The Medical Marijuana Catch-22: How the Federal Monopoly on Marijuana Research Unfairly Handicaps the Rescheduling Movement

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I. INTRODUCTION

II. RESCHEDULING MARIJUANA AND AMERICANS FOR SAFE ACCESS
   A. THE CONTROLLED SUBSTANCES ACT AND REQUIREMENTS FOR RESCHEDULING
   B. EARLY RESCHEDULING CASES
   C. AMERICANS FOR SAFE ACCESS V. DEA

III. RESEARCHING MARIJUANA AND CRAKER
   A. PROCEDURE AND REQUIREMENTS FOR BECOMING A PRIVATE MANUFACTURER OF MARIJUANA
   B. PROCEDURE AND REQUIREMENTS FOR OBTAINING MARIJUANA FOR RESEARCH
   C. CRAKER’S PETITION
   D. DECISION OF THE ADMINISTRATIVE LAW JUDGE
   E. DECISION OF THE DEA ADMINISTRATOR
   F. DECISION OF THE COURT OF APPEALS

IV. RESULTING OBSTRUCTION TO RESEARCH AND POSSIBLE SOLUTIONS
   A. THE CATCH-22 AT THE INTERSECTION OF AMERICANS FOR SAFE ACCESS AND CRAKER
   B. POSSIBLE SOLUTIONS
   C. POTENTIAL IMPROVEMENTS ON THE HORIZON

V. CONCLUSION

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I. INTRODUCTION

As of April 2015, twenty-three states and the District of Columbia permit the therapeutic use of marijuana to treat various illnesses or conditions, with legalization statutes currently pending in eight other states. Despite the growing number of states that allow for the prescription and use of medicinal marijuana, the federal government still classifies the drug as a Schedule I controlled substance, the strictest classification of controlled substances and the only type healthcare providers may not legally prescribe. As states continue to deliberate the merits of allowing access to marijuana for therapeutic use, it is useful to examine the structural and political forces that have prevented a similar movement at the federal level. This Note does so, and argues that proactive changes—either legislative or administrative—are necessary to remove the handicap that the current regulatory system places on attempts to change federal marijuana policy.

Two recent federal appeals court decisions have together created an obstacle for the federal rescheduling movement—one by establishing a high standard for reclassification of a controlled substance, and the other by perpetuating an administrative impediment to meeting that standard. Americans for Safe Access v. DEA arose after a patient advocacy group petitioned the Drug Enforcement Administration (DEA) arguing that the DEA should reclassify marijuana from Schedule I to Schedule III, IV, or V under the Controlled Substances Act (CSA). The group argued that the reclassification was appropriate because of marijuana’s accepted medical use in the United States. The D.C. Circuit ultimately upheld a DEA order denying the petition on the grounds that marijuana has no accepted medical use. The court agreed with the DEA’s view that formal clinical trials, such as those the Food and Drug Administration (FDA) requires for prescription drugs, are necessary to prove that a controlled substance has an accepted medical use.

The DEA standard requiring formal clinical trials that the court upheld in Americans for Safe Access effectively precludes rescheduling reform because of existing barriers to conducting marijuana research. The barriers exist at two levels: procuring research-grade marijuana and obtaining approval for studies on marijuana’s potential therapeutic benefits. To conduct research on marijuana, researchers must

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1 While “cannabis” is the preferred term among the scientific community to refer to the plants of the genus cannabis and their byproducts, this paper will use “marijuana” to reference same, owing to the widespread use of this term in the statutes and case law of the United States.


6 Americans for Safe Access v. DEA, 706 F.3d 438, 452 (D.C. Cir. 2013) (holding that reclassification by FDA must rely on “adequate and well-controlled studies”).

7 See generally Craker v. DEA, 714 F.3d 17 (1st Cir. 2013).


9 Americans for Safe Access, 706 F.3d at 452.
register with the DEA and request marijuana from the National Institute on Drug Abuse (NIDA). NIDA—a federal research institute—controls the supply of research-grade marijuana from the only federally registered marijuana manufacturer in the country, and conducts its own research on the harmful effects of marijuana and other drugs. There is evidence, however, that NIDA refuses to supply marijuana to research studies with otherwise adequate credentials, even studies with FDA approval. NIDA itself has stated that it is generally not in the business of funding or supporting research into the therapeutic benefits of marijuana or other drugs, thus revealing its own bias against medical marijuana research. Together, the DEA’s requirement of formal research studies to show accepted medical use and the inaccessibility of research-grade marijuana have created a regulatory catch-22: researchers attempting to show a medical use are unable to conduct the necessary studies given NIDA’s monopoly.

At least one attempt has been made to establish a federally registered private manufacturer to supply marijuana for research studies. Dr. Lyle Craker, a Plant, Soil, and Insect Sciences professor at the University of Massachusetts petitioned the DEA in 2001 with support from the Multidisciplinary Association for Psychedelic Studies (MAPS). Dr. Craker wanted to be registered as a private manufacturer of marijuana for clinical research pursuant to the CSA requirements for manufacturers of controlled substances in Schedule I or II. In Craker v. DEA, the First Circuit upheld the DEA’s denial of Craker’s petition, granting Chevron deference to the DEA Administrator’s decision and holding that Craker “failed to demonstrate that the current supply of marijuana was not adequate and uninterrupted,” as required by the CSA.

Together, Americans for Safe Access and Craker effectively leave control of the rescheduling of marijuana in the hands of NIDA. The prohibition against the private manufacturing of research marijuana allows NIDA to maintain its monopoly over the supply of marijuana. Therefore, NIDA can continue to deny marijuana for qualified research studies, preventing anyone from conducting the research necessary to show the accepted medical use required to reschedule marijuana. This Note outlines this problem and provides an argument in favor of allowing greater access to research-grade marijuana to give researchers the opportunity to show a medical use sufficient to meet the DEA’s rescheduling standards.

