No. _____

In The

Supreme Court of the United States

AMERICANS FOR SAFE ACCESS, et al.,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

PETITION FOR WRIT OF CERTIORARI

JOSEPH D. ELFORD
AMERICANS FOR SAFE ACCESS
600 Fell Street #101
San Francisco, CA 94102
Tel: (415) 573-7842
Email: joeelford@yahoo.com

Counsel for Petitioners

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

QUESTIONS PRESENTED

1. Whether FDA marketing approval, or the equivalent thereof, is necessary to a finding that a substance has a "currently accepted medical use in treatment in the United States" under the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq*. ("CSA").

2. Whether the CSA requires the Drug Enforcement Administration ("DEA") to consider the relative abuse potential of controlled substances when making scheduling determinations under the CSA.

PARTIES TO THE PROCEEDINGS BELOW

Petitioners Americans for Safe Access ("ASA"), William Britt ("Britt"), the Coalition to Reschedule Cannabis ("CRC"), Cathy Jordan ("Jordan"), Michael Krawitz ("Krawitz"), Rick Steeb ("Steeb"), and Patients Out of Time (collectively "Petitioners") filed a Petition with respondent the Drug Enforcement Administration ("DEA") to reschedule marijuana, in accordance with the rescheduling provisions of 21 U.S.C. § 877.

CORPORATE DISCLOSURE STATEMENT

Petitioners report that they are non-profit corporations and individuals that do not have parent corporations.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.

OPINIONS BELOW

The District of Columbia Circuit's opinion of January 22, 2013, is published at *Americans for Safe Access v. Drug Enforcement Administration*, 706 F.3d 438 (D.C. Cir. 2013) App. 1-52. The District of Columbia Circuit's orders denying panel rehearing and rehearing en banc are reported at App. 123, 125.

JURISDICTION

The District of Columbia Circuit had original jurisdiction over the Petition for review of the decision of a federal agency pursuant to 21 U.S.C. § 877. It denied Petitioners' petitions for panel rehearing and rehearing en banc on April 15, 2013. App. 123, 125. Pursuant to Rule 13(3) of the Rules of this Court, the time for filing a Petition for Writ of Certiorari in this Court elapses ninety days later, which is July 15, 2013. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The appendix reproduces the relevant provisions of the CSA, which consist of 21 U.S.C. §§ 801(1), 812(a)-(c), and 877 at App. 127-130.

INTRODUCTION

The profoundly important question whether marijuana has medical efficacy and should be rescheduled has been debated for decades. When Congress enacted the federal CSA in 1970, it impacted the lives of millions of people, particularly with respect to marijuana. Since then, eighteen states and the District of Columbia have enacted legislation recognizing that marijuana has therapeutic value and should not be treated as criminal when used for medical purposes. Indeed, the federal government has sought and obtained a patent for the medical use of cannabinoids, which are the active components of marijuana; yet, it continues to maintain for others that the marijuana containing these cannabinoids has no medical use.

Contrary to the federal government's current position under the CSA that marijuana does not have a "currently accepted use for medical treatment in the United States," App. 8, 108, there are numerous peer-reviewed studies establishing that marijuana is effective in treating AIDS wasting syndrome, muscle spasticity, emesis, appetite loss, chronic pain, and

negative side effects associated with chemotherapy, as several of the government's own Commissions and a DEA Administrative Law Judge have recognized. The government, however, simply ignores these well-controlled studies and, instead, demands proof of medical efficacy for marijuana far beyond that which it requires for other scheduled substances – proof that is not required by the federal Controlled Substances Act ("CSA") or the federal agencies' own regulations. To make matters worse, and further demonstrating the Drug Enforcement Agency's ("DEA") bias on this topic, the DEA fails to compare the abuse potential of marijuana to other scheduled substances, as the CSA requires. It is only by failing to apply the appropriate standards and make the required comparisons that the federal government could conclude that marijuana is as harmful as heroin and PCP and even more harmful than methamphetamine, cocaine and opium, and should remain in the CSA's most restrictive Schedule I.

In ruling as it did, the Court of Appeals committed two fundamental errors. *First*, the Court of Appeals' decision conflicts with the holding of the First Circuit in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987) (cited with approval in *Doe v. DEA*, 484 F.3d 561 (D.C. Cir. 2007)), which held that the DEA cannot treat the lack of FDA marketing approval as conclusive evidence that a substance has no "currently accepted medical use in treatment in the United States," *see* 21 U.S.C. § 812(b)(1)(B), under the CSA. As with the substance addressed by Dr. Grinspoon,

"there is no economic or other incentive to seek interstate marketing approval for a drug like [marijuana] because it cannot be patented and exploited commercially." *See Grinspoon*, 828 F.2d at 887. The District of Columbia Circuit, in this case, however, held that phase II or III testing must be accomplished before a substance can be deemed to have a "currently accepted medical use" under the CSA. App. 28-33. This creates an essential conflict with *Grinspoon*.

Second, the District of Columbia Circuit's decision conflicts with the CSA's requirement that the DEA must consider the relative abuse potential of controlled substances when making scheduling determinations under the CSA, as an earlier panel of the District of Columbia Circuit held in *National Organization for the Reform of Marijuana Laws ("NORML") v. DEA*, 559 F.2d 735 (D.C. Cir. 1977).

This Court should review the decision below to resolve the conflict it creates with the decisions of other appellate tribunals, restore the federalist balance, and allow for the proper application of the CSA.

STATEMENT OF THE CASE

The CSA enacts a comprehensive regulatory scheme to regulate controlled substances, many of which "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1).

To this end, the CSA classifies substances into five categories based on their: (1) medical utility, (2) abuse potential, and (3) safety of use under medical supervision. 21 U.S.C. § 812(b)(1)(A)-(C). The most restrictive category, Schedule I, is reserved for substances with no currently accepted medical use, the highest abuse potential, and lack of safety under medical supervision. *See* 21 U.S.C. § 812. Schedule I substances may only be used for research purposes under strict guidelines. 21 U.S.C. § 823. The government currently classifies marijuana as a Schedule I substance. *See* 21 C.F.R. § 1308.11.

When Congress initially placed marijuana in Schedule I in enacting the CSA, it did not make any specific findings regarding marijuana as medicine or its relative abuse potential. Rather, the House Report recommending marijuana's initial placement in Schedule I reveals Congress' uncertainty about the harms associated with marijuana and its medical benefits. *See* H.R. Rep. No. 91-1444, P.L. 91-513, U.S. Code Cong. & Admin. News 1970, pp. 4566, 4629 ("Some question has been raised whether the use of the plant itself produces 'psychological or physical dependence' as required by a schedule I or even schedule II criterion. Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marihuana be retained within Schedule I at least until the completion of certain studies now underway to resolve this issue.") (quoting letter from Roger Egeberg, M.D.O. to Hon. Harley O. Staggers,

dated August 14, 1970); *National Org. for the Reform of Marijuana Laws v. Ingersoll ("NORML")*, 497 F.2d 654, 657 (D.C. Cir. 1974); *see also Gonzales v. Raich*, 545 U.S. 1, 14 & n.22 (2005). As an interim solution, Congress placed marijuana in Schedule I and convened a Commission on Marihuana and Drug Abuse ("Commission") to research the issue, which it viewed as an "aid in determining the appropriate disposition of this question in the future." *See* 21 U.S.C. § 812(c)(10); H.R. Rep. No. 91-1444, P.L. 91-513, U.S. Code Cong. & Admin. News 1970, pp. 4566, 4625-26; *Ingersoll*, 497 F.2d at 657 (quoting House Report); *see also NORML v. Bell*, 488 F.Supp. 123, 141 (D.D.C. 1980) ("In making the initial determination, Congress placed marijuana in Schedule I. The clear meaning of section 812(c) is that Congress intended marijuana to remain in Schedule I until such time as it might be reclassified by the Attorney General on the basis of more complete scientific information about the drug.").

Approximately one year later, on March 22, 1972, the Commission determined that the harms associated with marijuana were overstated and it recommended its decriminalization for personal medical use. *See* Commission, *Marijuana: A Signal of Misunderstanding* (General Accounting Press March 22, 1972) [found at: http://www.sciencemag.org/content/179/4069/167.2.citation]. Following suit, after a comprehensive review of the therapeutic uses of marijuana commissioned by the White House's Office of National Drug Control Policy, the prestigious Institute of Medicine ("IOM"), in 1999, reported a medical basis

for using marijuana to treat a variety of conditions. *See* Joy, Janet E., Stanley J., Watson, and John A. Benson, Jr., (eds) *Marijuana as Medicine: Assessing the Science Base*, at 4 (National Academy Press 1999) ("The accumulated data indicate a potential therapeutic value for cannabinoid drugs, particularly for symptoms such as pain relief, control of nausea and vomiting, and appetite stimulation.") [found at http://books.nap.edu/openbook.php?record_id=6376&page=4]. Notwithstanding these scientific recommendations and repeated efforts to reschedule marijuana, neither Congress nor the executive branch has reclassified marijuana from Schedule I. *Cf.* Smith, Annaliese, *Marijuana as a Schedule I Substance: Political Ploy or Accepted Science?*, 40 Santa Clara L. Rev. 1137 (2000) (arguing that government's continued maintenance of marijuana in Schedule I is motivated by politics, rather than science).

Under the CSA, however, the Attorney General has the authority to reschedule a drug if he finds that it does not meet the criteria for the schedule to which it has been assigned. 21 U.S.C. § 811(a)(2); *see also Alliance for Cannabis Therapeutics ("ACT") v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994); *Kuromiya v. United States*, 37 F.Supp.2d 717, 722 (E.D. Pa. 1999) ("There are provisions by which the Attorney General may change the designation of a particular controlled substance, either to move it up, down, or off of the schedules.") (citing 21 U.S.C. § 811). The Attorney General has delegated this authority to the

Administrator of the DEA ("Administrator"). *See* 28 C.F.R. § 0.100(b); *ACT*, 15 F.3d at 1133.

To initiate the rescheduling process, "any interested party" may petition the Attorney General (or DEA) to analyze the properties and medical utility of a drug in efforts to have it rescheduled from one classification to another. 21 U.S.C. § 811(a). Before initiating formal proceedings to schedule or reschedule a drug in accordance with 21 U.S.C. § 811(a), the Administrator must request a scientific and medical evaluation and recommendation from the Secretary of HHS whether the substance "should be so controlled or removed as a controlled substance." 21 U.S.C. § 811(b). This evaluation and recommendation must be in writing and submitted to the Attorney General "within a reasonable time." 21 U.S.C. § 811(b). When transmitted, the evaluation and recommendations of HHS are binding on the Administrator with respect to scientific and medical matters. *See* 21 U.S.C. § 811(b).

Following the receipt of HHS' findings and recommendations, the DEA Administrator must take into account the following factors to determine whether to initiate rulemaking proceedings:

> (1) [The drug's] actual or 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 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(c). "If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he *shall* initiate proceedings for control or removal, as the case may be, under subsection (a) of this section." 21 U.S.C. § 811(b) (emphasis added). In addition, the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* ("APA") requires agencies presented with such petitions to decide the petition "within a reasonable period of time." 5 U.S.C. § 555(b).

Petitioners availed themselves of this process by filing a marijuana rescheduling Petition with the DEA on October 9, 2002, requesting that marijuana be rescheduled to Schedule III, IV, or V because marijuana has an accepted medical use in the United States; it is safe for use under medical supervision; it has an abuse potential lower than Schedule I or II

drugs; and it has a lower dependence liability than Schedule I or II drugs. App. 56; 76 Fed. Reg. 40,552, 40,566 (July 8, 2011). The DEA accepted the Petition for filing on April 3, 2003. App. 56; 76 Fed. Reg. 40,552, 40,566 (July 8, 2011). And, on July 12, 2004, the DEA requested a scientific evaluation and scheduling recommendation for marijuana from HHS, as required by 21 U.S.C. § 811(b). App. 56; 76 Fed. Reg. 40,552, 40,566 (July 8, 2011). After nearly a decade of delay, the DEA formally denied the marijuana rescheduling Petition July 8, 2011. App. 53-122; 76 Fed. Reg. 40,551 (July 8, 2011). This prompted Petitioners to file an original Petition for administrative review with the Court of Appeals. *See* 21 U.S.C. § 877.

On standing, the majority of the panel found that:

> [A]t least one of the named Petitioners, Michael Krawitz, has standing to challenge the agency's action. Krawitz, who is a disabled veteran, is entitled to medical care through the U.S. Department of Veterans Affairs ("VA"). Krawitz has suffered injury-in-fact because he must shoulder a financial cost for services he could otherwise obtain free of charge from the VA. There is a causal connection between the DEA's continuing decision to classify marijuana as a Schedule I drug and the VA's policy of refusing to provide referrals for state medical marijuana programs. And a favorable decision from this court would likely redress Krawitz's injury because, if the DEA rescheduled marijuana,

> the VA could no longer use the CSA to justify its policy of refusing to complete medical marijuana referral forms. Krawitz thus satisfies the requirements of Article III standing. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992).

App. 4.[1]

Turning to the merits, despite more than two hundred peer-reviewed studies presented by Petitioners demonstrating that marijuana does, in fact, have medical use, *see* App. 28, the District of Columbia Circuit denied the Petition for review by published decision, dated January 22, 2013. App. 1-52; *Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013). The Court of Appeals held as follows:

> On the merits, Petitioners claim that the DEA's final order denying their request to initiate proceedings to reschedule marijuana was arbitrary and capricious. Under the terms of the CSA, marijuana cannot be rescheduled to Schedules III, IV, or V without a "currently accepted medical use." 21 U.S.C. § 812(b)(3)-(5). To assess whether marijuana has such a medical use, the agency applies a five-part test: "(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

[1] Judge Henderson dissented from the majority's opinion regarding standing. App. 33-52. She issued no opinion regarding the merits.

> efficacy; (4) The drug must be accepted by qualified experts; and (5) The scientific evidence must be widely available." See Denial, 76 Fed. Reg. 40,552, 40,579. The DEA's five-part test was expressly approved by this court in Alliance for Cannabis Therapeutics, 15 F.3d at 1135. Because the agency's factual findings in this case are supported by substantial evidence and because those factual findings reasonably support the agency's final decision not to reschedule marijuana, we must uphold the agency action.

App. 25, 26.

In particular, the Court of Appeals "need[ed] only look at one factor, the existence of 'adequate well-controlled studies proving efficacy,' to resolve Petitioners' claim." *Id.* at 23. It contended that:

> The DEA interprets "adequate and well-controlled studies" to mean studies similar to what the Food and Drug Administration ("FDA") requires for a New Drug Application ("NDA"). See id. at 40,562. DHHS found that "there have been no NDA-quality studies that have scientifically assessed the efficacy of marijuana for any medical condition." Id. It is well understood that, under FDA protocols, "adequate and well-controlled investigations" require "clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the

> effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

21 U.S.C. § 355(d). *Id.* at 26. Without citing, or even mentioning the First Circuit's decision in *Grinspoon*, which held that FDA marketing approval is not necessary to a finding of lack of "currently accepted medical use" under the CSA, *see Grinspoon v. DEA*, 828 F.2d 881, 888-90 (1st Cir. 1987), or making *any* comparisons of marijuana's relative abuse potential under the CSA, the District of Columbia Circuit denied the Petition for Review. App. 25-32.

Petitioners timely requested panel rehearing and rehearing *en banc*, which were denied by the District of Columbia Circuit on April 15, 2013. App. 123-126. Accordingly, Petitioners now seek review of the District of Columbia's holding denying their Petition for review of the DEA's failure to reclassify marijuana.

REASONS FOR GRANTING THE WRIT

I. THE DECISION BELOW CONFLICTS WITH ESTABLISHED AUTHORITY FROM THE FIRST CIRCUIT AND THE DISTRICT OF COLUMBIA CIRCUIT THAT FDA MARKETING APPROVAL IS NOT NECESSARY TO A FINDING THAT A SUBSTANCE HAS A "CURRENTLY ACCEPTED MEDICAL USE IN TREATMENT IN THE UNITED STATES" UNDER THE CSA

In *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), which was cited with approval by the District of Columbia Circuit in *DOE v. DEA*, 484 F.3d 561, 571 (D.C. Cir. 2007), the First Circuit held that

> the absence of FDA approval for interstate commerce does not foreclose the possibility that a substance might still possess an accepted medical use or even be considered safe for use under medical supervision. It appears, instead, that blind reliance on the lack of FDA interstate marketing approval could cause a substance to be placed in Schedule I, even though one or two of the three requirements for placement of a drug in Schedule I have not been proven.

828 F.2d at 888. One presumable reason, as eloquently stated by Dr. Grinspoon, is that "there is no economic or other incentive to seek interstate marketing approval for a drug like [marijuana] because it cannot be patented and exploited commercially." *See Grinspoon*, 828 F.2d at 887. As a result, FDA marketing approval

is sufficient, but not necessary to a finding that a substance has a "currently accepted medical use for treatment in the United States" under the CSA. *See Grinspoon*, 828 F.2d at 890 ("the methaqualone legislation demonstrates Congress' belief that FDA approval is sufficient to establish the existence of an accepted medical use, but not that the lack of FDA approval – the issue in this case – necessarily negates the possibility that the substance in question has an accepted medical use and is safe for use under medical supervision"); *see also Doe v. DEA*, 484 F.3d 561, 571 (D.C. Cir. 2007) ("Whereas the *absence* of FDA marketing approval may not be a reasonable proxy for lack of currently accepted medical use, the *presence* of FDA marketing approval obviously *is* powerful evidence that a drug has currently accepted medical use" "The fact that the DEA has apparently accepted FDA marketing approval as *one* way to demonstrate currently accepted medical use is not the equivalent of a broad declaration saying FDA approval is the *only* way") (emphasis in original).

