CONTROLLED SUBSTANCES, UNCONTROLLED LAW

Alex Kreit[*]

INTRODUCTION 332
I. AN OVERVIEW OF THE CONTROLLED SUBSTANCES ACT 333
II. CLASSIFICATION UNDER THE CSA 336
A. The CSA's Conflicting Criteria 338
B. Eight Factors Plus Three Findings Equals Confusion .342
III. BARRIERS TO RESEARCH 351
A. Schedule First, Study Later (or Never) 352
B. *The Rationale for Restricting Research into Schedule I Substances* 355
CONCLUSION 357

[*] Associate Professor and Director, Center for Law and Social Justice, Thomas Jefferson School of Law.

INTRODUCTION

For more than forty years, the Controlled Substances Act (CSA) has served as the foundation for federal drug control.[1] Since the law's enactment, drug policy in the United States has experienced significant changes. In the 1980's and 1990's we saw the rise of the war on drugs[2] and the development of drug quantity-based mandatory minimum sentencing.[3] Since the mid-1990's, the states and the federal government have battled over medical marijuana.[4] There has been a rich and lively debate about each of these issues and many others—from the impact of drug enforcement on the Fourth Amendment to the link between race and the drug war.

However, almost nothing has been written about the classification and regulatory provisions of the Controlled Substances Act. With the exception of the narrow question of marijuana's status as a Schedule I substance, the CSA's classification scheme rarely enters the policy or legal discussion. Somehow, the underpinnings of our current drug policy have slipped through the cracks.

In some ways, the inattention to the CSA's arcane regulatory structure is understandable. The details of the CSA's classification scheme would do little to inform any debate on the merits of drug prohibition. The federal government had already outlawed most of the substances prohibited by the CSA long before its passage.[5] And, in any event, the CSA makes it illegal to distribute or possess *any* controlled substance for recreational use, regardless of its schedule.[6] Likewise, most other major federal drug policy questions—from sentencing to budget allocation to racial disparities in enforcement—are only

[1] *Controlled Substances Act of 1970*, NAT'L SUBSTANCE ABUSE INDEX, http://nationalsubstanceabuseindex.org/act1970.htm (last visited Apr. 30, 2013).

[2] *See generally* Corey Rayburn Yung, *The Emerging Criminal War on Sex Offenders,* 45 HARV. C.R.-C.L. L. REV. 435 (2010) (discussing the rise of the war on drugs).

[3] William W. Wilkins, Jr., Phyllis J. Newton & John R. Steer, *Competing Sentencing Policies in a "War on Drugs" Era*, 28 WAKE FOREST L. REV. 305, 318 (1993) (discussing the passage of federal mandatory minimum sentencing laws).

[4] Alex Kreit, *The Federal Response to State Marijuana Legalization: Room for Compromise?*, 91 OR. L. REV. 1029, 1029 (2013).

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

[6] *Controlled Substances Act*, 21 U.S.C. §§ 841(a)(1), 844(a) (2006).

tangentially related to the CSA's administrative provisions.

Although an understanding of how the federal government classifies and regulates controlled substances may not have much relevance to many of the hot-button drug policy topics, it is still an incredibly worthy concern in its own right. This essay calls attention to this important but critically under-examined area of drug control by focusing on two key aspects of the CSA: classification and research. Part I introduces the Controlled Substances Act. Part II analyzes the CSA's approach to scheduling, and I argue that the CSA's open-ended classification scheme fails to adequately control the scheduling of substances and gives the Drug Enforcement Administration nearly unfettered discretion to decide how to classify a drug. Regardless of one's views on the wisdom of prohibition, the CSA's byzantine scheduling structure should concern anyone with an interest in having a predictable, uniform, science-based approach to drug regulation.

Part III of this essay turns to the barriers to research the CSA imposes on Schedule I substances. This section highlights a strange feature of the CSA's approach to research. Schedule I substances include both substances that show early (but unproven) promise as medicines and those that we already know have no medical value. Yet, all Schedule I substances are equally—and incredibly—difficult to research. Part IV concludes that it is time for Congress to revisit the administrative provisions of the CSA. Though not as glamorous as issues like the federal response to state marijuana legalization laws, there are compelling reasons to rethink the CSA's classification criteria and research restrictions for Schedule I drugs.

I. AN OVERVIEW OF THE CONTROLLED SUBSTANCES ACT

Prior to passage of the Controlled Substances Act (CSA) in 1970, federal drug prohibition had been built over time through "[a] patchwork of regulatory, revenue, and criminal measures[.]"[7]

Congress first banned the nonmedical market for opiates and cocaine in 1914 with passage of the Harrison Narcotics Act, and marijuana in 1937 with the Marihuana Tax Act.[8] Because the

[7] RICHARD J. BONNIE & CHARLES H. WHITEBREAD II, THE MARIHUANA CONVICTION: A HISTORY OF MARIHUANA PROHIBITION IN THE UNITED STATES 242 (1974).

[8] *See generally* Quinn & McLaughlin, *supra* note 5.

"commerce clause was still read rather restrictively by the courts[,]"[9] both laws were framed as revenue measures.[10] In part because of its awkward construction, the scope of the Harrison Narcotics Act was not immediately clear. In particular, there was a dispute over whether the law was intended to prohibit distribution of opiates and cocaine entirely, or whether addiction maintenance under a doctor's supervision would be considered an allowable medical use.[11] After a short period of ambiguity, however, the Harrison Narcotics Act's restrictions came into focus and "effectively ushered in an era of national drug control."[12]

Between 1914 and 1970, Congress expanded federal drug prohibition with "'more than [fifty] pieces of legislation' relating to the regulation of dangerous drugs."[13] By the time the Controlled Substances Act was drafted, opiates and cocaine were controlled by one law (the 1914 Harrison Act), marijuana by another (the 1937 Marihuana Tax Act), and hallucinogens, stimulants and depressants by a third (the Food, Drug and Cosmetic Act, under amendments passed in 1965).[14] Meanwhile, other statutes filled in various regulatory gaps.[15] Adding to the confusion, in a pair of decisions in 1969 and 1970, the Supreme Court held aspects of the pre-CSA scheme unconstitutional.[16] The CSA, enacted as part of the Comprehensive Drug Abuse

[9] *Id.* at 593.

[10] *Id.; see also* ALFRED R. LINDESMITH, THE ADDICT AND THE LAW 3 (1965) ("Another unusual feature of the federal narcotic laws is that, while they are in legal theory revenue measures, they contain penalty provisions that are among the harshest and most inflexible in our legal code.").

[11] *See* Joseph F. Spillane, *Building a Drug Control Regime, 1919–1930*, *in* FEDERAL DRUG CONTROL: THE EVOLUTION OF POLICY AND PRACTICE 25, 25–30 (Jonathon Erlen & Joseph F. Spillane eds., 2004) (providing a history of implementation and interpretation of the Harrison Narcotics Act and describing how drug abuse came to be defined "as a police problem" at the federal level).