Part II of this paper analyzes the CSA, focusing on the requirements for rescheduling a controlled substance and the application process and requirements to become a manufacturer or distributor of a controlled substance. Part III discusses the

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12 See Gardiner Harris, Researchers Find Study of Medical Marijuana Discouraged, N.Y. TIMES, January 19, 2010, at A14.
14 Craker v. DEA, 714 F.3d 17, 20 (1st Cir. 2013).
16 Craker, 714 F.3d at 27-29.
decision in *Americans for Safe Access* and relevant statutes, regulations, and precedents. Part IV moves to *Craker* and the current availability of research-grade marijuana. Part V of the paper addresses the catch-22 created by the intersection of these two decisions and offers possible solutions to facilitate a more considered decision on the rescheduling of marijuana.

II. RESCHEDULING MARIJUANA AND *AMERICANS FOR SAFE ACCESS*

A. THE CONTROLLED SUBSTANCES ACT AND REQUIREMENTS FOR RESCHEDULING

Passed in 1970 as part of the Comprehensive Drug Abuse Prevention and Control Act, the CSA establishes five schedules into which all controlled substances are classified.\(^\text{17}\) The CSA authorizes the Attorney General to add to, transfer between, or remove from schedules any substance deemed to meet, or not meet, the inclusion criteria of a schedule.\(^\text{18}\) Each schedule requires the Attorney General to make specific findings with respect to a substance’s potential for abuse, the existence of a currently accepted medical use, and the danger of dependence when using the substance.\(^\text{19}\) For example, to classify a substance in Schedule I, the Attorney General must first find that the substance has a high potential for abuse, that it has no currently accepted medical use, and that there is a lack of accepted safety for its use under medical supervision due to a high likelihood of physical or psychological dependence. Schedule I currently includes, among other substances, heroin, lysergic acid diethylamide (LSD), 3,4-methylenedioxymethamphetamine (MDMA), and marijuana.\(^\text{20}\)

The CSA provides that the Attorney General may initiate formal rulemaking procedures to make changes to substance classification on his or her own motion, by request of the Secretary of Health and Human Services (the “Secretary”), or upon petition by an interested party.\(^\text{21}\)

DEA rules control these petitions by interested parties. The petitions serve to “initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of [21 U.S.C. § 811].”\(^\text{22}\) The DEA requires that petitions include “[t]he proposed rule in the form proposed by the petitioner . . . [and a] statement of the grounds [upon which the petitioner relies for the issuance (amendment or repeal) of the rule].”\(^\text{23}\) Furthermore, in stating the grounds for the rule, the petitioner “shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner . . . .”\(^\text{24}\) The DEA Administrator is not required to initiate proceedings to reschedule a controlled substance upon petition by an interested party. The Administrator may deny a petition if she finds that the petition is lacking any of

\(^{18}\) Id. § 811(a).
\(^{19}\) Id. § 812(b).
\(^{23}\) Id. §1308.43(a).
\(^{24}\) Id.
the regulatory requirements or that “the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.”\textsuperscript{25}

Before initiating rescheduling proceedings, the Attorney General must “request from the Secretary 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.”\textsuperscript{26} The CSA requires that in issuing the scientific and medical evaluation and recommendations, the Secretary must consider the following factors about the drug or other substance in question:

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 [the CSA].\textsuperscript{27}

The CSA also provides that the scientific and medical evaluations and recommendations of the Secretary are binding on the Attorney General, “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.”\textsuperscript{28}

The CSA does not define “currently accepted medical use,”\textsuperscript{29} and the DEA rules shed no further light on the meaning of the phrase or what sort of evidence is necessary to show an accepted medical use.\textsuperscript{30} The DEA rules simply provide lists of controlled substance in each Schedule,\textsuperscript{31} certain exemptions from classification,\textsuperscript{32} and procedures for petitions and hearings.\textsuperscript{33}

Sections 1308.21 through 1308.35 list numerous substances, or classes of substances, that are excluded or exempted from scheduling under the CSA.\textsuperscript{34} Excluded or exempted substances include certain nonnarcotics,\textsuperscript{35} chemical preparations,\textsuperscript{36} veterinary anabolic steroid implant products,\textsuperscript{37} prescription products,\textsuperscript{38} and anabolic steroid products.\textsuperscript{39} Section 1308.35 actually exempts from scheduling “certain cannabis plant material, and products made therefrom, that contain.

\begin{itemize}
\item \textsuperscript{25} Id. §1308.43(c).
\item \textsuperscript{26} Authority and Criteria for Classification of Substances, 21 U.S.C. § 811(b).
\item \textsuperscript{27} Id. § 811(c).
\item \textsuperscript{28} Id. § 811(b).
\item \textsuperscript{29} Id. § 802.
\item \textsuperscript{30} 21 C.F.R. § 1308.02.
\item \textsuperscript{31} Id. §§ 1308.11—15.
\item \textsuperscript{32} Id. §§ 1308.21—35.
\item \textsuperscript{33} Id. §§ 1308.41—45.
\item \textsuperscript{34} Id. §§ 1308.21—35.
\item \textsuperscript{35} Id. §§ 1308.21—22.
\item \textsuperscript{36} Id. §§ 1308.23—24.
\item \textsuperscript{37} Id. §§ 1308.25—26.
\item \textsuperscript{38} Id. §§ 1308.31—32.
\item \textsuperscript{39} Id. §§ 1308.33–34.
tetrahydrocannabinols.”40 The exempted plant material41 must be “[m]ade from any portion of a plant of the genus Cannabis excluded from the definition of marijuana under the [CSA]” and “not used, or intended for use, for human consumption.”42 The CSA’s definition of marijuana excludes “mature stalks . . . , fiber produced from such stalks, [and] oil or cake made from the seeds of such plant . . . “43 Section 1308.35 also states that “the burden of [proving] that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption.”44 Furthermore, anyone attempting to meet this burden must present “rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans.”45 Although the inquiries are distinct, this section—regarding a claimant’s burden of proving that some marijuana product is exempt from the CSA—provides greater clarity in defining an evidentiary standard than do the CSA provisions establishing the standard for initiating reclassification proceedings.46

The remaining sections of 1308 deal with hearings and proceedings for rulemaking,47 control required by international treaties,48 and emergency scheduling of substances.49 They provide that the DEA Administrator must schedule substances in accordance with international treaties in effect at the time of the CSA’s passage (May 1, 1971), without regard to the many requirements and procedures found elsewhere in the CSA.50 These sections also permit the Administrator to schedule a substance in Schedule I on a temporary basis, without regard to the CSA’s other requirements, “if [the Administrator] determines that such action is necessary to avoid an imminent hazard to the public safety.”51 Such temporary scheduling may be extended for up to six months before an official proceeding must occur to make it permanent.52

As the above discussion makes clear, while the DEA regulations regarding controlled substances are extensive, they say little about the standard that outside parties must meet when petitioning to reschedule a controlled substance. The resolution of that issue is ultimately left to the courts, and the relevant decisions are covered in detail below.