Based on these authorities, the government itself did not contend that Phase II or Phase III FDA-approved studies are necessary to a finding that a substance has a currently accepted medical use for treatment in the United States in its Respondents' Brief. Rather, the government simply noted that "[n]o Phase II or Phase III studies of marijuana have been conducted." App. 29-33 (citing 76 Fed. Reg. at 40,579-80). Read in light of *Grinspoon* and its progeny, *see Doe v. DEA*, 484 F.3d at 571, this statement meant

that petitioners could not establish "currently accepted medical use" simply by reference to FDA approval. It did not mean, as the panel of the District of Columbia Circuit in this case construed it, that FDA approval was *necessary* to prove that a substance has an accepted medical use under the CSA. *Compare* App. 30 ("The DEA interprets 'adequate and well-controlled studies' to mean studies similar to what the Food and Drug Administration ('FDA') requires for a New Drug Application ('NDA')") *with Doe*, 484 F.3d at 571; *Grinspoon*, 828 F.2d at 888 (FDA marketing approval is not necessary to a finding of "currently accepted medical use" under the CSA).

Indeed, as the First Circuit observed in *Grinspoon*, "we fail to see how the interpretation of the Uniform CSA offered by the Commissioners has any bearing at all on the intent of Congress, which enacted the federal CSA *prior to* the creation of the Uniform CSA." 828 F.2d at 887 (emphasis in original). "[W]e find no necessary linkage between failure to obtain FDA interstate marketing approval and a determination that the substance in question is unsafe *and* has no medical use. Indeed, [Food and Drug Cosmetic Act ("FDCA")] does not even mention the term "medical use." In short, it is plainly possible that a substance may fail to obtain interstate marketing approval even if it has an accepted medical use." *Id.* (emphasis in original). Congress did not seek "to permit blind reliance on FDA standards as a legitimate shortcut in the general run of cases." *Id.* at 889; *see also id.* at 890 ("We believe . . . absolute reliance on the absence

of FDA approval would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA").

Were it otherwise, as the panel of the District of Columbia Circuit erroneously held in the instant case, a substance could have medical use, yet be deemed not to have such medical use by the DEA, due to market barriers to FDA approval. As the court stated in *Grinspoon*, "the impermissibility of substituting FDCA standards for CSA scheduling criteria becomes even more apparent when we compare the dearth of support in the legislative history for such an interpretation with the language and history of several subsequent legislative enactments in the controlled substances field." *See Grinspoon*, 828 F.2d at 888-89.

Despite the conflicting authorities from the First Circuit and its own court, *see Grinspoon*; *Doe v. DEA*, 484 F.3d 561, 571 (D.C. Cir. 2007), the panel in this case essentially equated "currently accepted medical use" with FDA-approved studies. *See* Opinion at 26. This Court should grant the writ to resolve this extremely important conflict among the Courts of Appeals. *See* Rule 10(a), Supreme Court of the United States.

II. THE DECISION BELOW CONFLICTS WITH THE CSA'S REQUIREMENT THAT SCHEDULING DETERMINATIONS MUST INVOLVE A CONSIDERATION OF RELATIVE ABUSE POTENTIAL

Under the CSA, a substance is to be placed in Schedule I, the most restrictive category, only if it has (1) a "high potential for abuse," (2) no currently accepted medical use, and (3) there is a lack of accepted safety for use under medical supervision. *See* 21 U.S.C. § 812(b)(1)(A)-(C). Although the CSA does not define the term "high potential for abuse," *see Grinspoon v. DEA*, 828 F.2d 881, 893 (1st Cir. 1987); 76 Fed. Reg. 40,552, 40,567 & 40,568 (July 8, 2011), its statutory language and framework make clear that a substance must be compared to other scheduled substances to determine whether its abuse potential is sufficiently "high" to warrant Schedule I treatment. *See* 21 U.S.C. § 812(b). For instance, Schedule I and II substances require a "high" potential for abuse, while Schedule III substances must have a potential for abuse "less than the drugs or other substances in schedules I and II." *Compare* 21 U.S.C. § 812(b)(1)(A) & (2)(A) *with* 21 U.S.C. § 812(b)(3)(A). Similarly, Schedule IV drugs must have "a low potential for abuse relative to the drugs or other substances in Schedule III," 21 U.S.C. § 812(b)(4)(A), and Schedule V drugs must have "a low potential for abuse relative to the drugs or other substances in Schedule IV." 21 U.S.C. § 812(b)(5)(A). Notably, in discussing "abuse" as it relates to scheduling,

the only factors expressly listed by the CSA are psychological and physical dependence. *See* 21 U.S.C. §§ 812(b)(2)(C), (b)(3)(C), (b)(4)(C) & (b)(5)(C).[2] Congress, however, did not explicitly state where to place a substance under the CSA that has a low abuse potential compared to other drugs, which is found by the federal government to lack a currently accepted medical use. The District of Columbia Circuit previously resolved this question in favor of requiring the relative abuse comparison.

In *NORML v. DEA*, 559 F.2d 735, 747 (1977), a unanimous panel of the District of Columbia Circuit flatly rejected "the assumption that placement in CSA Schedule I is automatically required if the substance has no currently accepted medical use in the United States." As the Court of Appeals explained in *NORML*, the DEA must engage in a "finely tuned balancing process involving several medical and scientific considerations" in making a scheduling determination. *See* 559 F.2d at 748. "If, as [the DEA] contends, a determination that the substance has no accepted

[2] Under the CSA, the Attorney General has the authority to reschedule a substance if he finds that it does not meet the criteria for the schedule to which it has been assigned. 21 U.S.C. § 811(a)(2); *see also ACT v. DEA*, 15 F.3d at 1133; *Kuromiya v. United States*, 37 F.Supp.2d 717, 722 (E.D. Pa.1999) ("There are provisions by which the Attorney General may change the designation of a particular controlled substance, either to move it up, down, or off of the schedules.") (citing 21 U.S.C. § 811). The Attorney General has delegated this authority to the Administrator of the DEA ("Administrator"). *See* 28 C.F.R. § 0.100(b); *ACT*, 15 F.3d at 1133.

medical use ends the inquiry, then presumably Congress would have spelled that out in its procedural guidelines." *Id.* Indeed, as recognized in *NORML*, the House Report accompanying the enactment of the CSA specifically states that the DEA must consider numerous criterion, in addition to relative abuse potential, in making scheduling determinations. *See id.* at 748 n.56 (citing H.R. Rep. No. 91-1444, pt. 1, at 35). The *NORML* Court explained as follows:

> Admittedly, Section 202(b), 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*. Like that of Section 201(c), the structure of Section 202(b) contemplates balancing of medical usefulness along with several other considerations, including potential for abuse and danger of dependence. To treat medical use as the controlling factor in classification decisions is to render irrelevant the other "findings" required by Section 202(b). 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.

NORML v. DEA, 559 F.2d at 748 (emphasis added) (footnotes omitted).

The decision below in the instant case, by sharp contrast, holds, without discussion, that "[u]nder the terms of the CSA, marijuana cannot be rescheduled to Schedules III, IV, or V without a 'currently accepted medical use.'" *See* Cite Opinion at 21 (citing 21 U.S.C. § 812(b)(3)-(5)). The panel, then, simply ignored that marijuana has an extremely low abuse potential relative to other controlled substances, despite having been presented voluminous evidence presented by Petitioners in the Petition for review that marijuana does not have a sufficiently high relative abuse potential to warrant placement in Schedule I. Under the District of Columbia Circuit's prior decision in *NORML v. DEA*, the panel in this case erred in failing to give *any* consideration to marijuana's relatively low potential for abuse in reviewing the DEA's scheduling determination. *Cf. NORML v. DEA*, 559 F.2d 753, 748 n.58 (1977) ("[a] key criterion for controlling a substance. . . . is the substance's potential for abuse") (quoting H.R. Rep. No. 91-1444, pt. 1, at 34).[3] Marijuana does not have

[3] If it were otherwise, poppy straw would not have been deemed suitable for placement in Schedule II by Congress; however, Congress deemed this so, despite the admitted lack of any medical use for this substance. *See* 21 U.S.C. §§ 812(b)(2)(B) & (C), Schedule II(a)(3) & (4); *NORML*, 559 at 748 ("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.").

nearly as high a potential for abuse as methamphetamine and cocaine, which are categorized in Schedule II. *See* Nutt, David, *et al.*, *Development of a Rational Scale to Assess the Harm of Drugs of Potential Abuse*, 369 Lancet 1047 (2007)); Smith, Annaliese, *Marijuana as a Schedule I Substance: Political Ploy or Accepted Science?*, 40 Santa Clara L. Rev. 1137, 1164-65 (2000) ("With limited potential for physical and psychological dependence, rescheduling marijuana appears appropriate"). This Court should review the decision below to resolve the important question whether the CSA requires that a substance have a high potential for abuse to warrant placement in the most restrictive schedule. *See* Rule 10(c), Supreme Court of the United States.

CONCLUSION

Accordingly, the petition for a writ of certiorari should be granted.

DATED: July 15, 2013

Respectfully submitted,

JOSEPH D. ELFORD
AMERICANS FOR SAFE ACCESS
600 Fell Street #101
San Francisco, CA 94102
Tel: (415) 573-7842
Email: joeelford@yahoo.com

Counsel for Petitioners

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 16, 2012 Decided January 22, 2013

No. 11-1265

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DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

CARL ERIC OLSEN,
INTERVENOR

On Petition for Review of a Final Order of the
United States Drug Enforcement Administration

Joseph D. Elford argued the cause and filed the briefs for petitioners.

Carl E. Olsen, pro se, filed briefs for intervenor.

Lena Watkins, Senior Trial Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the briefs were Lanny A. Breuer, Assistant Attorney General, and Anita J. Gay, Senior Trial Attorney.

Before: HENDERSON and GARLAND, Circuit Judges, and EDWARDS, Senior Circuit Judge.

Opinion for the Court filed by Senior Circuit Judge EDWARDS.

Dissenting opinion filed by Circuit Judge HENDERSON.

EDWARDS, Senior Circuit Judge: There is a serious debate in the United States over the efficacy of marijuana for medicinal uses. Although marijuana has been legalized in a number of states, it is classified as a "Schedule I" drug by the Drug Enforcement Administration ("DEA"), pursuant to its authority under the Controlled Substances Act of 1970 ("CSA" or "Act"). The DEA has maintained this listing because it has determined that marijuana "has no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B). Because Schedule I is the most restricted drug classification under the CSA, the production, sale, and use of marijuana are largely banned by federal law. Petitioners in this case – Americans for Safe Access, the Coalition to Reschedule Cannabis, Patients Out of Time, and several individuals – challenge DEA's denial of its petition to initiate proceedings to reschedule marijuana.

The CSA permits the DEA to reclassify drugs to less restrictive schedules according to various statutory criteria, and interested parties can petition the DEA for such action. *See* 21 U.S.C. §§ 811, 812. In October 2002, the Coalition to Reschedule Cannabis petitioned the DEA to reschedule marijuana as a Schedule III, IV, or V drug. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana ("*Denial*"), 76 Fed. Reg.

40,552, 40,552 (July 8, 2011). The DEA denied the petition on July 8, 2011, finding that "[t]here is no currently accepted medical use for marijuana in the United States," and that "[t]he limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA." *Id.* at 40,552, 40,567. On July 22, 2011, Petitioners filed a timely petition for review of the DEA action.

Petitioners claim that "[n]umerous peer-reviewed scientific studies demonstrate that marijuana is effective in treating various medical conditions, but the DEA simply ignores them to conclude that marijuana should remain in Schedule I." Pet'rs' Br. at 20. Petitioners thus contend that the DEA's denial of their petition was arbitrary and capricious and ask this court to remand the case to the agency for further consideration.

The Government, in turn, argues that we should dismiss the petition for review on jurisdictional grounds because Petitioners and Intervenor lack Article III standing. The Government also asserts that, even if the court determines that Petitioners or Intervenor have standing, the petition for review should be denied on the merits. According to the Government, in the record reviewed by the DEA, "there was no available evidence of adequate, well-controlled studies demonstrating marijuana's safety and effectiveness as a medicine and no consensus among experts as to these issues. The enactment of state laws allowing the use of marijuana for medical

purposes did not constitute the required science-based evidence." Br. for Resp't at 23.

We deny the Government's jurisdictional challenge because we find that at least one of the named Petitioners, Michael Krawitz, has standing to challenge the agency's action. Krawitz, who is a disabled veteran, is entitled to medical care through the U.S. Department of Veterans Affairs ("VA"). Krawitz has suffered injury-in-fact because he must shoulder a financial cost for services he could otherwise obtain free of charge from the VA. There is a causal connection between the DEA's continuing decision to classify marijuana as a Schedule I drug and the VA's policy of refusing to provide referrals for state medical marijuana programs. And a favorable decision from this court would likely redress Krawitz's injury because, if the DEA rescheduled marijuana, the VA could no longer use the CSA to justify its policy of refusing to complete medical marijuana referral forms. Krawitz thus satisfies the requirements of Article III standing. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

On the merits, the question before the court is not whether marijuana could have some medical benefits. Rather, the limited question that we address is whether the DEA's decision declining to initiate proceedings to reschedule marijuana under the CSA was arbitrary and capricious. These questions are not coterminous. "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the

agency." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). On the record before us, we hold that the DEA's denial of the rescheduling petition survives review under the deferential arbitrary and capricious standard. The petition asks the DEA to reclassify marijuana as a Schedule III, IV, or V drug, which, under the terms of the CSA, requires a "currently accepted medical use." The DEA's regulations, which we approved in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994), define "currently accepted medical use" to require, *inter alia*, "adequate and well-controlled studies proving efficacy." *Id.* at 1135. We defer to the agency's interpretation of these regulations and find that substantial evidence supports its determination that such studies do not exist.

I. Background

A. The Controlled Substances Act

We have previously described marijuana's listing as a Schedule I drug under the CSA as follows:

> The [CSA] places hazardous drugs in five categories, or schedules, which impose varying restrictions on access to the drugs. *See* 21 U.S.C. § 812 (1988). Marijuana is assigned by statute to Schedule I, the most restrictive of these. Schedule I drugs may be obtained and used lawfully only by doctors who submit a detailed research protocol for approval by the Food and Drug Administration and

> who agree to abide by strict recordkeeping and storage rules.
>
> The CSA allows the Attorney General to reschedule a drug if he finds that it does not meet the criteria for the schedule to which it has been assigned. 21 U.S.C. § 811(a). The Attorney General has delegated this authority to the [DEA] Administrator. In rescheduling a drug, the Administrator must consider, *inter alia*, "[s]cientific evidence of [the drug's] pharmacological effect, if known," and "[t]he state of current scientific knowledge regarding the drug or other substance." 21 U.S.C. § 811(c)(2), (3).
>
> A drug is placed in Schedule I if (1) it "has a high potential for abuse," (2) it has "no *currently accepted medical use* in treatment in the United States," and (3) "[t]here is a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(1) (1988) (emphasis added).

Alliance for Cannabis Therapeutics, 15 F.3d at 1133.

A criterion for Schedule III, IV, and V drugs is the existence of "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(3)-(5). To assess whether there is a "currently accepted medical use," the DEA looks for five necessary elements: "(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." *See Denial*, 76 Fed. Reg. at 40,579. Unlike Schedule I drugs, federal law permits individuals to obtain Schedule II, III, IV, or V drugs for personal medical use with a valid prescription. *See* 21 U.S.C. § 829(a)-(c).

Under the CSA, "any interested party" may petition the DEA to reschedule a drug. 21 U.S.C. § 811(a). In reaching a final scheduling decision, the DEA must request from the Department of Health & Human Services ("DHHS") a "scientific and medical evaluation," as well as a recommendation for the drug's appropriate schedule. 21 U.S.C. § 811(b). These recommendations are binding on the DEA insofar as they rest on scientific and medical determinations. *Id.*

B. Procedural History

As noted above, Petitioners in this case include three advocacy organizations and several individuals. On September 1, 2011, Carl Olsen intervened on behalf of Petitioners. He asserts a religious interest in the use of marijuana.

On October 9, 2002, the Coalition to Reschedule Cannabis petitioned the DEA to reschedule marijuana as a Schedule III, IV, or V drug. *See Petition to Reschedule Cannabis (Marijuana), reprinted in* Joint Appendix ("J.A.") 46-162. Petitioners assert that marijuana's Schedule I status is inappropriate because, *inter alia*, it "has an accepted medical use in the United States." The petition to reschedule supported this assertion with citations to alleged

peer-reviewed, published studies on the potential medical applications of marijuana. *See*, *e.g.*, *id.* at 38-56, *reprinted in* J.A. 86-104. The DEA submitted Petitioner's rescheduling request to DHHS. *Denial*, 76 Fed. Reg. at 40,552.

In its scientific and medical evaluation, DHHS concluded that marijuana lacks a currently accepted medical use in the United States. In reaching this conclusion, DHHS applied the DEA's established five-prong test, which requires a known and reproducible drug chemistry, adequate safety studies, adequate and well-controlled studies demonstrating efficacy, acceptance of the drug by qualified experts, and widely available scientific evidence. *See id.* at 40,559-60. DHHS stated that there are approximately 483 known components of the cannabis plant. *Id.* at 40,554. The components include 66 compounds called cannabinoids, and marijuana is the only plant in which these compounds are known to exist. *Id.* DHHS stated, however, that marijuana's chemistry was not "known and reproducible" as there had not been "a complete scientific analysis" of its components. *Id.* at 40,552, 40,560. In addition, although there was ongoing research, there were no studies of sufficient quality to assess "the efficacy and full safety profile of marijuana for any medical condition." *Id.* at 40,560. Further, there was "a material conflict of opinion among experts" as to medical safety and efficacy, thereby precluding a finding that qualified experts accepted marijuana as a medicine. *Id.* Additionally, the raw research data typically were not available in

a format that would allow "adequate scientific scrutiny of whether the data demonstrate safety or efficacy." *Id.*

DHHS gave the DEA its evaluation and scheduling recommendation on December 6, 2006. *See id.* at 40,552-66. The DEA subsequently denied the petition to reschedule on July 8, 2011, finding that "[t]he limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA." *Id.* at 40,567.

On July 22, 2011, Petitioners filed a timely petition for review of the DEA's decision. Petitioners argue that the DEA acted arbitrarily and capriciously when it concluded that marijuana lacks a "currently accepted medical use" and has a "high potential for abuse." They ask this court to remand the case to the DEA for reconsideration of its decision. The Government contests these assertions and responds further that Petitioners, for various reasons, lack standing to challenge the DEA's determination in court.

