break from every past evaluation either agency had conducted, HHS concluded that marijuana has a CAMU and thus could be rescheduled.[49] In a pivotal move, the agency refused to apply the DEA's science-focused CAMU test. Instead, HHS devised a new CAMU test that considers both practical experience and science. Here is the agency's synopsis of the new two-part test:

> Under Part 1 of the CAMU test, the [agency] considered whether there is widespread current experience with medical use of marijuana in the United States by licensed HCPs operating in accordance with implemented state-authorized programs, where such medical use is recognized by entities that regulate the practice of medicine under these state jurisdictions. Part 2 of the CAMU test . . . evaluated whether there exists some credible scientific support for at least one of the medical conditions for which the Part 1 test is satisfied.[50]

The new test departs from the DEA's CAMU test in two notable ways. First, "Part 1" of HHS's new CAMU test puts significant weight on the actions of HCPs and state regulators. Recall that the DEA had previously dismissed these actors as irrelevant for scheduling, because neither had the requisite expertise to judge the efficacy of a drug and because Congress expected the federal agencies to make their own independent assessments.[51]

When it delivered its evaluation and recommendation to the DEA in August 2023, HHS did not explain why it was using a new test; indeed, it did not even acknowledge that it was doing anything differently than what the agencies had always done.[52] But in April 2024, the OLC in the U.S. Department of Justice (DOJ) issued a legal opinion defending HHS's new CAMU test, effectively ordering the DEA to accept it.[53]

In relevant part, the OLC concluded that the DEA's past refusal to consider the actions of HCPs and state regulators "is at odds with the plain meaning" of the CSA.[54] The OLC explained:

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49. *See generally* BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7.

50. *Id.* at 2.

51. *See supra* notes 42–43 and accompanying text.

52. *See generally* BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7.

53. *See* Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C., 2024 WL 2412009 (Apr. 11, 2024). It appears the OLC had to intervene because the DEA objected to HHS's CAMU test (among other matters). *See, e.g.*, David Pozen, *Reading the Tea Leaves on Marijuana Rescheduling*, BALKINIZATION (May 20, 2024, 4:07 PM), https://balkin.blogspot.com/2024/05/reading-tea-leaves-on-marijuana.html [https://perma.cc/X6UP-2U8R]; Mikos, *supra* note 3 (manuscript at 14–18) (articulating possible DEA objections to the new CAMU test).

54. Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 14 ("[I]gnoring widespread clinical experience with a drug that is sanctioned by state medical licensing regulators when evaluating whether a drug has a CAMU is at odds with the plain meaning of section 812(b)."). The OLC also noted that the language of the FDCA did not closely track the language of the CSA, suggesting the DEA had erred in concluding that the CSA's CAMU criterion was based on the FDCA's requirements for new drug approval. *Id.* at 15–16.

> DEA's approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard [for CAMU]. At the time the CSA was adopted (and as is still true today) the word "accepted" meant "widely used or found" or "generally approved." And the focus on "medical use" suggests that the relevant inquiry is whether the medical community has accepted that a drug has a "use in treatment."
>
> Any examination of whether the medical community "accept[s]" that a drug has a "use in treatment," . . . naturally requires an examination of what licensed health care practitioners are actually doing . . . . Moreover, an understanding of what the medical community accepts would also naturally require consideration of the views of the principal regulators of the medical profession: state entities that license and police healthcare practitioners.[55]

On this view, "currently accepted medical use" means there is "widespread agreement within the medical community that using the drug would be a reasonable treatment option,"[56] and not, as the DEA claimed, that the drug is FDCA compliant. So understood, the OLC reasoned that "the actual recommendations of practitioners made under applicable regulatory guidelines constitute strong evidence of whether the medical community understands a drug to be a reasonable treatment option."[57] The OLC noted that satisfying the DEA's CAMU test would also demonstrate widespread agreement within the medical community, but it was not the only way to do so.[58]

In its basis for recommendation, HHS listed three specific factors that would establish widespread agreement within the medical community that use of a drug is a reasonable treatment option:

> a) Whether a substantial number of HCPs have gained clinical experience with at least one specific medical use of the substance under existing and implemented state authorized programs;
>
> b) Whether a substantial number of entities that regulate the practice of medicine recognize at least one specific medical use of the substance; and
>
> c) Whether an HCPs' clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses and longer-term toxicities and potential harms of the substance when used under medical supervision.[59]

HHS found that marijuana satisfied each of these factors. The agency noted that more than 30,000 HCPs had recommended marijuana to more than six million patients enrolled in state medical marijuana programs.[60]

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55. *Id.* at 13 (citations omitted).
56. *Id.* at 18–19.
57. *Id.* at 18.
58. *See id.* at 14.
59. DEP'T OF HEALTH & HUM. SERVS., *Part 1 Analysis*, *in* BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7, at 2.
60. *Id.* at 1.

Similarly impressive, thirty-eight states had authorized the medical use of marijuana (so far).[61] Finally, HHS reported that eight states had been operating their medical marijuana programs for more than twenty years, and that many of those states required HCPs to have an "established, bona-fide relationship" with their patients before recommending marijuana to them.[62] To the agency, these latter facts demonstrated that clinical experience with medical marijuana was not only widespread (per "Part 1(a)" and "1(b)" of its test) but also long-term and extensive (as required by "Part 1(c)").[63]

In a second break from the DEA CAMU test, the HHS test markedly lowers the quantum and/or quality of scientific research needed to show that a drug has a CAMU, at least when the agency has determined there is widespread clinical experience with the drug under Part 1. Recall that the DEA has made the existence of RCTs the sine qua non for demonstrating that a drug has a CAMU. But "Part 2" of the new HHS test instead requires only "*some credible scientific support*" for the medical use of a drug.[64] HHS makes it clear that RCTs are not required under the new test. For example, in describing what it takes to demonstrate "some credible scientific support," HHS indicated that "favorable clinical studies of the medical use of marijuana, *although not necessarily adequate and well-controlled clinical studies* that would support approval of a [new drug application (NDA)]," would do the job.[65]

This change in scientific standards was key to enabling the agency's scheduling recommendation. Had the agency applied the same standard the DEA uses, it would have had to conclude that marijuana (still) lacks a CAMU, and thus, would have to remain on Schedule I. Despite the publication of hundreds of new scientific papers in the eight years since the agency had completed its last marijuana scheduling evaluation, HHS still could not find even a single RCT demonstrating marijuana's medical utility.[66] In its 2023 basis for recommendation, HHS rattled off a list of shortcomings in the research it reviewed. It repeatedly described study findings as "mixed," "inconclusive," and hampered by a host of all-too-familiar methodological limitations, including small subject pools, missing dosing information, and a lack of double-blinding, among others.[67]

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61. *Id.* at 4.

62. *Id.* at 5.

63. *Id.* at 5–6.

64. *Id.* at 2 (emphasis added). The new test also drops the other four findings that are required by the DEA's CAMU test. Those requirements are listed in note 40.

65. BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7, at 25 (emphasis added).

66. *Id.* at 24–28.

67. *See generally id.* An outside team of researchers from the University of Florida assisted HHS by identifying relevant studies and giving each one a "quality of evidence" rating. *See* FDA'S CTR. FOR DRUG EVALUATION & RSCH., *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*, *in* BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7, at 35–70 tbls. 17–49 (2023).

The HHS's bottom-line conclusion was hardly enthusiastic. In one of the key lines in the agency's basis for recommendation, it states that, "there is low to moderate quality evidence supporting efficacy of marijuana as medical treatment for outcomes in anorexia, nausea and vomiting, and PTSD."[68] Simply put, if one thought there had been a major scientific breakthrough in the years since the federal government had last considered and rejected rescheduling marijuana in 2016—studies that finally met the DEA's lofty standards for demonstrating CAMU, one would be sorely disappointed.