[12] Joseph F. Spillane, *The Road to the Harrison Narcotics Act: Drugs and Their Control, 1875–1918*, *in* FEDERAL DRUG CONTROL: THE EVOLUTION OF POLICY AND PRACTICE 1, 1 (Jonathon Erlen & Joseph F. Spillane eds., 2004); *see also* DAVID F. MUSTO, THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL 68 (3d ed. 1999) ("[T]he evolution of the Harrison Act's enforcement policies, after initial setbacks, ended in the triumph of those who believed the law had a moral effect and was designed to prohibit the use of narcotics for the maintenance of 'mere' addiction.").

[13] Ams. for Safe Access v. Drug Enforcement Admin., No. 11-1265, 2013 U.S. App. LEXIS 1407, at *25 (D.C Cir. Jan. 19, 2013) (quoting H.R. REP. NO. 91–1444, pt. 1, at 598 (1970)).

[14] Quinn & McLaughlin, *supra* note 5, at 593, 600, 603.

[15] *See generally id.* at 592, 597, 600.

[16] *See* Leary v. United States, 395 U.S. 6, 37 (1969); Turner v. United States, 396 U.S. 398, 424 (1970).

Prevention and Control Act of 1970, was designed to "'collect[] and conform[] these diverse laws in one piece of legislation.'"[17]

The basic structure of the CSA's classification system is easily stated.[18] The law prohibits the manufacture, sale, and possession for recreational use of any substance it controls. To do this, the CSA divides controlled substances into five "schedules."[19] Schedule I substances are the most strictly regulated as they do not have a "currently accepted medical use in treatment in the United States."[20] As a result, it is only legal to produce or possess Schedule I substances for research in accordance with the CSA's very tight controls.[21] Substances in Schedules II through V all have recognized medical uses and can be legally distributed as medicines.[22] Substances in these schedules are differentiated mainly based on their relative abuse potential, with Schedule V substances having the lowest potential for abuse and subject to the most modest controls.[23]

To put an end to the piecemeal approach to federal drug regulation that had developed before 1970, the CSA granted rule-making power to the Attorney General to schedule new substances, and reschedule ones that are already controlled, administratively.[24] Since 1973, the Attorney General's scheduling authority has been sub-delegated to the head of the Drug Enforcement Administration (DEA).[25] With the exception of alcohol and tobacco, which Congress exempted from the CSA,[26]

[17] *Ams. for Safe Access*, 2013 U.S. App. LEXIS 1407, at *25 (quoting H.R. REP. NO. 91–1444, pt. 1, at 598 (1970)).

[18] For a detailed overview of the regulatory provisions of the Controlled Substances Act, *see generally* GERALD F. UELMEN ET AL., DRUG ABUSE AND THE LAW: SOURCEBOOK (forthcoming 2013).

[19] 21 U.S.C. § 812(a) (2006).

[20] 21 U.S.C. § 812(b)(1)(B) (2006).

[21] JOSEPH T. RANNAZZISI & MARK W. CAVERLY, DRUG ENFORCEMENT ADMIN., PRACTITIONER'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 5 (2006), http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf.

[22] *Id.*

[23] *Id.* at 5–6.

[24] *See* Exec. Order No. 11,727, 38 Fed. Reg. 18,357 (July 10, 1973).

[25] *Id.* at 18,357; 28 C.F.R. § 0.100 (2003). In *Touby v. U.S.*, 500 U.S. 160, 164–65 (1991), the Supreme Court upheld this scheme against a challenge that it ran afoul of Article I of the Constitution, which provides that "all legislative Powers herein granted shall be vested in a Congress of the United States" (quoting U.S. CONST. art. I, § 1).

[26] 21 U.S.C. § 802(6) (2006); *see also* Nat'l Org. for the Reform of Marijuana Laws v. Bell, 488 F. Supp. 123, 136 (D.D.C. 1980) (holding that the decision to exempt alcohol and tobacco from the CSA while placing marijuana in Schedule I

the DEA can place any substance it determines to meet the CSA's scheduling criteria under its control.[27] This feature marked an important change in federal drug control. Prior to the CSA, it was up to Congress to decide whether or how to address any newly discovered substance on a drug-by-drug basis.[28] Through the CSA's administrative scheduling system, Congress established an ongoing national policy of prohibition of the recreational market for mind-altering substances.[29]

II. CLASSIFICATION UNDER THE CSA

The CSA has been a very successful statute as measured by Congress's goal of placing essentially all drugs of abuse under a single regulatory scheme.[30] Hundreds of substances are currently scheduled under the CSA[31] and the DEA's scheduling process generally functions smoothly, at least when the agency is seeking to add a new drug to Schedule I.[32]

To the extent the CSA was designed to be more than just an efficient tool for the DEA to ban new substances, however, the law leaves a lot to be desired. Time and experience have revealed fundamental flaws in the CSA's scheduling criteria as well as its approach to research of Schedule I substances. These shortcomings should concern anyone interested in a predictable, uniform, and science-based approach to categorizing and regulating controlled substances, regardless of their position on the wisdom of drug prohibition or the war on drugs.

The CSA claims to classify substances based on three criteria: whether they have a medical use, their potential for abuse, and their safety and dependence.[33] Schedule I substances are those

survived rational basis review).

[27] *See* RANNAZZISI & CAVERLY, *supra* note 21, at 4.

[28] *See* Quinn & McLaughlin, *supra* note 5, at 597, 600.

[29] S.E. Smith, *Under the Controlled Substances Act, What Are the Five Classes of Controlled Substances?*, WISEGEEK, http://www.wisegeek.com/under-the-controlled-substances-act-what-are-the-five-classes-of-controlled-substances.htm (last visited Mar. 12, 2013).

[30] Not all substances that appear to meet the CSA's scheduling criteria are controlled. The hallucinogenic plant salvia, for example, remains unscheduled under the federal CSA although it is controlled under some state laws. *See* Corin Saxton, *Chapter 184 and Salvia Divinorum: Electric Kool-Aid Salvia Tests?*, 40 MCGEORGE L. REV. 509, 514–515 (2009).

[31] 21 C.F.R. § 1308 (2012).

[32] John J. Coleman, *Drug Scheduling*, TUFTS HEALTHCARE INST., http://www.thci.org/opioid/sept06docs/coleman.pdf (last visited Feb. 18, 2013).

[33] RANNAZZISI & CAVERLY, *supra* note 21, at 5.

that have "a high potential for abuse," "no currently accepted medical use," and for which "[t]here is a lack of accepted safety for use of the drug or other substance under medical supervision."[34] Schedule II substances also have "a high potential for abuse."[35] They are distinguished from Schedule I because they have "a currently accepted medical use in treatment in the United States" and there is not a complete lack of safety for their use, although their abuse "may lead to severe psychological or physical dependence."[36] Substances in Schedule III have a lower potential for abuse and risk of dependence than those in Schedule II, and so on.

Figure 1 – The Controlled Substances Act Scheduling Criteria

	Abuse Potential	Medical Use	Safety and dependence
Schedule I	High potential for abuse	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

[34] 21 U.S.C. § 812 (b)(1) (2006).
[35] 21 U.S.C. § 812 (b)(2)(A).
[36] 21 U.S.C. § 812 (b)(2)(B).

This deceptively simple system masks significant problems.