After oral argument, "mindful of our independent obligation to be sure of our jurisdiction," we requested supplemental filings on Petitioners' standing. *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002); *see also Am. Library Ass'n v. FCC*, 401 F.3d 489, 492, 496 (D.C. Cir. 2005) (requesting supplemental filings on standing where the parties reasonably believed that the initial filings had sufficiently addressed the issue).

II. Analysis

A. Standing

"To satisfy the requirements of Article III standing in a case challenging government action, a party must allege an injury in fact that is fairly traceable to the challenged government action, and 'it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.'" *Nat'l Wrestling Coaches Ass'n v. U.S. Dep't of Educ.*, 366 F.3d 930, 937 (D.C. Cir. 2004) (quoting *Defenders of Wildlife*, 504 U.S. at 560-61). Petitioners have advanced several theories of standing in this case for each of the various parties. However, to proceed to the merits of their claims, we need only find one party with standing. *See Tozzi v. U.S. Dep't of Health and Human Servs.*, 271 F.3d 301, 310 (D.C. Cir. 2001) (declining to address standing of remaining appellants after finding one appellant with standing). Because we conclude that petitioner Michael Krawitz has individual standing, we need not address the issue for the other Petitioners.

1. *Petitioners' Burden of Production*

Before seeking review in this court, Petitioners were under no obligation to establish Article III standing. *See Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999) ("An administrative agency, which is not subject to Article III of the Constitution of the United States and related prudential limitations, may issue a declaratory order in mere anticipation of

a controversy or simply to resolve an uncertainty."). However, when a federal court of appeals reviews an agency action, Article III standing must be demonstrated "as it would be if such review were conducted in the first instance by the district court." *Sierra Club*, 292 F.3d at 899.

A "petitioner's burden of production in the court of appeals is accordingly the same as that of a plaintiff moving for summary judgment in the district court: it must support each element of its claim to standing 'by affidavit or other evidence.'" *Id.* (quoting *Defenders of Wildlife*, 504 U.S. at 561). "Its burden of proof is to show a 'substantial probability' that it has been injured, that the defendant caused its injury, and that the court could redress that injury." *Id.* (quoting *Am. Petroleum Inst. v. EPA*, 216 F.3d 50, 63 (D.C. Cir. 2000)). "In assessing [Petitioners'] standing, we must assume they will prevail on the merits of their claims." *NB ex rel. Peacock v. District of Columbia*, 682 F.3d 77, 82 (D.C. Cir. 2012).

If the parties reasonably, but mistakenly, believed that the initial filings before the court had sufficiently demonstrated standing, the court may – as it did here, *see* Order, Oct. 16, 2012 – request supplemental affidavits and briefing to determine whether the parties have met the requirements for standing. *See*, *e.g.*, *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1296-97 (D.C. Cir. 2007) (noting that it was "prudent" for the court to seek supplemental submissions where there was a question about standing); *Am. Library Ass'n*, 401 F.3d

at 492, 496. Petitioners submitted supplemental filings on October 25, 2012, offering factual information in support of Krawitz's standing. *See generally* Supp. Krawitz Aff; Pet'rs' Supp. Br. The Government was afforded an opportunity to respond to Petitioners' supplemental filing and did so on November 1, 2012.

The dissenting opinion argues that we should decline to consider Petitioners' supplemental filings because they allegedly rest on a new theory of standing and, thus, violate the commands of Circuit Rule 28(a)(7) and, relatedly, *Sierra Club* and its progeny. We disagree.

Circuit Rule 28(a)(7) states:

> In cases involving direct review in this court of administrative actions, the brief of the appellant or petitioner must set forth the basis for the claim of standing. . . . When the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of standing.

D.C. CIR. R. 28(a)(7). In this case, Petitioners obviously made a serious effort to satisfy the requirements of the rule by setting forth their evidence and arguments in support of standing in their opening brief to the court. *See* Pet'rs' Br. at 5-7. In addition, Circuit Rule 28(a)(7) does not itself impose any jurisdictional requirements. So even assuming, *arguendo*, that Petitioners failed to adhere to the briefing requirements of the rule – which has not been shown in this

case – this would not compel *sua sponte* dismissal by the court.

Because the briefing requirements of Circuit Rule 28(a)(7) are not jurisdictional, they have no relevance here unless the Government raised a viable objection pursuant to the rule. The Government raised no such objection to Petitioners' opening brief to the court. Likewise, in its response to Petitioners' supplemental filings, the Government did not contend that Petitioners had infringed Circuit Rule 28(a)(7) or *Sierra Club* and its progeny. Rather, the Government merely noted that Petitioners' supplemental filings stated, "for the first time, that [Krawitz] participates in the 'Oregon Medical Marijuana Program.'" Supp. Br. for Resp't at 1. The Government did not "protest that Krawitz raised a new standing theory," as the dissenting opinion argues. Nor did the Government claim that Petitioners' supplemental submissions on standing should not be addressed by the court because they failed to satisfy the requirements of Circuit Rule 28(a)(7) or the controlling law of the circuit. Indeed, the Government did not even suggest that it was disadvantaged in the adversarial process because of the nature of Petitioners' supplemental filings. *See Sierra Club*, 292 F.3d at 901. The Government's arguments in response to Petitioners' supplemental filings focused on its claim that Petitioners had failed to demonstrate Krawitz's Article III standing.

Although Petitioners made a reasonable effort to satisfy the command of Circuit Rule 28(a)(7) in their opening brief by advancing evidence and arguments

in support of standing, the court still had questions regarding whether the facts asserted by Petitioners were sufficient to satisfy the requirements of Article III standing. Therefore, the panel majority, adhering to well-established circuit law, requested supplemental briefing after oral arguments. Nothing in the text of the rule bars the court from requesting such filings. As Judge Kavanaugh noted in *Public Citizen, Inc. v. National Highway Traffic Safety Administration*:

> This Court "retains the discretion to seek supplemental submissions from the parties if it decides that more information is necessary to determine whether petitioners, in fact, have standing." *Am. Library Ass'n v. FCC*, 401 F.3d 489, 494 (D.C. Cir. 2005); *see*, *e.g.*, *Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 815 (D.C. Cir. 2006) ("[W]e raised the issue of standing at oral argument and requested supplemental briefing."); *Action on Smoking & Health v. Dep't of Labor*, 100 F.3d 991, 992 (D.C. Cir. 1996) (petitioner "furnished post-argument affidavits at our request"); *see also Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 469 F.3d 129, 132 (D.C. Cir. 2006) (supplemental briefing sought where agency first challenged standing after panel opinion issued).

489 F.3d at 1296.

The point here is simple: under the law of this circuit, the members of a panel retain discretion to

seek supplemental submissions on standing to fulfill the obligation of the court to determine whether the requirements of Article III have been met. Circuit Rule 28(a)(7) does not preclude this, nor does the law of the circuit. The reason is clear. Circuit Rule 28(a)(7) says only that "[w]hen the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of standing." D.C. CIR. R. 28(a)(7). This language is hardly free from ambiguity because what may be "apparent from the administrative record" to one reasonable person may seem less clear to another. And some parties may be unsure whether to explore every conceivable avenue of standing in the first instance in light of the admonition in *Sierra Club* cautioning advocates to submit only "a *concise* recitation of the basis [for standing]." 292 F.3d at 901 (emphasis added); *see also Am. Library Ass'n*, 401 F.3d at 494 (noting that a "gotcha" construction of Circuit Rule 28(a)(7) and *Sierra Club* "is inconsistent with our precedent and would have the undesirable effect of causing parties to include long jurisdictional statements in practically all opening briefs for fear that the court might find their standing less than self-evident"). So it is hardly surprising that it sometimes happens, as it did in this case, that a party advances plausible arguments and offers concrete evidence in support of standing in its opening brief, reasonably assuming that nothing more is necessary, and the members of the panel still have questions. In such circumstances, as our case law shows, the court acts with prudence in applying

Circuit Rule 28(a)(7) and in determining whether supplemental submissions are necessary. That is what was done in this case.

2. *The Elements of Standing in this Case*

Petitioners' strongest theory of standing is that Krawitz, a veteran of the United States Air Force, is harmed by the DEA's continued classification of marijuana as a Schedule I drug because it deprives him of services that he is entitled to receive free of charge from the VA. The record indicates that, as a condition of his pain management treatment, Krawitz was asked by VA officials to sign a "Contract for Controlled Substance Prescription" that would prohibit him from, *inter alia*, using medical marijuana. *See* Supp. Krawitz Aff ¶ 7; *see also* Krawitz Aff. Ex.1. Krawitz claims that, because he refused to sign this contract, he is now required to seek pain treatment outside the VA system. *See* Supp. Krawitz Aff. ¶¶ 8-10. Petitioners also contend that Krawitz suffers injury because a separate VA policy forces him to pay for a non-VA physician in Oregon to obtain the referral forms required to participate in that state's medical marijuana program. *See id.* ¶¶ 11-15. Petitioners argue that both of these injuries are caused by the DEA's continued decision to classify marijuana as a Schedule I drug and would be redressed by a favorable decision from this court. In response, the Government argues that Petitioners cannot prove redressability because their conclusion that rescheduling will result in any relief from the VA is too speculative.

The first element of the "irreducible constitutional minimum of standing" is injury in fact, meaning "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Defenders of Wildlife*, 504 U.S. at 560 (citations omitted) (internal quotation marks omitted). Petitioners clearly establish injury in fact here and Respondents do not seriously question it. As a veteran, Krawitz is entitled to free medical care from the VA system. This care normally includes the "[c]ompletion of forms . . . by healthcare professionals based on an examination or knowledge of the veteran's condition." 38 C.F.R. § 17.38(a)(1)(xv) (2012). This policy is implemented by VHA Directive 2008-071, which states that "clinicians must honor all requests by patients for completion of non-VHA medical forms." Supp. Krawitz Aff. Ex. 2. However, pursuant to VHA Directive 2011-004: "It is VHA policy to prohibit VA providers from completing forms seeking recommendations or opinions regarding a Veteran's participation in a State marijuana program." Supp. Krawitz Aff. Ex. 1. Thus, to participate in Oregon's medical marijuana program, Krawitz consults with a non-VA physician in Oregon at an annual cost of approximately $140.00. *See* Supp. Krawitz Aff. ¶ 15. In being forced to pay out-of-pocket for care that he could otherwise receive freely from the VA system, Krawitz clearly suffers an "actual" and "concrete" injury to his "legally protected interest." *Defenders of Wildlife*, 504 U.S. at 560; *cf. Peacock*, 682 F.3d at 83 (holding that "procedural violations that threaten an individual's ability to

obtain Medicaid coverage of prescription medications" constitute injury in fact).

Beyond injury in fact, we must determine whether Krawitz's injuries have been caused by the DEA's decision to continue listing marijuana as a Schedule I drug and whether there is a "substantial probability" that the relief requested would redress the injury. *See Nat'l Wrestling Coaches Ass'n*, 366 F.3d at 944. The modest complexity of these questions arises from the fact that the agency action challenged by Petitioners – *i.e.* the DEA's continued classification of marijuana as a Schedule I drug – is not the direct cause of Krawitz's injury. Rather, his injury is caused by the actions of the VA system, which has decided as a matter of policy not to assist patients in obtaining substances illegal under federal law. This court has addressed standing under analogous circumstances in at least four previous decisions. In those cases, we looked for whether "the record presented substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Id.* at 941. In two of those decisions, we found standing. In the other two, we denied standing. This case more strongly resembles the former two.

In *Block v. Meese*, 793 F.2d 1303, 1308 (D.C. Cir. 1986), the plaintiff's company owned exclusive distribution rights to a film that the Justice Department classified as "political propaganda." The plaintiff alleged injury to his economic interests because the classification deterred potential customers. *Id.* To

support this assertion, the plaintiff submitted declarations and affidavits from potential customers who were dissuaded from purchasing the film because of its status as "propaganda." *Id.* We held that there was sufficient factual evidence on the record to establish that the harm was "attributable to the classification." *Id.*

In *Tozzi v. U.S. Department of Health and Human Services*, 271 F.3d 301 (D.C. Cir. 2001), a manufacturer of PVC plastic challenged a decision by the Secretary of Health and Human Services to list dioxin, a chemical released through the incineration of PVC plastic, as a "known" carcinogen. Though this triggered no new federal regulation, the manufacturer sued on the theory that the classification had prompted state and local entities to regulate to the detriment of the manufacturer. *Id.* at 309. Looking carefully at the record, we found several reasons to conclude that the government action was "at least a substantial factor motivating the third parties' actions." *Id.* at 308. We noted that Congress intended the Secretary's determination "to serve as the federal government's authoritative statement on the current state of knowledge regarding the carcinogenicity of various chemicals." *Id.* at 309 (citing H.R. REP. NO. 95-1192, at 28 (1978) (describing the Secretary's list as a "comprehensive document" containing "all known or suspected carcinogenic agents")). We also noted that the Secretary's list of carcinogens "is widely disseminated and highly influential," and we pointed to several local government restrictions on the use of

PVC plastic that explicitly cited the Secretary's determination that dioxin is a "known" carcinogen. *Id.* We also found it significant that the term "carcinogen" is "inherently pejorative and damaging," noting that this increased the probability of an economically harmful third party response. *Id.*

In at least two other cases, we have denied standing when a non-party's conduct was the most direct cause of the alleged injury. In *National Wrestling Coaches Ass'n*, 366 F.3d at 933, "several membership organizations that represent[ed] the interests of collegiate men's wrestling coaches, athletes, and alumni" challenged the government's Title IX enforcement policy, alleging that it had caused several schools to cancel their men's wrestling programs. We denied standing, reasoning that the plaintiffs "offer[ed] nothing but speculation to substantiate their claim that a favorable decision from this court [would] redress their injuries by altering these schools' independent decisions." *Id.* at 937. And in *Renal Physicians Ass'n v. U.S. Department of Health & Human Services*, 489 F.3d 1267 (D.C. Cir. 2007), a medical association challenged a government regulation that allegedly depressed their compensation for in-house patient referrals. Once again, this court denied standing, concluding it was "speculative," not "likely," that rescinding the regulation would increase the rate of compensation. *Id.* at 1277.

Turning to the facts of this case, the causation element is satisfied because Krawitz's injury is fairly traceable to the Government's decision to continue

listing marijuana as a Schedule I drug. As with the statute in *Tozzi*, Congress made clear when it passed the CSA that the agency's scheduling decisions should serve as the federal government's "authoritative statement" on the legitimacy of particular narcotics and dangerous drugs. 271 F.3d at 309. The House Report for the CSA explains that Congress had already enacted "more than 50 pieces of legislation" relating to the regulation of dangerous drugs. H.R. REP. NO. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571. Congress intended the CSA and its scheduling program to "collect[ ] and conform [ ] these diverse laws in one piece of legislation." *Id.* Furthermore, the Government's classification of marijuana under Schedule I is "inherently pejorative." *Tozzi*, 271 F.3d at 309. Under the terms of the Act, a Schedule I drug "has a high potential for abuse," "has no currently accepted medical use," and has "a lack of accepted safety for use." 21 U.S.C. § 812(b)(1). When the DEA classified marijuana as a Schedule I drug, pursuant to its delegated authority under the CSA, it announced an authoritative value judgment that surely was meant to affect the policies of third-party federal agencies.

Unsurprisingly, the VA has heeded the DEA's judgment regarding marijuana, thus making the question of causation relatively easy in this case. The record before the court clearly shows that the VA's refusal to complete Krawitz's medical marijuana forms is traceable to the DEA's continued decision to classify marijuana as Schedule I. VHA Directive

2011-004, which prohibits VA providers from completing state medical marijuana forms, cites three times to marijuana's Schedule I status. *See* Supp. Krawitz Aff. Ex. 1. Indeed, compliance with the CSA is the only justification the Directive cites for this policy. *See id.* ("[VA] providers must comply with all Federal laws, including the Controlled Substances Act. Marijuana is classified as a Schedule I drug under the Controlled Substances Act."). In light of this evidence, the Government, in its brief to the court, offers nothing more than a perfunctory challenge to causation. This case is nothing like the situations in *National Wrestling* and *Renal Physicians*, where the records contained only weak evidence of causal links between the claimants' injuries and the contested actions of third-party defendants.

The Government focuses most on redressability in contesting Krawitz's standing in this case. The Government argues that rescheduling marijuana would not "generate a significant increase in the likelihood" that the VA would authorize its physicians to recommend marijuana in Oregon. *See Town of Barnstable v. FAA*, 659 F.3d 28, 32 (D.C. Cir. 2011). In support of this argument, the Government suggests that, based on the current scientific evidence, there would be no approval by the Food & Drug Administration of medical marijuana, and, absent such approval, VA physicians would be unlikely to recommend a substance that could not be prescribed or readily subjected to supervised use.

The Government's argument against redressability fails. The issue is not whether VA physicians would recommend marijuana usage to patients. The issue is only whether rescheduling marijuana would "generate a significant increase in the likelihood" that Krawitz could obtain completed state medical marijuana forms from the VA. *See id.* Under existing regulations and VHA Directive 2008-071, VA clinicians are subject to a non-discretionary duty to "honor all requests by patients for completion of non-VHA medical forms." *See* 38 C.F.R. § 17.38(a)(1)(xv) (2012); Supp. Krawitz Aff. Ex. 2. The only thing stopping VA clinicians from performing this duty with respect to Krawitz's request is VHA Directive 2011-004. *See* Supp. Krawitz Aff. Ex. 1. The only reason the VA cites for implementing VHA Directive 2011-004 is the classification of marijuana as a Schedule I drug. *Id.* Therefore, were marijuana rescheduled to reflect its potential for medical use, the VA would have no expressed reason to retain VHA Directive 2011-004 and VA clinicians would likely be subject to a non-discretionary duty to complete Krawitz's state medical marijuana forms.