But new test, new conclusion. While "low to moderate quality evidence" would not pass muster under the DEA's CAMU test, it was plainly good enough to satisfy HHS's new CAMU test. In applying Part 2 of its new test, the agency concluded that, "[o]n balance, the available data indicate that there is some credible scientific support for the use of marijuana in the treatment of pain, anorexia related to a medical condition, and nausea and vomiting, with varying degrees of support and consistency of findings."[69] In other words, "low to moderate quality evidence" constitutes "some credible scientific support."

Somewhat awkwardly, given its assertion that CAMU means widespread agreement among HCPs and state regulators, the OLC acknowledged that any CAMU test must also consider the views of scientists. It based this conclusion on the fact that many of the eight factors Congress expressly instructed the DEA and HHS to consider in scheduling decisions "inherently require consideration of scientific evidence."[70] At the same time, however, the OLC asserted that the CSA (unlike the FDCA) did not require "a particular threshold of scientific support to conclude that a drug has a CAMU."[71] For this reason, it found that Part 2 of HHS's test constituted a reasonable interpretation of the scientific proof required by the CSA, even though it differed (significantly) from the DEA's interpretation.[72]

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 through V). 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).[73] 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

68. BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7, at 26 (footnote omitted).

69. *Id.* at 28.

70. Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 17. The eight factors are listed in note 30.

71. Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 19.

72. *Id.*

73. BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7, at 5.

and less severe than some other comparator drugs."[74] Put more simply, the agency concluded that although marijuana is dangerous, it is not as dangerous as many other controlled (and uncontrolled) substances. Accordingly, HHS concluded that marijuana belonged on Schedule III, alongside a variety of other (legal) medications like ketamine, Tylenol with Codeine, and Suboxone.[75]

In May 2024, after HHS delivered its evaluation and recommendation, and after the OLC endorsed HHS's reinterpretation of CAMU, the DEA promulgated a proposed final rule to move marijuana to Schedule III.[76]

Although the DEA's rule is based on HHS's new two-part CAMU test, it is important to note that DEA's own CAMU test is still in effect. In other words, petitioners now have two distinct pathways to establishing CAMU: (1) demonstrate that a drug is FDCA compliant (the DEA test), or (2) demonstrate that a drug has widespread acceptance in the medical community (the HHS test).[77] In the parts that follow, I critique both agency CAMU tests for imposing impossible demands, but I also propose a novel way to enable removing drugs from Schedule I that does not require satisfying or revising the tests.

II. THE TYRANNIES OF SCHEDULING

Although the competing CAMU tests championed by the DEA and HHS emphasize different evidence (science and experience), each test imposes one or more requirements that are nearly impossible for any Schedule I drug other than marijuana to satisfy. Part II.A illuminates the daunting challenge posed by assembling the gold-standard scientific proof demanded by the DEA's CAMU test. I refer to this challenge as the "Tyranny of the Scientists." Part II.B then illuminates the distinct challenges posed by building the widespread agreement demanded by HHS's CAMU test. I refer to these challenges as the "Tyranny of the Majority."

A. The DEA and the Tyranny of the Scientists

The DEA's CAMU test is tyrannical because it requires a very specific type of evidence (RCTs) that is almost impossible to generate, especially when a drug is already on Schedule I. Conducting successful RCTs is difficult enough even without considering the research barriers the CSA imposes on Schedule I drugs. Among other things, RCTs must include large numbers of subjects, they must be well controlled (e.g., double-blinded, with standardized dosage), and they must be well executed.[78] Due to these

74. *Id.* at 7–8.

75. *Id.* at 5.

76. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597 (proposed May 16, 2024) (to be codified at 21 C.F.R. pt. 1308).

77. The OLC expressly indicated that the DEA's CAMU tests were still valid; they were just no longer the only way to establish CAMU. *See* Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 4.

78. *See supra* text accompanying note 41.

requirements, the process of completing even a single RCT takes several years.[79] And even after investing the time and resources to complete a trial, there is no guarantee it will be successful—i.e., that it will demonstrate with a sufficient level of statistical confidence that the drug actually works as expected.[80]

But the challenges of conducting RCTs are greatly magnified for Schedule I drugs. The 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).[81] Among other things, the extra regulatory requirements applicable to Schedule I drugs include

> mandatory FDA approval of research . . . ; 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.[82]

It should come as no surprise, then, that very few Schedule I drugs have ever been able to satisfy the DEA's demanding CAMU test.[83] GW Pharmaceutical's Epidiolex is the most recent example.[84] The active ingredient in Epidiolex is cannabidiol (CBD), a chemical produced by the cannabis plant.[85] Based on company-sponsored RCTs demonstrating that the drug is effective at treating severe forms of childhood epilepsy, Epidiolex

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79. *See* 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, 282 (1998) (calculating median time to completion at 5.5 years).

80. For analyses of the success rates of new drug trials, see Katarzyna Smietana, Marcin Siatkowski & Martin Møller, *Trends in Clinical Success Rates*, 15 NATURE REVS. DRUG DISCOVERY 379 (2016) (reporting overall success rates between 10 and 29 percent).

81. *See, e.g.*, David J. Nutt, Leslie A. King & David E. Nichols, *Effects of Schedule I Drug Laws on Neuroscience Research and Treatment Innovation*, 14 NATURE REVS. NEUROSCIENCE 577 (2013).

82. Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 896 (1st Cir. 1987) (citations omitted); *see also* Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 352–58 (2013). Notably, just prior to the DEA's rescheduling announcement, Congress relaxed some of the controls that the CSA had imposed on scientific research involving marijuana, thus making the DEA's CAMU test less tyrannical for that drug. *See* Medical Marijuana and Cannabidiol Research Expansion Act of 2022, Pub. L. No. 117-215, 136 Stat. 2257 (codified as amended in scattered sections of 21 and 42 U.S.C.). However, Congress did not relax controls on research involving any other Schedule I drugs.

83. *See* DRUG ENF'T ADMIN., SCHEDULING ACTIONS - CHRONOLOGICAL ORDER (2024), https://www.deadiversion.usdoj.gov/schedules/orangebook/b_sched_chron.pdf [https://perma.cc/T2HY-KYV9] (listing all past administrative scheduling actions).

84. Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements, 83 Fed. Reg. 48950, 48951 (Sept. 28, 2018) (to be codified at 21 C.F.R. pts. 1308, 1312).

85. *Id.*

was approved by the FDA in 2018.[86] When those RCTs were being conducted, the CBD in Epidiolex was a Schedule I drug (this may be why at least some of the research on the drug was completed outside the United States).[87] Following the FDA's approval, however, the DEA recognized that Epidiolex has a CAMU and moved the drug all the way down to Schedule V, reflecting its very low potential for abuse and dependence liability.[88] But apart from Epidiolex, very few drugs have been able to obtain FDA approval after they were placed on Schedule I.[89]

By contrast, it is notable that several drugs have been approved by the FDA *after* Congress placed them on one of the CSA's *lower* schedules. For example, Congress placed cocaine on Schedule II in 1970, but the drug was approved by the FDA for use as an anesthetic in 2017; and Congress placed phenobarbital on Schedule IV in 1970, but that drug was approved by the FDA for the treatment of childhood epilepsy in 2022.[90] Neither of these drugs, of course, were ever subject to the onerous research controls the CSA imposes on Schedule I drugs, making it comparatively easy to test their therapeutic potential.

Because it makes it extraordinarily difficult to reschedule a drug once the drug is assigned to Schedule I, the DEA CAMU test is tyrannical. I label this

86. Press Release, FDA, FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (June 25, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms [https://perma.cc/922E-TEPV].

87. *See, e.g.*, Elizabeth A Thiele, Eric D Marsh, Jacqueline A French, Maria Mazurkiewicz-Beldzinska, Selim R Benbadis, Charuta Joshi, Paul D Lyons, Adam Taylor, Claire Roberts & Kenneth Sommerville, *Cannabidiol in Patients with Seizures Associated with Lennox-Gastaut Syndrome (GWPCARE4): A Randomised, Double-Blind, Placebo-Controlled Phase 3 Trial*, 391 THE LANCET 1085, 1085 (2018) (noting that RCT on CBD had been conducted at clinical sites in the United States and Europe).