A. The CSA's Conflicting Criteria

The CSA provides that "a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance."[37] This language suggests that for a substance to be placed in a given schedule, it must meet all three criteria for that schedule. And yet, it is possible for the criteria to point in three different directions for a single drug.

To understand the problem, imagine a substance with a low potential for abuse and dependence profile. Specifically, this substance—Substance X—has "a low potential for abuse relative to the drugs or other substances in schedule IV" and its abuse might "lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV."[38] Based on these two characteristics, Substance X should be in Schedule V. But what if Substance X has no currently accepted medical use in treatment in the United States? This characteristic would seem to place it in Schedule I.

Figure 2 – Substance X

	Abuse Potential	Medical Use	Safety and Dependence
Schedule I	High potential for abuse	**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

[37] 21 U.S.C. § 812(b).
[38] 21 U.S.C. § 812(b)(5).

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**

There is no doubt that Substance X should be scheduled under the CSA; but in which schedule? Substance X does not meet the scheduling requirements for any one category.

That the CSA's scheduling criteria "cannot logically be read as cumulative in all situations"[39] presents what seems to be a central question about the law—particularly in light of the statute's constraint that "a drug . . . may not be placed in any schedule unless the findings required for such schedule are made[.]"[40] More than forty years after the CSA's enactment, however, this basic problem has not yet been definitively tested in the courts. A small handful of judicial and administrative opinions have discussed the issue in dicta,[41] but no published decision has squarely confronted it.

The 1977 D.C. Circuit Court decision, *National Organization for the Reform of Marijuana Laws (NORML) v. Drug Enforcement Administration (DEA)*, is the only to have considered the conflict in any detail.[42] There, NORML challenged the denial of its petition to reschedule marijuana.[43] The DEA had denied the petition on the basis of a letter from the Acting Assistant Secretary of Health, Education, and Welfare,[44] which stated that

[39] United States v. Maiden, 355 F. Supp. 743, 749 n.4 (D. Conn. 1973).

[40] 21 U.S.C. § 812(b).

[41] *See, e.g.*, United States v. Fogarty, 692 F.2d 542, 548 (8th Cir. 1982) (arguing without elaboration that "the three statutory criteria for Schedule I classification . . . should not be read as being either cumulative or exclusive"); Nat'l Org. Reform of Marijuana Laws v. Bell, 488 F. Supp. 123, 140 (D.D.C. 1980) ("Indeed, the classifications at times cannot be followed consistently, and some conflict exists as to the main factor in classifying a drug . . . ."); *Maiden*, 355 F. Supp. at 749 n.4 (observing the conflict without offering an opinion as to how it should be resolved).

[42] Nat'l Org. Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d 735, 737 (D.C. Cir. 1977).

[43] *Id.* at 738.

[44] The predecessor agency to the Department of Health and Human Services.

there "is currently no accepted medical use of marihuana in the United States"[45] without analyzing any of the other medical and scientific issues outlined in the CSA.[46]

In the course of holding that the DEA was required to obtain the complete medical and scientific evaluation from the Department of Health, Education, and Welfare described in the CSA,[47] the D.C. Circuit indicated that a substance without an accepted medical use was not necessarily required to be placed in Schedule I. The Court explained:

> Admittedly, . . . 21 U.S.C. § 812(b), which sets forth the criteria for placement in each of the five CSA schedules, established medical use as the factor that distinguishes substances in Schedule II from those in Schedule I. However, placement in Schedule I does not appear to flow inevitably from lack of a currently accepted medical use. . . . To treat medical use as the controlling factor in classification decisions is to render irrelevant the other "findings" required by [the CSA's scheduling criteria]. 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.
>
> Moreover, DEA's own scheduling practices support the conclusion that substances lacking medical usefulness need not always be placed in Schedule I. At the hearing before ALJ Parker DEA's Chief Counsel, Donald Miller, testified that several substances listed in CSA Schedule II, including poppy straw, have no currently accepted medical use. He further acknowledged that marihuana could be rescheduled to Schedule II without a currently accepted medical use. Neither party offered any contrary evidence.[48]

Though this discussion supports the view that a lack of medical use is not dispositive in scheduling, it came in dicta.[49] The case

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Id. at 742–43.

[45] *Id.* at 742.

[46] *See* 21 U.S.C. § 811(c) (2006).

[47] Nat'l Org. Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d at 748 (concluding that the CSA "does not in any way qualify the [Health, Education, and Welfare] Secretary's duty of evaluation").

[48] *Id.* (internal citations omitted).

[49] *See id.* at 748–49

> [E]ven if lack of medical use is dispositive of a classification decision, we do not think the finding in this case was established in conformity with the statute. Dr. Cooper's letter is addressed to a member of DEA's legal staff, in response to the latter's inquiry; the letter was not solicited by the Acting Administrator, and it can hardly take the place of the elaborate referral machinery contemplated by Congress.

Id.

only raised the question of whether the Secretary of Health, Education, and Welfare was required to make additional findings on order for the DEA's scheduling determination to be valid.[50] It did not present the problem of a substance that has been found to have a relatively low potential for abuse but no accepted medical use.

Contrary to the D.C. Circuit's dicta, the DEA has recently stated it believes all substances without an accepted medical use must be placed in Schedule I, regardless of the other scheduling criteria.[51] In a 2001 administrative decision denying another petition to reschedule marijuana, the DEA explained its rationale:

> 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." To be classified in schedules II through V, a drug of abuse must have a "currently accepted medical use in treatment in the United States." This is why the CSA allows practitioners to prescribe only those controlled substances that are listed in schedules II through V. Drugs listed in schedule I, by contrast, may not be prescribed for patient use; they may only be dispensed by practitioners who are conducting FDA-approved research and have obtained a schedule I research registration from DEA.
>
> . . . .
>
> Thus, when it comes to a drug that is currently listed in schedule I, if it is undisputed that such drug has no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision, and it is further undisputed that the drug has at least some potential for abuse sufficient to warrant control under the CSA, the drug must remain in schedule I. In such circumstances, placement of the drug in schedules II through V would conflict with the CSA since such drug would not meet the criterion of "a currently accepted medical use in treatment in the United States."
>
> Therefore, 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

[50] *Id.* at 754.

[51] Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,566 (Dep't of Justice July 8, 2011) ("If a controlled substance has no such currently accepted medical use, it must be placed in schedule I.").

> III through V since it has no currently accepted medical use in treatment in the United States . . . .[52]

The point here is not to take sides in this dispute, but to highlight what this dispute says about the CSA's scheduling system. A classification scheme premised on criteria that "at times cannot be followed consistently"[53] is incoherent—flawed at a fundamental level.

Strangely, forty-three years into the CSA's existence, this problem has yet to be tested in any judicial or administrative opinion.[54] This is so only because the DEA appears never to have found a substance without an accepted medical use to have a low abuse potential. In other words, *every* substance the DEA has administratively classified[55] in the past four decades has conveniently satisfied the three scheduling criteria for a single schedule. It seems implausible that every single substance without a medical use also happens to have a high abuse potential.