This case is fully distinguishable from *National Wrestling* and *Renal Physicians*, where we found redressability lacking. In both those cases, in addition to a tenuous showing of causation, there were reasons beyond the challenged government action for the third parties to continue the conduct that caused injury to the plaintiffs. In *National Wrestling* there were many factors that led each school to cancel its

men's wrestling program, such as "the absence of league sponsorship for wrestling, budgetary concerns, and the need to balance the athletic program with other University priorities." 366 F.3d at 942. Furthermore, Title IX and its accompanying regulations would have remained in force regardless of the case's outcome. *See id.* at 943. Indeed the plaintiffs in *National Wrestling* did not even contest the legality of the Title IX regulations. *Id.* In *Renal Physicians* the court found that the plaintiffs had failed to demonstrate redressability in part because, even if the challenged regulation were struck down, market forces might drive the injurious conduct to continue. *See* 489 F.3d at 1277.

In contrast, this case is more like *Tozzi.* There we found it significant for redressability that the Secretary's listing of dioxin as a "known" carcinogen was the only such pronouncement by the federal government. *See* 271 F.3d at 309-10. Therefore, if we had set aside that listing, "dioxin activists could no longer point to an authoritative determination by the United States government that dioxin is 'known' to cause cancer in humans. . . . State and local governments would be less likely to regulate dioxin, and healthcare companies would in turn be less likely to stop using PVC plastic." *Id.* at 310. Here, the Schedule I listing is the authoritative federal declaration of marijuana's illegality and unfitness for medical use. The VA is a federal agency and thus surely inclined to subscribe to such a federal declaration. Were the substance rescheduled, the VA would lose the only express

justification for its policy against completing state medical marijuana forms. Therefore, it is "likely" instead of merely "speculative" that Krawitz's injury would be redressed.

Because Krawitz has Article III standing due to his inability to have the VA system complete his state medical marijuana forms, we need not consider whether his alleged inability to obtain pain management services from the VA in Virginia warrants standing. We also need not consider whether the other Petitioners have standing as well. *See Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 160 (1981) ("Because we find [one plaintiff] has standing, we do not consider the standing of the other plaintiffs."); *see also Tozzi*, 271 F.3d at 310 (same).

B. The DEA's Denial of the Petition to Initiate Proceedings to Reschedule Marijuana

On the merits, Petitioners claim that the DEA's final order denying their request to initiate proceedings to reschedule marijuana was arbitrary and capricious. Under the terms of the CSA, marijuana cannot be rescheduled to Schedules III, IV, or V without a "currently accepted medical use." 21 U.S.C. § 812(b)(3)-(5). To assess whether marijuana has such a medical use, the agency applies a five-part test: "(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." *See Denial*, 76 Fed. Reg. 40,552, 40,579. The DEA's five-part test was expressly approved by this court in *Alliance for Cannabis Therapeutics*, 15 F.3d at 1135. Because the agency's factual findings in this case are supported by substantial evidence and because those factual findings reasonably support the agency's final decision not to reschedule marijuana, we must uphold the agency action.

Under the Administrative Procedure Act, a court may set aside an agency's final decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "We will not disturb the decision of an agency that has 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *MD Pharm. Inc. v. DEA*, 133 F.3d 8, 16 (D.C. Cir. 1998) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Furthermore, the agency's interpretation of its own regulations "must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). The CSA also directs this court to review the agency's findings of fact for substantial evidence. *See* 21 U.S.C. § 877. Under this standard, we must "ask whether a reasonable mind might accept a particular evidentiary

record as adequate to support a conclusion." *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999).

Petitioners do not seriously dispute the propriety of the five-part test approved in *Alliance for Cannabis Therapeutics*. Thus, they are left with the difficult task of showing that the DEA has misapplied its own regulations. Petitioners challenge the agency's reasoning on each of the five factors. However, "[a] drug will be deemed to have a currently accepted medical use for CSA purposes only if all five of the foregoing elements are demonstrated." *Denial*, 76 Fed. Reg. at 40,579. In this case, we need only look at one factor, the existence of "adequate and well-controlled studies proving efficacy," to resolve Petitioners' claim.

In its scientific and medical evaluation, DHHS concluded that "research on the medical use of marijuana ha[d] not progressed to the point that marijuana [could] be considered to have a 'currently accepted medical use' or a 'currently accepted medical use with severe restrictions.'" *Id.* at 40,560. As noted above, DHHS' recommendations are binding on the DEA insofar as they rest on scientific and medical determinations. 21 U.S.C. § 811(b). After an exhaustive examination of the issue, the DEA, adhering to DHHS' recommendation, reached the following conclusion:

> To establish accepted medical use, the effectiveness of a drug must be established in well-controlled, well-designed, well-conducted, and well-documented scientific studies, including studies performed in a large number

> of patients (57 FR 10499, 1992). To date, such studies have not been performed. The small clinical trial studies with limited patients and short duration are not sufficient to establish medical utility. Studies of longer duration are needed to fully characterize the drug's efficacy and safety profile. Scientific reliability must be established in multiple clinical studies. Furthermore, anecdotal reports and isolated case reports are not adequate evidence to support an accepted medical use of marijuana (57 FR 10499, 1992). The evidence from clinical research and reviews of earlier clinical research does not meet this standard.

Denial, 76 Fed. Reg. at 40,579.

Petitioners contest these findings, arguing that their petition to reschedule marijuana cites more than two hundred peer-reviewed published studies demonstrating marijuana's efficacy for various medical uses, and that those studies were largely ignored by the agency. As we explain below, Petitioners' singular reliance on "peer-reviewed" studies misses the mark. It is also noteworthy that Petitioners' brief to this court fails to convincingly highlight any significant studies allegedly ignored by DHHS or the DEA.

Petitioners' argument focuses at length on one study – the March 1999 report from the Institute of Medicine ("IOM") – that was clearly addressed by the DEA. The IOM report does indeed suggest that marijuana might have medical benefits. *See*, *e.g.*, INST. OF MEDICINE, MARIJUANA AND MEDICINE: ASSESSING THE

SCIENCE BASE 177 (Janet E. Joy et al. eds., 1999), *reprinted in* J.A. 208 ("For patients such as those with AIDS or who are undergoing chemotherapy, and who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication."). However, the DEA fairly construed this report as calling for "more and better studies to determine potential medical applications of marijuana" and not as sufficient proof of medical efficacy itself. *Denial*, 76 Fed. Reg. at 40,580. In other words, "while the IOM report did support further research into therapeutic uses of cannabinoids, the IOM report did not '*recognize marijuana's accepted medical use*' but rather the potential therapeutic utility of cannabinoids." *Id.*

At bottom, the parties' dispute in this case turns on the agency's interpretation of its own regulations. Petitioners construe "adequate and well-controlled studies" to mean peer-reviewed, published studies suggesting marijuana's medical efficacy. The DEA, in contrast, interprets that factor to require something more scientifically rigorous. In explaining its conclusion that there is a lack of clinical evidence establishing marijuana's "currently accepted medical use," the agency said the following:

> [A] limited number of Phase I investigations have been conducted as approved by the FDA. Clinical trials, however, generally proceed in three phases. See 21 C.F.R. 312.21 (2010). Phase I trials encompass initial

> testing in human subjects, generally involving 20 to 80 patients. *Id.* They are designed primarily to assess initial safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary studies of potential therapeutic benefit. (62 FR 66113, 1997). Phase II and Phase III studies involve successively larger groups of patients: usually no more than several hundred subjects in Phase II and usually from several hundred to several thousand in Phase III. 21 C.F.R. 312.21. These studies are designed primarily to explore (Phase II) and to demonstrate or confirm (Phase III) therapeutic efficacy and benefit in patients. (62 FR 66113, 1997). No Phase II or Phase III studies of marijuana have been conducted. Even in 2001, DHHS acknowledged that there is "suggestive evidence that marijuana may have beneficial therapeutic effects in relieving spasticity associated with multiple sclerosis, as an analgesic, as an antiemetic, as an appetite stimulant and as a bronchodilator." (66 FR 20038, 2001). But there is still no data from adequate and well-controlled clinical trials that meets the requisite standard to warrant rescheduling.

Id. at 40,579-80.

The DEA interprets "adequate and well-controlled studies" to mean studies similar to what the Food and Drug Administration ("FDA") requires for a New Drug Application ("NDA"). *See id.* at 40,562. DHHS found that "there have been no NDA-quality studies

that have scientifically assessed the efficacy of marijuana for any medical condition." *Id.* It is well understood that, under FDA protocols, "adequate and well-controlled investigations" require "clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. § 355(d). This is a rigorous standard. *See*, *e.g.*, *Edison Pharm. Co. v. FDA*, 600 F.2d 831, 843 (D.C. Cir. 1979) (holding that substantial evidence supported the FDA's conclusion that double-blind testing of a new drug was necessary before the drug could be administered to cardiac patients); *Holland-Rantos Co. v. U.S. Dep't of Health, Educ. and Welfare*, 587 F.2d 1173, 1174 (D.C. Cir. 1978) (refusing to construe the requirement of a "well-controlled investigation" in a "self-defeating fashion").

Contrary to what Petitioners suggest, something more than "peer-reviewed" studies is required to satisfy DEA's standard, and for good reason. "[S]cientists understand that peer review per se provides only a minimal assurance of quality, and that the public conception of peer review as a stamp of authentication is far from the truth." Charles Jennings, *Quality and Value: The True Purpose of Peer Review*, NATURE.COM (2006), http://www.nature.com/

nature/peerreview/debate/nature05032.html; *see also* Lynn S. McCarty et al., *Information Quality in Regulatory Decision Making: Peer Review versus Good Laboratory Practice*, 120 ENVTL. HEALTH PERSP. 927, 930 (2012) ("It is difficult to extract from the extensive body of work and commentary published over the last 25-30 years that scientific journal peer review is a coherent, consistent, reliable, evaluative procedure. . . . [T]he opposite conclusion may be more accurate."). Petitioners may have cited some peer-reviewed articles in support of their position, but they have not pointed to "adequate and well-controlled studies" confirming the efficacy of marijuana for medicinal uses. If, as is the case here, "there is substantial evidence to support the [agency's] finding that the[ ] studies [offered by petitioner] are not helpful, then petitioner must fail." *Unimed, Inc. v. Richardson*, 458 F.2d 787, 789 (D.C. Cir. 1972). In making this assessment, we must "remind ourselves that our role in the Congressional scheme is not to give an independent judgment of our own, but rather to determine whether the expert agency entrusted with regulatory responsibility has taken an irrational or arbitrary view of the evidence assembled before it." *Id.*

The DEA's construction of its regulation is eminently reasonable. Therefore, we are obliged to defer to the agency's interpretation of "adequate and well-controlled studies." *See Thomas Jefferson Univ.*, 512 U.S. at 512 (deferring to "an agency's interpretation of its own regulations"). Judged against the DEA's

standard, we find nothing in the record that could move us to conclude that the agency failed to prove by substantial evidence that such studies confirming marijuana's medical efficacy do not exist.

Finally, Petitioners suggested during oral argument that the Government had foreclosed the research that would be necessary to create sufficiently reliable clinical studies of marijuana's medical efficacy. Because Petitioners did not properly raise this issue with the DEA and there is nothing in the record to support it, we do not consider it here. We note, however, that DHHS' recommendation explained that "[t]he opportunity for scientists to conduct clinical research with marijuana exists under the [D]HHS policy supporting clinical research with botanical marijuana." *Denial*, 76 Fed. Reg. at 40,562. Thus, it appears that adequate and well-controlled studies are wanting not because they have been foreclosed but because they have not been completed.

III. Conclusion

For the reasons discussed above, we hereby deny the petition for review.

KAREN LECRAFT HENDERSON, *Circuit Judge*, dissenting:

Over a decade ago, our court was compelled to remind all petitioners of first principles, namely, they

must assure us that they meet Article III's case or controversy requirement if their standing is not "self-evident" from the record. *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002). We subsequently transformed the holding into D.C. Circuit Rule 28(a)(7) to tell the litigating world we really meant what we said in *Sierra Club*. Since then, our precedent and our Rule seem to have been honored more in the breach than in compliance. We have issued pre-argument orders alerting the parties to be prepared to address standing at oral argument because of our uncertainty regarding standing based on the briefing. *See*, *e.g.*, Order, *Cherry v. FCC*, No. 10-1151 (Feb. 23, 2012). We have allowed a second – late – opportunity to establish standing at the reply brief stage. *See Exxon Mobil Corp. v. FERC*, 571 F.3d 1208, 1219 (D.C. Cir. 2008). We have even asked for post-argument briefs based on the petitioner's failure theretofore to establish standing. *See Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1297 (D.C. Cir. 2007); *see also id.* at 462-63 (Sentelle, J., dissenting). Some of us have been more forgiving than others. *See*, *e.g.*, *Am. Library Ass'n v. FCC*, 401 F.3d 489, 492 (D.C. Cir. 2005) (Edwards, J.) (articulating *Sierra Club* exception if petitioners "reasonably [but mistakenly] believed their standing [was] self-evident"); *Communities Against Runway Expansion, Inc. v. FAA*, 355 F.3d 678, 685 (D.C. Cir. 2004) (Edwards, J.) (excusing belated submissions attached to reply brief because they made standing "patently obvious"); *KERM, Inc. v. FCC*, 353 F.3d 57, 60-61 (D.C. Cir. 2004) (noting petitioner's belated assertion

of standing but nonetheless analyzing standing arguments) (Edwards, J.). Perhaps it is too late to blow the whistle but I do not share the solicitude my colleagues show the petitioners – no novices on their merits claim[1] – here, especially in view of the fact that their standing theory for the lone petitioner *with standing* is, post-argument, brand new.

Petitioners Americans for Safe Access (ASA), Coalition for Rescheduling Cannabis (CRC), Patients Out of Time (POT), Kathy Jordan, Michael Krawitz, Richard Steeb and William Britt (petitioners) petition for review of the decision of the Drug Enforcement Administration (DEA or Agency), *Denial of Petition To Initiate Proceedings To Reschedule Marijuana*, 76 Fed. Reg. 40,552 (Jul. 8, 2011), denying their petition to initiate rulemaking proceedings to reschedule marijuana as a Schedule I substance under the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq*. The majority determines – based on his post-argument submission – that Krawitz has standing and thus proceeds to the merits. I believe the post-argument submission should not have been allowed. Once allowed, it should not have been considered because it asserts a new theory of standing. The

[1] Two individuals who joined the petitioners' quest to reschedule marijuana at the administrative stage – Jon Gettman and High Times – had petitioned for review of DEA's earlier failure to reschedule marijuana. We dismissed their petition for lack of standing. *Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002).

remaining petitioners also lack standing and therefore the petition for review should have been dismissed.

I.

To press their claim, the petitioners must establish that at least one of them has standing. *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006). Article III standing has three elements: "(1) injury-in-fact, (2) causation, and (3) redressability." *Sierra Club*, 292 F.3d at 898. Reviewing administrative action, we require that the petitioner "either identify in that record evidence sufficient to support its standing to seek review or, if there is none because standing was not an issue before the agency, submit additional evidence to the court of appeals." *Id.* at 899. Three of the seven petitioners – ASA, CRC and POT – are organizations. The remaining petitioners – Jordan, Krawitz, Steeb and Britt – are members of ASA (ASA Members). Neither CRC nor POT has attempted to establish its standing. The remaining petitioners assert three theories of standing: ASA's standing as an association, the individual standing of the four ASA Members and ASA's standing representing its members. I begin with Krawitz's standing as he is the one whose standing the majority affirms.

II.

A. Krawitz's Standing

In their opening brief, the petitioners did not distinguish Krawitz from the other ASA Members. With that brief, the petitioners submitted an affidavit executed by Krawitz. Krawitz declared therein that he was a disabled veteran and that he used marijuana to alleviate his pain. Krawitz explained that he received medical benefits from the United States Department of Veterans Affairs (VA) but that

> [b]ecause of my medical cannabis use, *I am currently being denied my prescription pain treatment by the VA* based upon their illegal drug policy that routinely, administratively, denies pain treatment as punishment for using cannabis by veterans that do not live in a state with legal medical cannabis, based on VA's policy regarding medical cannabis, which, among other things, prohibits VA physicians from discussing therapeutic uses of cannabis with me. A true and correct copy of that policy is attached hereto as Exhibit 1. Although the bulk of my medical care still occurs at VA hospital I am now seeing an outside M.D. for my pain treatment under the VA's fee basis program.

Krawitz Aff. ¶ 4 (bracketed text omitted) (emphasis added). To his affidavit, Krawitz attached a document entitled "CONTRACT FOR CONTROLLED SUBSTANCE PRESCRIPTION." Krawitz Aff. Ex. 1 at 1. The document is confusing at best, and, at worst, makes it appear as if the VA itself could be providing

Krawitz with marijuana. *See*, *e.g.*, Krawitz Aff. Ex. 1 at 1 ("I will not request or accept controlled substance medication from any other physician or individual while I am receiving such medication from my physician at the Salem VAMC Clinic"). The petitioners, unhelpfully, provided no explanation of the contract in either their opening or their reply briefs.

Krawitz's affidavit and exhibit failed to establish standing. His affidavit boiled down to the averment that he was injured because the VA had a drug policy that "denies pain treatment as punishment for using cannabis by veterans that do not live *in a state with legal medical cannabis,*" Krawitz Aff. ¶ 4 (emphasis added). But Krawitz challenges federal, not state law, and he has provided no evidence or argument that rescheduling marijuana under the CSA will change the way any state regulates marijuana. Indeed, state marijuana legislation in recent years has distinctly diverged from federal law. *See*, *e.g.*, *Gettman v. DEA*, 290 F.3d 430, 435 (D.C. Cir. 2002) ("[S]peculative claims dependent upon the actions of third parties do not create standing.").

