

---

## FEDERAL MARIJUANA REFORM AND THE CONTROLLED SUBSTANCES ACT

ALEX KREIT\*

### ABSTRACT

*A resolution to the conflict between federal and state marijuana laws is finally in sight. In December 2020, the House of Representatives passed a bill—the Marijuana Opportunity Reinvestment and Expungement Act (“MORE Act”)—which would legalize marijuana at the federal level. Although the MORE Act stalled in the Senate, its passage in the House has led to renewed attention to the particulars of federal marijuana reform with respect to taxes, regulation, and social equity. Curiously, the federal law that currently polices marijuana, the Controlled Substances Act (“CSA”), has been mostly absent from this discussion. Rather than attempting to amend the CSA drug scheduling provisions, the MORE Act and other legislative proposals address the CSA’s problems by simply removing marijuana from its reach entirely. From the perspective of solving the conflict between federal and state marijuana laws, this is a wise approach; reworking the CSA’s regulatory structure would be an enormous legislative undertaking and make achieving federal marijuana reform much more difficult. But while there are good reasons to leave the CSA out of federal marijuana reform efforts, the experience of regulating marijuana under the CSA suggests that it is also in need of significant reform. This Essay considers the CSA’s scheduling system through the lens of its treatment of marijuana. I argue that Congress should view its marijuana reform effort as a beginning—not an end—when it comes to rethinking how federal law treats controlled substances.*

---

\* Assistant Professor of Law and Director of the Center on Addiction Law & Policy, Salmon P. Chase College of Law, Northern Kentucky University.

## CONTENTS

INTRODUCTION .....	1233
I. THE CSA AND MARIJUANA'S PLACEMENT IN SCHEDULE I .....	1236
II. INSIGHTS FOR THE CSA .....	1244
A. <i>Marijuana and the CSA's Scheduling Criteria</i> .....	1244
B. <i>Schedule I and Research of Medical Uses</i> .....	1248
C. <i>The CSA and Nonmedical Uses</i> .....	1251
CONCLUSION .....	1252

## INTRODUCTION

Twenty-five years after California became the first state to legalize medical marijuana,<sup>1</sup> a resolution to the conflict<sup>2</sup> between federal and state marijuana<sup>3</sup> laws is finally in sight. The House of Representatives approved the Marijuana Opportunity Reinvestment and Expungement Act (“MORE Act”) by a vote of 228 to 164 in early December 2020.<sup>4</sup> The “historic”<sup>5</sup> vote marked the first time a bill to permanently solve the conflict between state and federal marijuana laws passed a chamber of Congress.<sup>6</sup> The MORE Act stalled in the Senate, where it did not receive a vote. But with Democrats now in control of the Senate, some legalization advocates are hopeful that the MORE Act (or a competing proposal) could have a path to becoming law in this session of Congress.<sup>7</sup> More fundamentally, the MORE Act’s passage in the House seemed to confirm what has been apparent to close observers for some time now: federal marijuana reform is not a question of if but when.

As the *when* of federal marijuana reform draws nearer, the question of *how* becomes increasingly important. Should the federal government leave marijuana regulation entirely to the states or create its own licensing system?<sup>8</sup> How much,

---

<sup>1</sup> See *People v. Mower*, 49 P.3d 1067, 1070 (Cal. 2002) (discussing California’s Compassionate Use Act, CAL. HEALTH & SAFETY CODE §§ 11357-11358 (West 2021)).

<sup>2</sup> For an overview of the conflict between state and federal marijuana laws, see Sam Kamin, *Marijuana Law Reform in 2020 and Beyond: Where We Are and Where We’re Going*, 43 SEATTLE U. L. REV. 883, 884-88 (2020).

<sup>3</sup> The term marijuana carries a troubling racialized history, but it is also the term that is used in the federal Controlled Substances Act (“CSA”), 21 U.S.C. §§ 801-904. Because this Essay focuses on federal law, I use the term marijuana—instead of cannabis—to accurately reflect the terminology used in the CSA.

<sup>4</sup> MORE Act of 2020, H.R. 3884, 116th Cong. (2020).

<sup>5</sup> Kyle Jaeger, *House Approves Federal Marijuana Legalization Bill in Historic Vote*, MARIJUANA MOMENT (Dec. 4, 2020), <https://www.marijuanamoment.net/house-approves-federal-marijuana-legalization-bill-in-historic-vote/> [<https://perma.cc/Z535-N47E>].

<sup>6</sup> *Id.* Although the MORE Act marked the first congressional vote in favor of a bill to amend federal marijuana law, since December 2014, Congress has included in the federal budget a provision that prevents the DOJ from using funds to interfere with state medical marijuana laws. Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113-235, § 538, 128 Stat. 2130, 2217 (2014) (codified in scattered sections of 2 U.S.C. and 48 U.S.C.); see also *United States v. Pisarski*, 965 F.3d 738, 741 (9th Cir. 2020) (discussing the budget rider); Florence Shu-Acquaye, *Rohrabacher-Blumenauer Amendment, Case Law and the Department of Justice: Who Prevails in the Medical Marijuana Legalization Debate?*, 54 GONZ. L. REV. 127, 129-31 (2018) (providing history of budget rider).

<sup>7</sup> Natalie Fertig, *Democratic-Led Senate Could Clear a Path to Marijuana Legalization*, POLITICO (Jan. 8, 2021, 8:00 AM), <https://www.politico.com/news/2021/01/08/senate-democrats-marijuana-legislation-456074> [<https://perma.cc/LT8B-EEA9>].

<sup>8</sup> See Erwin Chemerinsky, Jolene Forman, Allen Hopper & Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. REV. 74, 116-22 (2015) (arguing for

if at all, should the federal government tax marijuana commerce?<sup>9</sup> To what extent should federal marijuana reform address the injustices of prohibition through measures like expungements?<sup>10</sup> As the prospects of changing federal marijuana laws have grown brighter, advocates have understandably begun to focus more and more on these kinds of details.

For the most part, the federal law that currently polices marijuana, the Controlled Substances Act (“CSA”),<sup>11</sup> has been noticeably absent from this discussion.<sup>12</sup> Enacted in 1970, the CSA replaced what had been “[a] patchwork of regulatory, revenue, and criminal measures”<sup>13</sup> with a single comprehensive statutory scheme for federal drug control.<sup>14</sup> The CSA gives the Drug Enforcement Administration (“DEA”) the power<sup>15</sup> to prohibit and regulate drugs pursuant to a five-schedule system. Schedule I is reserved for substances that have “no currently accepted medical use in treatment in the United States” and

---

“cooperative federalism” approach to resolving the conflict between state and federal marijuana laws); Alex Kreit, *What Will Federal Marijuana Reform Look Like?*, 65 CASE W. RESV. L. REV. 689, 699-711 (2015) (providing a broad overview of possible models for federal marijuana reform); Susan F. Mandiberg, *A Hybrid Approach to Marijuana Federalism*, 23 LEWIS & CLARK L. REV. 823, 842-49 (2019) (arguing for a hybrid model of federal-state regulation, drawing upon existing regulatory schemes in the environmental context).

<sup>9</sup> See Ulrik Boesen, *Flawed Federal Taxation of Recreational Marijuana*, TAX FOUND. (Sept. 3, 2020), <https://taxfoundation.org/more-act-federal-taxation-of-recreational-marijuana/> [<https://perma.cc/JZN6-VWVZ>] (discussing the MORE Act’s approach to marijuana taxation); Pat Oglesby, *State-of-the-Art Federal Marijuana Tax Bills* (Dec. 7, 2017) (unpublished manuscript), <https://ssrn.com/abstract=3084105> [<https://perma.cc/LHJ2-KMHV>].