How can this be? The answer lies in the overly broad discretion the CSA gives a highly political law enforcement agency—the DEA—to define and apply its scheduling criteria.

B. Eight Factors Plus Three Findings Equals Confusion

What is an "accepted medical use in treatment in the United States"? How does one measure "potential for abuse"? The CSA gives surprisingly little guidance. Indeed, the term United States "is the only portion of the Schedule I criteria that Congress has expressly defined in the CSA[.]"[56] The CSA's poorly defined

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[52] Notice of Denial of Petition, 66 Fed. Reg. 20,038, 20,038–39 (Dep't of Justice Apr. 18, 2001) (citations omitted).

[53] Nat'l Org. Reform of Marijuana Laws v. Bell, 488 F. Supp. 123, 140 (D.D.C. 1980).

[54] *See* United States v. Maiden, 355 F. Supp. 743, 749 (D. Conn. 1973); United States v. Fogarty, 692 F.2d 542 (8th Cir. 1982); Nat'l Org. Reform of Marijuana Laws v. Bell, 488 F. Supp. 123 (court and administrative opinions have discussed this problem only in dicta).

[55] Congress placed a handful of plant material without an accepted medical use were placed outside of Schedule I when it enacted the CSA—for example, poppy straw. Though these unprocessed plants do not have recognized medical uses, recognized medicines are derived from them. *See* Raymond J. Walsh, Jr., Note, *Populations at Risk for Criminal Liability Under Compassionate Use Acts*, 25 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 275, 282 (1999) ("[P]lant material containing the same therapeutic substance should not be restricted more severely than the therapeutic substances themselves.") (citation omitted).

[56] Grinspoon v. Drug Enforcement Admin., 828 F.2d 881, 885 (1st Cir. 1987).

scheduling criteria and process helps to explain how the DEA has been able to find that substance after substance neatly satisfies all three criteria for a single schedule, freeing itself from the headache of litigating the question of where a substance should be classified when the scheduling criteria point in different directions.[57]

The CSA's problematic scheduling process was the subject of some debate and litigation in the 1970s.[58] Shortly after passage of the CSA, for example, an internal Department of Health, Education, and Welfare memo expressed serious concern about the classification scheme.[59] The memo worried the CSA's scheduling scheme would "provide little practical guidance in deciding particular cases" in part because the law left "undefined the concepts of drug abuse potential, of drug dependence, and of risk to public health."[60]

Over time, however, less and less attention has been paid to the Kafkaesque quality of the CSA's scheduling system. To be sure, it has not been entirely forgotten. In 1994, when the National Conference of Commissioners on Uniform State Laws updated the model state law based on the Federal Act, they noted concern about the scheduling requirements but retained them "[w]ith extreme reluctance" in order to maintain uniformity with federal law.[61] But in general, to the extent the CSA's classification system is debated, the focus is whether a specific substance has been properly classified.[62] It is almost as if the

The definitions provision of the CSA defines the term "United States" as "when used in a geographic sense, [to] mean[] all places and waters, continental or insular, subject to the jurisdiction of the United States." 21 U.S.C. § 802(28) (2006).

[57] *See* United States v. Fogarty, 692 F.2d at 548.

[58] *See, e.g.*, Nat'l Org. Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d 735 (D.C. Cir. 1977).

[59] United States v. Pastor, 419 F. Supp. 1318, 1339 n.6 (S.D.N.Y. 1975).

[60] *Id.*

[61] UNIF. CONTROLLED SUBSTANCES ACT § 203, cmt. at 16 (1994), http://www.iowamedicalmarijuana.org/petitions/pdfs/ucsa94.pdf.

> With extreme reluctance the requirements for placing substances in the various schedules are being retained in substantially the form contained in the 1970 Uniform Act and the federal Controlled Substances Act. The primary reason for the retention is that requirements for scheduling particular substances should parallel one another at the state and federal levels.

Id.

[62] *See generally* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552 (Dep't of Justice July 8, 2011).

peculiarity of the CSA's scheduling provisions has been buried underneath a mountain of the DEA's technocratic administrative opinions that apply them.

To begin, although the CSA's scheduling criteria appear to make up self-contained "findings required for each of the schedules,"[63] a different provision of the CSA lists eight additional "[f]actors determinative of control or removal from schedules."[64] This provision instructs the DEA, when applying the CSA's three scheduling criteria,

> [to] consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules: (1) Its actual or relative potential for abuse. (2) Scientific evidence of its pharmacological effect, if known. (3) The state of current scientific knowledge regarding the drug or other substance. (4) Its history and current pattern of abuse. (5) The scope, duration, and significance of abuse. (6) What, if any, risk there is to the public health. (7) Its psychic or physiological dependence liability. (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.[65]

The exact relationship between these eight "factors" and the three "findings required for each of the schedules" remains somewhat mysterious. The Department of Health, Education, and Welfare memo mentioned above observed that the "eight factors . . . unfortunately are for the most part vague and redundant. The list exhibits circular reasoning and lack of parallelism, particularly when viewed together with the definitions of the schedules."[66] The first factor—"actual or relative potential for abuse"[67]—appears to duplicate the first scheduling finding, which also measures potential for abuse.[68] Similarly, a substance's "psychic or physiological dependence liability"[69] (factor seven) mirrors the third scheduling requirement, which considers the degree of "psychological or physical dependence" that abuse of that substance "may lead to."[70]

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[63] 21 U.S.C. § 812(b) (2006).
[64] 21 U.S.C. § 811(c) (2006).
[65] *Id.*
[66] United States v. Pastor, 419 F. Supp. 1318, 1339 n.6 (S.D.N.Y. 1975).
[67] 21 U.S.C. § 811(c)(1).
[68] 21 U.S.C. § 812(b)(1)(A).
[69] 21 U.S.C. § 811(c)(7).
[70] 21 U.S.C. § 812(b)(2)(C). The third finding for Schedules II through V focuses on psychological or physical dependence. In Schedule I, the third finding

Factors four and five, meanwhile, relate directly to abuse potential, calling on the DEA to consider the drug's "history and current pattern of abuse"[71] and its "scope, duration, and significance of abuse."[72] What these factors add to the first factor's focus on relative abuse potential, however, is unclear. The remaining factors seem to have a broad and imprecise relationship to the three scheduling findings. The third factor, for instance, instructs the DEA to consider "[t]he state of current scientific knowledge regarding the drug or other substance"[73]—an inquiry that one imagines would necessarily be conducted when assessing all three of the scheduling criteria.[74]

The CSA does not explicitly require the DEA make a written assessment of the eight factors, providing only that the Administrator must "consider" them.[75] At least one court has concluded that the DEA can make scheduling decisions without

breaks from that pattern, requiring that there be "a lack of accepted safety for use of the drug or other substance under medical supervision." *Id.*

[71] 21 U.S.C. § 811(c)(4); *see also* Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55, 67 n.63 (2003) (observing that section 811's factors seem to "relate primarily to the potential for abuse rather than what qualifies as currently accepted medical use").

[72] 21 U.S.C. § 811(c)(5).

[73] 21 U.S.C. § 811(c)(3).