Notwithstanding the failure of the petitioners' showing regarding standing – specifically, Krawitz's affidavit with attachment – we issued a post-argument order, giving them yet another opportunity[2]

[2] The petitioners' reply brief, while providing a more detailed standing argument and including (improperly) a supplemental affidavit, was nonetheless deficient. With their post-argument opportunity to supplement, the petitioners have now been allowed three chances to establish standing.

to "clarify and amplify the assertions made in paragraph 4 of the Affidavit of Michael Krawitz regarding his individual standing." I dissented from the order because our precedent unequivocally directs the method by which a petitioner must establish standing, a method the petitioners ignored. In 2002, we explained:

> Henceforth, therefore, a petitioner whose standing is not self-evident should establish its standing by the submission of its arguments and any affidavits or other evidence appurtenant thereto *at the first appropriate point in the review proceeding.* In some cases that will be in response to a motion to dismiss for want of standing; in cases in which no such motion has been made, it will be with the petitioner's opening brief – and not, as in this case, in reply to the brief of the respondent agency. In either procedural context the petitioner may carry its burden of production by citing any record evidence relevant to its claim of standing and, if necessary, appending to its filing additional affidavits or other evidence sufficient to support its claim. In its opening brief, the petitioner should also include in the "Jurisdictional Statement" a concise recitation of the basis upon which it claims standing.
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> . . . . [A]ll too often the petitioner does not submit evidence of those facts with its opening brief and the respondent is therefore left to flail at the unknown in an attempt to prove the negative, or the court raises its own question about the petitioner's standing and ends up having to direct the parties to

> file supplemental briefs in order to ensure that the issue is joined in a fair and thorough adversarial process.

Sierra Club, 292 F.3d at 900-01 (emphasis added). We cautioned that "[a]bsent good cause shown . . . a litigant should not expect the court" to depart from the above procedure. *Id.* at 900. *Sierra Club* does not make the petitioner's showing optional – it instead constitutes binding Circuit law. As noted earlier, we codified *Sierra Club* in our Circuit Rules as follows:

> In cases involving direct review in this court of administrative actions, the brief of the appellant or petitioner must set forth the basis for the claim of standing. This section, entitled "Standing," must follow the summary of argument and immediately precede the argument. When the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of standing. *See Sierra Club v. EPA*, 292 F.3d 895, 900-01 (D.C. Cir. 2002). If the evidence is lengthy, and not contained in the administrative record, it may be presented in a separate addendum to the brief.

D.C. Cir. R. 28(a)(7); *see also Int'l Bhd. of Teamsters v. Transp. Sec. Admin.*, 429 F.3d 1130, 1134-35 & n.2 (D.C. Cir. 2005) (dismissing petition for review because petitioner "first addressed its standing at oral argument, in response to questioning by the court"); *Exxon Mobil*, 571 F.3d at 1220 (declining to consider standing theory first articulated at oral argument).

The petitioners had made no effort to show "good cause"[3] for their initial failure to establish standing. And, this being so, I opposed giving them yet another opportunity to establish standing.

In response to the order, the petitioners filed a supplemental brief with a new Krawitz affidavit, featuring a new theory of standing. He avers, *for the first time*, that he spends one or two months per year in Oregon, where he obtains marijuana for medical use. To obtain medicinal marijuana in Oregon, a person must apply for a registration card, which requires him to submit annually "[v]alid, written documentation from the person's attending physician stating that the person has been diagnosed with a debilitating medical condition and that the medical use of marijuana may mitigate the symptoms or effects of the person's debilitating medical condition." *See* Or. Rev. Stat § 475.309(2), (7)(C)(i). Krawitz complains that the VA has a policy – VHA Directive 2011-004 – prohibiting its physicians from providing such documentation, thus forcing him to pay $140.00 per year to consult an Oregon physician who can so provide.

Unlike his original affidavit – in which Krawitz declared that the VA denied him pain treatment – Krawitz's new affidavit states that the VA is *not*

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[3] We have found "good cause" if, for example, a petitioner had a reasonable belief its standing was self-evident, *see Am. Library Ass'n*, 401 F.3d at 492 or if supplemental declarations submitted with a reply brief made standing "patently obvious," *see Communities Against Runway Expansion*, 355 F.3d at 685.

denying him treatment for pain based on his marijuana use. Moreover, VHA Directive 2011-004 makes plain that the VA does *not* have a policy of denying pain treatment to veterans who are using marijuana, instead declaring: "VHA policy does not administratively prohibit Veterans who participate in State marijuana programs from also participating in VHA . . . pain control programs . . . [D]ecisions to modify treatment plans in those situations need to be made by individual providers in partnership with their patients." VHA Directive 2011-004 (Jan. 31, 2011), *available at* http://www.va.gov/VHAPUBLICATIONS/View Publication.asp?pub – ID=2362.

In other words, Krawitz asserts a new injury-in-fact – a $140.00 per year pocketbook injury – that is nowhere to be found in even the most generous reading of his original affidavit. As we have earlier held, however, "we are aware of no authority which permits a party to assert an entirely new injury (and thus, an entirely new theory of standing) in its *reply* brief." *Coal. for Responsible Regulation, Inc. v. EPA*, 684 F.3d 102, 147 (D.C. Cir. 2012) (per curiam) (emphasis added). And plainly – until today – we have *never* permitted a petitioner to assert an entirely new injury and theory of standing in a post-argument submission.[4]

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[4] Oregon's policy – not that of the VA or of DEA – is the direct cause of Krawitz's annual $140.00 injury because, if Oregon eliminated the physician documentation requirement, Krawitz's injury would be immediately redressed. By contrast, if

(Continued on following page)

Because my colleagues found that Krawitz has standing, they proceeded directly to the merits. *Rumsfeld*, 547 U.S. at 52 n.2 ("[T]he presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement."). Because I believe Krawitz lacks standing, I must consider the other petitioners' standing.

B. Other Petitioners' Standing

ASA's Organizational Standing

In their opening brief, the petitioners asserted that ASA has standing as an organization because it must expend "significant resources combatting the DEA's positions respecting marijuana's medical use and abuse potential, which would be redressed by a favorable decision." Pet'rs' Opening Br. 6. In their reply brief, they argue "ASA has been unable to employ a full-time California Director to interface with government agencies in California and those of

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we ordered DEA to reschedule marijuana, the VA *might* rescind VHA Directive 2011-004 and Krawitz's VA physician *might* complete the Oregon documentation for Krawitz. *See Memorandum Regarding State Medical Marijuana Registration Forms* from Department of Veterans Affairs General Counsel to Under Secretary of Health at 5 (May 21, 2008) (cited by VHA Directive 2011-004) (stating, prior to promulgation of VHA Directive 2011-004, "[a]t present, the language of 38 C.F.R. § 17.38(c)(3) does not require the completion of [medical marijuana] forms by VHA physicians [because t]his regulatory provision eliminates non-FDA approved drugs from the basic care provided to veterans"); *see also* VHA Directive 2011-004, *supra*.

other medical marijuana states to implement state law, in particular, the regulation of medical marijuana dispensaries." Pet'rs' Reply Br. 3 (citing Sherer Supp. Aff. ¶ 2).

An organization does not have standing based on a mere "'setback to [its] abstract social interests.'" *Nat'l Ass'n of Home Builders v. EPA*, 667 F.3d 6, 11 (D.C. Cir. 2011) (quoting *Nat'l Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1433 (D.C. Cir. 1995)). An association's "self-serving observation that it has expended resources to educate its members and others regarding [a challenged statutory provision] does not present an injury in fact," particularly if "[t]here is no evidence that [the challenged provision] has subjected [the association] to operational costs beyond those normally expended to review, challenge, and educate the public." *Nat'l Taxpayers Union*, 68 F.3d at 1434. Nor is standing found "when the only 'injury' arises from the effect of the regulations on the organizations' lobbying activities." *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1161 (D.C. Cir. 2005).

The petitioners support ASA's organizational standing by relying on *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982). In *Havens*, a nonprofit corporation sued the owner of an apartment complex for damages under the Fair Housing Act because "the [discriminatory] practices of [the apartment complex] had frustrated the organization's counseling and referral services, with a consequent drain on resources." *Id.* at 369. The Supreme Court upheld the nonprofit's standing because the "practices have

perceptibly impaired [its] ability to provide counseling and referral services for low-and moderate-income homeseekers. . . . Such concrete and demonstrable injury to the organization's activities – with the consequent drain on the organization's resources – constitutes far more than simply a setback to the organization's abstract social interests." *Id.* at 379.

We considered a similar standing issue in *Spann v. Colonial Vill., Inc.*, 899 F.2d 24 (D.C. Cir. 1990), where we found two organizations had standing to assert a claim for injunctive relief and damages under the Fair Housing Act because the discriminatory conduct "required [plaintiffs] to devote more time, effort, and money to endeavors designed to educate not only black home buyers and renters, but the D.C. area real estate industry and the public that racial preference in housing is indeed illegal." *Id.* at 27; *see also id.* at 28-29 ("increased education and counseling could plausibly required"). We emphasized "the difference between this suit and one presenting only abstract concerns or complaints about government policy;" specifically, the plaintiffs "do not seek to compel government action, [or] to involve the courts in a matter that could be resolved in the political branches" but rather "are private actors suing other private actors, traditional grist for the judicial mill." *Id.* at 30.

Unlike *Havens* and *Spann*, this case does not involve "private actors suing other private actors, traditional grist for the judicial mill." *Id.* Nor does it involve a suit for damages under a federal statute

(like the Fair Housing Act) that creates a cause of action. Instead, it serves "to compel government action, [and] to involve the courts in a matter that could be resolved in the political branches."[5] *Id.* Moreover, ASA's asserted injury – that it must spend money to "educate the public about the true benefits of marijuana" and to "lobby[ ] local, state and federal governments," Sherer Aff. ¶¶ 8, 12 – is essentially an argument that ASA cannot allocate issue advocacy expenses in the way it would prefer, which is insufficient to establish standing. *See Ctr. for Law & Educ.*, 396 F.3d at 1162 ("The only 'service' impaired is pure issue-advocacy – the very type of activity distinguished by *Havens*."). Nor have the petitioners explained how ASA would be able to avoid these expenditures if marijuana were rescheduled. For example, ASA would still need to meet the substantial scientific evidence – identified by DEA – that rejects its position regarding marijuana's medical efficacy. Similarly, ASA would need to counter statements made by entities other than DEA (including the very state and local governments they are lobbying) that oppose legalization of marijuana for medical use. *See Nat'l Taxpayers Union*, 68 F.3d at 1434 ("There is no evidence that [the challenged statutory provision] has

[5] ASA and similar organizations have had great *political* success in recent years. *See*, *e.g.*, Louise Radnofsky, *Voters Weigh Social Issues*, Wall St. J., Nov. 7, 2012 (seventeen states and District of Columbia have legalized the medicinal use of marijuana; Washington and Colorado have legalized marijuana for recreational use).

subjected [the association] to operational costs beyond those normally expended to review, challenge, and educate the public").

The closest the petitioners come to establishing an injury to ASA as an organization is their statement that "[s]ince 2006, due to expenditures made by ASA to offset the false statements made by the [DEA and HHS] that marijuana has no medical use and is extremely dangerous, ASA has been unable to hire a full-time California Director." Sherer Supp. Aff ¶ 2. But whatever happened in 2006 that prevented ASA from hiring a full-time California Director, it could not have been marijuana's Schedule I listing because marijuana has been so listed *since 1970*. *See* 21 U.S.C. § 812(c) (establishing initial schedules of controlled substances).

ASA Members' Individual Standing

The petitioners also assert that the three ASA Members other than Krawitz have their own individual standing. In their opening brief, they assert that if marijuana were removed from Schedule I, the three would no longer be "deterred from cultivating their own medicine . . . since they would likely be afforded a medical necessity defense in federal court." Pet'rs' Opening Br. 7. Nevertheless, "speculative claims dependent upon the actions of third parties do not create standing." *Gettman*, 290 F.3d at 434-35 (dismissing petition – for lack of standing – of marijuana researcher who argued DEA decision not to reschedule

marijuana decreased his potential customers and diminished his ability to conduct research). Here, the causal chain is even more speculative. ASA's Members allege that their injury could be redressed by a favorable ruling because (1) if marijuana were rescheduled; *and* (2) if they chose to cultivate marijuana; *and* (3) if the federal government detected the cultivation; *and* (4) if the federal government prosecuted the cultivators; *and* (5) if the cultivators asserted a medical necessity defense; *and* (6) if the court accepted the medical necessity defense; *then* (7) they would avoid criminal liability for cultivation.[6]

Moreover, the existence of a medical necessity defense for marijuana cultivation is tenuous at best. The petitioners assert that marijuana's Schedule I status is the only thing preventing courts from

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[6] The ASA Members' standing argument is reminiscent of the nursery rhyme "For Want of a Nail:"

> For want of a nail, the shoe was lost,
> For want of the shoe, the horse was lost,
> For want of the horse, the rider was lost,
> For want of the rider, the battle was lost,
> For want of the battle, the kingdom was lost,
> And all for the want of a horse-shoe nail!

Stuart Minor Benjamin, *Proactive Legislation and the First Amendment*, 99 MICH. L. REV. 281, 329 n.168 (2000) (quoting Mother Goose's Nursery Rhymes 191 (Walter Jerrold ed., Alfred A. Knopf Inc. 1993) (1903)). While a lost nail may lead to a lost kingdom, establishing Article III standing requires more than a good imagination.

recognizing the defense, citing *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001), which held that no medical necessity defense exists for the illegal distribution of various controlled substances, including marijuana, because the CSA "reflects a determination that marijuana has no medical benefits worthy of an exception." *Id.* at 491. The Court's reasoning made clear, however, that rescheduling marijuana would not necessarily produce a medical necessity defense because "it is an open question whether federal courts ever have authority to recognize a necessity defense not provided by statute." *Id.* at 490 ("Even at common law, the defense of necessity was somewhat controversial.").

Assuming *arguendo* the three ASA Members decide to cultivate marijuana, it is far from likely that a federal prosecutor would exercise his discretion to prosecute. In fact, the Department of Justice recently suggested that it did not consider it an efficient use of resources to prosecute "individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable law, or those caregivers in clear and unambiguous compliance with existing state law who provide such individuals with marijuana." David W. Ogden, Deputy Attorney General, U.S. Dep't of Justice, *Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana* (Oct 19, 2009),

available at http://www.justice.gov/opa/documents/medical-marijuana.pdf.[7]

ASA's Representational Standing

Finally, I believe that ASA lacks standing to bring this action on behalf of its members because ASA has failed to establish that one of its members has standing to sue in his own right. *Fund Democracy, LLC v. SEC*, 278 F.3d 21, 25 (D.C. Cir. 2002) ("An association only has standing to bring suit on behalf of its members when[, *inter alia,*] its members would otherwise have standing to sue in their own right. . . .")[8]

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[7] *But see* James M. Cole, Deputy Attorney General, U.S. Dep't of Justice, *Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use* (June 29, 2011), *available at* http://www.azdhs.gov/medicalmarijuana/documents/resources/guidance_regarding_medical_marijuana.pdf (Ogden Memorandum was not intended to shield from prosecution "planned facilities" with "revenue projections of millions of dollars" and that "[p]ersons who are in the business of cultivating, selling or distributing marijuana . . . are in violation of the Controlled Substances Act, regardless of state law").

[8] In addition, intervenor Carl Olsen lacks standing. He concedes that his injury can be redressed only if marijuana is removed from all CSA schedules, a remedy the petitioners do not seek. Furthermore, Olsen makes distinct arguments from those of the petitioners – for example, he invokes "federalism" – and thus he cannot supply the requisite standing. *See Ill. Bell Tel. Co. v. FCC*, 911 F.2d 776, 786 (D.C. Cir. 1990).

Because I believe that no petitioner possesses Article III standing, I respectfully dissent.[9]

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[9] While my dissent begins with the observation that some of my colleagues are more forgiving than others in allowing exceptions to the *Sierra Club* rule, codified in Rule 28(a)(7), it is now apparent the majority would have the exceptions swallow the Rule. Ignoring our longstanding precedent that arguments may not be made for the first time in a reply brief, *see*, *e.g.*, *Porter v. Shah*, 606 F.3d 809, 814 n.3 (D.C. Cir. 2010), during oral argument, *see*, *e.g.*, *United States v. Southerland*, 486 F.3d 1355, 1360 (D.C. Cir. 2007), or during rebuttal oral argument, *see*, *e.g.*, *Coal. of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010) – they would revise Rule 28(a)(7) to create a "reasonable belief/effort" mega-exception permitting any party to assert an entirely new standing theory not only in a reply brief or during oral argument but even after oral argument.

The elephant in the room is that we do not allow "a party to assert an entirely new injury (and thus, an entirely new theory of standing) in its reply brief," *Coal. for Responsible Regulation*, 684 F.3d at 147, much less in a supplemental brief. As already noted, in his supplemental affidavit Krawitz raises a new injury and, thus, a new theory of standing. Yet in response to this undisputed fact, my colleagues do not attempt to claim Krawitz's theory of standing is *not* new. Instead, they skirt the issue by noting that DEA did not so argue in its supplemental brief. First and foremost, whether a party has established standing is for the court – not the parties – to decide. *See*, *e.g.*, *Animal Legal Defense Fund, Inc. v. Espy*, 29 F.3d 720, 723 n.2 (D.C. Cir. 1994) ("Standing . . . is a jurisdictional issue which cannot be waived or conceded."); *cf. Am. Library Ass'n*, 401 F.3d at 495 ("[W]hether standing is self-evident must be judged from the perspective of the court[.]"). And the majority's statement that Rule 28(a)(7) (let alone *Sierra Club*) "ha[s] no relevance" absent an objection, *see* Maj. Op. 11, is wholly unsupported. In any event, DEA *did* protest that Krawitz raised a new standing theory. While DEA did not cite *Sierra Club* or Rule 28(a)(7), it maintained that Krawitz "states, for the first time, that he participates in the

(Continued on following page)

'Oregon Medical Marijuana Program;' " and now "claims not that he is denied VA pain treatment in Oregon but that the VA prohibits its physicians from completing a state program form." Resp't Supp. Br. 1.

The majority's new exception declares that "[i]f the parties reasonably, but mistakenly, believed that the initial filings before the court had sufficiently demonstrated standing, the court may – as it did here – request supplemental affidavits and briefing." Maj. Op. 10 (citing *Pub. Citizen, Inc.*, 489 F.3d at 1296-97; *Am. Library Ass'n*, 401 F.3d at 492, 496); *see also* Maj. Op. 12 (suggesting we should allow supplemental briefing if parties make a "reasonable effort" to satisfy Rule 28(a)(7)). But *Public Citizen* and *American Library Association* establish no such exception to our Rule. *See*, *e.g.*, *Am. Library Ass'n*, 401 F.3d at 492 (establishing exception if the petitioners "reasonably [but mistakenly] believed their standing [was] self-evident"). Moreover, I do not see how the majority's new exception would not apply in virtually every case – presumably parties do not make "unreasonable" standing arguments or fail to use reasonable efforts to establish their standing.