<sup>10</sup> See *Recent Proposed Legislation: Drug Policy—Marijuana Justice Act of 2017—Senator Cory Booker Introduces Act to Repair the Harms Exacted by Marijuana Prohibition—Marijuana Justice Act of 2017, S. 1689, 115th Cong.*, 131 HARV. L. REV. 926, 926-31 (2018) (considering the proposed Marijuana Justice Act of 2017 and arguing in support of including measures to address the harms of marijuana in federal marijuana reform proposals).

<sup>11</sup> Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified at 21 U.S.C. §§ 801-889).

<sup>12</sup> But see Oliver J. Kim, *Preemption Up in Smoke: Should States Be Allowed a Voice in Scheduling Under the Controlled Substances Act?*, 18 OHIO ST. J. CRIM. L. 61, 91-97 (2020) (discussing issues related to the CSA including equity for communities harmed by it, evidence supporting policy changes, and future federal-state conflicts).

<sup>13</sup> RICHARD J. BONNIE & CHARLES H. WHITEBREAD II, *THE MARIHUANA CONVICTION: A HISTORY OF MARIHUANA PROHIBITION IN THE UNITED STATES* 242 (1974).

<sup>14</sup> See *Nat’l Org. for the Reform of Marijuana L. (NORML) v. Bell*, 488 F. Supp. 123, 126 (D.D.C. 1980) (explaining that the CSA “ended the patchwork federal effort against drug abuse and signaled a national commitment to deal with this problem by committing federal funds for rehabilitation programs”).

<sup>15</sup> The Attorney General subdelegated authority over the CSA to the DEA. See Exec. Order No. 11,727, 38 Fed. Reg. 18,357 (July 10, 1973); 28 C.F.R. § 0.100 (2020).

can only be manufactured and distributed for authorized research.<sup>16</sup> Substances in Schedules II through V are legal to manufacture and sell for medical uses and are subject to progressively less restrictive controls based on their abuse potential.<sup>17</sup>

Marijuana is famously stationed in Schedule I of the CSA.<sup>18</sup> Congress placed it there provisionally when it passed the CSA,<sup>19</sup> and despite a number of administrative rescheduling petitions,<sup>20</sup> it has stayed there ever since. The conflict between federal and state marijuana laws is primarily due to marijuana's status under the CSA. As a Schedule I substance, marijuana is illegal under federal law, except for in connection with authorized research. But merely shifting marijuana to a different CSA schedule would not change much about the current federal-state impasse.<sup>21</sup> So long as marijuana is classified anywhere under the CSA schedules, it is illegal to manufacture and distribute for nonmedical uses.<sup>22</sup>

The MORE Act and other legislative proposals to resolve the conflict between state and federal marijuana laws address the problem of the CSA by simply removing marijuana from the CSA's reach entirely.<sup>23</sup> This is the most efficient and politically practicable approach; reworking the CSA's regulatory structure in a way that could accommodate state marijuana legalization laws would be an enormous legislative undertaking. From this perspective, it is understandable that the CSA has been all but ignored in the conversation about federal marijuana

---

<sup>16</sup> 21 U.S.C. § 812(b)(1)(B).

<sup>17</sup> See GERALD F. UELMEN & ALEX KREIT, *DRUG ABUSE AND THE LAW SOURCEBOOK* § 1:2 (2021 ed. 2021) (providing an overview of the CSA's scheduling system).

<sup>18</sup> 21 U.S.C. § 812(c) (listing marijuana as a Schedule I substance); 21 C.F.R. § 1308.11(d)(23) (2020) (same).

<sup>19</sup> See Melanie Reid, *Goodbye Marijuana Schedule I—Welcome to a Post-Legalization World*, 18 OHIO ST. J. CRIM. L. 169, 175-76 (2020).

<sup>20</sup> See Grace Wallack & John Hudak, *Marijuana Rescheduling: A Partial Prescription for Policy Change*, 14 OHIO ST. J. CRIM. L. 207, 209-10 (2016) (providing a brief overview of rescheduling efforts).

<sup>21</sup> *Id.* at 210-14 (discussing the practical effects of rescheduling).

<sup>22</sup> 21 U.S.C. § 829(c) (“No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.”). Indeed, moving marijuana to a different schedule would not do much to solve the conflict even with state *medical* marijuana laws, because “the fact that a substance is in Schedule II (or even III-V) does not mean that the substance itself . . . can be directly prescribed and dispensed.” Kevin A. Sabet, *Much Ado About Nothing: Why Rescheduling Won't Solve Advocates' Medical Marijuana Problem*, 58 WAYNE L. REV. 81, 87 (2012).

<sup>23</sup> MORE Act of 2020, H.R. 3884, 116th Cong. § 3 (2020). Although removing marijuana from the CSA would address the primary source of the conflict between federal and state law in this space, it would not address all potential conflicts on its own. See Sean M. O'Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. U. L. REV. 823, 907-24 (2019) (discussing continuing FDA authority over marijuana if it were to be removed from the CSA).

reform. But while leaving the CSA out of federal marijuana reform efforts may be wise, the experience of marijuana's treatment under federal law over the past five decades suggests that the CSA itself is also in need of reform.

In this Essay, I argue that federal marijuana reform should also be an occasion to begin rethinking the CSA's scheduling system.<sup>24</sup> Part I provides an overview of the CSA and marijuana's Schedule I status. Part II examines three aspects of the CSA that the experience of marijuana suggests may be in need of reform. Part III concludes.

### I. THE CSA AND MARIJUANA'S PLACEMENT IN SCHEDULE I

Before 1970, a jumbled web of federal laws controlled illegal drugs.<sup>25</sup> The CSA was designed to bring order to the chaos with "a unified framework of federal controlled substance regulation."<sup>26</sup> The CSA applies to substances "that are considered to pose a risk of abuse and dependence"<sup>27</sup> and gives the DEA authority to control potentially all such substances by adding substances to the schedules administratively.<sup>28</sup> The DEA also has the power to move substances that are already in one schedule into a different schedule (rescheduling) or remove scheduled substances from the CSA entirely (descheduling). Substances that are scheduled under the CSA are subject to "two overlapping legal

---

<sup>24</sup> This Essay does not consider issues related to the CSA's criminal enforcement provisions, such as mandatory minimum penalties. For recent analysis of some of these issues, see, for example, Stephanie Holmes Didwania, *Mandatory Minimum Entrenchment and the Controlled Substances Act*, 18 OHIO ST. J. CRIM. L. 25, 54-56 (2020) (proposing amendments to the CSA to reduce or eliminate its mandatory minimum provisions); and Erica Zunkel & Alison Siegler, *The Federal Judiciary's Role in Drug Law Reform in an Era of Congressional Dysfunction*, 18 OHIO ST. J. CRIM. L. 283, 312-28 (2020) (discussing ways in which judges can use their discretion to moderate the harsh treatment of drug defendants under federal law).

<sup>25</sup> See generally Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 CATH. U. L. REV. 586 (1973) (discussing the history of federal drug laws through passage of the CSA). Opiates and cocaine were controlled by the Harrison Narcotics Tax Act of 1914, Pub. L. No. 63-223, 38 Stat. 785; marijuana by the Marihuana Tax Act of 1937, Pub. L. No. 75-238, 50 Stat. 551; and hallucinogens, stimulants, and depressants by the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 50 Stat. 1040 (1938). Still more federal drug statutes filled other regulatory gaps. See Quinn & McLaughlin, *supra*, at 588-605.

<sup>26</sup> JOANNA R. LAMPE, CONG. RSCH. SERV., R45948, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 116TH CONGRESS 2 (2019), <https://crsreports.congress.gov/product/pdf/R/R45948/2>.