40 Id. § 1308.35.
41 The regulation specifically states “processed plant material or animal feed mixture,” perhaps indicating that its main purpose was to exempt livestock feed containing marijuana plant material. This inference is further supported by the requirement that the material not be intended for human consumption. Id.
42 Id. § 1308.35(a)(1).
45 Id. Presumably, the scientific evidence is offered to prove that some material is chemically inert and would not have an intoxicating effect on humans.
47 See 21 C.F.R. §§ 1308.41–.45.
48 See id. § 1308.46.
49 See id. § 1308.49.
50 See id. § 1308.46.
51 Id. § 1308.49.
52 See id. § 1308.49(b).
B. EARLY RESCHEDULING CASES

Since the CSA’s passage in 1970, numerous parties have petitioned the DEA requesting the reclassification of marijuana or its removal from Schedule I.\(^5\) The National Organization for Reform of Marijuana Laws (NORML) filed the first such petition only two years after the CSA’s passage.\(^5\) The Bureau of Narcotics and Dangerous Drugs (predecessor to the DEA) rejected the petition because an international treaty—the Single Convention on Narcotic Drugs (the “Single Convention”), ratified by the United States in 1967—prevented the rescheduling of marijuana out of Schedule I.\(^5\) The DEA’s decision rested on language in the CSA stating that the Attorney General must schedule controlled substances in accordance with international treaty obligations.\(^5\) Specifically, the CSA referenced language states:

\[
\text{If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [this Act].}\]

The Single Convention requires the control of marijuana, and places cannabis in its Schedule I,\(^5\) so the DEA argued that the treaty prevented it from moving cannabis out of the CSA Schedule I.

The D.C. Circuit held that cannabis could be rescheduled to Schedule II without violating U.S. treaty obligations,\(^5\) but that it was within the DEA Administrator’s discretion to determine whether to schedule it in Schedule I or II.\(^5\) The court remanded the case to the DEA for further proceedings, NORML appealed, and the petition bounced between the DEA and the D.C. Circuit in this way for over a decade.\(^5\) In 1994, in its final decision on the matter, the D.C. Circuit held that the DEA Administrator’s refusal of the petition, based on his conclusion that marijuana lacked an accepted medical use, was reasonable under the DEA’s newly formed five-factor test for establishing “currently accepted medical use”:

1. The drug’s chemistry must be known and reproducible;


\(^5\) See Ingersoll, 497 F.2d at 655.

\(^5\) Id. at 656.

\(^5\) Id. at 657-58.


\(^5\) Id. at 752.

\(^5\) See Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1133 (D.C. Cir. 1994) (“The petition to reschedule marijuana was first filed in 1972 and has been before this court on four prior occasions—National Org. for the Reform of Marijuana Laws v. Ingersoll, 497 F.2d 654 (D.C.Cir.1974); National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d 735 (D.C.Cir.1977); National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin. & Dep’t of Health Education & Welfare, No. 79–1660 (D.C.Cir. Oct. 16, 1980); and most recently, ACT, 930 F.2d 936 (D.C.Cir.1991).”); see also Annaliese Smith, Comment, Marijuana as a Schedule I Substance: Political Ploy or Accepted Science?, 40 SANTA CLARA L. REV. 1137, 1151-56 (2000).
The court found that there was substantial evidence to support the Administrator’s finding that the drug lacked an accepted medical use, especially in light of the fact that none of the numerous doctors who testified in favor of rescheduling referenced a single scientific study that found medical efficacy of marijuana.

Soon after this decision, Jon Gettman, a marijuana reform activist, and High Times magazine filed a petition with the DEA to reschedule marijuana. In support of the petition, they argued that the drug lacked the high potential for abuse necessary for inclusion in Schedule I.

Following a recommendation from the Department of Health and Human Services (HHS), the DEA denied the petition, and the plaintiffs sought review in the United States Court of Appeals for the D.C. Circuit in 2001. The D.C. Circuit failed to reach the merits of the case and held that the plaintiffs lacked sufficient standing to challenge the denial because neither Gettman nor High Times could establish an injury in fact.

C. AMERICANS FOR SAFE ACCESS V. DEA

The most recent attempt to reschedule marijuana, and the attempt of most interest to this Note, occurred in 2002, when Americans for Safe Access (ASA) petitioned the DEA to reschedule cannabis from Schedule I to Schedule III, IV, or V, on the ground that cannabis has an accepted medical use. ASA included in its petition over 200 peer-reviewed studies supporting its argument, including a 1999 Institute of Medicine report that suggested that marijuana could have some therapeutic benefit. The DEA denied the petition in 2011, and ASA appealed the DEA order to the Court of Appeals. The D.C. Circuit upheld the DEA order, finding that “substantial evidence supported DEA’s finding that no adequate and well-controlled studies had established that marijuana had [a] currently accepted medical use.” The court said that peer-reviewed studies were insufficient to satisfy the regulatory requirement, and that the Institute of Medicine report clearly suggested that more and better studies were needed to establish any medical benefit.