[SEAL]

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Part IV

Department of Justice

Drug Enforcement Administration

21 CFR Chapter II

Denial of Petition To Initiate Proceedings To Reschedule Marijuana; Proposed Rule

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA-352N]

Denial of Petition To Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Denial of petition to initiate proceedings to reschedule marijuana.

SUMMARY: By letter dated June 21, 2011, the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule

marijuana.[1] Because DEA believes that this matter is of particular interest to members of the public, the agency is publishing below the letter sent to the petitioner (denying the petition), along with the supporting documentation that was attached to the letter.

FOR FURTHER INFORMATION CONTACT:

Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

SUPPLEMENTARY INFORMATION:

June 21, 2011.

Dear Mr. Kennedy:

On October 9, 2002, you petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). Specifically, you petitioned DEA to have marijuana removed from schedule I of the CSA and rescheduled as cannabis in schedule III, IV or V.

You requested that DEA remove marijuana from schedule I based on your assertion that:

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[1] Note that "marihuana" is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, "marijuana."

(1) Cannabis has an accepted medical use in the United States;

(2) Cannabis is safe for use under medical supervision;

(3) Cannabis has an abuse potential lower than schedule I or II drugs; and

(4) Cannabis has a dependence liability that is lower than schedule I or II drugs.

In accordance with the CSA rescheduling provisions, after gathering the necessary data, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (DHHS). DHHS concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, DHHS recommended that marijuana remain in schedule I. The scientific and medical evaluation and scheduling recommendation that DHHS submitted to DEA is attached hereto.

Based on the DHHS evaluation and all other relevant data, DEA has concluded that there is no substantial evidence that marijuana should be removed from schedule I. A document prepared by DEA addressing these materials in detail also is attached hereto. In short, marijuana continues to meet the criteria for schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The DHHS evaluation and the additional data gathered by DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* According to established case law, marijuana has no "currently accepted medical use" because: The drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.

(3) *Marijuana lacks accepted safety for use under medical supervision.* At present, there are no U.S. Food and Drug Administration (FDA)-approved marijuana products, nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

You also argued that cannabis has a dependence liability that is lower than schedule I or II drugs. Findings as to the physical or psychological dependence of a drug are only one of eight factors to be considered. As discussed further in the attached

documents, DHHS states that long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence.

The statutory mandate of 21 U.S.C. 812(b) is dispositive. Congress established only one schedule, schedule I, for drugs of abuse with "no currently accepted medical use in treatment in the United States" and "lack of accepted safety for use under medical supervision." 21 U.S.C. 812(b).

Accordingly, and as set forth in detail in the accompanying DHHS and DEA documents, there is no statutory basis under the CSA for DEA to grant your petition to initiate rulemaking proceedings to reschedule marijuana. Your petition is, therefore, hereby denied.

Sincerely,

Michele M. Leonhart,
Administrator.

Attachments:

Marijuana. Scheduling Review Document: Eight Factor Analysis

Basis for the recommendation for maintaining marijuana in schedule I of the Controlled Substances Act

Date: June 30, 2011

Michele M. Leonhart
Administrator

Department of Health and Human Services,
Office of the Secretary Assistant Secretary for Health, Office of Public Health and Science
Washington, D.C. 20201.

December 6, 2006.

The Honorable Karen P. Tandy *Administrator, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C. 20537*

Dear Ms. Tandy:

This is in response to your request of July 2004, and pursuant to the Controlled Substances Act (CSA), 21 U.S.C. 811(b), (c), and (f), the Department of Health and Human Services (DHHS) recommends that marijuana continue to be subject to control under Schedule I of the CSA.

Marijuana is currently controlled under Schedule I of the CSA. Marijuana continues to meet the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(l). As discussed in the attached analysis, marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of an accepted level of safety for use under medical supervision. Accordingly, HHS recommends that marijuana continue to be subject to control under Schedule I of the CSA. Enclosed is a document prepared by FDA's Controlled Substance Staff that is the basis for this recommendation.

Should you have any questions regarding this recommendation, please contact Corinne P. Moody, of

the Controlled Substance Staff, Center for Drug Evaluation and Research. Ms. Moody can be reached at 301-827-1999.

Sincerely yours,

John O. Agwunobi,
Assistant Secretary for Health.

Enclosure:

Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

BASIS FOR THE RECOMMENDATION FOR MAINTAINING MARIJUANA IN SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT

On October 9, 2002, the Coalition for Rescheduling Cannabis (hereafter known as the Coalition) submitted a petition to the Drug Enforcement Administration (DEA) requesting that proceedings be initiated to repeal the rules and regulations that place marijuana in Schedule I of the Controlled Substances Act (CSA). The petition contends that cannabis has an accepted medical use in the United States, is safe for use under medical supervision, and has an abuse potential and a dependency liability that is lower than Schedule I or II drugs. The petition requests that marijuana be rescheduled as "cannabis" in either Schedule III, IV, or V of the CSA. In July 2004, the DEA Administrator requested that the Department of Health and Human Services (HHS) provide a scientific and medical evaluation of the available information

and a scheduling recommendation for marijuana, in accordance with the provisions of 21 U.S.C. 811(b).

In accordance with 21 U.S.C. 811(b), DEA has gathered information related to the control of marijuana (*Cannabis sativa*)[2] under the CSA. Pursuant to 21 U.S.C. 811(b), the Secretary is required to consider in a scientific and medical evaluation eight factors determinative of control under the CSA. Following consideration of the eight factors, if it is appropriate, the Secretary must make three findings to recommend scheduling a substance in the CSA. The findings relate to a substance's abuse potential, legitimate medical use, and safety or dependence liability.

Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA), as described in the Memorandum of Understanding (MOU) of March 8, 1985 (50 FR 9518-20).

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[2] The CSA defines marijuana as the following: all parts of the plant Cannabis Sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted there from), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (21 U.S.C. 802(16)).

In this document, FDA recommends the continued control of marijuana in Schedule I of the CSA. Pursuant to 21 U.S.C. 811(c), the eight factors pertaining to the scheduling of marijuana are considered below.

1. ITS ACTUAL OR RELATIVE POTENTIAL FOR ABUSE

The first factor the Secretary must consider is marijuana's actual or relative potential for abuse. The term "abuse" is not defined in the CSA. However, the legislative history of the CSA suggests the following in determining whether a particular drug or substance has a potential for abuse:

a. Individuals are taking the substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

b. There is a significant diversion of the drug or substance from legitimate drug channels.

c. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances.

d. The substance is so related in its action to a substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant

diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970) reprinted in U.S.C.C.A.N. 4566, 4603.

In considering these concepts in a variety of scheduling analyses over the last three decades, the Secretary has analyzed a range of factors when assessing the abuse liability of a substance. These factors have included the prevalence and frequency of use in the general public and in specific subpopulations, 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.

Abuse liability is a complex determination with many dimensions. There is no single test or assessment procedure that, by itself, provides a full and complete characterization. Thus, no single measure of abuse liability is ideal. Scientifically, a comprehensive evaluation of the relative abuse potential of a drug substance can include consideration of the drug's receptor binding affinity, preclinical pharmacology, reinforcing effects, discriminative stimulus effects, dependence producing potential, pharmacokinetics and route of administration, toxicity, assessment of

the clinical efficacy-safety database relative to actual abuse, clinical abuse liability studies, and the public health risks following introduction of the substance to the general population. It is important to note that abuse may exist independent of a state of tolerance or physical dependence, because drugs may be abused in doses or in patterns that do not induce these phenomena. Animal data, human data, and epidemiological data are all used in determining a substance's abuse liability. Epidemiological data can also be an important indicator of actual abuse. Finally, evidence of clandestine production and illicit trafficking of a substance are also important factors.

* * *

3. THE STATE OF CURRENT SCIENTIFIC KNOWLEDGE REGARDING THE DRUG OR OTHER SUBSTANCE

The third factor the Secretary must consider is the state of current scientific knowledge regarding marijuana. Thus, this section discusses the chemistry, human pharmacokinetics, and medical uses of marijuana.

Chemistry

According to the DEA, Cannabis sativa is the primary species of cannabis currently marketed illegally in the United States of America. From this plant, three derivatives are sold as separate illicit drug products: marijuana, hashish, and hashish oil.

Each of these derivatives contains a complex mixture of chemicals. Among the components are the 21 carbon terpenes found in the plant as well as their carboxylic acids, analogues, and transformation products known as cannabinoids (Agurell et al., 1984 and 1986; Mechoulam, 1973). The cannabinoids appear to naturally occur only in the marijuana plant and most of the botanically-derived cannabinoids have been identified. Among the cannabinoids, delta^{9}-THC (alternate name delta^{1}-THC) and delta-8-tetrahydrocannabinol (delta^{8}-THC, alternate name delta^{6}-THC) are both found in marijuana and are able to produce the characteristic psychoactive effects of marijuana. Because delta^{9}-THC is more abundant than delta^{8}-THC, the activity of marijuana is largely attributed to the former. Delta^{8}-THC is found only in few varieties of the plant (Hively et al., 1966).

Delta^{9}-THC is an optically active resinous substance, insoluble in water, and extremely lipid soluble. Chemically delta^{9}-THC is (6aR-trans)-6a, 7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo-[b,d]pyran-1-ol or (-)-delta^{9}-(trans)-tetrahydrocannabinol. The (-)-trans isomer of delta^{9}-THC is pharmacologically 6 to 100 times more potent than the (+)-trans isomer (Dewey et al., 1984).

Other cannabinoids, such as cannabidiol (CBD) and cannabinol (CBN), have been characterized. CBD is not considered to have cannabinol-like psychoactivity, but is thought to have significant anticonvulsant, sedative, and anxiolytic activity (Adams and

Martin, 1996; Agurell et al., 1984 and 1986; Hollister, 1986).

Marijuana is a mixture of the dried flowering tops and leaves from the plant and is variable in content and potency (Agurell et al., 1984 and 1986; Graham, 1976; Mechoulam, 1973). Marijuana is usually smoked in the form of rolled cigarettes while hashish and hash oil are smoked in pipes. Potency of marijuana, as indicated by cannabinoid content, has been reported to average from as low as 1 to 2 percent to as high as 17 percent.

The concentration of delta^{9}-THC and other cannabinoids in marijuana varies with growing conditions and processing after harvest. Other variables that can influence the strength, quality, and purity of marijuana are genetic differences among the cannabis plant species and which parts of the plant are collected (flowers, leaves, stems, etc.) (Adams and Martin, 1996; Agurell et al., 1984; Mechoulam, 1973). In the usual mixture of leaves and stems distributed as marijuana, the concentration of delta^{9}-THC ranges widely from 0.3 to 4.0 percent by weight. However, specially grown and selected marijuana can contain even 15 percent or greater delta^{9}-THC. Thus, a 1 gm marijuana cigarette might contain as little as 3 mg or as much as 150 mg or more of delta^{9}-THC.

Hashish consists of the cannabinoid-rich resinous material of the cannabis plant, which is dried and compressed into a variety of forms (balls, cakes, etc.). Pieces are then broken off, placed into a pipe and

smoked. DEA reports that cannabinoid content in hashish averages 6 percent.

Hash oil is produced by solvent extraction of the cannabinoids from plant material. Color and odor of the extract vary, depending on the type of solvent used. Hash oil is a viscous brown or amber-colored liquid that contains approximately 15 percent cannabinoids. One or two drops of the liquid placed on a cigarette purportedly produce the equivalent of a single marijuana cigarette (DEA, 2005).

The lack of a consistent concentration of delta^{9}-THC in botanical marijuana from diverse sources complicates the interpretation of clinical data using marijuana. If marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing, and specifications of marijuana must be developed.

Human Pharmacokinetics

Marijuana is generally smoked as a cigarette (weighing between 0.5 and 1.0 gm), or in a pipe. It can also be taken orally in foods or as extracts of plant material in ethanol or other solvents.

The absorption, metabolism, and pharmacokinetic profile of delta^{9}-THC (and other cannabinoids) in marijuana or other drug products containing delta^{9}-THC vary with route of administration and formulation (Adams and Martin, 1996; Agurell et al., 1984 and 1986). When marijuana is administered by

smoking, delta^{9}-THC in the form of an aerosol is absorbed within seconds. The psychoactive effects of marijuana occur immediately following absorption, with mental and behavioral effects measurable up to 6 hours (Grotenhermen, 2003; Hollister, 1986 and 1988). Delta^{9}-THC is delivered to the brain rapidly and efficiently as would be expected of a very lipid-soluble drug.

The bioavailability of the delta^{9}-THC from marijuana in a cigarette or pipe can range from 1 to 24 percent with the fraction absorbed rarely exceeding 10 to 20 percent (Agurell et al., 1986; Hollister, 1988). The relatively low and variable bioavailability results from the following: significant loss of delta^{9}-THC in side-stream smoke, variation in individual smoking behaviors, cannabinoid pyrolysis, incomplete absorption of inhaled smoke, and metabolism in the lungs. A individual's experience and technique with smoking marijuana is an important determinant of the dose that is absorbed (Herning et al., 1986; Johansson et al., 1989).

After smoking, venous levels of delta^{9}-THC decline precipitously within minutes, and within an hour are about 5 to 10 percent of the peak level (Agurell et al., 1986; Huestis et al., 1992a and 1992b). Plasma clearance of delta^{9}-THC is approximately 950 ml/min or greater, thus approximating hepatic blood flow. The rapid disappearance of delta^{9}-THC from blood is largely due to redistribution to other tissues in the body, rather than to metabolism (Agurell et al., 1984 and 1986). Metabolism in most tissues is

relatively slow or absent. Slow release of delta^9-THC and other cannabinoids from tissues and subsequent metabolism results in a long elimination half-life. The terminal half-life of delta^9-THC is estimated to range from approximately 20 hours to as long as 10 to 13 days (Hunt and Jones, 1980), though reported estimates vary as expected with any slowly cleared substance and the use of assays of variable sensitivities. Lemberger et al. (1970) determined the half-life of delta^9-THC to range from 23 to 28 hours in heavy marijuana users to 60 to 70 hours in naive users.

Characterization of the pharmacokinetics of delta^9-THC and other cannabinoids from smoked marijuana is difficult (Agurell et al., 1986; Herning et al., 1986; Huestis et al., 1992a), in part because a subject's smoking behavior during an experiment is variable. Each puff delivers a discrete dose of delta^9-THC. An experienced marijuana smoker can titrate and regulate the dose to obtain the desired acute psychological effects and to avoid overdose and/or minimize undesired effects. For example, under naturalistic conditions, users will hold marijuana smoke in the lungs for an extended period of time, in order to prolong absorption and increase psychoactive effects. The effect of experience in the psychological response may explain why venous blood levels of delta^9-THC correlate poorly with intensity of effects and level of intoxication (Agurell et al., 1986; Barnett et al., 1985; Huestis et al., 1992a).

Additionally, puff and inhalation volume changes with phase of smoking, tending to be highest at the

beginning and lowest at the end of smoking a cigarette. Some studies found frequent users to have higher puff volumes than less frequent marijuana users. During smoking, as the cigarette length shortens, the concentration of delta^{9}-THC in the remaining marijuana increases; thus, each successive puff contains an increasing concentration of delta^{9}-THC.

In contrast to smoking, the onset of effects after oral administration of delta^{9}-THC or marijuana is 30 to 90 min, which peaks after 2 to 3 hours and continues for 4 to 12 hours (Grotenhermen, 2003; Adams and Martin, 1996; Agurell et al., 1984 and 1986). Oral bioavailability of delta^{9}-THC, whether pure or in marijuana, is low and extremely variable, ranging between 5 and 20 percent (Agurell et al., 1984 and 1986). Following oral administration of radioactive-labeled delta^{9}-THC, delta^{9}-THC plasma levels are low relative to those levels after smoking or intravenous administration. There is inter- and intra-subject variability, even when repeated dosing occurs under controlled conditions. The low and variable oral bioavailability of delta^{9}-THC is a consequence of its first-pass hepatic elimination from blood and erratic absorption from stomach and bowel. It is more difficult for a user to titrate the oral delta^{9}-THC dose than marijuana smoking because of the delay in onset of effects after an oral dose (typically 1 to 2 hours).

Cannabinoid metabolism is extensive. Delta^{9}-THC is metabolized via microsomal hydroxylation to both active and inactive metabolites (Lemberger et al., 1970, 1972a, and 1972b; Agurell et al., 1986;

Hollister, 1988) of which the primary active metabolite was 11-hydroxy-delta^{9}-THC. This metabolite is approximately equipotent to delta^{9}-THC in producing marijuana-like subjective effects (Agurell et al., 1986; Lemberger and Rubin, 1975). After oral administration, metabolite levels may exceed that of delta^{9}-THC and thus contribute greatly to the pharmacological effects of oral delta^{9}-THC or marijuana. In addition to 11-hydroxy-delta^{9}-THC, some inactive carboxy metabolites have terminal half-lives of 50 hours to 6 days or more. The latter substances serve as long-term markers of earlier marijuana use in urine tests. The majority of the absorbed delta^{9}-THC dose is eliminated in feces, and about 33 percent in urine. Delta^{9}-THC enters enterohepatic circulation and undergoes hydroxylation and oxidation to 11-nor-9-carboxy-delta^{9}-THC. The glucuronide is excreted as the major urine metabolite along with about 18 nonconjugated metabolites. Frequent and infrequent marijuana users are similar in the way they metabolize delta^{9}-THC (Agurell et al., 1986).

Medical Uses for Marijuana

A NDA for marijuana/cannabis has not been submitted to the FDA for any indication and thus no medicinal product containing botanical cannabis has been approved for marketing. However, small clinical studies published in the current medical literature demonstrate that research with marijuana is being conducted in humans in the United States under

FDA-authorized investigational new drug (IND) applications.