<sup>27</sup> *Id.*

<sup>28</sup> The CSA only applies to substances that are administratively "identified for control"—scheduled, in the parlance of the CSA—by the DEA or added to the schedules by Congress. *Id.* But the scheduling criteria permit the DEA to add any substance it finds has a potential for abuse to the schedules through the administrative process. For an overview of the scheduling process, see *id.* at 9-10.

schemes”<sup>29</sup>—a set of administrative provisions that governs approved traffic in controlled substances and a set of criminal provisions that applies to unapproved traffic in controlled substances.

The foundation of the CSA is its five-schedule system, which classifies drugs based on three criteria: potential for abuse, medicinal value, and safety and dependence. The CSA provides that a substance “may not be placed in any schedule unless the findings required for such schedule are made”<sup>30</sup> by the DEA. Substances in Schedule I have “a high potential for abuse,” “no currently accepted medical use in treatment in the United States,” and “a lack of accepted safety for use . . . under medical supervision.”<sup>31</sup> Schedule II substances also have “a high potential for abuse”; they are distinguished from Schedule I because they have a currently accepted medical use.<sup>32</sup> The third criterion for scheduling a drug in Schedule II strikes a discordant note by moving its attention from safety to dependence, requiring a finding that “[a]buse of the drug . . . may lead to severe psychological or physical dependence.”<sup>33</sup> From there, substances in the remaining schedules all have an accepted medical use with progressively lower potential for abuse and risk of dependence than the previous schedule. For example, Schedule III requires findings that the substance “has a potential for abuse less than the drugs or other substances in schedules I and II” and that abuse “may lead to moderate or low physical dependence or high psychological dependence” (as opposed to Schedule II’s “severe” dependence requirement).<sup>34</sup>

---

<sup>29</sup> *Id.* at 2.

<sup>30</sup> 21 U.S.C. § 812(b).

<sup>31</sup> *Id.* § 812(b)(1).

<sup>32</sup> *Id.* § 812(b)(2).

<sup>33</sup> *Id.* § 812(b)(2)(C).

<sup>34</sup> *Id.* § 812(b)(3).

**Table 1.** The CSA Scheduling Criteria.<sup>35</sup>

	<b>Abuse Potential</b>	<b>Medical Use</b>	<b>Safety and Dependence</b>
Schedule I	High potential for abuse	Has no currently accepted medical use	Lack of accepted safety for use under medical supervision
Schedule II	High potential for abuse	Has a currently accepted medical use	Abuse may lead to severe dependence
Schedule III	Potential for abuse less than Schedules I and II	Has a currently accepted medical use	Abuse may lead to moderate or low physical dependence or high psychological dependence
Schedule IV	Low potential for abuse relative to Schedule III	Has a currently accepted medical use	Abuse may lead to limited dependence relative to Schedule III
Schedule V	Low potential for abuse relative to Schedule IV	Has a currently accepted medical use	Abuse may lead to limited dependence relative to Schedule IV

Behind this deceptively simple scheduling system lies a number of complications and peculiarities. Two are particularly notable in the context of marijuana scheduling. First, the CSA grants the DEA an extraordinary amount of discretion to define the scheduling criteria. This is because “the term ‘United States’ as used in ‘accepted medical use in treatment in the United States’ . . . is the *only* portion of the Schedule I criteria that Congress has expressly defined in the CSA.”<sup>36</sup> The CSA is silent as to the meaning of potential for abuse,<sup>37</sup> accepted medical use,<sup>38</sup> and safety and dependence.<sup>39</sup> As a result, even though the CSA did not expressly delegate to the DEA the authority to define scheduling

<sup>35</sup> See *id.* § 812(b).

<sup>36</sup> *Grinspoon v. Drug Enf’t Admin.*, 828 F.2d 881, 885 (1st Cir. 1987) (emphasis added) (quoting 21 U.S.C. § 812(b)(1)(B)). The CSA defines “United States” to “mean[] all places and waters, continental or insular, subject to the jurisdiction of the United States.” 21 U.S.C. § 802(28).

<sup>37</sup> See Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49,661, 49,667 (Aug. 22, 2014) (codified at 21 C.F.R. § 1308.12 (2020)).

<sup>38</sup> Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,503 (Mar. 26, 1992) (“Regrettably, the Controlled Substances Act does not speak directly to what is meant by ‘currently accepted medical use.’” (quoting 21 U.S.C. § 812(b)(2)-(5))).

<sup>39</sup> See *Grinspoon*, 828 F.2d at 885 (“Our review of the sources identified by the litigants convinces us that Congress neither expressed nor implied an affirmative intent regarding how the second and third Schedule I criteria should be interpreted.”).



criteria via regulation,<sup>40</sup> the absence of congressional definitions of the scheduling criteria has implicitly given the DEA nearly unfettered discretion over their meaning.<sup>41</sup>

Second, the CSA does not say how the criteria fit together. At first glance, this omission might not seem problematic; there are only three criteria for each schedule, and the CSA provides that a “substance may not be placed in any schedule unless the [requisite] findings” are met.<sup>42</sup> But closer inspection of the scheduling criteria reveals that it is possible for them to point in different directions for a single drug.<sup>43</sup> Put differently, the CSA’s scheduling criteria “cannot logically be read as cumulative in all situations.”<sup>44</sup> Imagine, for example, a drug with (1) “a low potential for abuse relative to the drugs or other substances in schedule IV,”<sup>45</sup> (2) “no currently accepted medical use in treatment in the United States,”<sup>46</sup> and (3) a “moderate or low physical dependence or high psychological dependence” profile.<sup>47</sup> The first characteristic suggests this hypothetical drug belongs in Schedule V, the second would place it in Schedule I, and according to the third it would be in Schedule III. In short, this hypothetical drug would not fit into any of the schedules. As a result, it would be impossible for the DEA to comply with the CSA’s statutory command that a substance only be placed in a given schedule if “the findings required for such schedule are made with respect to such drug or other substance.”<sup>48</sup> How should the DEA handle a circumstance when the scheduling findings for a substance each point to a different schedule? As discussed more below, more than fifty years after the CSA’s passage, this basic problem has not yet been definitively tested in the courts.<sup>49</sup>

No scheduling issue has generated as much interest (or litigation) as marijuana’s classification in Schedule I. As already noted, Congress put marijuana in Schedule I when it passed the CSA. Over the years, a number of different organizations have petitioned the DEA to reschedule or deschedule

---

<sup>40</sup> *Id.* at 885 n.5 (“[T]his is not a situation in which Congress has expressly vested the Administrator with authority to define general statutory criteria by issuing regulations.”).

<sup>41</sup> *Id.* at 892 (“It appears to us that Congress has implicitly delegated to the Administrator the authority to interpret these portions of the CSA, and we must therefore refrain from imposing our own statutory interpretation upon the agency.”). For an overview of how the DEA defines each of the scheduling criteria and litigation regarding its definitions, see UELMEN & KREIT, *supra* note 17, §§ 1:10-:12.

<sup>42</sup> 21 U.S.C. § 812(b).

<sup>43</sup> For a discussion of this problem, see Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV’T L. REV. 332, 339-43 (2013).

<sup>44</sup> *United States v. Maiden*, 355 F. Supp. 743, 748 n.4 (D. Conn. 1973).

<sup>45</sup> 21 U.S.C. § 812(b)(5)(A).

<sup>46</sup> *Id.* § 812(b)(1)(B).

<sup>47</sup> *Id.* § 812(b)(3)(C).

<sup>48</sup> *Id.* § 812(b).