In upholding the DEA’s denial, the court evaluated the DEA’s five-factor test previously upheld in Alliance for Cannabis Therapeutics v. DEA. Specifically, the court looked at the third factor, which requires “adequate and well-controlled studies.
proving efficacy.” The DEA held that this factor required multiple lengthy clinical studies with large numbers of patients. The DEA suggested that studies similar in quality to those that FDA requires for a New Drug Application would be necessary to satisfy this requirement. The court found this interpretation of the CSA regulations reasonable, and thus deferred to the DEA’s conclusion that FDA or similarly formal clinical trials would be needed to prove accepted medical use of a controlled substance. The court then held that there was substantial evidence to support the DEA’s assessment that petitioners had failed to make a showing sufficient to meet this interpretation of the accepted medical use requirement.

In response to petitioners’ argument that “the Government had foreclosed the research that would be necessary to create sufficiently reliable clinical studies of marijuana’s medical efficacy,” the court referred to language in a HHS recommendation to the DEA suggesting that current HHS regulations do allow for clinical research of marijuana. The court concluded that “it appears that adequate and well-controlled studies are wanting not because they have been foreclosed but because they have not been completed.” As illuminated in Part III below, however, obtaining the marijuana necessary to conduct the requisite research is very difficult, and the court would have done well to investigate this claim further.

The First Circuit, however, had previously held in Grinspoon v. DEA that “the [DEA] will not be permitted to treat the absence of FDA interstate marketing approval as conclusive evidence that [a controlled substance] has no currently accepted medical use . . . .” On July 15, 2013, ASA filed a petition for certiorari with the United States Supreme Court, asking it to settle the split over what sort of evidence a petitioner must present to show that a controlled substance has an “accepted medical use.” ASA stated in its petition for writ of certiorari that the D.C. Circuit had essentially decided “that FDA approval was necessary to prove that a substance has an accepted medical use under the CSA.” On October 7, 2013, the United States Supreme Court denied certiorari and declined to settle the issue.

Despite ASA’s characterization of the difference in opinion between the First and D.C. Circuits, the two decisions do not stand opposed. Though the First Circuit held that lack of FDA approval is not grounds for denying a rescheduling petition for want of an accepted medical use, the decision did not foreclose the DEA’s interpretation of the standard upheld by the D.C. Circuit. Requiring a petitioner to point to clinical trial results as evidence of medical use is not the same as requiring a controlled substance to have FDA approval. The D.C. Circuit’s opinion is consistent with the principle suggested by the First Circuit that FDA approval is likely sufficient, but not

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74 Id. at 1136-37.
75 Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 FR 40,552, 40,579 (July 8, 2011).
76 Id. at 40,562.
77 See Americans for Safe Access v. DEA, 706 F.3d 438, 450-52 (D.C. Cir. 2011).
78 Id. at 452 (citing Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,562 (July 8, 2011)).
79 Id.
80 Grinspoon v. DEA, 828 F.2d 881, 891 (1st Cir. 1987).
82 Id. at 16.
84 See id.; see also Grinspoon, 828 F.2d at 891.
necessary, to satisfy the DEA standard. The D.C. Circuit’s opinion does not suddenly make FDA approval necessary, but instead holds that the DEA can reasonably require something akin to FDA clinical trials to meet its rescheduling requirement. In light of the rather deferential standard of review for administrative decisions on appeal, it was certainly valid for the D.C. Circuit to uphold the DEA’s standard as a reasonable interpretation of its own regulation. Thus, the Supreme Court’s decision to deny certiorari was reasonable.

III. RESEARCHING MARIJUANA AND CRAKER

A. PROCEDURE AND REQUIREMENTS FOR BECOMING A PRIVATE MANUFACTURER OF MARIJUANA

The CSA established requirements for individuals and entities who wish to manufacture, distribute, or dispense controlled substances. It provides that “[e]very person who manufactures . . . any controlled substance . . . , or who proposes to engage in the manufacture . . . of any controlled substance . . . , shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.”

The Attorney General has the authority to register manufacturers of controlled substances if “he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.” In assessing the public interest in registering the manufacturer, the Attorney General is directed to consider the following factors:

1. maintenance of effective controls against diversion . . . by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
2. compliance with applicable State and local law;
3. promotion of technical advances in the art of manufacturing these substances and the development of new substances;
4. prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
5. past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
6. such other factors as may be relevant to and consistent with the public health and safety.

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86 See Grinspoon, 828 F.2d at 891.
87 See Americans for Safe Access, 706 F.3d at 451-52.
89 Id. § 822(a)(1).
90 Id. § 823(a).
91 Id.
Cases that have addressed the Attorney General’s public interest determinations regarding applications to manufacture marijuana have focused primarily on factors (1) and (4), with some discussion of factors (2), (3), and (5).92

B. PROCEDURE AND REQUIREMENTS FOR OBTAINING MARIJUANA FOR RESEARCH

Researchers hoping to conduct research on the therapeutic benefits of marijuana must receive approval from four administrative entities: FDA, NIDA, HHS, and the DEA.93 The first hurdle for any aspiring marijuana researcher intending to market a marijuana product as a drug is to submit an Investigational New Drug (IND) application to FDA.94 FDA must evaluate the proposed research protocol for safety and effectiveness.95 The researcher can use a new drug in a research study thirty days after FDA receives the IND application, unless FDA places the application on a clinical hold or requests modification to the protocol, or FDA notifies the researcher that the new drug can be used prior to the expiration of the thirty days.96

Once FDA approves the clinical research study, the researcher must navigate the process for requesting marijuana from NIDA. This includes filling out and filing specific DEA forms, because the CSA makes it unlawful for “any person to distribute a controlled substance in [S]chedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed,” made on a form provided by the Attorney General.97 The DEA regulations specify that “[e]ither a DEA Form 222 or its electronic equivalent . . . is required for each distribution of a Schedule I or II controlled substance . . . .”98

The National Center for Natural Products Research (NCNPR) at the University of Mississippi is currently the only marijuana manufacturer registered with the DEA, and NIDA is responsible for administering the NCNPR’s supply of marijuana to researchers.99 In addition to the statutory and regulatory requirements for obtaining DEA approval, NIDA has its own requirements for entities that wish to order marijuana:100