HHS states in a published guidance that it is committed to providing "research-grade marijuana for studies that are the most likely to yield usable, essential data" (HHS, 1999). The opportunity for scientists to conduct clinical research with botanical marijuana has increased due to changes in the process for obtaining botanical marijuana from NIDA, the only legitimate source of the drug for research in the United States. In May 1999, HHS provided guidance on the procedures for providing research-grade marijuana to scientists who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials (DHHS, 1999). This action was prompted by the increasing interest in determining whether cannabinoids have medical use through scientifically valid investigations.

In February 1997, a National Institutes of Health (NIH)-sponsored workshop analyzed available scientific information and concluded that "in order to evaluate various hypotheses concerning the potential utility of marijuana in various therapeutic areas, more and better studies would be needed" (NIH, 1997). In addition, in March 1999, the Institute of Medicine (IOM) issued a detailed report that supported the need for evidence-based research into the effects of marijuana and cannabinoid components of marijuana, for patients with specific disease conditions. The IOM report also emphasized that smoked marijuana is a crude drug delivery system that

exposes individuals to a significant number of harmful substances and that "if there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives." As such, the IOM recommended that clinical trials should be conducted with the goal of developing safe delivery systems (Institute of Medicine, 1999). Additionally, state-level public initiatives, including referenda in support of the medical use of marijuana, have generated interest in the medical community for high quality clinical investigation and comprehensive safety and effectiveness data.

For example, in 2000, the state of California established the Center for Medicinal Cannabis Research (CMCR) (*www.cmcr.ucsd.edu*) "in response to scientific evidence for therapeutic possibilities of cannabis and local legislative initiatives in favor of compassionate use" (Grant, 2005). State legislation establishing the CMCR called for high quality medical research that will "enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent," but stressed that the project "should not be construed as encouraging or sanctioning the social or recreational use of marijuana." CMCR has thus far funded studies on the potential use of cannabinoids for the treatment of multiple sclerosis, neuropathic pain, appetite suppression and cachexia, and severe pain and nausea related to cancer or its treatment by chemotherapy. To date, though, no NDAs utilizing marijuana for these indications have been submitted to the FDA.

However, FDA approval of an NDA is not the sole means through which a drug can be determined to have a "currently accepted medical use" under the CSA. According to established case law, a drug has a "currently accepted medical use" if all of the following five elements have been satisfied:

a. the drug's chemistry is known and reproducible;

b. there are adequate safety studies;

c. there are adequate and well-controlled studies proving efficacy;

d. the drug is accepted by qualified experts; and

e. the scientific evidence is widely available.

[*Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994)]

Although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted. Safety studies for acute or subchronic administration of marijuana have been carried out through a limited number of Phase 1 clinical investigations approved by the FDA, but there have been no NDA-quality studies that have scientifically assessed the efficacy and full safety profile of marijuana for any medical condition. A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At this time, it is clear that there is

not a consensus of medical opinion concerning medical applications of marijuana. Finally, the scientific evidence regarding the safety or efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. As such, there is no opportunity for adequate scientific scrutiny of whether the data demonstrate safety or efficacy.

Alternately, a drug can be considered to have "a currently accepted medical use with severe restrictions" (21 U.S.C. 812(b)(2)(B)), as allowed under the stipulations for a Schedule II drug. However, as stated above, a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts, even under conditions where its use is severely restricted. Thus, to date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a "currently accepted medical use" or a "currently accepted medical use with severe restrictions."

* * *

RECOMMENDATION

After consideration of the eight factors discussed above, HHS recommends that marijuana remain in Schedule I of the CSA. Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1):

1) Marijuana has a high potential for abuse:

The large number of individuals using marijuana on a regular basis, its widespread use, and the vast amount of marijuana that is available for illicit use are indicative of the high abuse potential for marijuana. Approximately 14.6 million individuals in the United States (6.1 percent of the U.S. population) used marijuana monthly in 2003. A 2003 survey indicates that by 12th grade, 33.6 percent of students report having used marijuana in the past year, and 19.8 percent report using it monthly. In Q3 to Q4 2003, 79,663 ED visits were marijuana-related, representing 13 percent of all drug-related episodes. Primary marijuana use accounted for 15.5 percent of admissions to drug treatment programs in 2003. Marijuana has dose-dependent reinforcing effects, as demonstrated by data that humans prefer higher doses of marijuana to lower doses. In addition, there is evidence that marijuana use can result in psychological dependence in at risk individuals.

2) Marijuana has no currently accepted medical use in treatment in the United States:

The FDA has not yet approved an NDA for marijuana. The opportunity for scientists to conduct clinical research with marijuana exists under the HHS policy supporting clinical research with botanical marijuana. While there are INDs for marijuana active at the FDA, marijuana does not have a currently accepted medical use for treatment in the

United States, nor does it have an accepted medical use with severe restrictions.

A drug has a "currently accepted medical use" if all of the following five elements have been satisfied:

a. The drug's chemistry is known and reproducible;

b. There are adequate safety studies;

c. There are adequate and well-controlled studies proving efficacy;

d. The drug is accepted by qualified experts; and

e. The scientific evidence is widely available.

[*Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994)]

Although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted. Safety studies for acute or subchronic administration of marijuana have been carried out through a limited number of Phase 1 clinical investigations approved by the FDA, but there have been no NDA-quality studies that have scientifically assessed the efficacy of marijuana for any medical condition. A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At this time, it is clear that there is not a consensus of medical opinion concerning medical applications of

marijuana. Finally, the scientific evidence regarding the safety or efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. As such, there is no opportunity for adequate scientific scrutiny of whether the data demonstrate safety or efficacy.

Alternately, a drug can be considered to have "a currently accepted medical use with severe restrictions" (21 U.S.C. 812(b)(2)(B)), as allowed under the stipulations for a Schedule II drug. However, as stated above, a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts, even under conditions where its use is severely restricted. To date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a "currently accepted medical use" or a "currently accepted medical use with severe restrictions."

3) There is a lack of accepted safety for use of marijuana under medical supervision.

At present, there are no FDA-approved marijuana products, nor is marijuana under NDA evaluation at the FDA for any indication. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. The Center for Medicinal Cannabis Research in California, among others, is conducting research with marijuana at the IND level,

but these studies have not yet progressed to the stage of submitting an NDA. Thus, at this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

In addition, the agency cannot conclude that marijuana has an acceptable level of safety without assurance of a consistent and predictable potency and without proof that the substance is free of contamination. If marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing, and specifications of marijuana must be developed. Therefore, HHS concludes that, even under medical supervision, marijuana has not been shown at present to have an acceptable level of safety.

* * *

Marijuana

Scheduling Review Document: Eight Factor Analysis

Drug and Chemical Evaluation Section Office of Diversion Control
Drug Enforcement Administration, April 2011

INTRODUCTION

On October 9, 2002, the Coalition for Rescheduling Cannabis submitted a petition to the Drug Enforcement Administration (DEA) to initiate proceedings for a repeal of the rules or regulations that place

marijuana[3] in schedule I of the Controlled Substances Act (CSA). The petition requests that marijuana be rescheduled as "cannabis" in either schedule III, IV, or V of the CSA. The petitioner claims that:

1. Cannabis has an accepted medical use in the United States;

2. Cannabis is safe for use under medical supervision;

3. Cannabis has an abuse potential lower than schedule I or II drugs; and

4. Cannabis has a dependence liability that is lower than schedule I or II drugs.

The DEA accepted this petition for filing on April 3, 2003. In accordance with 21 U.S.C. 811(b), after gathering the necessary data, the DEA requested a

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[3] The Controlled Substances Act (CSA) defines marijuana as the following:

All parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted there from), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. 21 U.S.C. 802(16).

Note that "marihuana" is the spelling originally used in the CSA. This document uses the spelling that is more common in current usage, "marijuana."

medical and scientific evaluation and scheduling recommendation for cannabis from the Department of Health and Human Services (DHHS) on July 12, 2004. On December 6, 2006, the DHHS provided its scientific and medical evaluation titled *Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act* and recommended that marijuana continue to be controlled in schedule I of the CSA.

The CSA requires DEA to determine whether the DHHS scientific and medical evaluation and scheduling recommendation and "all other relevant data" constitute substantial evidence that the drug should be rescheduled as proposed in the petition. 21 U.S.C. 811(b). This document is prepared accordingly.

The Attorney General "may by rule" transfer a drug or other substance between schedules if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by subsection (b) of Section 812 for the schedule in which such drug is to be placed. 21 U.S.C. 811(a)(1). In order for a substance to be placed in schedule I, the Attorney General must find that:

A. The drug or other substance has a high potential for abuse.

B. The drug or other substance has no currently accepted medical use in treatment in the United States.

C. There is a lack of accepted safety for use of the drug or other substance under medical supervision.

21 U.S.C. 812(b)(1)(A)-(C). To be classified in one of the other schedules (II through V), a drug of abuse must have either a "currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. 812(b)(2)-(5). If a controlled substance has no such currently accepted medical use, it must be placed in schedule I. *See* Notice of Denial of Petition, 66 FR 20038, 20038 (Apr. 18, 2001) ("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.' ").

In deciding whether to grant a petition to initiate rulemaking proceedings with respect to a particular drug, DEA must determine whether there is sufficient evidence to conclude that the drug meets the criteria for placement in another schedule based on the criteria set forth in 21 U.S.C. 812(b). To do so, the CSA requires that DEA and DHHS consider eight factors as specified in 21 U.S.C. 811(c). This document is organized according to these eight factors.

With specific regard to the issue of whether the drug has a currently accepted medical use in treatment in the United States, DHHS states that the FDA has not evaluated nor approved a new drug application (NDA) for marijuana. The long-established

factors applied by the DEA for determining whether a drug has a "currently accepted medical use" under the CSA are:

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.

57 FR 10,499, 10,506 (1992); *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994) (*ACT*) (upholding these factors as valid criteria for determining "accepted medical use"). A drug will be deemed to have a currently accepted medical use for CSA purposes only if all five of the foregoing elements are demonstrated. This test is considered here under the third factor.

Accordingly, as the eight factor analysis sets forth in detail below, the evidence shows:

1. *Actual or relative potential for abuse.* Marijuana has a high abuse potential. It is the most widely used illicit substance in the United States. Preclinical and clinical data show that it has reinforcing effects characteristic of drugs of abuse. National databases on actual abuse show marijuana is the

most widely abused drug, including significant numbers of substance abuse treatment admissions. Data on marijuana seizures show widespread availability and trafficking.

2. *Scientific evidence of its pharmacological effect.* The scientific understanding of marijuana, cannabinoid receptors, and the endocannabinoid system has improved. Marijuana produces various pharmacological effects, including subjective (e.g., euphoria, dizziness, disinhibition), cardiovascular, acute and chronic respiratory, immune system, cognitive impairment, and prenatal exposure effects as well as possible increased risk of schizophrenia among those predisposed to psychosis.

3. *Current scientific knowledge.* There is no currently accepted medical use for marijuana in the United States. Under the five-part test for currently accepted medical use approved in *ACT*, 15 F.3d at 1135, there is no complete scientific analysis of marijuana's chemical components; there are no adequate safety studies; there are no adequate and well-controlled efficacy studies; there is not a consensus of medical opinion concerning medical applications of marijuana; and the scientific evidence regarding marijuana's safety and efficacy is not widely available. While a number of states have passed voter referenda or legislative actions authorizing the use of marijuana for medical purposes, this does not establish a currently accepted medical use under federal law. To date, scientific and medical research has not progressed to the point that marijuana has a currently accepted

medical use, even under conditions where its use is severely restricted.

4. *History and current pattern of abuse.* Marijuana use has been relatively stable from 2002 to 2009, and it continues to be the most widely used illicit drug. In 2009, there were 16.7 million current users. There were also 2.4 million new users, most of whom were less than 18 years of age. During the same period, marijuana was the most frequently identified drug exhibit in federal, state, and local laboratories. High consumption of marijuana is fueled by increasing amounts of both domestically grown and illegally smuggled foreign source marijuana, and an increasing percentage of seizures involve high potency marijuana.

5. *Scope, duration, and significance of abuse.* Abuse of marijuana is widespread and significant. In 2008, for example, an estimated 3.9 million people aged 12 or older used marijuana on a daily or almost daily basis over a 12-month period. In addition, a significant proportion of all admissions for treatment for substance abuse are for primary marijuana abuse: in 2007, 16 percent of all admissions were for primary marijuana abuse, representing 287,933 individuals. Of individuals under the age of 19 admitted to substance abuse treatment, more than half were treated for primary marijuana abuse.

6. *Risk, if any, to public health.* Together with the health risks outlined in terms of pharmacological effects above, public health risks from acute use of

marijuana include impaired psychomotor performance, including impaired driving, and impaired performance on tests of learning and associative processes. Public health risks from chronic use of marijuana include respiratory effects, physical dependence, and psychological problems.

7. *Psychic or physiological dependence liability.* Long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation, as well as psychic addiction or dependence.

8. *Immediate precursor.* Marijuana is not an immediate precursor of any controlled substance.

This review shows, in particular, that the evidence is insufficient with respect to the specific issue of whether marijuana has a currently accepted medical use under the five-part test. The evidence was insufficient in this regard on the prior two occasions when DEA considered petitions to reschedule marijuana in 1992 (57 FR 10499)[4] and in 2001 (66 FR 20038).[5] Little has changed since then with respect to the lack of clinical evidence necessary to establish that marijuana has a currently accepted medical use: only a limited number of FDA-approved Phase 1 clinical investigations have been carried out, and there

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[4] *Petition for review dismissed, Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).

[5] *Petition for review dismissed, Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002).

have been no studies that have scientifically assessed the efficacy and full safety profile of marijuana for any medical condition.[6] The limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA.

To the contrary, the data in this Scheduling Review document show that marijuana continues to meet the criteria for schedule I control under the CSA for the following reasons:

1. Marijuana has a high potential for abuse.

2. Marijuana has no currently accepted medical use in treatment in the United States.

3. Marijuana lacks accepted safety for use under medical supervision.

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[6] Clinical trials generally proceed in three phases. *See* 21 CFR 312.21 (2010). Phase I trials encompass initial testing in human subjects, generally involving 20 to 80 patients. Id. They are designed primarily to assess initial safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary studies of potential therapeutic benefit. 62 FR 66113, 1997. Phase II and Phase III studies involve successively larger groups of patients: usually no more than several hundred subjects in Phase II, and usually from several hundred to several thousand in Phase III. 21 CFR 312.21. These studies are designed primarily to explore (Phase II) and to demonstrate or confirm (Phase III) therapeutic efficacy and benefit in patients. 62 FR 66113, 1997. *See also Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1018-19 n.15 (2008) (Ginsburg, J., dissenting).

FACTOR 1: THE DRUG'S ACTUAL OR RELATIVE POTENTIAL FOR ABUSE

Marijuana is the most commonly abused illegal drug in the United States. It is also the most commonly used illicit drug by American high-schoolers. Marijuana is the most frequently identified drug in state, local and federal forensic laboratories, with increasing amounts both of domestically grown and of illicitly smuggled marijuana. Marijuana's main psychoactive ingredient, $\triangle^9$-THC, is an effective reinforcer in laboratory animals, including primates and rodents. These animal studies both predict and support the observations that $\triangle^9$-THC, whether smoked as marijuana or administered by other routes, produces reinforcing effects in humans. Such reinforcing effects can account for the repeated abuse of marijuana.

A. Indicators of Abuse Potential

DHHS has concluded in its document, "Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act", that marijuana has a high potential for abuse. The finding of "abuse potential" is critical for control under the Controlled Substances Act (CSA). Although the term is not defined in the CSA, guidance in determining abuse potential is provided in the legislative history of the Act (Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-144, 91st Cong., Sess.1 (1970), reprinted in 1970 U.S.C.C.A.N.

4566, 4603). Accordingly, the following items are indicators that a drug or other substance has potential for abuse:

- There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

- There is significant diversion of the drug or other substance from legitimate drug channels; or

- Individuals are taking the drug or substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or

- The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

After considering the above items, DHHS has found that marijuana has a high potential for abuse.

1. There is evidence that individuals are taking the drug or other substance in amounts sufficient to

create a hazard to their health or to the safety of other individuals or to the community.

Marijuana is the most highly used illicit substance in the United States. Smoked marijuana exerts a number of cardiovascular and respiratory effects, both acutely and chronically and can cause chronic bronchitis and inflammatory abnormalities of the lung tissue. Marijuana's main psychoactive ingredient $\triangle^{9}$-THC alters immune function and decreases resistance to microbial infections. The cognitive impairments caused by marijuana use that persist beyond behaviorally detectable intoxication may have significant consequences on workplace performance and safety, academic achievement, and automotive safety, and adolescents may be particularly vulnerable to marijuana's cognitive effects. Prenatal exposure to marijuana was linked to children's poorer performance in a number of cognitive tests. Data on the extent and scope of marijuana abuse are presented under factors 4 and 5 of this analysis. DHHS's discussion of the harmful health effects of marijuana and additional information gathered by DEA are presented under factor 2, and the assessment of risk to the public health posed by acute and chronic marijuana abuse is presented under factor 6 of this analysis.

2. There is significant diversion of the drug or other substance from legitimate drug channels.

DHHS states that at present, marijuana is legally available through legitimate channels for

research only and thus has a limited potential for diversion. (DEA notes that while a number of states have passed voter referenda or legislative actions authorizing the use of marijuana for medical purposes, this does not establish a currently accepted medical use under federal law.) In addition, the lack of significant diversion of investigational supplies may result from the ready availability of illicit cannabis of equal or greater quality.

DEA notes that the magnitude of the demand for illicit marijuana is evidenced by information from a number of databases presented under factor 4. Briefly, marijuana is the most commonly abused illegal drug in the United States. It is also the most commonly used illicit drug by American high-schoolers. Marijuana is the most frequently identified drug in state, local, and federal forensic laboratories, with increasing amounts both of domestically grown and of illicitly smuggled marijuana. An observed increase in the potency of seized marijuana also raises concerns.