[74] Under the CSA, the Secretary of Health and Human Services is tasked with providing the DEA with "a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance." 21 U.S.C. § 811(b). In making this evaluation "the Secretary shall consider" the following 21 U.S.C. § 811(c) factors:

> (2) Scientific evidence of its pharmacological effect, if known[;] (3) The state of current scientific knowledge regarding the drug or other substance[;] . . . (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.

21 U.S.C. § 811(b). The Secretary must also consider any scientific or medical considerations involved in the remaining 21 U.S.C. § 811(c) factors: "(1) Its actual or relative potential for abuse; (4) Its history and current pattern of abuse; (5) The scope, duration, and significance of abuse." The statute also provides that "[t]he recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." 21 U.S.C. § 811(b). The meaning of this language and the precise impact of the HHS evaluation and recommendations on the scheduling process also remain somewhat ambiguous. *See* UELMEN ET AL., *supra* note 18.

[75] UNIF. CONTROLLED SUBSTANCES ACT § 201(b) (1994), http://www.iowamedicalmarijuana.org/petitions/pdfs/ucsa94.pdf.

written findings for the eight factors.[76] Nevertheless, the DEA's current approach to scheduling includes a written discussion of the eight factors.[77]

Court decisions that mention the relationship between the eight factors and the three scheduling requirements are few and far between, and none have addressed the issue in significant detail.[78] One representative opinion, for example, noted simply that the eight "more subjective factors significantly broaden the scope of issues to be considered in classifying a drug."[79]

The DEA has similarly declined to articulate its own view of exactly how its consideration of the eight factors should inform the three required scheduling findings. Instead, the typical DEA scheduling decision simply analyzes the eight factors one by one, and then, in a separate section, analyzes the three scheduling requirements.[80] The ambiguous relationship between the CSA's eight "factors" and three "findings" might be easier to overlook if the findings themselves were more clearly defined. The meaning of the findings, however, remains nearly impossible to pin down.

Although "potential for abuse" is "nowhere defined in the [CSA]",[81] a House Committee report accompanying the bill did

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[76] United States v. Pastor, 419 F. Supp. 1318 (S.D.N.Y. 1975)

> [T]he statute does not require any findings as to the factors listed in § 811(c); the statute merely requires that the Attorney General and, where applicable the Secretary 'consider' the factors there prescribed. Where the Congress intended that the Attorney General make formal findings, it so specified, as in §§ 811(a) and 812(b)[.]"

Id. at 1341.

> Although Congress has not required that he make written findings as to the factors he must consider in § 811(c), any allegation that he failed to make the requisite consideration can be tested—and his discretion reviewed—in precisely the manner in which it is being tested in this case, by procuring the sworn testimony of those individuals who participated in the process, and, if necessary, obtaining further documentation.

Id. at 1348.

[77] *See, e.g.*, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,553–62 (Dep't of Justice July 18, 2011).

[78] For example, a Lexis search of all federal and state cases for the eight-factor provision's central instruction ("shall consider the following factors with respect to each drug or other substance") returns only 6 results. A search for "811(c) and 'controlled substance!'" returns just 55 results.

[79] Nat'l Org. Reform of Marijuana Laws v. Bell, 488 F. Supp. 123, 141 (D.D.C. 1980).

[80] *See, e.g.,* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. at 40,553–62.

[81] *Pastor*, 419 F. Supp. at 1339.

articulate four factors to consider when "the Administrator may determine a substance has potential for abuse."[82] Whatever the value of legislative history in statutory interpretation as a general matter, this guidance is, at most, marginally useful. This is because it addresses only the threshold "as to the minimum needed to show *any* potential for abuse."[83] It says nothing about how to assess *relative* abuse—the determination called for by the CSA's classification scheme. Nevertheless, the DEA relies on the House Committee report's four factors as "concepts" when attempting to analyze abuse potential.[84]

Is data that a large number of people use a substance recreationally evidence of a "high potential for abuse"? Or, does relative abuse potential turn on factors like problematic use and addiction? Is it based on the potential harms that use might cause? Like many aspects of the CSA, these questions remains largely untested in the courts, though overall use rates and comparisons to already-scheduled substances have been common features in the DEA's scheduling findings.[85]

In *Grinspoon v. DEA*, a 1987 decision from the First Circuit concerning the scheduling of MDMA ("ecstasy"), the Court found the DEA "Administrator articulated no standard for showing that MDMA had a *relative* potential for abuse sufficient to warrant placement in Schedule I."[86] Nevertheless, the Court found the DEA's abuse potential determination was not arbitrary and capricious, on the grounds that the Administrator can permissibly reach a conclusion regarding a substance's level of potential for abuse by comparing the substance to drugs already scheduled under the CSA.[87] "Here the Administrator has done just that, offering several findings concerning the evidence of close structural and pharmacological similarity between MDMA and other substances, such as MDA, which already have been found to have a high potential for abuse and have been placed in Schedule I or II."[88]

With such broad discretion, it is not surprising that the DEA

[82] Grinspoon v. Drug Enforcement Admin., 828 F.2d 881, 893 (1st Cir. 1987).
[83] *Id.*
[84] *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,553 (Dep't of Justice July 18, 2011) (relying on the four factors outlined in the legislative history to determine abuse potential).
[85] *Id.*
[86] *Grinspoon*, 828 F.2d at 893.
[87] *Id.* at 893–94
[88] *Id.*

has been able to shape its abuse potential findings to avoid encountering a substance with an abuse potential lower than Schedule I but no currently accepted medical use.[89] It also helps to explain how a substance like marijuana, which is relatively benign in terms of harm and potential for addiction in comparison to many other substances,[90] has the same abuse potential as heroin under the CSA.[91] Or how the DEA could place Marinol, a synthetic pill containing the chief psychoactive component of marijuana (THC) in Schedule III while marijuana remains a Schedule I substance.[92]

The medical use finding has been perhaps the most litigated of the three CSA scheduling criteria, often in the context of petitions to reschedule marijuana.[93] The CSA does not define "currently accepted medical use in treatment in the United States" with the exception of the term "United States," which "means all places and waters, continental or insular, subject to the jurisdiction of the United States."[94]

It took the DEA twenty-two years following passage of the CSA to adopt an accepted medical use standard that withstood court scrutiny.[95] When announcing the current standard in 1992, then head of the DEA, Robert C. Bonner, lamented the lack of

[89] *See id.* at 892–94.

[90] *See, e.g.,* DAVID NUTT, DRUGS—WITHOUT THE HOT AIR 43 (2012) (reporting on a panel of experts who rated cannabis a 20 out of 100 on a harm scale, with heroin at 55).

[91] In its 2011 denial of a petition to reschedule marijuana, for example, the DEA cited to factors including:

> [T]he prevalence and frequency of use in the general public and in specific sub-populations, the amount of the material that is available for illicit use, the ease with which the substance may be obtained or manufactured, the reputation or status of the substance "on the street," as well as evidence relevant to population groups that may be at particular risk.

Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,553 (Dep't of Justice July 18, 2011) (relying on the four factors outlined in the legislative history to determine abuse potential).