88. Press Release, DEA, FDA-Approved Drug Epidiolex Placed in Schedule V of Controlled Substance Act (Sept. 27, 2018), https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act [https://perma.cc/TY3X-5XXS]. After the DEA rescheduled Epidiolex, Congress amended the CSA's definition of "marihuana" to exclude low THC cannabis, which it rechristened "hemp." *See* Robert A. Mikos, *New Congressional Farm Bill Legalizes Some Marijuana*, VANDERBILT UNIV: MARIJUANA L., POL'Y, & AUTH. BLOG (Dec. 13, 2018), https://my.vanderbilt.edu/marijuanalaw/2018/12/new-congressional-farm-bill-legalizes-some-marijuana/ [https://perma.cc/XCN6-HGCZ]. Because Epidiolex can be made from hemp, and because hemp was descheduled, the DEA decided to deschedule Epidiolex as well in 2020. *See* Mary Chapman, *Epidiolex Now Available in the US as a Non-controlled Substance*, DRAVET SYNDROME NEWS (Apr. 7, 2020), https://dravetsyndromenews.com/news/epidiolex-available-united-states-non-controlled-substance/ [https://perma.cc/N2RB-L5WA].

89. The other drugs are difenoxin with atrophine (moved to Schedules IV and V in 1978 following FDA approval), sufentanil (moved to Schedule II in 1984 following FDA approval), dronabinol (moved to Schedule II in 1986 following FDA approval), alfentanil (moved to Schedule II in 1987 following FDA approval), and levo-alphacetylmethadol (moved to Schedule II in 1993 following FDA approval). *See* Drug Enf't Admin., *supra* note 83.

90. *See Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book*, FDA (Aug. 9, 2024), https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book [https://perma.cc/Y7WV-E3TT].

the "Tyranny of the Scientists" because it emphasizes gold-standard scientific research (RCTs) to the exclusion of all other types of evidence that could potentially demonstrate that a drug has beneficial therapeutic uses—i.e., other evidence (e.g., real-world experience or small studies) that could help the agency make more accurate scheduling decisions.[91]

If Congress had more clearly indicated a desire to base CAMU on the FDCA requirements for new drug approval, we would be stuck with the DEA's CAMU test. But as the OLC and others have explained, the DEA's CAMU test does not necessarily reflect the will of Congress, and we are not bound to accept it.

B. HHS and the Tyranny of the Majority

At first glance, HHS's new two-part CAMU test appears less tyrannical than the DEA's CAMU test. For one thing, the HHS test considers a broader range of evidence—both scientific and experiential—to determine whether a drug has a CAMU, including the decisions of HCPs and state regulators, as well as scientific studies that do not meet all the lofty standards for RCTs. The new test also appears less tyrannical because we already have one case (marijuana) demonstrating it can be satisfied.

But on closer inspection, HHS's new two-part test is no less tyrannical than the test the DEA has championed. HHS simply imposes a new form of tyranny—the "Tyranny of the Majority"—in the place of the DEA's Tyranny of the Scientists.

This Tyranny of the Majority emerges from Part 1 of the HHS test, which requires demonstrating "widespread agreement within the medical community that using the drug would be a reasonable treatment option."[92] Achieving such consensus poses two daunting challenges for any Schedule I drug.

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91. In this sense, the "Tyranny of the Scientists" resembles the "Tyranny of the .05" in the social sciences. The Tyranny of the .05 describes the orthodox view that empirical findings must have a p-value of <.05 to wield any influence over decision-making. *See, e.g.*, Andreas Stang, Charles Poole & Oliver Kuss, *The Ongoing Tyranny of Statistical Significance Testing in Biomedical Research*, 25 EUR. J. EPIDEMIOLOGY 225, 226 (2010) ("Studies with $P \geq 0.05$ are commonly considered as failed studies."); Geoffrey R. Loftus & E.F. Loftus, *On the Tyranny of Hypothesis Testing in the Social Sciences*, 36 CONTEMP. PSYCH. 102, 104 (1991) (describing orthodox view as "if $p < .05$ (or so) an effect is real; otherwise, it is not"). This myopic focus on a single measure of validity can lead decision-makers to ignore relevant information that might help them make better decisions. The American Statistical Association's statement on p-values nicely captures the concern:

> Practices that reduce data analysis or scientific inference to mechanical "bright-line" rules (such as "$p < 0.05$") for justifying scientific claims or conclusions can lead to erroneous beliefs and poor decision making. A conclusion does not immediately become "true" on one side of the divide and "false" on the other.

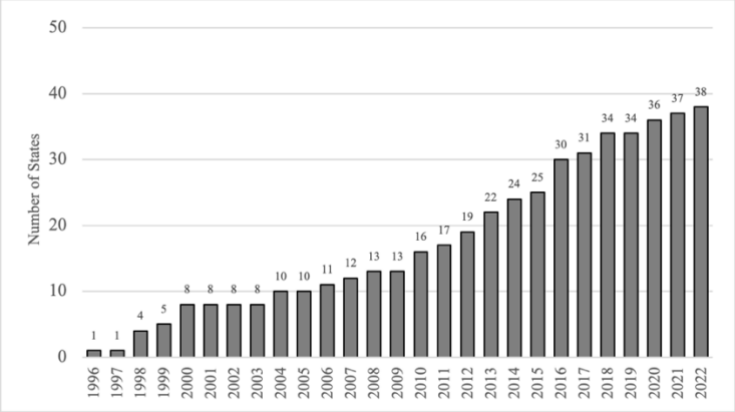
Ronald L. Wasserstein & Nicole A. Lazar, *The ASA Statement on P-values: Context, Process, and Purpose*, 70 AM. STATISTICIAN 129, 131 (2016).

92. Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 18–19.

First, there is a political challenge. The OLC downplays the role of politics in Part 1 by asking "whether a 'substantial number' of *entities that regulate the practice of medicine* have authorized the use of a drug for medical purposes,"[93] suggesting that nonpolitical administrative bodies—like state medical boards[94]—are primarily responsible for legalizing the use of a drug under state law. But the "entities that license and police healthcare practitioners" have no power to authorize medical use of a substance the state has forbidden. Instead, such authorization must come from the people themselves or their elected legislators. Indeed, every state that has legalized the medical use of marijuana has done so through the political process.[95] It would thus be more accurate to say that Part 1 of the HHS CAMU test requires widespread agreement *among the general electorate* that a drug is a reasonable treatment option. At bottom, this means that advocates must convince a majority of voters in a substantial number of states to support legalizing medical use of a drug.

For this reason alone, the HHS CAMU test may be no easier to satisfy than the DEA's science-focused CAMU test. I recognize, of course, that advocates have succeeded in convincing majorities in a substantial number of states (thirty-eight) to embrace medical marijuana reforms. But it should not be forgotten that this remarkable feat took decades to accomplish.

Figure 1: States Authorizing Medical Use of Marijuana[96]



93. *Id.* at 18 (emphasis added).

94. *Id.* at 13.

95. In the vast majority of these states, authorization came through a ballot initiative approved by the people; in the remainder, it came through legislation passed by the state legislature. *See State Medical Cannabis Laws*, NAT'L CONF. OF STATE LEGISLATURES, https://www.ncsl.org/health/state-medical-cannabis-laws [https://perma.cc/8H4U-VKMB] (July 12, 2024) (see Table 1). At most, administrative bodies have played a small role in expanding some medical marijuana reforms that were enacted through the political process, by authorizing the use of the drug to treat additional conditions. *See* DEP'T OF HEALTH & HUM. SERVS., *supra* note 59, at 3–5; Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 10.

96. *See State Medical Cannabis Laws*, *supra* note 95.