<sup>49</sup> *See infra* notes 96-99.

marijuana. Although none of these efforts has been successful, the story of marijuana rescheduling efforts exposes some of the CSA's flaws.

The National Organization for the Reform of Marijuana Laws ("NORML") filed the most significant marijuana rescheduling petition in 1972. Initially, NORML's petition requested that marijuana be removed from the CSA's control entirely, "or in the alternative, transfer[red] . . . from Schedule I to Schedule V."<sup>50</sup> After a lengthy, winding journey that included an admonition to the DEA by the D.C. Circuit regarding "an agency's obligation on remand not to 'do anything which is contrary to either the letter or spirit of the mandate'" in the court's opinion, the petition came before an administrative law judge in 1988.<sup>51</sup> By then, NORML had lowered its sights and was requesting only that marijuana be moved to Schedule II.<sup>52</sup> This new posture put the meaning of the CSA's "currently accepted medical use" criterion front and center.

The DEA had not yet adopted an authoritative definition for "currently accepted medical use" at the time of the administrative law judge's ruling in 1988. In the absence of one, the administrative law judge, Judge Francis Young, proposed adopting a standard employed in medical malpractice cases—acceptance "by a respectable minority of physicians."<sup>53</sup> Applying that test, the judge concluded "that the marijuana plant considered as a whole has a currently accepted medical use in treatment in the United States" and recommended it be moved to Schedule II.<sup>54</sup>

The DEA rejected Judge Young's recommendation, of course. In the process, the DEA settled on the definition of "currently accepted medical use" that is still in effect today. In its 1989 order rejecting the rescheduling recommendation, the DEA used an eight-characteristic test:

1. Scientifically determined and accepted knowledge of its chemistry;
2. The toxicology and pharmacology of the substance in animals;
3. Establishment of its effectiveness in humans through scientifically designed clinical trials;
4. General availability of the substance and information regarding the substance and its use;
5. Recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks;

---

<sup>50</sup> Nat'l Org. for the Reform of Marijuana L. (NORML) v. Ingersoll, 497 F.2d 654, 655 (D.C. Cir. 1974).

<sup>51</sup> Marijuana Rescheduling Petition: Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge at 6, No. 86-22 (Drug Enf't Admin. Sept. 6, 1988) (quoting Nat'l Org. for the Reform of Marijuana L. v. Drug Enf't Admin., No. 79-01660, 1980 U.S. App. LEXIS 13099, at \*2 (D.C. Cir. 1980)).

<sup>52</sup> *Id.* at 7.

<sup>53</sup> *Id.* at 30.

<sup>54</sup> *Id.* at 68.

6. Specific indications for the treatment of recognized disorders;
7. Recognition of the use of the substance by organizations or associations of physicians; and
8. Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.<sup>55</sup>

The U.S. Court of Appeals for the District of Columbia found that three of these eight characteristics—namely numbers four, five, and eight—were “logically impossible to satisfy” and therefore unreasonable.<sup>56</sup> The problem with these three characteristics was that each required general availability or use of the substance, and “one cannot logically show that a drug enjoys general ‘availability’ or ‘use’ by a substantial segment of medical practitioners if the drug remains in Schedule I.”<sup>57</sup>

On remand, the DEA came up with a new five-factor test for the CSA’s medical use criterion that the agency continues to apply today. In addition to removing the three problem characteristics, the DEA tweaked some of the other factors. The resulting test requires that

- (1) [t]he drug’s chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.<sup>58</sup>

Despite mounting evidence of marijuana’s medicinal value,<sup>59</sup> the approval of cannabis-based pharmaceutical products,<sup>60</sup> and medical marijuana laws in thirty-

---

<sup>55</sup> Marijuana Scheduling Petition; Denial of Petition, 54 Fed. Reg. 53,767, 53,783 (Dec. 29, 1989). The DEA first adopted the eight-characteristic test a year earlier. *Id.*

<sup>56</sup> *All. for Cannabis Therapeutics v. Drug Enf’t Admin.*, 930 F.2d 936, 937 (D.C. Cir. 1991).

<sup>57</sup> *Id.* at 940.

<sup>58</sup> *All. for Cannabis Therapeutics v. Drug Enf’t Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

<sup>59</sup> See generally NAT’L ACADS. OF SCIS., ENG’G & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF THE EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 85-128 (2017), [https://www.ncbi.nlm.nih.gov/books/NBK423845/pdf/Bookshelf\\_NBK423845.pdf](https://www.ncbi.nlm.nih.gov/books/NBK423845/pdf/Bookshelf_NBK423845.pdf) [<https://perma.cc/EN4N-GURB>] (reviewing the literature and concluding that there “is conclusive or substantial evidence that cannabis or cannabinoids are effective” in treating chronic pain and chemotherapy-induced nausea and for improving patient-reported spasticity symptoms in multiple sclerosis patients); Kevin P. Hill, *Medical Use of Cannabis in 2019*, 322 JAMA 974 (2019).

<sup>60</sup> See Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements, 83 Fed. Reg. 48,950, 48,953 (Sept. 28, 2018) (codified at 21 C.F.R. § 1308.15 (2020)) (placing FDA-approved oral cannabidiol solution in Schedule V); Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688, 56,391-92 (Aug. 12, 2016)

six states and four territories,<sup>61</sup> the DEA has continued to reject rescheduling petitions on the ground that marijuana does not have a currently accepted medical use in treatment in the United States.<sup>62</sup> This state of affairs is surprising to some—after all, how can the DEA find that the medical use of marijuana is not “currently accepted”<sup>63</sup> when more than two-thirds of states have medical marijuana laws and Marinol, which contains synthetic tetrahydrocannabinol (“THC”), is an FDA-approved Schedule III substance?<sup>64</sup>

The answer lies in the DEA’s five-factor test. The chief impediment to a finding that marijuana has an accepted medical use is the first of the DEA’s five requirements—that the chemistry of the drug be “known and reproducible.”<sup>65</sup> Simply put, the marijuana plant as defined in the CSA<sup>66</sup> will never satisfy this requirement because the chemistry of the plant is not—and never will be—sufficiently known and reproducible. The DEA explained its view of the issue in its 2016 denial of a petition to initiate the rescheduling of marijuana:

The petition defines marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents including delta<sup>9</sup>-THC and other cannabinoids . . . . Thus, when considering all *Cannabis* strains together, because of the varying chemical constituents, reproducing consistent standardized doses is not possible.<sup>67</sup>

Because this will always be true of the marijuana plant as it is defined by the CSA, it is difficult to see how the DEA could ever move marijuana from Schedule I to a different schedule under the agency’s prevailing five-factor test.<sup>68</sup>

---

(rejecting an argument that placement of Marinol, which contains synthetic THC, in Schedule III is inconsistent with marijuana’s placement in Schedule I).

<sup>61</sup> *State Medical Marijuana Laws*, NAT’L CONF. OF ST. LEGISLATURES (Mar. 31, 2021), <https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx> [<https://perma.cc/8YVE-6ZN8>].

<sup>62</sup> *See, e.g.*, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53,706 (denying petition to reschedule marijuana in part because of the finding that it “has no currently accepted medical use in treatment in the United States”).

<sup>63</sup> 21 U.S.C. § 812(b)(1)(B).

<sup>64</sup> *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53,741-42.

<sup>65</sup> *Id.* at 53,700.

<sup>66</sup> 21 U.S.C. § 802(16)(A) (defining marijuana as “all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin” with the exception of hemp).

<sup>67</sup> Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53,700.

<sup>68</sup> *See* Rebecca S. Eisenberg & Deborah B. Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 FOOD & DRUG L.J. 246, 263 (2019).