1. Cover letter including the name and quantity of compounds being requested, grant number, name, phone number and email address of your program officer (for NIDA/NIH grantee), your shipping address, e-mail address, and phone and fax numbers
2. Recommendation letter from your program officer in support of your request, if you are not a NIDA grantee
3. Research protocol, including justification for quantities of drug(s) being requested

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92 See, e.g., discussion infra Part III.C; see generally MacKay v. DEA, 664 F.3d 808 (10th Cir. 2011); Volkman v. DEA, 567 F.3d 215 (6th Cir. 2009); Noramco of Delaware, Inc. v. DEA, 375 F.3d 1148 (D.C. Cir. 2004).
95 Id. § 312.22.
96 Id. § 312.40(b)(1).
98 21 C.F.R. § 1305.03.
99 See Craker v. DEA, 714 F.3d 17, 20 (1st Cir. 2013).
100 See generally NAT’L INST. ON DRUG ABUSE, supra note 10.
4. **DEA Form-222** (for controlled substances)
5. **Copy of your current DEA registration** (for controlled substances)
6. **Approved FDA letter and IND number** (for a clinical study)
7. **Copy of NRC license** for radioactive compounds
8. **Curriculum vitae** of the principal investigator, and
9. **Statement of commitment** that NIDA will be acknowledged in publications.

Once NIDA receives the necessary materials, it sends the request to HHS, whose Public Health Service Marijuana Research Review Committee will determine whether the study proposal has sufficiently met the requirements to receive marijuana from the federal government, and then make a recommendation to NIDA.\(^{101}\)

In addition to receiving approval from HHS and NIDA, the researcher must also apply to the DEA for registration to conduct research with a Schedule I substance.\(^{102}\) This registration will allow the researcher to receive, possess, and handle the marijuana without fear of prosecution. Within seven days of receipt, the DEA forwards the application to the Secretary, who then has thirty days to “determine the qualifications and competency of the applicant, as well as the merits of the protocol” and notify the DEA administrator of his or her decision.\(^{104}\) If the Secretary determines that the applicant and protocol are deserving of a certificate of registration, the DEA Administrator can still withhold such certificate if “he/she determines that the certificate of registration should be denied on a ground specified in section 304(a) of the [CSA] (21 U.S.C. 824(a)).”\(^{105}\) Section 304(a) of the CSA specifies that the DEA can deny, revoke, or suspend registration if it finds that a manufacturer, distributor, or dispenser of controlled substances:

1. has materially falsified any application filed pursuant to or required by [the CSA];
2. has been convicted of a felony under [the CSA] or any other law of the United States, or of any State, relating to any substance defined in [the CSA] as a controlled substance or a list I chemical;
3. has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;
4. has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

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\(^{101}\) See id. at 5.
\(^{103}\) See 21 C.F.R § 1301.32; see also Cha, supra note 102.
\(^{104}\) See 21 C.F.R § 1301.32.
\(^{105}\) Id.
(5) has been excluded (or directed to be excluded) from participation in
[Medicare and State health care programs] pursuant to section 1320a-
7(a) of Title 42.106
Thus, a researcher must contend with obtaining the approval of three government
agencies and a registered distributor of Schedule I substances—which involves
navigating the complexities of numerous scattered statutory provisions and
administrative regulations—before she ever gets her hands on the marijuana necessary
to conduct her research.

C. CRAKER’S PETITION

In 2001, Dr. Lyle Craker, a professor at the University of Massachusetts, with
support from MAPS, petitioned the DEA for registration as a manufacturer of
marijuana for clinical research107 pursuant to the CSA requirements for manufacturers
of controlled substances in Schedule I or II.108 Craker cited numerous reasons for
wanting to establish a source of marijuana separate from NIDA.109 One of Craker’s
primary concerns was the monopoly power the NCNPR is able to exert in setting its
prices for supplying marijuana for medical research.110

D. DECISION OF THE ADMINISTRATIVE LAW JUDGE

In December 2004, the DEA issued Craker an Order to Show Cause, concluding
that granting Craker’s desired registration to manufacturer marijuana would violate the
Single Convention and would not be in the public interest as required by the CSA at 21
U.S.C. § 823(a).111 Following a 2005 hearing, an administrative law judge (ALJ) found
that a preponderance of the evidence established that granting Craker’s application
would be in the public interest.112 The ALJ first addressed the DEA’s concern that
granting the application would violate the Single Convention obligations, namely that
“[t]he [DEA] shall . . . have the exclusive right of importing, exporting, wholesale
trading and maintaining stocks other than those held by manufacturers of [marijuana].”113 The ALJ pointed to language in the Single Convention providing that
the ratifying countries “need not extend this exclusive right to medicinal [marijuana
and marijuana] preparations,”114 and thus that the “medicinal” nature of any marijuana
cultivated by Craker would exempt it from the treaty’s prohibition.115

The ALJ then turned to the statutory provisions found at 21 U.S.C. § 823(a) that
govern the registration of marijuana manufacturers. The ALJ found that two factors—
diversion control and current level of competition—weighed heavily in favor of
granting registration.116 The ALJ found Craker’s proposed facilities and cultivation
and storing methods sufficient to prevent diversion of the marijuana. In addition, the ALJ found that the inadequacy of the current marijuana supply was symptomatic of a lack of competition in manufacturing marijuana, which greatly supports Craker’s registration. The ALJ concluded with a recommendation that the DEA grant the application.

E. DECISION OF THE DEA ADMINISTRATOR

On January 14, 2009, Michele M. Leonhart, the Deputy Administrator of the DEA, issued a Final Order denying Craker’s application to manufacture marijuana. Before entering into the “public interest” analysis, Leonhart addressed whether the United States’ obligations under the Single Convention prohibit granting Craker’s application. Leonhart found that Craker’s characterization of the Single Convention as not applying to “medicinal marijuana” was based on a false analogy to the exemption of “medicinal opium” in the treaty. Furthermore, Leonhart found that “while the Single Convention does not necessarily prohibit the registration of an additional [marijuana] manufacturer, what it does prohibit is the wholesale distribution of plant-form marijuana by any entity other than the United States Government.”