After convincing California to pass the nation's first medical marijuana reform in 1996, it took advocates another twenty-six years to convince the thirty-eighth state (Mississippi) to authorize medical use of the drug (as seen in Figure 1).

In any event, the fact that marijuana eventually achieved widespread acceptance among the general electorate does not guarantee that any other Schedule I drug could replicate this feat. Popular support for the legalization of other Schedule I drugs lags far behind support for legalizing marijuana. Consider psychedelics like psilocybin, MDMA, and LSD. Despite growing interest in the therapeutic value of such substances and talk of a psychedelics renaissance,[97] less than a quarter of all Americans support legalizing psychedelics like psilocybin.[98] By comparison, 90 percent of Americans support legalizing medical marijuana.[99] It is possible that the public "may eventually warm to psychedelics," but a general lack of familiarity with these substances complicates the task of convincing voters to legalize their use.[100] Although nearly half of Americans have some firsthand knowledge of the benefits and harms of marijuana use, only a trifling percentage of Americans have ever tried any psychedelic substance.[101]

Second, even if advocates can convince a substantial number of states to authorize medical use of a drug, they still need to accumulate widespread clinical experience with the drug (another factor in the HHS CAMU test). In part, this requires convincing a substantial number of HCPs to recommend the drug to their patients.[102] But it also implicitly requires obtaining consent from other actors outside the medical community. Namely, patients must be willing to try the drug, and someone must be willing to supply it to them.

Convincing all these actors to recommend, use, and supply a Schedule I drug poses a serious challenge. Each of these activities exposes the actor to harsh federal sanctions. For example, physicians can lose their DEA registration if they prescribe a Schedule I drug to a patient, and suppliers can be arrested, prosecuted, and imprisoned for years for making or distributing a Schedule I drug.[103] The threat of such sanctions makes it more difficult—

97. *See, e.g.*, Mason Marks, *Cognitive Content Moderation: Freedom of Thought and the First Amendment Right to Receive Subconscious Information*, 76 FLA. L. REV. 469 (2024).

98. *See* Robert A. Mikos, *Observations on 25 Years of Cannabis Law Reforms and Their Implications for the Psychedelic Renaissance in the United States*, 18 ANN. REV. L. & SOC. SCI. 155, 159 (2022) (surveying polling data on psychedelics reforms).

99. *See* Ted Van Green, *Americans Overwhelmingly Say Marijuana Should Be Legal for Medical or Recreational Use*, PEW RSCH. CTR. (Nov. 22, 2022), https://www.pewresearch.org/short-reads/2022/11/22/americans-overwhelmingly-say-marijuana-should-be-legal-for-medical-or-recreational-use/ [https://perma.cc/EZB6-F888].

100. Mikos, *supra* note 98, at 159.

101. *See id.* ("Drug survey data show that only 2.2% of Americans age 12 or older used any psychedelic . . . in 2019, a far cry from the 18% who used marijuana the same year.").

102. *See* Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 18.

103. *See* Robert A. Mikos, *On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power to Legalize Federal Crime*, 62 VAND. L. REV. 1421, 1465–66 (2009)

if not impossible—to accumulate the widespread clinical experience HHS requires to show that a drug has a CAMU. Indeed, the U.S. Court of Appeals for the District of Columbia Circuit once rejected a proposed CAMU test that demanded "widespread therapeutic use" of a drug precisely because that demand was "logically impossible to satisfy" for Schedule I drugs.[104] As the court observed, "[o]ne of the very purposes in placing a drug in Schedule I is to raise significant barriers to prevent doctors from obtaining the drugs too easily."[105]

Although marijuana advocates were able to overcome these roadblocks,[106] federal law arguably poses a less daunting hurdle for marijuana than it does for other Schedule I drugs. Consider the supply chain. The cannabis plant is widely available; it can be grown almost anywhere by almost anyone.[107] Indeed, many patients in state medical marijuana programs grow their own. The ease of entry into the market and diffusion of suppliers make it difficult for the federal government to disrupt the supply chain for marijuana.[108] But the federal government might have more success limiting the supply of Schedule I drugs like LSD and MDMA, which require more specialized equipment and skills to produce.

The upshot is that no other Schedule I drug is likely to satisfy the HHS CAMU test anytime soon (if ever). A cynic might even say that HHS designed its new CAMU test to ensure that marijuana—but only marijuana—could be rescheduled. Consider that HHS was under tremendous pressure to reschedule marijuana. The idea has broad public support—as noted above, 90 percent of Americans now support legalization for medical purposes.[109] Furthermore, even before he asked the agency to review marijuana's scheduling, President Biden had promised the nation that he would reschedule marijuana.[110] Because marijuana reform proposals had stalled in

(discussing federal sanctions levied against physicians who recommend marijuana to patients); *id.* at 1435–36 (discussing federal penalties for trafficking medical marijuana).

104. All. for Cannabis Therapeutics v. Drug Enf't Admin. (ACT I), 930 F.2d 936, 937 (D.C. Cir. 1991). The demand was part of an eight-part CAMU test the DEA proposed for drugs that had not been approved by the FDA. In response to the ruling in *ACT I*, the DEA dropped the three elements of that test that demanded widespread therapeutic use, leaving the five-part CAMU test the agency uses today for unapproved drugs. *See* All. for Cannabis Therapeutics v. Drug Enf't Admin. (ACT II), 15 F.3d 1131, 1133–35 (D.C. Cir. 1994) (discussing evolution of the DEA's five-part CAMU test).

105. *ACT I*, 930 F.2d at 940.

106. For a discussion of how states circumvented some of the obstacles the federal government tried to throw in the way of state medical marijuana programs, see Robert A. Mikos, *The Evolving Federal Response to State Marijuana Reforms*, 26 WIDENER L. REV. 1 (2020).

107. *See* Mikos, *supra* note 103, at 1467–68.

108. *See id.*

109. *See supra* note 99 and accompanying text.

110. *See* Arlette Saenz, *Joe Biden Supports Decriminalizing Marijuana, Stops Short of Calling for Legalization*, CNN (May 16, 2019, 2:39 PM), https://www.cnn.com/2019/05/16/politics/joe-biden-marijuana-decriminalization/index.html [https://perma.cc/RW5B-4ELG] (noting that then-candidate Biden "would seek to make it easier to conduct research on marijuana's positive and negative health impacts by rescheduling it").

Congress, it was obvious that HHS and HHS alone could deliver on that promise.[111]

In the face of such pressure, HHS realistically had no choice but to recommend rescheduling marijuana. But to do that, the agency first needed to find that marijuana has a CAMU.[112] Since it was apparent from the outset that marijuana still could not satisfy the DEA's CAMU test, HHS had to devise a new test that marijuana could satisfy.

To that end, HHS could have simply lowered the quantum of scientific evidence needed to demonstrate CAMU. In other words, it could have declared that CAMU may be demonstrated with "some credible scientific evidence" showing the drug works, without also demanding "widespread agreement" among the medical community. After all, the OLC concluded that the CSA does not require "a particular threshold of scientific support to conclude that a drug has a CAMU."[113] Neither does the CSA necessarily *require* agreement among HCPs or state regulators. The DEA's CAMU test ignores these actors, but the OLC confirmed that test may still be used.[114]

I suspect, however, that HHS did not necessarily want to allow any other drug to be removed from Schedule I. It was certainly under no pressure to do so; as noted above, there is little political support today for legalizing other Schedule I drugs. Thus, HHS may have required widespread clinical experience to ensure that its new CAMU test would only ever be used once—to reschedule marijuana. Indeed, Part 1 of its new CAMU seems almost custom designed with that purpose in mind.

But regardless of the agency's motivations, the fact remains that the new CAMU test is unlikely to help any drug besides marijuana escape Schedule I. For that reason, it is no less tyrannical than the DEA's science-focused CAMU test.