Of course, the medical use finding is only one of three scheduling criteria. In order to be placed in Schedule I, a substance must also have “a high potential for abuse”<sup>69</sup>—higher than substances in Schedule III,<sup>70</sup> such as ketamine or anabolic steroids.<sup>71</sup> The notion that marijuana has a high potential for abuse—on the level of heroin and cocaine—also strikes some as counterintuitive given the relatively low severity of marijuana dependence in comparison to other substances.<sup>72</sup> As with the medical-use finding, the DEA’s definition of potential for abuse explains the apparent incongruity.

The DEA has traditionally relied primarily on four factors to guide its potential-for-abuse finding: (1) evidence that people are taking the drug in amounts that would create a hazard to their health or others’ safety, (2) significant diversion of the drug from legitimate channels, (3) evidence that people are taking the drug on their own initiative rather than on the advice of a doctor, or (4) (for new drugs) how the drug’s potential for abuse compares to that of existing drugs.<sup>73</sup> These factors are derived from a House Committee on Interstate and Foreign Commerce report accompanying the bill that became the CSA, which “set[] forth four alternative legal standards for determining *when* a substance possesses a ‘potential for abuse.’”<sup>74</sup> Notably, the House Committee’s report “provides guidance only as to the minimum needed to show *any* potential for abuse,”<sup>75</sup> not *relative* abuse potential as is important for CSA scheduling. Nevertheless, the DEA continues to rely heavily on these four factors in its potential-for-abuse findings.<sup>76</sup>

Under this approach, the DEA has repeatedly cited the large number of people who use marijuana as a basis for finding that it has a high potential for abuse relative to substances in Schedules III and lower. For instance, in 2016, the DEA (relying on an FDA recommendation) explained that “[a] number of factors indicate marijuana’s high abuse potential, including the large number of individuals regularly using marijuana, marijuana’s widespread use, and the vast

---

<sup>69</sup> 21 U.S.C. § 812(b)(1)(A).

<sup>70</sup> *Id.* § 812(b)(3)(A) (requiring Schedule III substances to have “a potential for abuse less than the drugs or other substances in schedules I and II”).

<sup>71</sup> See *Drug Scheduling*, U.S. DRUG ENF’T ADMIN., <https://www.dea.gov/drug-scheduling> [<https://perma.cc/5VZK-GW8W>] (last visited Mar. 31, 2021).

<sup>72</sup> *E.g.*, Alan J. Budney, Roger Roffman, Robert S. Stephens & Denise Walker, *Marijuana Dependence and Its Treatment*, ADDICTION SCI. & CLINICAL PRAC., no. 1, 2007, at 4, 4 (“Marijuana dependence as experienced in clinical populations appears very similar to other substance dependence disorders, although it is likely to be less severe.”).

<sup>73</sup> *Grinspoon v. Drug Enf’t Admin.*, 828 F.2d 881, 893 (1st Cir. 1987).

<sup>74</sup> *Id.* (emphasis added); see also H.R. REP. NO. 91-1444 (1970).

<sup>75</sup> *Grinspoon*, 828 F.2d at 893.

<sup>76</sup> See Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,553 (July 8, 2011) (following the four factors outlined in legislative history to determine abuse potential).

amount of marijuana available for illicit use.”<sup>77</sup> Put a different way, under the DEA’s approach to analyzing a drug’s potential for abuse, marijuana’s popularity is proof that it has a high potential for abuse. As with the medical-use criterion, it would seem that marijuana will be stuck with its “high potential for abuse” designation so long as the DEA follows its current test for that finding. Regardless of any other evidence about marijuana’s abuse potential, “[a] large number of individuals use marijuana.”<sup>78</sup> And that appears to be enough to result in a “high potential for abuse” finding under the DEA’s test.

## II. INSIGHTS FOR THE CSA

Because of the DEA’s tests for the medical-use and potential-for-abuse scheduling criteria, the prospects for marijuana rescheduling are bleak. In part for this reason, proposed legislation to solve the conflict between state and federal marijuana laws circumvents the CSA entirely. The MORE Act, for example, would require the removal of marijuana from the CSA’s schedules—marijuana would be “deemed to be a drug or other substance that does not meet the requirements for inclusion in any schedule.”<sup>79</sup> The Marijuana Justice Act, a bill championed by Senator Cory Booker, would likewise deschedule marijuana by removing it from the schedules of controlled substances.<sup>80</sup> Other proposals, such as the Strengthening the Tenth Amendment Through Entrusting States Act (“STATES Act”), would leave marijuana’s Schedule I status unchanged but carve out an exception to the CSA for conduct that complies with state marijuana laws.<sup>81</sup>

From the perspective of achieving federal marijuana reform, sidestepping the CSA’s regulatory scheme makes a great deal of sense. Reevaluating the CSA would be a significant undertaking given its potential to impact the legal status of all currently illegal drugs. Still, the experience of marijuana under the CSA suggests that the CSA itself is in need of reform. This Part considers three shortcomings of the CSA brought to light by its treatment of marijuana.

### A. *Marijuana and the CSA’s Scheduling Criteria*

The DEA’s approach to marijuana rescheduling petitions reveals a flawed scheduling system, with insufficient guidance to adequately constrain the exercise of administrative discretion. Congress’s failure to define the scheduling

---

<sup>77</sup> Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688, 53,706 (Aug. 12, 2016); *see also* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. at 40,562 (“The large number of individuals using marijuana on a regular basis, its widespread use, and the vast amount of marijuana that is available for illicit use are indicative of the high abuse potential for marijuana.”).

<sup>78</sup> Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. at 53,691.

<sup>79</sup> MORE Act of 2020, H.R. 3884, 116th Cong. § 3(a)(2) (2020).

<sup>80</sup> Marijuana Justice Act of 2019, S. 597, 116th Cong. § 2 (2019).

<sup>81</sup> STATES Act, H.R. 2093, 116th Cong. § 2 (2019).

criteria has resulted in a system that is too malleable: one in which the DEA—an agency with an institutional focus on criminal enforcement<sup>82</sup>—has almost limitless power to define and apply the scheduling criteria. The DEA has used its discretion in such a way that every mind-altering substance that is not an FDA-approved drug is all but assured to be classified in Schedule I.

There is perhaps no better example of the DEA's broad discretion to define the scheduling criteria than its approach to determining what constitutes an accepted medical use. It took the DEA more than two decades after passage of the CSA to arrive at its current definition of accepted medical use.<sup>83</sup> This extended timeline is certainly due in part to the fact that the medical use finding is not in dispute when the DEA schedules FDA-approved drugs; the issue only arises in the context of non-FDA-approved drugs that the agency is considering assigning to (or keeping in) Schedule I. Although the DEA's five-factor test had roots in both MDMA and marijuana scheduling proceedings, the DEA finalized the test in the context of its denial of a marijuana rescheduling petition<sup>84</sup>—a denial in which the agency rejected an administrative law judge's contrary proposal to base the definition on a standard employed in medical malpractice cases.<sup>85</sup> Given this history, it is difficult to escape the feeling that the DEA may have developed the first factor in its test—the requirement that a substance's chemistry be known and reproducible—with marijuana in mind.<sup>86</sup> After all, as discussed above, this requirement makes it all but impossible for marijuana to ever satisfy the accepted-medical-use finding, at least as the CSA defines the plant.<sup>87</sup> To be sure, there may be good policy reasons for requiring a drug's chemistry to be sufficiently reproducible to be *marketed* as a medicine,<sup>88</sup> but the CSA's medical-use criterion was not designed to be synonymous with FDA

---

<sup>82</sup> See Lauren M. Ouziel, *The Bureaucratic Afterlife of the Controlled Substances Act*, 18 OHIO ST. J. CRIM. L. 151, 162 (2020) (discussing how “[t]he DEA, whose primary mission is reducing drug supply through criminal enforcement of federal drug laws, is incentivized to increase” supply-reduction measures).