Leonhart next turned to an analysis of the “public interest” requirement of 21 U.S.C. § 823(a). Leonhart determined that the first public interest factor should be read as requiring the “DEA to consider limiting the number of bulk manufacturers and importers of a given [S]chedule I or II controlled substance to that which can produce an adequate and uninterrupted supply under adequately competitive conditions.” Leonhart concluded that this factor places the burden on the applicant to demonstrate that current manufacturers are unable to produce an adequate supply under adequately competitive conditions.

Looking first at the adequacy of the existing supply, Leonhart initially noted that since 1999, requests from all seventeen of the University of California’s Center for Medicinal Cannabis Research (CMCR)-sponsored studies for research marijuana from NIDA were granted. While there was one MAPS-sponsored study whose request for research marijuana had been denied by HHS, “there is no basis to conclude that NIDA was incapable of providing [the requesting party] with the quantity of marijuana it was seeking.” Leonhart found that Craker’s assertion that the “process by which HHS provides marijuana to researchers . . . results in a barrier to research that effectively renders the supply of marijuana inadequate,” was unfounded because it was based solely on Craker’s assumption that research marijuana should be provided to anyone in

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117 See id. at *83-*84.
118 See id. at *84-*85.
119 Id. at *87.
121 Id. at 2114.
122 Id. at 2116 (“Respondent's reliance is misplaced as it ignores several critical distinctions between what was formerly known as ‘medicinal opium’ and what it contends is ‘medicinal marijuana.’”).
123 Id. at 2118.
124 See id.
125 Id.
126 See id. at 2119.
127 Id.
128 Id. (“Indeed, the ten grams of marijuana that [MAPS] requested is less than [sic] one 100,000th of the amount of marijuana that NIDA has available to supply researchers.”).
the United States with a proposed medical marijuana research study. Thus, Leonhart concluded that the current NIDA supply of research marijuana is adequate.

The last piece of Leonhart’s analysis of the first “public interest” factor was her treatment of Craker’s claim that the competition for the supply of marijuana was inadequate. In dispensing with this argument, Leonhart repeated her conclusion that the CSA does not require the DEA “simply to register as many bulk manufacturers of a given [S]chedule I or II controlled substance as the market will bear,” or to accept an assertion by the applicant that registration will result in decreased cost, increased quality, or some other perceived benefit. Leonhart also pointed to evidence suggesting that NIDA has always provided marijuana, and to statements by MAPS affiliates that Craker and MAPS would expect some profit from supplying marijuana to researchers. According to Leonhart, this expectation undercut Craker’s argument that his registration would decrease costs.

Leonhart denied Craker’s application, despite the ALJ’s recommendations to the contrary, after concluding that granting the application would violate the Single Convention obligations and would be contrary to the public interest because an adequate supply of marijuana already exists.

F. DECISION OF THE COURT OF APPEALS

Craker filed a petition for review in the Court of Appeals for the First Circuit in February 2009, and the First Circuit issued its decision in April of 2013. One major issue on review was “whether, as Dr. Craker argues, limiting supply is allowed only where diversion is a concern, or, as the Administrator contends on appeal, the statute must be construed to require that limiting supply be the means by which effective controls against diversion are implemented.” The court performed a Chevron analysis, and held that the DEA’s interpretation of the CSA’s ambiguous language regarding limiting supply was reasonable and therefore entitled to deference.

The court next addressed Craker’s argument that the DEA’s ruling was erroneous because competition in marijuana manufacturing and the supply of marijuana for research are both inadequate. In addressing the adequacy of competition in manufacturing, the court held that the DEA’s did not err in concluding that the competition was adequate. According to the court, because the case was not an antitrust matter, the competition in question need not meet the higher standards of

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129 Id. at 2120.
130 Id.
131 Id.
132 Id.
133 Id. at 2121.
134 Id. at 2120.
135 Id. at 2133.
136 Craker v. DEA, 714 F.3d 17, 18 (1st Cir. 2013).
137 Id. at 27
138 See id. at 26 (“In reviewing the Administrator's decision, we first address whether Congress has unambiguously spoken to the precise question that is at issue, Chevron, U.S.A. Inc. v. Natural Resources Defense Council Inc., 467 U.S. 837, 842–43, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1997). If it turns out that the statute is ambiguous, then Chevron deference must be afforded; the agency’s interpretation of the statute will be upheld as long as it is ‘based on a permissible construction of the statute.’”).
139 See id. at 28.
140 See id.
antitrust doctrine.\textsuperscript{141} The court found that the supply of marijuana—"over 1000 kilograms of marijuana in NIDA possession" at the time of the decision—far exceeded current demand for research marijuana, and was in fact ninety times the amount that Craker himself had proposed to manufacture.\textsuperscript{142} Therefore, the court concluded that Craker failed to prove that the supply was inadequate.\textsuperscript{143} The court denied Craker’s petition for review, agreeing with the DEA’s final ruling that granting his application would not be in the public interest as required by 21 U.S.C. § 823(a).\textsuperscript{144}

After Craker, the NCNPR remains the sole registered manufacturer of marijuana in the United States, and NIDA controls the entirety of the marijuana supply for researchers wishing to study the possible therapeutic effects of the drug.\textsuperscript{145}

IV. RESULTING OBSTRUCTION TO RESEARCH AND POSSIBLE SOLUTIONS

Despite assurances from the DEA and the First Circuit that the supply of marijuana for research studies is adequate, many proponents of medical marijuana research argue that NIDA’s continued monopoly on the supply of federally-sanctioned marijuana constitutes a barrier to research.\textsuperscript{146}

A. THE CATCH-22 AT THE INTERSECTION OF AMERICANS FOR SAFE ACCESS AND CRAKER

The ultimate barrier to the medical marijuana movement’s ability to have an impact at the federal level is marijuana’s placement in Schedule I under the CSA, because Schedule I controlled substances are the only substances that are illegal to prescribe as medication.\textsuperscript{147} Therefore, the legalization of medical marijuana at the state level cannot make a transition to the federal level while marijuana remains in Schedule I. While state and federal marijuana laws remain inconsistent, healthcare providers who prescribe marijuana legally under state law can still be prosecuted under the CSA.\textsuperscript{148}