[92] Rescheduling of the FDA Approved Product from Schedule II to III, 64 Fed. Reg. 35,928 (July 2, 1999) (to be codified at 21 C.F.R. pt. 1308, 1312).

[93] *See, e.g.*, *Grinspoon*, 828 F.2d at 884; Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., 930 F.2d 936, 939 (D.C. Cir. 1991).

[94] 21 U.S.C. § 802(28) (2006).

[95] *See Grinspoon*, 828 F.2d at 884 (rejecting a DEA interpretation of medical use as meaning "approved for interstate marketing by the FDA under the FDCA."); *Alliance for Cannabis Therapeutics*, 930 F.2d at 940 (rejecting an eight-factor test for medical use where "three of the factors in the Administrator's eight-factor test appear impossible to fulfill and thus must be regarded as arbitrary and capricious").

guidance on the meaning of medical use. "Regrettably," wrote Bonner, "the Controlled Substances Act does not speak directly to what is meant by 'currently accepted medical use.'"[96]

Today, the DEA employs a five-part test to determine whether medical marijuana has a currently accepted medical use.[97] The test requires that: "(1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available."[98] The DEA will find that a substance has an accepted medical use "only if all five of the foregoing elements are demonstrated."[99] The D.C. Circuit has found this test to be a permissible interpretation of the CSA's accepted medical use requirement.[100]

Though more precise than the test for abuse potential, the DEA's test for accepted medical use seems to be a creature of the marijuana and MDMA scheduling litigation during which it was created, not the result of dispassionate consideration of the issue.[101] In any event, regardless of the merits of this standard,[102] the absence of Congressional guidance on this critical question is cause for concern. Did Congress intend for the CSA to roughly mirror the Food, Drug, and Cosmetic Act approval process,[103]

[96] Marijuana Scheduling Petition, 57 Fed. Reg. 10,499, 10,503 (Dep't of Justice Mar. 26, 1992) (denial of petition and remand).

[97] Ams. for Safe Access v. Drug Enforcement Admin., No. 11-1265, 2013 U.S. App. LEXIS 1407, at *31 (D.D.C. Jan. 22, 2013).

[98] *Id*.

[99] Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,579 (Dep't of Justice July 18, 2011).

[100] *Ams. for Safe Access*, 2013 U.S. App. LEXIS 1407, at *31.

[101] Another curious aspect of the test for medical use is requirement of safety studies, which appears to be redundant in light of the third scheduling criteria for Schedule I. The DEA acknowledged this relationship in articulating the five-part test:

> The scheduling criteria of the Controlled Substances Act appear to treat the lack of medical use and lack of safety as separate considerations. Prior rulings of this Agency purported to treat safety as a distinct factor. In retrospect, this is inconsistent with scientific reality. Safety cannot be treated as a separate analytical question.

Marijuana Scheduling Petition, 57 Fed. Reg. at 10,504 (internal citation omitted).

[102] *Ams. for Safe Access*, 2013 U.S. App. LEXIS 1407, at *31–32.

[103] *See* Marijuana Scheduling Petition, 57 Fed. Reg. at 10,503–4 (arguing that "that Congress equated the term 'currently accepted medical use in treatment in the United States' as used in the Controlled Substances Act with the core FDCA standards for acceptance of drugs for medical use"). Interestingly, this approach

effectively relegating a non-patented substance like marijuana to Schedule I simply because no one had a sufficient financial interest to shepherd it through the expensive FDCA procedures?[104] Or, did Congress intend for the CSA's medical use standard to be more forgiving than the FDCA's, given that Schedule I status means prohibition, while a lack of FDCA approval means only that the drug cannot be marketed interstate as a medicine?[105] Without a definition from Congress, the DEA has been free to come to its own conclusion, with very little to constrain its discretion.

The CSA's third scheduling finding requires "a lack of accepted safety for use" in Schedule I, and measures relative potential for dependence in the remaining Schedules.[106] This finding has received far less attention in court and administrative decisions than the first two, which themselves have been only sparingly litigated over the CSA's four decade history.[107] Though the text of the CSA places all three findings on equal footing, the CSA's legislative history has been cited for the proposition that the first "[t]wo criteria—the potential for abuse and the medical applications of a drug—are the major bases for classification."[108] Indeed, for Schedule I substances, the DEA's current position appears to be that the third criteria is not, in fact, an independent required finding at all.[109] For the remaining schedules, however,

is at odds with the testimony of a representative from the DEA's predecessor agency, the Bureau of Narcotics and Dangerous Drugs, during consideration of the CSA. The Deputy Chief of the BNDD, whose office had also written the first draft of the CSA, testified before the House subcommittee that "this basic determination . . . is not made by any part of the federal government. It is made by the medical community as to whether or not the drug has medical use or doesn't." *In re* Marijuana Rescheduling Petition (Dep't of Justice Sept. 6, 1988) (opinion & recommended ruling).

[104] Jag Davies & Rick Doblin, *DEA Administrative Law Judge Finds DEA Obstruction of Medical Marijuana Research Against Public Interest*, DRUGSCIENCE (2007), http://www.drugscience.org/Archive/bcr3/n3_Davies_Doblin.html.

[105] *See In re* Marijuana Rescheduling Petition (Dep't of Justice Sept. 6, 1988) (opinion & recommended ruling) (proposing that the standard for "whether a medical procedure utilized by a doctor is actionable as malpractice" be used to determine accepted medical use).

[106] 21 U.S.C. § 812(b) (2006).

[107] *See generally* Marijuana Scheduling Petition, 57 Fed. Reg. at 10,504 (stating that "[s]afety cannot be treated as a separate analytical question").

[108] Nat'l Org. Reform of Marijuana Laws v. Bell, 488 F. Supp. 123, 126–27 (D.D.C. 1980).

[109] Marijuana Scheduling Petition, 57 Fed. Reg. at 10,504

> The scheduling criteria of the Controlled Substances Act

the DEA has applied a comparatively fixed definition, particularly in relation to the abuse potential standard.[110]

In sum, the CSA's scheduling system is built on three findings that are "nowhere defined" in the law,[111] and eight factors whose intended relationship to the three findings is still, four decades after passage of the law, a mystery.[112] The more closely one considers the CSA's scheduling scheme, the more difficult it is to make sense of.

III. BARRIERS TO RESEARCH

While the CSA's classification system has a certain impenetrable quality, the law's restrictions on the research of Schedule I substances are perhaps the most difficult to understand from a policy perspective.

Researchers and others have expressed concern about the extent of the CSA's research limitations before.[113] But critiques about the degree of restrictiveness have overlooked two more fundamental problems about the structure of the CSA with respect to research. First, the CSA does not require *any* studies into a substance's potential medical uses to be conducted before it is scheduled.[114] As a result, a substance discovered or popularized by recreational users—as opposed to one that is taken through the FDA's approval process by pharmaceutical companies[115]—can

> appear to treat the lack of medical use and lack of safety as separate considerations. Prior rulings of this Agency purported to treat safety as a distinct factor. In retrospect, this is inconsistent with scientific reality. Safety cannot be treated as a separate analytical question.

Id. (internal citation omitted).

[110] *See* Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV, 76 Fed. Reg. 77,330 (Dec. 12, 2011) (articulating the DEA's interpretation of the dependence finding).