<sup>83</sup> See *All. for Cannabis Therapeutics v. Drug Enf't Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

<sup>84</sup> See *id.*

<sup>85</sup> See *id.* at 1137.

<sup>86</sup> See *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 Fed. Reg. 10,499, 10,507 (Mar. 26, 1992) (“Marijuana is not recognized as medicine in generally accepted pharmacopeia, medical references and textbooks . . . I take this to mean, under initial factor (5), that he determined that *marijuana's chemistry is neither known, nor reproducible*, as evidenced by its absence from the official pharmacopeia.” (emphasis added) (citation omitted)).

<sup>87</sup> See *supra* text accompanying notes 65-68.

<sup>88</sup> See *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 Fed. Reg. at 10,506 (explaining this factor by concluding that a drug's chemistry must be reproducible so that it can “be reproduced into dosages which can be standardized”).

approval.<sup>89</sup> And yet, the DEA has defined accepted medical use in a way that very closely mirrors FDA standards.<sup>90</sup> The wide gap between this definition and the one proposed by the administrative law judge in the context of NORML's marijuana rescheduling petition (acceptance by a respectable minority of physicians) underscores how the CSA's failure to define the scheduling criteria has given the DEA significant policy making authority and suggests the need for further guidance from Congress.

The DEA's repeated conclusion that marijuana has a high potential for abuse under the CSA is similarly indicative of a statute in need of reform. As discussed above, the DEA has relied on the sheer number of people who use marijuana as evidence of the substance's high potential for abuse.<sup>91</sup> Meanwhile, dronabinol, a synthetic pill containing the chief psychoactive component of marijuana, THC, and marketed under the trade name Marinol, is a Schedule III substance.<sup>92</sup> This means that the DEA has found that dronabinol has a potential for abuse less than the substances in Schedule I, including marijuana. How can it be that marijuana has a higher potential for abuse than synthetic THC? The relatively small number of people who use Marinol outside of medical supervision appears to have been a decisive factor for the DEA. In placing the drug in Schedule III, the DEA noted that while studies did not "indicate that there are differences in its abuse liability compared to oral THC[,] . . . there is little evidence of actual abuse of Marinol[], despite modest annual increases in the total number of prescriptions written."<sup>93</sup>

Although a congressional committee cited "[i]ndividuals . . . taking the drug . . . on their own initiative"<sup>94</sup> as a reason to support the scheduling of a substance, it is not self-evident why use of a substance on one's own initiative "rather than on the basis of medical advice,"<sup>95</sup> standing alone, should be treated as conclusive evidence of a potential for abuse. Certainly, it is a strange basis for assessing relative potential for abuse *among* different substances. But, in the absence of a definition from Congress, the DEA has been given the freedom to

---

<sup>89</sup> See *Grinspoon v. Drug Enf't Admin.*, 828 F.2d 881, 891 (1st Cir. 1987) ("On remand, the Administrator will not be permitted to treat the absence of FDA interstate marketing approval as conclusive evidence that MDMA has no currently accepted medical use and lacks accepted safety for use under medical supervision.").

<sup>90</sup> Eisenberg & Leiderman, *supra* note 68, at 259 ("The five-factor test, as elaborated by DEA purportedly reflects its understanding of FDA standards and practices and attempts to conform to those standards.").

<sup>91</sup> See *supra* text accompanying notes 77-78.

<sup>92</sup> Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol (Marinol®; (-)- $\Delta^9$ -(trans)-Tetrahydrocannabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules) from Schedule II to Schedule III, 63 Fed. Reg. 59,751, 59,752 (Nov. 5, 1998) (codified at 21 C.F.R. § 1308.15).

<sup>93</sup> *Id.* at 59,752.

<sup>94</sup> *Grinspoon*, 828 F.2d at 893 (quoting H.R. REP. NO. 91-1444, at 38 (1970)).

<sup>95</sup> *Id.* (quoting H.R. REP. NO. 91-1444, at 38).



focus on factors like the number of users of a substance in assessing its abuse potential.

Finally, marijuana's status under the CSA also highlights the problems inherent in the CSA's failure to explain how the scheduling criteria fit together. As discussed above,<sup>96</sup> it is possible for the CSA's scheduling criteria to point to more than one schedule for the same substance. For example, a substance with a relatively low abuse potential but no accepted medical use would not fit neatly into any of the schedules. Based on its potential for abuse, this hypothetical substance should be in Schedule III or lower, but without an accepted medical use, the CSA would seem to require that the substance be placed in Schedule I.

Although the CSA has been federal law for more than five decades, this anomaly in the scheduling criteria has never been tested in court. This is because the DEA has, curiously, apparently never encountered a substance that it believes has both a low potential for abuse and no currently accepted medical use.<sup>97</sup> This has allowed the problem to go largely unnoticed by courts and commentators, but it does not make it any less concerning.

Although the issue has not been resolved by the courts, the DEA has taken the position, in administrative dicta, that every scheduled substance without an accepted medical use must be classified in Schedule I, regardless of its relative abuse potential. In 2002, marijuana reform advocates argued for rescheduling on the ground that marijuana has an accepted medical use and a relatively low potential for abuse.<sup>98</sup> As already discussed, the DEA has consistently found that marijuana has a high potential for abuse. But in its administrative decision denying the 2002 rescheduling petition, the agency stated that it believes all scheduled substances without an accepted medical use must be placed in Schedule I, even if they have a low potential for abuse.<sup>99</sup> And in a different administrative decision, the DEA concluded that

even if one were to assume, theoretically, that your assertions about marijuana's potential for abuse were correct (*i.e.*, that marijuana had some potential for abuse but less than the "high potential for abuse" commensurate with schedules I and II), marijuana would not meet the criteria for placement in schedules III through V since it has no currently accepted medical use in treatment in the United States.<sup>100</sup>

---

<sup>96</sup> See *supra* text accompanying notes 42-49 (describing hypothetical of drug made unclassifiable due to lack of logical harmony in scheduling criteria).

<sup>97</sup> See Kreit, *supra* note 43, at 339-43.

<sup>98</sup> Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,552 (July 8, 2011).

<sup>99</sup> *Id.* at 40,566. The DEA does not appear to take the position that *all* substances without a currently accepted medical use must be placed in Schedule I; rather its position is that all *scheduled* substances without a currently accepted medical use must be placed in Schedule I. See *id.*

<sup>100</sup> Notice of Denial of Petition, 66 Fed. Reg. 20,038, 20,039 (Apr. 18, 2001).

In sum, the DEA's marijuana scheduling decisions paint a picture of a scheduling system with few significant constraints, at least when it comes to substances without FDA approval. Because the CSA does not define accepted medical use or potential for abuse, the DEA has seized the power to come up with its own definitions for these incredibly open-ended terms. As noted, the DEA's definitions are so pliable that it has, implausibly, never encountered a substance that has both a low potential for abuse and no accepted medical use. If the DEA ever were to be confronted with such a substance, however, its position is that the substance would have to be placed in Schedule I. Congress should closely review this state of affairs and consider whether to take steps to rethink the scheduling criteria and cabin the DEA's discretion.