The problems I have illuminated here may be of little concern to marijuana advocates—marijuana will soon be removed from Schedule I, giving those advocates what they have long sought. But the CSA applies to 400 other substances as well, including over 150 other drugs now on Schedule I. Thus, even though the HHS CAMU test enables the rescheduling of marijuana, all other drugs remain subject to the Tyrannies of Scheduling.

III. A NEW WAY FORWARD

At this point, it would be tempting to suggest that the best way to combat the Tyrannies of Scheduling would be to devise a less tyrannical CAMU test. But that is easier said than done. Recall that the DEA spent decades

111. *See* Mikos, *supra* note 3 (manuscript at 33–34).

112. *See supra* Part I.A (discussing the DEA's insistence that CAMU is required for rescheduling). In the alternative, the agency could have rejected the CAMU requirement, as I suggest in Part III.

113. Questions Related to the Potential Rescheduling of Marijuana, *supra* note 53, at 19.

114. *See supra* note 77 and accompanying text (noting ongoing availability of the DEA's CAMU test).

developing and revising its science-focused CAMU test.[115] There is no guarantee that the agency (or anyone else) could come up with anything better in the short term, as the hastily developed and no-less-tyrannical HHS CAMU test arguably demonstrates.

In this part, however, I propose an alternative path forward, a way to soften the Tyrannies of Scheduling that does not require devising a new CAMU test. Namely, the DEA should drop its CAMU requirement. Without that requirement, the agency could move a drug off Schedule I even if it determined the drug has "no currently accepted medical use" (however it defined that phrase). Although my proposal would not make it any easier to demonstrate CAMU, it would reduce the influence the agencies' tyrannical CAMU tests now wield over scheduling and thereby foster more rational scheduling decisions.

The sections below make the case for dropping the CAMU requirement and briefly outline the role that CAMU determinations should play in the absence of that requirement. Part III.A begins by showing that there is no textual basis for prioritizing currently accepted medical use above all other scheduling considerations. Indeed, if anything, the text of the CSA suggests CAMU determinations should play a far more subdued role in scheduling decisions than they do now. Part III.B then demonstrates that there is also no policy justification for the CAMU requirement. Simply put, CAMU determinations alone do not provide enough information to make sensible decisions regarding how a drug should be controlled. Lastly, Part III.C discusses the role that CAMU should play in agency scheduling decisions once the DEA drops its misguided CAMU requirement.

A. The CAMU Requirement Is Contrary to the Text of the CSA

The CAMU requirement is contrary to the plain language of the CSA. Most obviously, the requirement contravenes Congress's express command that a drug "may not be placed in any schedule unless the *findings* required for such schedule are made."[116] As discussed above, Congress expressly enumerated *three* findings for placing a drug on Schedule I:

> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.[117]

The DEA disregards this plain language by claiming that one of these findings, (B) alone, is enough to place a drug on Schedule I. To be sure, the agency suggests it is unnecessary to consider (C) separately because a drug

115. *See supra* Part I.B.
116. 21 U.S.C. § 812(b) (emphasis added).
117. *Id.* § 812(b)(1).

that has "no CAMU" necessarily also lacks "accepted safety for use."[118] In other words, the agency has combined "lack of accepted safety for use" and "no currently accepted medical use" into a single inquiry, arguably making it unnecessary to consider each of them separately. More troublingly, however, the agency has claimed that the other finding Congress required for Schedule I—that a drug has a "high potential for abuse"—is simply irrelevant. In other words, the agency does not claim that the lack of a "currently accepted medical use" also necessarily implies that a drug has a "high potential for abuse."[119] Instead, the agency claims that Congress simply did not care about the abuse potential of drugs that have no CAMU—it wanted all such drugs to be subject to the strictest possible controls under the CSA, notwithstanding its declaration in § 812(b) that Schedule I drugs must exhibit a "high potential for abuse."[120]

The DEA has no authority to disregard the terms of the CSA in this way.[121] Indeed, in a very early case under the CSA, the D.C. Circuit criticized the CAMU requirement for ignoring the plain language of the statute. In *National Organization for the Reform of Marijuana Laws (NORML) v. Drug Enforcement Administration*,[122] the court ordered the DEA to reconsider its decision to reject the very first petition to reschedule marijuana.[123] In that decision, the DEA found that marijuana lacked a CAMU, and on that basis alone, the agency concluded that marijuana had to remain on Schedule I; it did not even bother to analyze the other scheduling criteria.[124] But the *NORML* court criticized the agency's approach, observing that, "[t]o treat

118. According to the agency, "the ultimate determination of whether a drug is safe for a specific use is not a distinct issue [from CAMU]. 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." 1992 Scheduling Decision, *supra* note 6, at 10504; *see also* 2016 Scheduling Decision, *supra* note 6, at 53701 ("[I]n the absence of an accepted therapeutic indication which can be weighed against marijuana's risks, marijuana does not satisfy the element for having adequate safety studies such that experts may conclude that it is safe for treating a specific, recognized disorder.").

119. To be sure, the two criteria are likely related, because drug abuse is defined in part as the nonmedical use of a drug. *See supra* note 20. A finding that a drug has "no CAMU" would arguably signify that all use of that drug is nonmedical. But abuse potential also hinges on other considerations, like the frequency with which use of the drug causes adverse outcomes (e.g., psychosis, fatal overdose). *See* BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7, at 6–8. The finding that a drug has no CAMU does not in any way signify that such adverse outcomes are common or serious enough to warrant the conclusion that the drug has a high potential for abuse.

120. 21 U.S.C. § 812(b)(1).

121. As the Supreme Court has warned, "no deference is due to agency interpretations at odds with the plain language of the statute itself. Even contemporaneous and longstanding agency interpretations must fall to the extent they conflict with statutory language." Pub. Emps. Ret. Sys. v. Betts, 492 U.S. 158, 171 (1989); *see also* Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984), *overruled on other grounds by* Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244 (2024) (holding that an agency "must give effect to the unambiguously expressed intent of Congress").

122. 559 F.2d 735 (D.C. Cir. 1977).

123. *Id.* at 757.

124. *Id.* at 743.

medical use as the controlling factor in classification decisions is to render irrelevant the other 'findings' required by Section [812(b)(1)]. The legislative history of the CSA indicates that medical use is but one factor to be considered, and by no means the most important one."[125] The court thus ordered the DEA to conduct a new (and more thorough) evaluation of all the scheduling criteria, including but not limited to, CAMU.[126]

125. *Id.* at 748. The idea that a CAMU might be required for a drug to be placed below Schedule I was raised in a few isolated instances in the voluminous legislative history. Perhaps most notably, in a March 1970 Senate committee hearing, the Director of the Bureau of Narcotics, John Ingersoll, briefly remarked that drugs with no CAMU would be placed on Schedule I under the proposed CSA, regardless of their abuse potential. Ingersoll made this remark when he was asked by Senator Peter H. Dominick to explain why marijuana was going to be placed on the same schedule as heroin, a far more dangerous substance (in Senator Dominick's view). Ingersoll replied, "The reason . . . is that marihuana has no recognized medical use. All the drugs classified in Schedule I, irrespective of the degree of danger or hazards they represent are those which are available and used only for research purposes. They have no recognized therapeutic use at all." *Federal Drug Abuse and Drug Dependence Prevention, Treatment, and Rehabilitation Act of 1970: Hearings on S. 3562 Before the Special Subcomm. on Alcoholism & Narcotics*, 91st Cong. 473 (1970) (testimony of John Ingersoll, Director, Bureau of Narcotics). Ingersoll did not elaborate, and the questioning quickly turned to other issues. But Ingersoll's brief remark apparently prompted Senator Dominick to propose an amendment to the CSA that would have explicitly allowed the Attorney General to reschedule marijuana even though the drug has no currently accepted medical use. *See* H.R. 18583, 91st Cong. (1970) (authorizing the Attorney General to "transfer between, or remove from, such schedules marijuana or tetrahydrocannabinols notwithstanding a finding that marijuana or tetrahydrocannabinols does not have a currently accepted medical use in treatment in the United States, if he determines that it is otherwise transferable or removable, as the case may be, under this section."). However, such terse allusions to a CAMU requirement are hardly enough to establish a congressional intent to place all drugs of abuse with no CAMU on Schedule I. Ingersoll's remarks (and Senator Dominick's response thereto) may simply have reflected the view of the Bureau of Narcotics, the predecessor to the DEA, rather than the view of Congress, or even any particular member of Congress. Indeed, it is notable that the DEA itself has not cited legislative history in its attempt to defend the CAMU requirement.