[111] United States v. Pastor, 419 F. Supp. 1318, 1339 (S.D.N.Y. 1975)

[112] *Id.* at 1340.

[113] *See, e.g.*, Pete J. Cohen, *Medical Marijuana: The Conflict Between Scientific Evidence and Political Ideology*, 2009 UTAH L. REV. 35, 89 (2009) (providing an overview of the problems researchers have faced obtaining marijuana for research into its potential medicinal value).

[114] *See generally* Marijuana Scheduling, 57 Fed. Reg. at 10,503–4 (discussing lack of understanding as to the standard for "accepted medical use").

[115] Although the CSA provides the same scheduling procedure for "street drugs" as for pharmaceuticals, because of the relationship between the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA), the origin of a scheduling petition can impact the scheduling procedure as a practical matter. Specifically, the scheduling process for new prescription drugs

land in Schedule I before *any* significant research into its potential medical uses has been performed.[116] Second, the stated purpose of the CSA's tight restrictions on research of Schedule I substances is to "safeguard against diversion" of the substance to the recreational market.[117] Given the extensive black market for Schedule I substances, however, it is hard to see why Schedule I substances should not be treated substantially like non-scheduled pharmaceuticals in the investigation stages for purposes of research.

A. Schedule First, Study Later (or Never)

The CSA's negative impact on medical research lies in its scheduling criteria. A Schedule I substance is one that the DEA has determined has "no currently accepted medical use in treatment in the United States."[118] A substance that has been the subject of 1,000 studies, all concluding it has no medical value, would meet this standard. But so would a substance that has never once been studied. Or, for that matter, a substance that studies show has some *promise* as a medicine but where there is not yet enough evidence to satisfy the CSA's strict "currently accepted medical use" test.[119] This is because, under the CSA, the burden rests with those who hope to prove an accepted medical

that may have a potential for recreational use typically begins prior to any DEA involvement. FDA regulations instruct applicants for FDA approval to provide the agency with information relevant to CSA scheduling. "If the drug has a potential for abuse," applicants are to submit "a description and analysis of studies or information related to abuse of the drug, including a proposal for scheduling under the Controlled Substances Act. A description of any studies related to overdosage is also required, including information on dialysis, antidotes, or other treatments, if known." 21 C.F.R. § 314.50(d)(5)(vii) (2012). Accordingly, scheduling of pharmaceutical drugs typically begins after the drug company has had the opportunity to conduct its research and is submitting its findings to the FDA. The scheduling of substances used for recreation, by contrast, generally begins with the DEA.

[116] *Cf.* Grinspoon v. Drug Enforcement Admin., 828 F.2d 881, 896–97 (1st Cir. 1987) (observing that "placement of MDMA in Schedule I will impede" research into the substance but finding that "Congress has already weighed the costs and benefits of legitimate research on dangerous drugs and has determined, in a categorical manner, that if the three Schedule I criteria are satisfied, then the substance should be subject to Schedule I controls"(internal citation omitted)).

[117] 21 U.S.C. § 823(f) (2006).

[118] 21 U.S.C. § 812(b)(1)(B) (2006).

[119] Ams. for Safe Access v. Drug Enforcement Admin., No. 11-1265, 2013 U.S. App. LEXIS 1407, at *31, *33–34 (D.D.C. Jan. 22, 2013) (quoting 21 U.S.C. § 812(b)(3)–(5)).

use.

It may make a great deal of sense to require proof of an accepted medical use when deciding whether to allow a substance to be marketed and sold to end-users as a medicine. But it borders on absurd to use this same threshold for researchers. The cost of restricting research into a substance that has been thoroughly studied but never shown to have medical value is likely minimal. But the cost of restricting research into a substance that has never been studied or, especially, a substance that has been studied and shown to have potential medical value, may be significant. If preliminary studies indicate a substance might be a useful medicine, any rational public policy would seek to encourage more research into the substance to confirm or disconfirm its potential. Under the CSA, however, a substance like this can be placed in Schedule I, making it extraordinarily difficult to research.[120]

The CSA's treatment of marijuana is instructive. The DEA acknowledges evidence supporting "the potential therapeutic utility of cannabinoids,"[121] including "a limited number of Phase I investigations."[122] But, because no "Phase II or III"[123] studies have been conducted into marijuana, the DEA's position is that "there is still no data from adequate and well-controlled clinical trials that meets the requisite standard to warrant rescheduling."[124] Regardless of merits of Schedule I-level restrictions on marijuana with respect to end-users, it is difficult to conceive of any public policy rationale for tightly restricting further research into a substance that preliminary data indicates may have value as a medicine.

And yet, this is exactly what the CSA's research and scheduling structure does.[125] Between 2000 and 2009, the federal government approved only eleven research projects into marijuana's value as a medicine,[126] fewer than the number of

[120] *See Grinspoon*, 828 F.2d at 896.

[121] Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,580 (Dep't of Justice July 18, 2011).

[122] *Id.* at 40,579.

[123] "Phase II and Phase III studies involve successively larger groups of patients . . . . These studies are designed primarily to explore (Phase II) and to demonstrate or confirm (Phase III) therapeutic efficacy and benefit in patients." *Id*.

[124] *Id.* at 40,580.

[125] *See, e.g.*, Gardiner Harris, *Researchers Find Study of Medical Marijuana Discouraged*, N.Y. TIMES, Jan. 19, 2010, at A14.

[126] State-by-State Medical Marijuana Laws, Marijuana Policy Project (2011)

states that passed medical marijuana laws during that same period.[127] Others have examined these roadblocks in detail,[128] but the perspective of AIDS researcher Donald Abrams is illuminating. In a letter to the National Institute on Drug Abuse, regarding his efforts to obtain and study marijuana, Abrams lamented:

> As an AIDS investigator who has worked closely with [the] National Institutes of Health and the U.S. Food and Drug Administration for the past 14 years of this [AIDS] epidemic, I must tell you that dealing with your Institute has been the worst experience of my career! The lack of any official communication for nine months is unheard of, even in the most cumbersome of government bureaucracies.[129]

The problem is not limited to marijuana, of course. MDMA provides another apt example. MDMA—also known as ecstasy—was placed in Schedule I in the late 1980s.[130] Harvard psychiatry professor Lester Grinspoon unsuccessfully challenged the DEA's scheduling action, in part on the grounds that the classification "would strongly discourage medical research on the drug[.]"[131] As Grinspoon predicted, until recently, there was essentially no research into MDMA.[132] Over the past few years, a non-profit organization named the Multidisciplinary Association for Psychedelic Studies, has invested resources to help researchers navigate the process for researching MDMA and a handful of other Schedule I substances.[133] Results from preliminary trials indicate that the substance may have some value as a medicine.[134]

(noting that between 2000 and 2009 Colorado, Nevada, Hawaii, Maryland, Vermont, Montana, Rhode Island, New Mexico, Michigan and Maine enacted medical marijuana laws).

[127] Robert A. Mikos, *On the Limits of Federal Supremacy When States Relax (or Abandon) Marijuana Bans*, 714 CATO INST. POL'Y ANALYSIS 6 (2012) (arguing that the federal government has been unable to effectively stop medical marijuana laws in part because of lack of resources).