B. *Schedule I and Research of Medical Uses*

Federal barriers to researching marijuana have rightfully drawn a good deal of attention over the years.<sup>101</sup> In part because of marijuana's Schedule I status, scientists have faced a wide range of obstacles to researching marijuana, including the inability to obtain suitable marijuana for research,<sup>102</sup> the need for approvals from multiple agencies to conduct research,<sup>103</sup> and additional regulatory requirements for approved research.<sup>104</sup> These barriers are such that Brookings Institution scholars Grace Wallack and John Hudak have argued that "[t]he biggest policy impact of rescheduling marijuana from Schedule I to Schedule II, III, IV or V would be in the area of medical research, particularly with regard to researcher certification and licensure."<sup>105</sup> Despite existing barriers, there is increasing evidence that marijuana and marijuana-derived products have medical uses. Even the DEA has acknowledged that there is

---

<sup>101</sup> See Peter J. Cohen, *Medical Marijuana: The Conflict Between Scientific Evidence and Political Ideology*, 2009 UTAH L. REV. 35, 76-86.

<sup>102</sup> *Id.* at 76-80; Joëlle Anne Moreno, *Half-Baked: The Science and Politics of Legal Pot*, 123 PENN. ST. L. REV. 401, 428-29 (2019).

<sup>103</sup> 21 U.S.C. § 823(f) (granting the authority to consider the "merits of the research protocol" of a Schedule I substance); Alexander W. Campbell, *The Medical Marijuana Catch-22: How the Federal Monopoly on Marijuana Research Unfairly Handicaps the Rescheduling Movement*, 41 AM. J.L. & MED. 190, 200-02 (2015) ("Researchers hoping to conduct research on the therapeutic benefits of marijuana must receive approval from four administrative entities: FDA, NIDA, HHS, and the DEA."); Moreno, *supra* note 102, at 429 (explaining that U.S. cannabis researchers must navigate a multiagency review process that often involves the NIDA, FDA, and DEA, plus institutional review boards, state government agencies, private institutions, and more).

<sup>104</sup> 21 U.S.C. § 823(f) (providing that proposed safeguards against diversion may be considered in determining the merits of a proposed research protocol for a Schedule I substance); Wallack & Hudak, *supra* note 20, at 212 ("Clinical trials with any Schedule I substance, however, always require a separate researcher registration, and [are] subject to more stringent controls and reporting requirements than any licensure required for research into non-Schedule I substances.").

<sup>105</sup> Wallack & Hudak, *supra* note 20, at 211.

evidence supporting “the potential therapeutic utility of cannabinoids”<sup>106</sup> and that “studies suggest that [the cannabinoid] CBD may have uses in the treatment of seizures and other neurological disorders.”<sup>107</sup>

This state of affairs highlights an important flaw in the CSA’s scheduling system with respect to Schedule I. Although the placement of a substance in Schedule I creates barriers to researching the substance, the CSA does not require *any* research into the potential medical value of a substance before it is scheduled.<sup>108</sup> So long as a substance has “no currently accepted medical use in treatment in the United States”<sup>109</sup> in the eyes of the DEA, it can be added to Schedule I. The result is that whether a substance has been the subject of thousands of studies or zero, it can be placed into Schedule I. Perhaps most problematic, the same is true of a substance that existing studies show may have medical promise. Unless the substance has an existing medical use at the time it is scheduled, the DEA will relegate that substance in Schedule I.

The experience of marijuana demonstrates why this feature of the CSA’s classification scheme is bad policy. For fifty years, marijuana’s placement in Schedule I has made it more difficult to study in the United States. This has continued to be the case, even as more and more evidence suggests it has medical uses and the FDA has approved one cannabis-derived drug (Epidiolex)<sup>110</sup> and three synthetic cannabis-related drugs (Marinol, Syndros, and Cesamet).<sup>111</sup> Barriers to research presented by marijuana’s Schedule I status have almost certainly delayed the creation of products such as Epidiolex and are continuing to delay other possible medical applications of marijuana.

Whatever the merits of the CSA’s scheduling scheme more broadly, it is difficult to justify making research into Schedule I substances as difficult as the

---

<sup>106</sup> Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,522, 40,580 (July 8, 2011).

<sup>107</sup> Applications to Become Registered Under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. 53,846, 53,846 (Aug. 12, 2016).

<sup>108</sup> The argument in this Section draws from my article, “Controlled Substances, Uncontrolled Laws.” See Kreit, *supra* note 43, at 353-56.

<sup>109</sup> 21 U.S.C. § 812(b)(1)(B).

<sup>110</sup> Press Release, FDA, FDA Approves New Indication for Drug Containing an Active Ingredient Derived from Cannabis to Treat Seizures in Rare Genetic Diseases, (July 31, 2020), <https://www.fda.gov/news-events/press-announcements/fda-approves-new-indication-drug-containing-active-ingredient-derived-cannabis-treat-seizures-rare> [<https://perma.cc/5JTU-6REC>]; Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements, 83 Fed. Reg. 48,950, 48,952 (Sept. 28, 2018) (codified at 21 C.F.R. pts. 1308, 1312) (placing the FDA-approved oral cannabidiol solution Epidiolex in Schedule V).

<sup>111</sup> Eisenberg & Leiderman, *supra* note 68, at 255; see also Ivan Urits, Matthew Borchart, Morgan Hasegawa, Justin Kochanski, Vwaire Orhurhu & Omar Viswanath, *An Update of Current Cannabis-Based Pharmaceuticals in Pain Medicine*, 8 PAIN & THERAPY 41, 47-49 (2019).

CSA does. It would be one thing if the CSA's barriers to research applied only to substances that have been exhaustively studied and found to have no potential medical uses. But the costs of restricting research into substances that have yet to be thoroughly studied—especially substances that existing studies suggest may have potential medical value—are significant. At best, barriers to researching Schedule I substances result in delays in the discovery of new medicines; at worst, they prevent the discovery of medical uses of a substance entirely.

Meanwhile, it is difficult to identify appreciable benefits of the current system. The primary rationale for restrictions into researching Schedule I substances is to safeguard against diversion.<sup>112</sup> But many Schedule I substances are already readily available in the illegal market. Indeed, a Schedule I substance that could be purchased in days or hours in the illegal market might take researchers months or years to get. For this reason, assuming *arguendo* that diversion were to become more likely without the CSA's strict regulations for researching Schedule I substances, any impact on overall availability of the substances would be negligible. As one marijuana researcher put it, the current system is a “comical” one in which the DEA can order a researcher “to do more to bolt down the locked [marijuana] freezer,” despite marijuana being openly sold in nearby dispensaries.<sup>113</sup>

Congress should draw on lessons from barriers to the research of marijuana to address this flaw in the CSA. Notably, there is good reason to think that doing so could lead to discoveries regarding the medical value of other Schedule I substances. Although this problem is perhaps most evident with respect to marijuana, it has caused delays in researching other Schedule I substances with medical promise as well.<sup>114</sup> Perhaps most notably, the FDA has granted “breakthrough therapy” status to the Schedule I substances MDMA and psilocybin and approved Phase 3 trials for MDMA.<sup>115</sup> Ironically, in the 1980s, a

---

<sup>112</sup> See Kreit, *supra* note 43, at 356-58.

<sup>113</sup> Janet Wells, *Dazed and Confused: Marijuana Legalization Raises the Need for More Research*, U.C.S.F. (June 20, 2017), <https://www.ucsf.edu/news/2017/06/407351/dazed-and-confused-marijuana-legalization-raises-need-more-research> [https://perma.cc/5DAT-RHTG].

<sup>114</sup> See Mason Marks, *Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles*, 21 N.Y.U. J. LEGIS. & PUB. POL'Y 69, 87-106 (2018) (discussing barriers to researching psychedelic substances, including legislation, regulation, stigmatization, and lack of incentivization).