\textit{Americans for Safe Access} establishes that anyone petitioning the DEA to reschedule marijuana out of Schedule I must provide evidence of marijuana’s “accepted medical use” through the results of FDA-caliber research studies.\textsuperscript{149} Anyone who wishes to conduct research on the potential medical benefits of marijuana must

\begin{itemize}
\item \textsuperscript{141} See id. at 29 ("That the current regime may not be the most competitive situation possible does not render it ‘inadequate.’").
\item \textsuperscript{142} Id.
\item \textsuperscript{143} See id.
\item \textsuperscript{144} See id.
\item \textsuperscript{145} See Vastag, supra note 11 ("[O]ne government agency, the National Institute on Drug Abuse, controls the nation’s supply of research marijuana. Any non-government researcher wanting access to it needs to satisfy the special HHS committee.").
\item \textsuperscript{147} See 21 U.S.C. § 812 (2012).
\item \textsuperscript{149} See Americans for Safe Access v. DEA, 706 F.3d 438, 452 (D.C. Cir. 2013).
\end{itemize}
first obtain research marijuana from the one federally-registered marijuana manufacturer (the NCNPR) through the one federally-sanctioned marijuana distributor (NIDA). With the adequacy of the supply of research marijuana from NIDA in question, a researcher may desire to look elsewhere for their marijuana. However, researchers who wish to fulfill that desire would find themselves faced with the task of convincing the DEA that granting their applications to grow marijuana is in the public interest, which Craker demonstrates can be quite daunting. While the First Circuit considers NIDA’s marijuana supply “adequate,” a number of marijuana researchers find it unsatisfactory.

B. POSSIBLE SOLUTIONS

This particular catch-22 lends itself to at least two clear solutions. First, the DEA could revise its current interpretation of the requirement of “adequate and well-controlled studies proving efficacy” to show an accepted medical use, thus lowering the standard for rescheduling. Second, the DEA and HHS could increase the supply of marijuana to medical researchers so those researchers can meet the Americans for Safe Access standard for proving accepted medical use.

The first solution, which seems on its face to create a simpler path to rescheduling, would still likely require researchers to conduct FDA clinical trials. Currently, doctors who prescribe marijuana, in states where it is legal, do so even though marijuana does not have FDA approval as a safe and effective drug. This does not appear to be a concern for doctors, because the state laws allow for prescriptions for marijuana regardless of its lack of FDA approval. But if the Americans for Safe Access standard for rescheduling were relaxed and marijuana were rescheduled into Schedule II, then the CSA would not permit prescriptions without FDA approval. So while a party may be able to successfully petition for the rescheduling of marijuana without presenting evidence of its accepted medical use from FDA clinical studies, these studies will likely be necessary before federal law permits providers to prescribe marijuana. This first possible solution—relaxing the rescheduling standard articulated in Americans for Safe Access—would merely create a gap between when marijuana is rescheduled and when it obtains FDA approval, during which prescriptions will remain illegal under federal law.

The second possible solution would be for the government to increase the supply of marijuana for research. This would facilitate clinical trials necessary to prove marijuana’s medical use and, ultimately, have it rescheduled. This can be accomplished either by relaxing the current requirements to obtain marijuana for research, or by registering additional marijuana manufacturers and/or distributors. If formal studies are necessary regardless, then this solution—increasing the availability of research-grade marijuana—is clearly preferable. Under this option, the research would occur before rescheduling, and no gap in prescriptions would appear.

The decision in Craker illustrates how difficult it can be to register as a marijuana manufacturer in an attempt to increase the supply of marijuana for researchers. The

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150 See Vastag, supra note 11.
151 See Smith, supra note 146; Conaboy, supra note 146.
152 See 21 U.S.C. § 829(a) (2012) (“Except when dispensed directly by a practitioner . . . to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], may be dispensed without the written prescription of a practitioner . . . .”).
153 Craker v. DEA, 714 F.3d 17 (1st Cir. 2013).
DEA, as an agency committed to limiting access to drugs, has little incentive to find, as it must in order to register a manufacturer of a Schedule I substance, that the current supplier (NIDA) is unable to “produce an adequate and uninterrupted supply of [marijuana] under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.”\textsuperscript{154} If the DEA is unwilling or unable to recognize a serious supply problem, then there is little hope of expanding the number of suppliers beyond NIDA’s current monopoly.

Therefore, changing the requirements for obtaining marijuana for research is the only other possible solution. As noted above, in addition to NIDA approval, researchers hoping to conduct studies on marijuana must obtain approval from FDA, HHS, and the DEA.\textsuperscript{155} To facilitate further meaningful research into marijuana’s potential medical benefits, Congress could provide that approval from these latter three federal agencies is sufficient. Under this rule, NIDA would be a mere a supplier with no authority to determine which research studies are worthy of receiving marijuana (aside from ensuring that all applicable forms are completed and filed). In this scenario, HHS would direct NIDA to provide marijuana for an approved study, rather than make a recommendation to NIDA regarding the provision of marijuana, as the current system requires.\textsuperscript{156} For most other research studies, FDA approval is sufficient to begin the protocol.\textsuperscript{157} Here, FDA and DEA approvals address the most pressing concerns related to research using controlled substances—the scientific merit and safety of the study, and responsible handling and control against diversion of the substance—to such an extent that one wonders what more protection another level of approval actually provides. Thus, the best possible solution to this particular catch-22 is to dramatically limit the role of NIDA in approving marijuana research studies. This would allow more studies to receive marijuana, which would in turn provide the investigative rigor necessary to prove the “accepted medical use” of marijuana that is required to reschedule it out of Schedule I.