[128] *See, e.g.*, Cohen, *supra* note 113, at 89 (providing an overview of the problems researchers have faced obtaining marijuana for research into its potential medicinal value).

[129] *In re* Lyle E. Craker (Dep't of Justice Feb. 12, 2007) (opinion & recommended ruling) (quoting Letter from Donald I. Abrams, M.D., to Alan I. Leshner, Ph.D. (Apr. 28, 1995)).

[130] Grinspoon v. Drug Enforcement Admin., 828 F.2d 881, 884 (1st Cir. 1987).

[131] *Id.* at 896.

[132] *See* Benedict Carey, *A 'Party Drug' May Help the Brain Cope With Trauma*, N.Y. TIMES, Nov. 20, 2012, at D1.

[133] *Mission*, MAPS: MULTIDISCIPLINARY ASS'N PSYCHEDELIC STUD., http://www.maps.org/about/mission/ (last visited Feb. 19, 2013).

[134] *See* Carey, *supra* note 132 (reporting on studies into whether MDMA may

But, because of the CSA's barriers to research, confirming or disconfirming MDMDA's potential use as a medicine will be much more difficult and take much longer than for a non-scheduled drug.

The point here is not to weigh whether MDMA or marijuana actually has medical uses. Perhaps further study will reveal that, despite showing promise in early studies, MDMA is not an effective medicine. Whatever further research reveals, however, the CSA's restrictions on conducting that research are difficult to justify. The CSA appears to take the position that Schedule I substances should be hard to study in part because they do not have a currently accepted medical use. This might make sense if Schedule I substances were limited to those that had been thoroughly vetted and found not to have medical value. But many substances are barely investigated at all before being placed into Schedule I.[135] In some cases, the studies that do exist indicate the substance may potentially have medical uses.[136] By design, the CSA makes it incredibly difficult to research these substances. This is a serious and underappreciated flaw in the CSA. It is hard to rationalize blocking research into a substance we know has potential as a medicine, particularly in comparison to new, unscheduled drugs. Why should regulations on research into marijuana or MDMA be more restrictive than a newly synthesized substance, about which very little is known?

B. The Rationale for Restricting Research into Schedule I Substances

In light of the FDA's drug approval process, what purpose do the CSA's added research restrictions serve? According to the CSA, strict research controls are needed to "adequately safeguard against diversion" of Schedule I drugs.[137] This rationale seems premised on the existence of a world in which it is nearly impossible to obtain Schedule I substances—a world where breaking into research laboratories[138] or manufacturing facilities would pose a real risk of letting otherwise unobtainable drugs out

be helpful for treating PTSD).

[135] *See* Cohen, *supra* note 113, at 88.

[136] *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,580 (Dep't of Justice July 8, 2011).

[137] 21 U.S.C. § 823(f) (2006).

[138] HALF BAKED (Universal Pictures 1998) (The Dave Chappelle movie is a humorous story based on this premise).

into the public. But this is not the world we live in. Widely abused Schedule I substances like marijuana, cocaine, or heroin are relatively easy to find and buy on the black market. According to one 2012 survey, for example, 31% of teens said they could obtain marijuana within a day.[139]

Guarding against diversion from Schedule I research may be a reasonable goal in the abstract, but in the context of the market for illegal drugs that exists today, it is hard to make sense of. To understand why, imagine that studies of a Schedule I substance like marijuana or MDMA were widespread and the studies suffered from an unusually severe diversion problem. The impact on the availability of either substance would be negligible at best. In other words, even if the CSA's research restrictions do significantly lower the risk of diversion relative to less burdensome regulations, this achievement is not worth very much.

One could also argue that the Schedule I drugs are unusually dangerous substances and so the CSA must significantly limit research into them in order to help protect would-be test subjects. The trouble with this rationale is that substances are placed into Schedule I because of their lack of accepted medical use and potential for abuse and dependency, not because they have particularly dangerous side effects.[140] There is thus little reason to think that a Schedule I substance would be riskier to study than a pharmaceutical substance going through the FDA approval process. To be sure, the potential for addiction of Schedule I substances is a legitimate concern, but Food, Drug, and Cosmetics Act regulations on medical research into non-Scheduled substances already accounts for even more significant risks, like the possibility that the substance being researched may increase the risk of cancer.[141]

In sum, strict research restrictions for Schedule I substances provide few tangible benefits at a significant cost. Under the current system, while one-third of teens can buy marijuana within a day, a researcher might have to wait years to get it. While some safeguards against diversion and additional safety

[139] NAT'L CTR. ON ADDICTION & SUBSTANCE ABUSE, COLUMBIA UNIV., NATIONAL SURVEY OF AMERICAN ATTITUDES ON SUBSTANCE ABUSE XVII: TEENS 27 (2012).

[140] *Cf, e.g.*, Am. Pharmaceutical Ass'n v. Weinberger, 377 F. Supp. 824, 828 (D.D.C. 1974) (discussing the meaning of the term "safe" under the FDCA).

[141] *See generally* Federal Food, Drugs and Cosmetics Act, 21 U.S.C § 355 (2011).

protections may be worthwhile, regulations that lead to this state of affairs make little sense.

CONCLUSION

Drug policy in the United States appears to be undergoing significant change. In November 2012, Washington and Colorado became the first states to pass marijuana legalization laws.[142] While the Obama administration remains opposed to marijuana legalization, it has voiced an interest in retiring the concept of the "war on drugs" to focus on a science-based, public health-oriented approach to drug policy.[143] In the midst of debates about the merits of issues like prohibition, racial disparities in drug enforcement, and the wisdom of mandatory minimum sentencing laws, the regulatory provisions of the Controlled Substances Act are—perhaps understandably—easy to overlook.

This essay aims to highlight some of the CSA's regulatory flaws. Though these problems may not be the most pressing in drug policy, they are worthy of much more attention than they have received to date. There is a range of options for addressing the issues discussed in this essay. For example, Congress could simplify and cabin the CSA's scheduling process by adding definitions to the criteria and targeting specific inconsistencies. Or, Congress could rebuild the entire classification system from the ground-up. The problem of the CSA's limitations on research into substances with potential—though not yet accepted—medical uses could be addressed by easing the statute's research restrictions for all Schedule I substances. Or, the concern could be addressed by separating Schedule I substances that have been thoroughly studied and found to have no medical value from those that have shown some promise for purposes of research requirements. This essay does not argue for any particular solution to the problems it identifies. Instead, the author's hope is that this examination of the CSA will help to stir and inform a debate over how to fix its significant defects.

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[142] Dan Frosch, *In Colorado, Getting Down to Business of Marijuana,* N.Y. TIMES, Dec. 18, 2012, at A18.

[143] Gary Fields, *White House Czar Calls for End to 'War on Drugs'*, WALL ST. J., May 14, 2009, at A3 (quoting Gil Kerlikowske, "[r]egardless of how you try to explain to people it's a 'war on drugs' or a 'war on a product,' people see a war as a war on them . . . . We're not at war with people in this country").