<sup>115</sup> Press Release, Multidisciplinary Ass'n for Psychedelic Stud., FDA Grants Breakthrough Therapy Designation for MDMA-Assisted Psychotherapy for PTSD, Agrees on Special Protocol Assessment for Phase 3 Trials (Aug. 26, 2017), <https://maps.org/news/media/6786-press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd,-agrees-on-special-protocol-assessment-for-phase-3-trials> [https://perma.cc/8VB5-HKHW]; Yasemin Saplakoglu, *FDA Calls Psychedelic Psilocybin a 'Breakthrough Therapy' for Severe Depression*, LIVE SCI. (Nov. 25, 2019),

Harvard psychiatry professor unsuccessfully sought to keep MDMA out of Schedule I, arguing in part that the designation “would strongly discourage medical research on the drug.”<sup>116</sup>

C. *The CSA and Nonmedical Uses*

Finally, the prospect of federal marijuana reform raises the question of whether Congress should revisit the CSA’s approach to the nonmedical uses of substances more broadly. A core feature of the CSA is that it leaves no room for the possibility of legal nonmedical uses of mind-altering substances. The CSA purports to be a “unified legal framework to regulate certain drugs—whether medical or recreational, legally or illicitly distributed—that are deemed to pose a risk of abuse and dependence.”<sup>117</sup> Importantly, for drugs that are deemed to pose a risk of abuse by the DEA, the CSA permits distribution only for research or (for substances in Schedules II through V) medical purposes.<sup>118</sup> Put differently, if a drug is classified anywhere under the CSA, it is illegal to manufacture, distribute, and possess for nonmedical (i.e., “recreational”<sup>119</sup>) purposes. This is true even for substances in Schedule V.<sup>120</sup> As a result, the CSA grants the DEA authority to criminalize the nonmedical use of potentially any and all substances with “a stimulant, depressant, or hallucinogenic effect on the central nervous system.”<sup>121</sup> In effect, the CSA created a standing policy of prohibition of the nonmedical use of all mind-altering substances.

The notion that the CSA uniformly regulates all substances that pose a risk of dependence has always been at odds with its treatment of alcohol and tobacco. Alcohol and tobacco are expressly exempted by the CSA; specifically, the CSA provides that the term controlled substance “does not include distilled spirits,

---

<https://www.livescience.com/psilocybin-depression-breakthrough-therapy.html> [https://perma.cc/V6LV-MXZN]; see also Marks, *supra* note 114, at 110-13 (discussing the FDA’s breakthrough therapy designation program in the context of psychedelics).

<sup>116</sup> *Grinspoon v. Drug Enf’t Admin.*, 828 F.2d 881, 896 (1st Cir. 1987). For an argument in favor of decriminalizing psychedelics, see Dustin Marlan, *Beyond Cannabis: Psychedelic Decriminalization and Social Justice*, 23 LEWIS & CLARK L. REV. 851, 874 (2019).

<sup>117</sup> LAMPE, *supra* note 26.

<sup>118</sup> 21 U.S.C. § 829(c) (“No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.”).

<sup>119</sup> I use the term “recreational use” here in order to distinguish permitted and nonpermitted uses under the CSA, but I am mindful of the fact that drawing the distinction between medical and recreational use is not as easy as it might seem. See Matt Lamkin, *Legitimate Medicine in the Age of Consumerism*, 53 U.C. DAVIS L. REV. 385, 421 (2019) (“As doctors increasingly prescribe psychotropic drugs to healthy people to relieve stress, enhance performance, and otherwise obtain desired mental states, it becomes harder to distinguish these uses from ‘recreational’ drug-taking.”).

<sup>120</sup> *Cf. Arellano v. Barr*, 784 F. App’x 609, 609 (10th Cir. 2019) (holding that an immigrant was ineligible for cancellation of removal due to a conviction for possession of a Schedule V substance).

<sup>121</sup> 21 U.S.C. § 811(f).

wine, malt beverages, or tobacco.”<sup>122</sup> If not for this exception, alcohol and tobacco would both surely be Schedule I substances—they are both widely used (and so would have a high potential for abuse under the DEA’s definition), and neither has a currently accepted use as a medicine. Indeed, one wonders whether caffeine—which is notably *not* subject to a statutory exemption from the CSA—would qualify as a Schedule I controlled substance if the DEA were ever faced with a petition to schedule it.<sup>123</sup>

If marijuana is excised from the CSA, as contemplated by leading federal marijuana reform proposals such as the MORE Act, that will make three substances that are legal for recreational use only because of an exception to the CSA’s usual scheduling requirements. This raises the question of whether, instead of exempting these substances from the CSA, Congress should revise the scheduling system in a way that would allow these substances to be regulated within it. One can imagine, for example, a scheduling designation that would expressly permit substances that carry a relatively lower risk of dependency (a category in which marijuana could arguably fall) and perhaps meet other criteria to be manufactured and distributed for nonmedical purposes.

Developing a scheduling designation along these lines would be a significant undertaking and may ultimately prove to be an impossible task. After all, if a relatively low risk of dependency were required for a substance to be placed in this hypothetical new schedule, both alcohol and tobacco would still require a separate exemption. With this in mind, exception making may be preferable to attempting to create a truly uniform approach to regulating all substances. Specifically, there may be good policy reasons for treating alcohol, tobacco, and marijuana—all widely used substances with a relatively high degree of social acceptance—differently than other mind-altering substances. Still, the prospect of marijuana reform does at least raise the question of whether Congress should consider developing a regulatory pathway within the CSA to expressly permit the nonmedical use of some substances.

#### CONCLUSION

State and federal marijuana laws have stood in conflict for at least twenty-five years, following the passage of California’s Compassionate Use Act in 1996. Congress may finally be on the verge of addressing the problem. Any solution seems likely to elide the broader question of the CSA, and for good reason. Resolving the conflict between federal and state marijuana laws has proven

---

<sup>122</sup> *Id.* § 802(6).

<sup>123</sup> In the context of probation conditions, for example, the Ninth Circuit has recognized that caffeine could be considered similar to a controlled substance in its effect. *See United States v. Aquino*, 794 F.3d 1033, 1037 (9th Cir. 2015) (finding that a condition of supervised release that forbid a probationer from using any substance “intended to mimic the effect[s]” of a controlled substance was impermissibly vague, and noting that “Red Bull, Diet Mountain Dew Code Red, Jolt Cola (popular in the 1980s), and countless other sodas, for instance, could fall into this category” (alteration in original)).

difficult enough on its own. In this context, simply removing marijuana from the CSA through legislation is surely the easiest way to address the barriers it would otherwise present.

But while marijuana reform likely will proceed apart from, and before, reform of the CSA, the experience of marijuana under the CSA suggests that it is also in need of change. This Essay has examined the CSA's scheduling system through the lens of its treatment of marijuana, with particular attention to what marijuana reveals about some of the CSA's flaws and quirks. This assessment has been far from exhaustive, and other aspects of the CSA's scheduling system may well be in need of reform as well.<sup>124</sup> My aim here has not been to propose any specific reform to the CSA but rather to highlight that Congress should view its marijuana reform effort as a beginning—not an end—when it comes to rethinking how federal law treats controlled substances and to help inform the conversation going forward.

---

<sup>124</sup> See, e.g., Joseph Hartunian, *Getting Back on Schedule: Fixing the Controlled Substances Act*, 12 ALB. GOV'T L. REV. 199, 217-23 (2019) (proposing several possible changes to the CSA, including adopting the standard used for admitting expert testimony to determine accepted medical use and requiring that all scheduled substances undergo annual review by the National Institute on Drug Abuse); Kim, *supra* note 12, at 91-97 (arguing in favor of reforms to the CSA that focus on issues of equity, scientific evidence, and the anticipation of future state-federal conflict).