126. *NORML*, 559 F.2d at 757. On remand from *NORML*, the DEA once again denied the first petition to reschedule, and petitioners once again appealed the decision to the D.C. Circuit. *See* All. for Cannabis Therapeutics v. Drug Enf't Admin. (ACT II), 15 F.3d 1131 (D.C. Cir. 1994). But by that point, petitioners had conceded that marijuana has a "high potential for abuse." Brief of Respondent at 3–4, *ACT II*, 15 F.3d 1131 (Nos. 92–1168, 92–1179), 1993 WL 13650668, at *3–4 ("All parties stipulated as to marijuana's high potential for abuse . . . . The parties agreed that resolution of the primary issue, whether or not the DEA could lawfully transfer marijuana to Schedule II, depended on . . . [w]hether the marijuana plant has a currently accepted medical use in treatment in the United States."). Given this concession, the DEA had no need to reassert its claim that a drug with no CAMU had to remain on Schedule I regardless of its abuse potential. Notably, the holding in *NORML* should have precluded the agency from reviving the CAMU requirement in later scheduling decisions. Although the *NORML* court provided an alternative basis for remand—it also thought DEA's CAMU analysis was too perfunctory because it was based on a conclusory one-page letter from the Assistant Secretary for Health—alternative holdings still have preclusive effect. *Cf.* United States v. Files, 63 F.4th 920, 926 (11th Cir. 2023) ("It is well-established in this Circuit that alternative holdings 'are as binding as solitary holdings.'"). Confusingly, however, the D.C. Circuit later recited the DEA's CAMU requirement without objection. In an appeal from the DEA's rejection of the third petition to reschedule marijuana, the court stated, "Under the terms of the CSA, marijuana cannot be rescheduled to Schedules III, IV, or V without a 'currently accepted medical use.'" Ams. for Safe Access v. Drug Enf't Admin., 706 F.3d 438, 449 (D.C. Cir. 2013). But the court gave no explanation for this terse remark, which played

In later scheduling decisions, however, the DEA would resurrect the CAMU requirement. To address the *NORML* court's criticism, the agency began to suggest that its CAMU requirement was in fact based on the text of the CSA. The agency recited the same textualist argument in each of its marijuana rescheduling decisions postdating *NORML*. Here is the version of the argument that appears in the agency's 2016 marijuana scheduling decision (also quoted above):

> 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." . . . 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.[127]

Put differently, the DEA suggests that because the CSA mentions "no currently accepted medical use" only once—under Schedule I— Congress must have intended for all drugs with no currently accepted medical use to be placed on that schedule, regardless of their abuse potential and dependence liability.

But the agency's textualist defense of the CAMU requirement is deeply flawed. The key problem is that "no CAMU" is not the only finding Congress mentions only once in the CSA. Indeed, eight of the fifteen scheduling findings Congress enumerated in § 812(b) could be described as unique—i.e., associated with only one schedule. If the DEA makes two such findings for a drug (no CAMU being only one of them), the DEA's reasoning fails to explain why the drug must be placed on Schedule I as opposed to the schedule dictated by the other finding.

To illustrate the problem, consider the following simple hypothetical. Section 812(b)(3) of the CSA specifies the three findings that are required for placing a drug on Schedule III:

> (A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
>
> (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
>
> (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.[128]

The third finding is unique to Schedule III. No other schedule includes drugs that "may lead to moderate or low physical dependence or high psychological

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no part in its decision. *Id.* The remark does not suggest that the court in *Americans for Safe Access v. Drug Enforcement Administration*, 706 F.3d 438 (D.C. Cir. 2013), somehow intended to reverse its CAMU holding in *NORML*, or even that it was aware of that holding (*NORML* addressed several other complicated issues). To this day, *NORML v. Drug Enforcement Administration* remains the most thorough analysis of the DEA's CAMU requirement.

127. *See* 2016 Scheduling Decision, *supra* note 6, at 53688, 53747.

128. 21 U.S.C. § 812(b)(3).

dependence."[129] By contrast, Schedule II drugs are supposed to lead to "severe psychological or physical dependence," while Schedule IV drugs are supposed to lead to only "limited physical or psychological dependence."[130] Now, imagine the DEA determines that a given drug has both "no currently accepted medical use," a "high potential for abuse," and a "moderate or low physical dependence or high psychological dependence." According to the agency, this drug must go on Schedule I because it has no CAMU. But using the agency's textualist reasoning, one could just as easily claim this drug must go on *Schedule III*. After all, to borrow the agency's language: Congress established only one schedule, Schedule III, for drugs of abuse that "may lead to moderate or low physical dependence or high psychological dependence."[131] Thus, any attempt to assess the currently accepted medical use of the drug or its potential for abuse is inconsequential since a drug found to have a moderate or low physical dependence or high psychological dependence must be placed on Schedule III.

In short, the DEA's textualist defense of the CAMU requirement is specious. The text of the CSA simply does not support the agency's claim that Congress wanted to make "no currently accepted medical use" the lone touchstone for placing a drug on Schedule I.

In fact, other language in the CSA strongly suggests that Congress did not want the DEA to ignore abuse potential or dependence liability when placing drugs on Schedule I. Namely, § 812(b) instructs the agency to place drugs on Schedules III through V by comparing their abuse potential to that of the drugs on higher schedules.[132] The CSA describes the abuse potential of drugs on Schedules I and II in absolute terms: drugs on both schedules are supposed to have the same "high potential for abuse."[133] The CSA then instructs the DEA to place drugs on progressively lower schedules as their abuse potential declines in comparison to the drugs on the higher schedules. For example, the drugs on Schedule III are supposed to have a potential for abuse "less than the drugs or other substances in schedules I and II."[134] In turn, the drugs on Schedule IV are supposed to have a "low potential for abuse relative to the drugs or other substances in schedule III."[135] Lastly, drugs on Schedule V are supposed to have a "low potential for abuse relative to the drugs or other substances in schedule IV."[136]

But by placing drugs on Schedule I regardless of their abuse potential, the DEA's CAMU requirement threatens to distort these comparative assessments and the scheduling decisions based on them. To see why, consider the following hypothetical. Suppose the DEA places a drug on Schedule I solely because the drug has no CAMU, even though the drug's

129. *Id.* § 812(b)(3)(C).
130. *Id.* § 812(b)(2)(C), (4)(C).
131. *Id.* § 812(b)(3)(C).
132. *Id.* § 812(b)(3)(A), (4)(A), (5)(A).
133. *Id.* § 812(b)(1), (2).
134. *Id.* § 812(b)(3)(A).
135. *Id.* § 812(b)(4)(A).
136. *Id.* § 812(b)(5)(A).

abuse potential is barely enough to warrant control in the first instance—indeed, suppose the agency concedes the drug's abuse potential is lower than that of any other controlled substance. As a Schedule I drug, this drug will now set the benchmark against which the abuse potential of all other scheduled drugs will be compared. Namely, to be placed on one of the lower Schedules (III through V), a drug with a CAMU would need to have an abuse potential *lower* than the abuse potential of this Schedule I drug. But that is an impossibility—on the facts just stipulated, no drug will have a lower abuse potential than this one. For this reason, the CAMU requirement would effectively preclude placing any drug below Schedule II. Of course, Congress did not intend for its scheduling rubric to unravel in this way, which suggests Congress did not intend for drugs to be placed on Schedule I unless they actually have a "high potential for abuse."