C. Potential Improvements on the Horizon

The recent decision by HHS to approve a study researching the therapeutic benefits of marijuana for Posttraumatic Stress Disorder (PTSD), recommending to NIDA that it release marijuana for use in the study was a glimmer of hope in an otherwise gloomy atmosphere for marijuana research.\textsuperscript{158} The study, entitled “Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Five Different Potencies of Smoked or Vaporized Marijuana in 50 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD),” is sponsored by MAPS and was to be conducted at the University of Arizona and led by

\textsuperscript{154} 21 U.S.C. § 823(a).

\textsuperscript{155} See Cha, supra note 102.

\textsuperscript{156} See id.

\textsuperscript{157} See id. (“Sisley’s study got the green light from the Food and Drug Administration in 2011, and for most studies, that would have been enough. But because the study is about marijuana, Sisley faced two additional hurdles.”).

Dr. Susan Sisley, MD, a psychiatrist who studies post-traumatic stress disorder.\textsuperscript{159} While Dr. Sisley was awaiting completion of her registration with the DEA, however, the University of Arizona fired her.\textsuperscript{160} In its letter to Dr. Sisley, the University claimed that it was terminating her because funding was no longer available for her project, but stated that it is “committed to continuing the project and is looking to replace Sisley with another researcher who can raise more money.”\textsuperscript{161} As of this writing, the University of Arizona has apparently passed on conducting the research altogether, and Dr. Sisley has been attempting, albeit rather unsuccessfully, to find another institution at which to conduct her study.\textsuperscript{162}

In addition to this encouraging move by HHS, there has been a recent legislative update that brings greater hope to marijuana scheduling reform. In March of 2015, a bill was introduced in the U.S. Senate that would drastically change the landscape of federal marijuana policy. Sponsored by Senators Cory Booker (D-NJ), Rand Paul (R-KY), and Kirsten Gillibrand (D-NY), the Compassionate Access, Research Expansion and Respect States (CARERS) Act would amend the CSA in multiple ways to make federal medical marijuana policy more consistent with the trends being seen at the state level.\textsuperscript{163} If passed, the CARERS Act would amend the CSA to reschedule marijuana from Schedule I to Schedule II.\textsuperscript{164} The Act would also add language to the CSA that would exempt from enforcement anyone who is in compliance with his or her state’s medical marijuana laws.\textsuperscript{165} In addition the Act includes provisions for expanding access to marijuana for research: it terminates the current restrictive review process conducted by the Public Health Service and NIDA, and requires the DEA to issue at least three licenses to manufacture marijuana for distribution to FDA-approved research studies.\textsuperscript{166} Finally, the Act addresses an issue that is not specifically discussed by this Note, but is nonetheless of great importance to the continued success of the medical marijuana industry: the Act removes certain regulatory obstacles that have prevented banks from legally accepting profits from marijuana businesses.\textsuperscript{167}

If passed, the CARERS Act would enact most of the changes necessary to make the federal marijuana laws more consistent with the laws of states that have legalized medical marijuana. Within a year of passage, citizens who comply with state marijuana laws would be free from federal prosecution under the CSA, and many of the barriers to federal marijuana research would be removed. Needless to say, this would be a huge step forward for medical marijuana advocates and patients, and would

\textsuperscript{160} Astrid Galvan, Fired Professor Suzanne Sisley Isn’t Giving up on Marijuana Research, HUFFINGTON POST (July 20, 2014), http://www.huffingtonpost.com/2014/07/20/suzanne-sisley-marijuana-research_n_5603547.html.
\textsuperscript{161} Id.
\textsuperscript{164} Id. § 3.
\textsuperscript{165} Id. § 2 (“Notwithstanding any other provision of law, the provisions of this title relating to marihuana shall not apply to any person acting in compliance with State law relating to the production, possession, distribution, dispensation, administration, laboratory testing, or delivery of medical marihuana.”).
\textsuperscript{166} Id. § 7.
\textsuperscript{167} Id. § 6.
allow for a greater understanding of the potential therapeutic uses of what is now one of the substances most tightly controlled by the United States federal government.

V. CONCLUSION

Since the passage of the CSA, advocates have continuously, but unsuccessfully, petitioned the DEA to reschedule marijuana out of Schedule I. As more states legalize the prescription, possession, and sale of marijuana for therapeutic use, its status as a Schedule I controlled substance has become the chief roadblock in the path of a similar movement at the federal level. In order to remove marijuana from Schedule I, a party petitioning the DEA must point to “adequate and well-controlled studies proving efficacy” of the drug in order to show that it has an “accepted medical use.” In Americans for Safe Access, the D.C. Circuit held that the petitioners must use studies akin to the New Drug Application clinical trials required for FDA approval. Despite the DEA’s assertion to the contrary, there is evidence to suggest that an insufficient supply of research-grade marijuana inhibits the research necessary to meet the rescheduling standard. Obtaining marijuana for research involves obtaining FDA approval for the study, and then DEA, HHS, and NIDA approval for the receipt and possession of the marijuana. The First Circuit held in Craker that the current supply of marijuana was sufficiently adequate, severely hindering any future attempt to establish an alternative to NIDA as a source of marijuana.

This landscape creates a catch-22: The rescheduling of marijuana out of Schedule I requires fairly rigorous and extensive clinical research showing the drug’s medical efficacy. But a uniquely arduous approval process and a shortage of marijuana, due to its designation as a Schedule I controlled substance, prevent the research necessary to reschedule.

The most sensible and least extreme solution to this dilemma is to relax the approval process for obtaining marijuana for FDA- and DEA-approved clinical studies. This will provide a fair method for advocates to conduct the research necessary to propel the medical marijuana legalization movement upward to the federal level. This is the minimum that can be done to fix a system that is clearly not consistent with current trends in public and scientific opinion on the therapeutic use of marijuana.

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168 Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994).
171 Id. at 452 (citing Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,562 (July 8, 2011)).
172 See Cha, supra note 102 (“[M]any would-be marijuana researchers are driven to abandon projects after they discover how time-consuming and expensive it can be to obtain the drug.”).
173 See Bilz, supra note 93, at 132.
174 Craker v. DEA, 714 F.3d 17, 29 (1st Cir. 2013).
176 Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994).
177 See Cha, supra note 102.