B. The CAMU Requirement Is Irrational

The CAMU requirement is also difficult to justify on policy grounds. The determination that a drug has no CAMU by itself fails to provide enough information about a drug's benefits and risks to determine how the drug should be regulated.

First, a CAMU determination provides, at best, a very limited gauge of a drug's benefits (i.e., its usefulness). The finding that a drug has a CAMU merely tells us that there is some threshold level of consensus among scientists or HCPs that the drug is effective at treating some medical condition. But a drug's efficacy could be more helpfully described in continuous terms. After all, a drug that has not yet passed the applicable CAMU test might still show promise at effectively treating some medical condition. But because CAMU is a binary criterion, this promise will not be reflected in CAMU determinations—i.e., it will be accorded no value whatsoever until the drug reaches the agency-established threshold level of consensus. What is more, CAMU determinations do not indicate anything about the seriousness of the condition the drug is being used to treat (e.g., whether it is major disease or a minor illness), or whether there are any other medications available to treat that same condition. For these and similar reasons, it is not safe to presume that a drug with no CAMU lacks any value and thus should be tightly restricted.

To illustrate, imagine a fictional drug called Queasiless that has some potential for abuse (for now, assume we only know that its abuse potential is high enough to warrant control under the CSA). Researchers have published one RCT demonstrating that Queasiless is highly effective at treating nausea in chemotherapy patients who do not respond well to other approved antiemetics. However, due to a lack of funding, no other RCTs are presently underway. Based on these facts, the DEA would conclude that Queasiless has no CAMU and must be placed on Schedule I, per its CAMU requirement. But given the promise shown by the one RCT, the seriousness of the condition Queasiless is being used to treat, and the lack of other viable treatment options for some chemotherapy patients, it is hard to see why one

should criminalize the manufacture, sale, and even possession of the drug, or restrict research on it, just because there is not yet enough consensus among scientists or HCPs to show that the drug has a CAMU.

To be sure, there are good reasons for the government to regulate claims about medical efficacy. For example, the government may want to protect consumers from being duped into buying drugs that are not effective. But there is no need to place a drug on Schedule I under the CSA just to protect consumers from overhyped claims of efficacy. After all, the FDCA already prohibits false or misleading claims concerning the medical efficacy of drugs.[137] In the illustration, for example, if a party markets Queasiless to consumers without first obtaining FDA new drug approval, it can be sanctioned under the FDCA irrespective of how (or even whether) the drug is scheduled under the CSA.[138]

Second, because CAMU is focused on efficacy (benefits), it tells us nothing about the risks posed by a drug. Those risks are instead captured by the CSA's other two scheduling criteria—abuse potential and dependence liability. Abuse potential and dependence liability determinations reflect a broad range of harms attributable to drug use, including the danger that use of the drug will lead to a fatal overdose or addiction.[139] Such harms are plainly relevant for determining the need to limit access to a drug and, thus, how tightly the drug should be controlled. After all, the primary purpose of the CSA is to combat drug abuse, not to police claims of drug efficacy.[140] There is no obvious reason to ignore these harms simply because a drug may not have a CAMU.

Return to the illustration above. If the drug Queasiless has a high potential for abuse and can lead to severe physical dependence among users, those findings would provide good grounds to strictly limit access to the drug, even if it has shown some therapeutic promise. But if Queasiless has only a low potential for abuse and leads to only limited physical or psychological dependence, imposing the same controls on the drug would seem irrational. Criminalizing all manufacture, distribution, and simple possession of the drug, and furthermore, limiting all research on it, would appear to be grossly out of proportion to the dangers it poses to society. Placing the drug on Schedule I also risks diverting scarce enforcement resources away from drugs like heroin, fentanyl, or methamphetamine that plainly pose more serious public health threats. Indeed, placing the drug on Schedule I could even undermine respect for the CSA and the rule of law. After all, if the public recognizes that Queasiless is a fairly innocuous drug, it might think the agency has made a grievous mistake placing the drug on the same

137. *Id.* § 352.

138. *See* Sean M. O'Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 823, 888 (2019); Mikos, *supra* note 3 (manuscript at 30–31).

139. *See generally* BASIS FOR THE RECOMMENDATION TO RESCHEDULE MARIJUANA INTO SCHEDULE III OF THE CONTROLLED SUBSTANCES ACT, *supra* note 7 (discussing factors that contribute to abuse potential and dependence liability).

140. 21 U.S.C. § 801.

schedule as heroin. Thus, if we know that the risks posed by a drug are relatively low, placement on one of the statute's lower schedules would seem more appropriate, even if the drug still has no CAMU.

The danger posed by the CAMU requirement is far from hypothetical. In effect, the requirement forces the DEA to ignore any new information it might acquire about a drug's abuse potential or dependence liability after the drug is placed on Schedule I and before the drug is demonstrated to have a CAMU. By limiting the information the DEA may use to make scheduling decisions, the CAMU requirement helps to entrench scheduling decisions that have come to appear increasingly irrational over time as new scientific discoveries have been made. In this way, the DEA's CAMU requirement hobbles the agency's ability to fulfill its statutory mandate to update past scheduling decisions as scientific knowledge expands.

Marijuana is a case in point. In legislative hearings on the CSA, Congress heard testimony suggesting that use of marijuana commonly leads to the use of harder drugs (like heroin).[141] Due to such concerns, it may have been rational for Congress to place marijuana on Schedule I. In other words, circa 1970, it might have been rational for the legislature to conclude that marijuana has a "high potential for abuse" in part because it serves as a gateway to harder drugs. But in the decades since Congress made that decision, assessments of marijuana's harms have softened considerably. For example, in its 2016 marijuana scheduling evaluation (if not before), HHS dismissed concerns over the gateway hypothesis, concluding that there was little credible scientific evidence to support the claim that use of marijuana would lead to the use of harder drugs.[142] But rather than reschedule marijuana on the basis of this new information about marijuana's abuse potential, the DEA ignored it; it dug in its heels and insisted marijuana had to remain on Schedule I until it was demonstrated to have a CAMU.[143]

Marijuana is hardly the only drug for which past scheduling decisions seem out of sync with more recent assessments of drug harms. Figure 2 below illustrates this point. It displays the overall harm scores for a sampling of prominent drugs on Schedules I through III. The scores are based on an expert panel's 2009 assessment of sixteen different harm-related criteria that are similar (but not identical) to the CSA's potential for abuse and dependence liability criteria.[144]

141. For a thoughtful examination of how the Congress that passed the CSA viewed marijuana's harms, see generally DAVID POZEN, THE CONSTITUTION OF THE WAR ON DRUGS (2024).

142. *See* 2016 Scheduling Decision, *supra* note 6, at 53705. Overall, the agency's 2016 scheduling evaluation makes marijuana's harms seem rather tame.

143. *Id.* at 53700 (reciting CAMU requirement).

144. The data are adapted from David J. Nutt, Leslie A. King & Lawrence D. Phillips, *Drug Harms in the UK: A Multicriteria Decision Analysis*, 376 LANCET 1558 (2010).

Figure 2: The Harms of Drugs by Schedule[145]

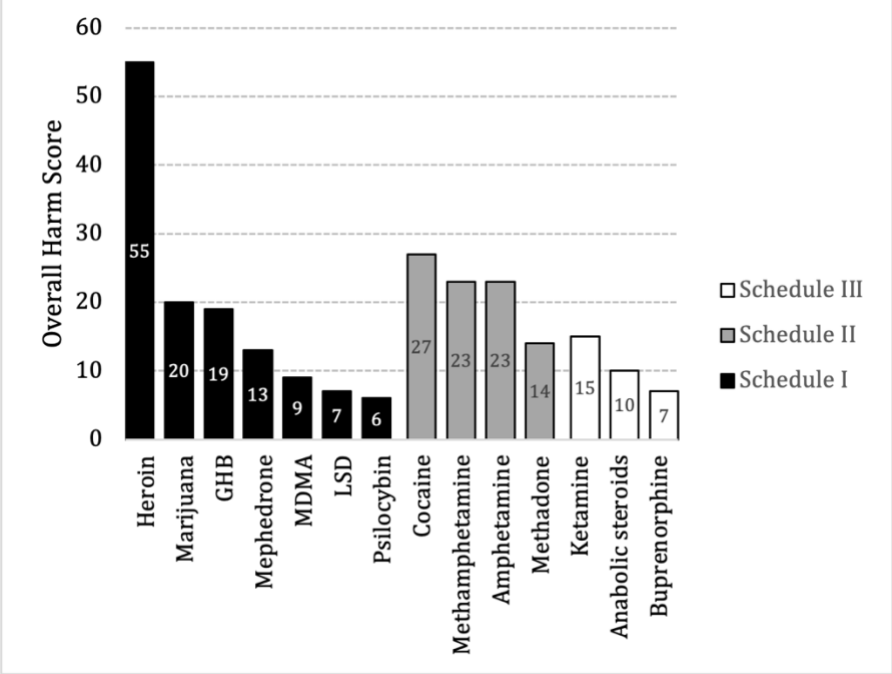

Figure 2 shows wide variation in the harms of different Schedule I drugs. But it also shows that some Schedule I drugs—including psilocybin, LSD, and MDMA—had lower harm scores than drugs on Schedule III (including soon-to-be-rescheduled marijuana). To the extent the harm scores correlate with the abuse potential and dependence liability findings required by the CSA, they suggest these drugs no longer belong on Schedule I (even assuming they once did). To get them off, however, the DEA needs to abandon the notion that they must first be demonstrated to have a CAMU.

C. Reimagining the Role of CAMU

Based on the text and purposes of the CSA, the DEA's CAMU requirement is ultra vires and irrational. The agency has no authority, and no good reason, to hold (or place) a drug on Schedule I solely because the drug lacks a currently accepted medical use. Of course, CAMU should continue to play some role in scheduling decisions (the statute requires as much). But in future scheduling decisions, the agency should also consider a drug's abuse potential and dependence liability to determine whether it needs to be subjected to the statute's most restrictive controls.

145. *See id.*

In at least some cases, these other statutory scheduling criteria could suggest that a drug should be placed below Schedule I, even if it lacks a CAMU. Identifying such drugs is beyond the scope of this Essay, but Figure 2 above suggests a few notable examples of drugs that might be removed from Schedule I in the absence of the CAMU requirement. Among these examples are three noteworthy psychedelics that have long shown therapeutic potential but as yet have no demonstrated CAMU: psilocybin, LSD, and MDMA.[146]

The DEA has several options for deciding how to schedule a drug when abuse potential, dependence liability, and CAMU findings do not all align (i.e., when they suggest placing the drug on more than one schedule). For example, the agency could give each criterion equal weight and place the drug on the schedule closest to the average suggested by its findings. To illustrate, if the findings suggest Schedules I (no CAMU), III (low potential for abuse relative to I and II), and V (low threat of dependence relative to IV), the agency might choose to place the drug on Schedule III.

To be sure, some cases will pose difficult choices for the agency. But the difficulty is created by the statute itself, not by my proposed approach. Because the CSA uses three unrelated criteria to schedule drugs, there are bound to be cases where the same drug exhibits traits associated with different schedules. The DEA's rigid CAMU requirement is one possible response to this reality, but it is hardly the best response (for reasons explained above). The more flexible approach I propose here would address the conflict among scheduling criteria in a more holistic manner that is more consistent with statutory text and purposes.

By enabling the rescheduling of certain drugs that would otherwise remain trapped indefinitely on Schedule I, the flexible approach proposed will generate substantial benefits. For one thing, it could help shift more enforcement resources toward the drugs that pose a greater danger to society, i.e., drugs that are on Schedule I because they have a high potential for abuse rather than just no currently accepted medical use. Rescheduling certain drugs would also enhance respect for the CSA's scheduling system. In the public eye, Schedule I is supposed to be reserved for the most dangerous drugs in society. The DEA's past insistence that drugs belong on that schedule even when they are not especially dangerous is irreconcilable with public perceptions and could breed contempt for the agency and the scheduling system.

My approach would also enable some people to tap into the therapeutic promise of the substances that are moved off Schedule I. Although rescheduling would not eliminate all controls on access to these drugs, it

146. *See, e.g.*, Robin L. Carhart-Harris & Guy M. Goodwin, *The Therapeutic Potential of Psychedelic Drugs: Past, Present, and Future*, 42 NEUROPSYCHOPHARMACOLOGY 2105 (2017); BEAU KILMER, MICHELLE PRIEST, RAJEEV RAMCHAND, RHIANNA C. ROGERS, BEN SENATOR & KEYTIN PALMER, RAND, CONSIDERING ALTERNATIVES TO PSYCHEDELIC DRUG PROHIBITION (2024), https://www.rand.org/content/dam/rand/pubs/research_reports/RRA2800/RRA2825-1/RAND_RRA2825-1.pdf [https://perma.cc/BFT7-E3H6].

would remove at least some of the penalties that now apply, including penalties for simple possession.[147] Lastly, rescheduling would help facilitate more scientific research on these drugs, because they would no longer be subject to the cumbersome controls the CSA imposes on research involving Schedule I drugs. The additional knowledge about therapeutic benefits and risks gleaned from such research would, in turn, help further refine how best to regulate the substances. For example, the additional research fostered by this approach might help demonstrate CAMU and obtain FDA approval for a drug.

At the same time, enabling drugs that have low comparative harms to be removed from Schedule I poses few risks to society. These drugs will remain subject to a variety of controls under both the CSA and the FDCA. These controls limit the risk that the drugs would be diverted to nonmedical uses, or that patients would be duped into using them.

In short, on balance, taking a more holistic approach to scheduling that incorporates all three scheduling criteria will create a more rational system of regulation for drugs of abuse.

For all the foregoing reasons, the DEA's CAMU requirement should be abolished. The requirement is contrary to the text and purposes of the CSA. Although abolishing the requirement will not make it any easier to demonstrate CAMU under the CSA—i.e., it would not change the content of the tyrannical CAMU tests the agencies have developed—it would reduce the influence that those CAMU tests have over scheduling decisions. In so doing, it would soften the Tyrannies of Scheduling and enable the DEA to make more rational decisions regarding which drugs should be placed (or kept) on Schedule I.

CONCLUSION

For decades, the DEA has insisted that drugs may be removed from Schedule I only by demonstrating that they have a currently accepted medical use. In effect, this CAMU requirement serves to trap drugs on Schedule I. The draconian controls applicable to such drugs make it virtually impossible to assemble the rigorous scientific evidence or widespread clinical experience necessary to demonstrate CAMU, creating what I call the Tyrannies of Scheduling. Although marijuana was finally able to run the gauntlet, no other Schedule I drug is likely to replicate that feat anytime soon. Other promising Schedule I drugs like psilocybin, MDMA, and LSD are likely to remain trapped on that schedule for the foreseeable future.

It does not have to be this way. The DEA erred in assuming that drugs with no CAMU cannot be removed from Schedule I. This Essay shows that the agency's CAMU requirement is inconsistent with both the text and the policy of the CSA. Simply put, Congress did not order the agency—and had no reason to want the agency—to keep a drug on Schedule I merely because it lacks a currently accepted medical use.

147. *See* Mikos, *supra* note 3 (manuscript at 7).

The DEA should drop its misguided CAMU requirement. In its place, the agency should take a more flexible approach to deciding whether a drug belongs on Schedule I. Pursuant to this new approach, the agency would consider all three statutory scheduling criteria, including abuse potential, dependence liability, and CAMU. Although my approach would not make it any easier to demonstrate CAMU, it would reduce the dominant influence CAMU determinations now wield over scheduling decisions. As a result, my approach would foster more rational administrative scheduling decisions going forward.