3. Individuals are taking the drug or substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs.

16.7 million adults over the age of 12 reported having used marijuana in the past month, according to the 2009 National Survey on Drug Use and Health (NSDUH), as further described later in this factor. DHHS states in its 2006 analysis of the petition that the FDA has not evaluated or approved a new drug

application (NDA) for marijuana for any therapeutic indication, although several investigational new drug (IND) applications are currently active. Based on the large number of individuals who use marijuana, DHHS concludes that the majority of individuals using cannabis do so on their own initiative, not on the basis of medical advice from a practitioner licensed to administer the drug in the course of professional practice.

4. The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

Marijuana is not a new drug. Marijuana's primary psychoactive ingredient delta-9-tetrahydrocannabinol ($\triangle^9$-THC) is controlled in schedule I of the CSA. DHHS states that there are two drug products containing cannabinoid compounds that are structurally related to the active components in marijuana. Both are controlled under the CSA. Marinol is a schedule III drug product containing synthetic $\triangle^9$-THC, known generically as dronabinol, formulated in sesame oil in soft gelatin capsules. Marinol was approved by the

FDA in 1985 for the treatment of two medical conditions: nausea and vomiting associated with cancer chemotherapy in patients that had failed to respond adequately to conventional anti-emetic treatments, and for the treatment of anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS). Cesamet is a drug product containing the schedule II substance, nabilone, that was approved for marketing by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. All other structurally related cannabinoids in marijuana are already listed as Schedule I drugs under the CSA.

In addition, DEA notes that marijuana and its active ingredient $\triangle^{9}$-THC are related in their action to other controlled drugs of abuse when tested in preclinical and clinical tests of abuse potential. Data showing that marijuana and $\triangle^{9}$-THC exhibit properties common to other controlled drugs of abuse in those tests are described below in this factor.

In summary, examination of the indicators set forth in the legislative history of the CSA demonstrates that marijuana has a high potential for abuse. Indeed, marijuana is abused in amounts sufficient to create hazards to public health and safety; there is significant trafficking of the substance; individuals are using marijuana on their own initiative, for the vast majority, rather than on the basis of medical advice; and finally, marijuana exhibits several properties common to those of drugs already listed as having abuse potential.

The petitioner states that, "widespread use of cannabis is not an indication of its abuse potential [. . .] ." (Exh. C, Section IV(15), pg. 87).

To the contrary, according to the indicators set forth in the legislative history of the CSA as described above, the fact that "Individuals are taking the drug or substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs" is indeed one of several indicators that a drug has high potential for abuse.

* * *

FACTOR 3: THE STATE OF THE CURRENT SCIENTIFIC KNOWLEDGE REGARDING THE DRUG OR SUBSTANCE

DHHS states that marijuana is a mixture of the dried leaves and flowering tops of the cannabis plant (Agurell *et al*., 1984; Graham, 1976; Mechoulam, 1973). These portions of the plant have the highest levels of $\triangle^9$-THC, the primary psychoactive ingredient in marijuana. The most potent product (i.e., that having the highest percentage of $\triangle^9$-THC) of dried material is sinsemilla, derived from the unpollinated flowering tops of the female cannabis plant. Generally, this potent marijuana product is associated with indoor grow sites and may have a $\triangle^9$-THC content of 15 to 20 percent or more. Other, less common forms of marijuana found on the illicit market are hashish and hashish oil. Hashish is a $\triangle^9$-THC-rich resinous

material of the cannabis plant which is dried and compressed into a variety of forms (balls, cakes or sticks). Dried pieces are generally broken off and smoked. $\triangle^9$-THC content is usually about five percent. The Middle East, North Africa and Pakistan/Afghanistan are the main sources of hashish. Hashish oil is produced by extracting the cannabinoids from plant material with a solvent. Hashish oil is a light to dark brown viscous liquid with a $\triangle^9$-THC content of about 15 percent. The oil is often sprinkled on cigarettes, allowed to dry, and then smoked.

Chemistry

DHHS states that some 483 natural constituents have been identified in marijuana, including 66 compounds that are classified as cannabinoids (Ross and El Sohly, 1995). Cannabinoids are not known to exist in plants other than marijuana, and most naturally occurring cannabinoids have been identified chemically. The psychoactive properties of cannabis are attributed to one or two of the major cannabinoid substances, namely delta-9-tetrahydrocannabinol ($\triangle^9$-THC) and delta-8-tetrahydrocannabinol ($\triangle^8$-THC). Other natural cannabinoids, such as cannabidiol (CBD) and cannabinol (CBN), have been characterized. CBD does not possess $\triangle^9$-THC-like psychoactivity. Its pharmacological properties appear to include anticonvulsant, anxiolytic and sedative properties (Agurell *et al.*, 1984, 1986; Hollister, 1986).

DHHS states that $\triangle^9$-THC is an optically active resinous substance, extremely lipid soluble, and insoluble in water. Chemically, $\triangle^9$-THC is known as (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo-[b,d]pyran-1-ol or (-)$\triangle^9$-(trans)-tetrahydrocannabinol. The pharmacological activity of $\triangle^9$-THC is stereospecific: the (-)-trans isomer is 6-100 times more potent than the (+)-trans isomer (Dewey *et al.*, 1984).

DEA notes a review of the contaminants and adulterants that can be found in marijuana (McPartland, 2002). In particular, DEA notes that many studies have reported contamination of both illicit and NIDA-grown marijuana with microbial contaminants, bacterial or fungal (McLaren *et al.*, 2008; McPartland, 1994, 2002; Ungerleider *et al.*, 1982; Taylor *et al.*, 1982; Kurup *et al.*, 1983). Other microbial contaminants include Klebsiella pneumoniae, salmonella enteritidis, and group D Streptococcus (Ungerlerder *et al.*, 1982; Kagen *et al.*, 1983; Taylor *et al.*, 1982). DEA notes that a review by McLaren and colleagues (2008) discusses studies showing that heavy metals present in soil may also contaminate cannabis, and states that these contaminants have the potential to harm the user without harming the plant. Other sources of contaminants discussed by McLaren and colleagues (2008) include growth enhancers and pest control products related to marijuana cultivation and storage.

Human Pharmacokinetics

DHHS states that marijuana is generally smoked as a cigarette (weighing between 0.5 and 1.0 gm; Jones, 1980) or in a pipe. It can also be taken orally in foods or as extracts of plant material in ethanol or other solvents. The absorption, metabolism, and pharmacokinetic profile of $\triangle^9$-THC (and other cannabinoids) in marijuana or other drug products containing $\triangle^9$-THC vary with route of administration and formulation (Adams and Martin, 1996; Agurell *et al.*, 1984, 1986). When marijuana is administered by smoking, $\triangle^9$-THC in the form of an aerosol is absorbed within seconds. The psychoactive effects of marijuana occur immediately following absorption, with mental and behavioral effects measurable up for to six hours after absorption (Grotenhermen, 2003; Hollister, 1986, 1988). $\triangle^9$-THC is delivered to the brain rapidly and efficiently as would be expected of a highly lipid-soluble drug.

The petitioner provided a discussion of new, or less common, routes and methods of administration being currently explored (pg. 57, line 1). These include vaporization for the inhalation route, as well as rectal, sublingual, and transdermal routes.

DEA notes that respiratory effects are only part of the harmful health effects of prolonged marijuana exposure, as described further under factor 2 of this document. DEA also notes that at this time, the majority of studies exploring the potential therapeutic uses of marijuana use smoked marijuana, and the

pharmacokinetics and bioavailability from routes of administration other than smoked and oral are not well-known.

The pharmacokinetics of smoked and orally ingested marijuana are thoroughly reviewed in DHHS's review document.

Medical Utility

The petition filed by the Coalition to Reschedule Cannabis (Marijuana) aims to repeal the rule placing marijuana in schedule I of the CSA, based in part on the proposition that marijuana has an accepted medical use in the United States. However DHHS has concluded in its 2006 analysis that marijuana has no accepted medical use in treatment in the United States. Following is a discussion of the petitioner's specific points and a presentation of DHHS's evaluation and recommendation on the question of accepted medical use for marijuana.

The petitioner states (pg. 48, line 2), "Results from clinical research demonstrated that both dronabinol and whole plant cannabis can offer a safe and effective treatment for the following illnesses: muscle spasm in multiple sclerosis, Tourette syndrome, chronic pain, nausea and vomiting in HIV/AIDS and cancer chemotherapy, loss of appetite from cancer, hyperactivity of the bladder in patients with multiple sclerosis and spinal cord injury, and dyskinesia caused by levodopa in Parkinson's disease."

To support its claim that marijuana has an accepted medical use in the United States, the petitioner listed supporting evidence that included the following:

- Evidence from clinical research and reviews of earlier clinical research (Exh. C, Section I (4, 6), pg. 29)

- Acceptance of the medical use of marijuana by eight states since 1996 and state officials in these states establishing that marijuana has an accepted medical use in the United States (Exh. C, Section I (1), pg. 13)

- Increased recognition by health care professionals and the medical community, including the Institute of Medicine (IOM) (Exh. C, Section I (2), pg. 15)

- Patients' experience in which they reported benefits from smoking marijuana (Exh. C, Section I (3), pg. 22)

- *Evidence from clinical research (Exh. C, Section I (4, 6), pg. 29)*

DHHS states that a new drug application (NDA) for marijuana has not been submitted to the FDA for any indication and thus no medicinal product containing botanical cannabis has been approved for marketing. Only small clinical studies published in the current medical literature demonstrate that research with marijuana is being conducted in humans in the United States under FDA-authorized investigational new drug (IND) applications.

There are ongoing clinical studies of the potential utility of marijuana in medical applications. DHHS states that in 2000, the state of California established the Center for Medicinal Cannabis Research (CMCR) which has funded studies on the potential use of cannabinoids for the treatment of multiple sclerosis, neuropathic pain, appetite suppression and cachexia, and severe pain and nausea related to cancer or its treatment by chemotherapy. To date, though, no NDAs utilizing marijuana for these indications have been submitted to the FDA.

To establish accepted medical use, among other criteria, the effectiveness of a drug must be established in well-controlled scientific studies performed in a large number of patients. To date, such studies have not been performed for marijuana. Small clinical trial studies with limited patients and short duration such as those cited by the petitioner are not sufficient to establish medical utility. Larger studies of longer duration are needed to fully characterize the drug's efficacy and safety profile. Anecdotal reports, patients' self-reported effects, and isolated case reports are not adequate evidence to support an accepted medical use of marijuana (57 FR 10499, 1992).

In addition to demonstrating efficacy, adequate safety studies must be performed to show that the drug is safe for treating the targeted disease. DHHS states that safety studies for acute or subchronic administration of marijuana have been carried out through a limited number of Phase 1 clinical investigations approved by the FDA, but there have been

no NDA-quality studies that have scientifically assessed the efficacy and full safety profile of marijuana for any medical condition.

DEA further notes that a number of clinical studies from CMCR have been discontinued. Most of these discontinuations were due to recruitment difficulties (http://www.cmcr.ucsd.edu/geninfo/research.htm (last retrieved 07/07/2010) (listing 6 discontinued studies, 5 of which were discontinued because of recruitment issues)).

The petitioner states that the pharmacological effects are well established for marijuana and $\triangle^9$-THC, using the argument that Marinol (containing synthetic $\triangle^9$-THC, known generically as dronabinol) and Cesamet (containing nabilone, a synthetic cannabinoid not found in marijuana) are approved for several therapeutic indications. The approvals of Marinol and Cesamet were based on well-controlled clinical studies that established the efficacy and safety of these drugs as a medicine. Smoked marijuana has not been demonstrated to be safe and effective in treating these medical conditions. Marijuana is a drug substance composed of numerous cannabinoids and other constituents; hence the safety and efficacy of marijuana cannot be evaluated solely on the effects of $\triangle^9$-THC. Adequate and well-controlled studies must be performed with smoked marijuana to establish efficacy and safety. DHHS states that there is a lack of accepted safety for the use of marijuana under medical supervision.

The petitioner has not submitted any new data meeting the requisite scientific standards to support the claim that marijuana has an accepted medical use in the United States. Hence, the new information provided by the petitioner does not change the federal government's evaluation of marijuana's medical use in the United States.

- Petitioner's claim of acceptance of the medical use of marijuana by eight states since 1996 and state officials in these states establishing that marijuana has an accepted medical use in the United States

Petitioner argues that, "[t]he acceptance of cannabis's medical use by eight states since 1996 and the experiences of patients, doctors, and state officials in these states establish marijuana's accepted medical use in the United States." Petition at 10, 13. This argument is contrary to the CSA's statutory scheme. The CSA does not assign to the states the authority to make findings relevant to CSA scheduling determinations. Rather, the CSA expressly delegates the task of making such findings – including whether a substance has any currently accepted medical use in treatment in the United States – to the Attorney General. 21 U.S.C. 811(a). The CSA also expressly tasks the Secretary of DHHS to provide a scientific and medical evaluation and scheduling recommendations to inform the Attorney General's findings. 21 U.S.C. 811(b); *see also* 21 C.F.R. 308.43. That Congress explicitly provided scheduling authority to these two federal entities in this comprehensive and exclusive statutory scheme precludes the argument

that state legislative action can establish accepted medical use under the CSA.

The CSA explicitly provides that in making a scheduling determination, the Attorney General shall consider the following eight factors:

1. The drug's actual or relative potential for abuse

2. Scientific evidence of its pharmacological effect, if known;

3. The state of current scientific knowledge regarding the drug;

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. The drug's psychic or physiological dependence liability; and

8. Whether the substance is an immediate precursor of a substance already controlled under the CSA.

21 U.S.C. 811(c). These factors embody Congress's view of the specialized agency expertise required for drug rescheduling decisions. The CSA's statutory text thus further evidences that Congress did not envision such a role for state law in establishing the schedules of controlled substances under the CSA. *See Krumm*

v. Holder, 2009 WL 1563381, at *16 (D.N.M. 2009) ("The CSA does not contemplate that state legislatures' determinations about the use of a controlled substance can be used to bypass the CSA's rescheduling process.").

The long-established factors applied by DEA for determining whether a drug has a "currently accepted medical use" under the CSA are:

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.

57 FR 10,499, 10,506 (1992), *ACT*, 15 F.3d at 1135 (upholding these factors as valid criteria for determining "currently accepted medical use"). A drug will be deemed to have a currently accepted medical use for CSA purposes only if all five of the foregoing elements are demonstrated. The following is a summary of information as it relates to each of these five elements.

1. The drug's chemistry must be known and reproducible

DHHS states that although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted.

DEA notes that in addition to changes due to its own genetic plasticity, marijuana and its chemistry have been throughout the ages, and continue to be, modified by environmental factors and human manipulation (Paris and Nahas, 1984).

2. There must be adequate safety studies

DHHS states that safety studies for acute or subchronic administration of marijuana have been carried out only through a limited number of Phase 1 clinical investigations approved by the FDA. There have been no NDA-quality studies that have scientifically assessed the safety profile of marijuana for any medical condition. DHHS also states that at this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

DHHS further states that it cannot conclude that marijuana has an acceptable level of safety without assurance of a consistent and predictable potency and without proof that the substance is free of contamination.

As discussed in Factors 1 and 2, current data suggest that marijuana use produces adverse effects on the respiratory system, memory and learning. Marijuana use is associated with dependence and addiction. In addition, large epidemiological studies indicate that marijuana use may exacerbate symptoms in individuals with schizophrenia.

Therefore DHHS concludes that, even under medical supervision, marijuana has not been shown to have an accepted level of safety. Furthermore, if marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing, and specifications of marijuana must be developed.

3. There must be adequate and well-controlled studies proving efficacy

DHHS states that no studies have been conducted with marijuana showing efficacy for any indication in controlled, large scale, clinical trials.

To establish accepted medical use, the effectiveness of a drug must be established in well-controlled, well-designed, well-conducted, and well-documented scientific studies, including studies performed in a large number of patients (57 FR 10499, 1992). To date, such studies have not been performed. The small clinical trial studies with limited patients and short duration are not sufficient to establish medical utility. Studies of longer duration are needed to fully characterize the drug's efficacy and safety profile.

Scientific reliability must be established in multiple clinical studies. Furthermore, anecdotal reports and isolated case reports are not adequate evidence to support an accepted medical use of marijuana (57 FR 10499, 1992). The evidence from clinical research and reviews of earlier clinical research does not meet this standard.

As noted, DHHS states that a limited number of Phase I investigations have been conducted as approved by the FDA. Clinical trials, however, generally proceed in three phases. *See* 21 C.F.R. 312.21 (2010). Phase I trials encompass initial testing in human subjects, generally involving 20 to 80 patients. *Id.* They are designed primarily to assess initial safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary studies of potential therapeutic benefit. (62 FR 66113, 1997). Phase II and Phase III studies involve successively larger groups of patients: usually no more than several hundred subjects in Phase II and usually from several hundred to several thousand in Phase III. 21 C.F.R. 312.21. These studies are designed primarily to explore (Phase II) and to demonstrate or confirm (Phase III) therapeutic efficacy and benefit in patients. (62 FR 66113, 1997). No Phase II or Phase III studies of marijuana have been conducted. Even in 2001, DHHS acknowledged that there is "suggestive evidence that marijuana may have beneficial therapeutic effects in relieving spasticity associated with multiple sclerosis, as an analgesic, as an antiemetic, as an appetite stimulant and as a bronchodilator." (66 FR 20038, 2001). But there

is still no data from adequate and well-controlled clinical trials that meets the requisite standard to warrant rescheduling.

DHHS states in a published guidance that it is committed to providing "research-grade marijuana for studies that are the most likely to yield usable, essential data" (DHHS, 1999). DHHS states that the opportunity for scientists to conduct clinical research with botanical marijuana has increased due to changes in the process for obtaining botanical marijuana from NIDA, the only legitimate source of the drug for research in the United States. It further states that in May 1999, DHHS provided guidance on the procedures for providing research-grade marijuana to scientists who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials (DHHS, 1999).

4. The drug must be accepted by qualified experts

A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts (57 FR 10499, 1992). DHHS states that, at this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana, even under conditions where its use is severely restricted. DHHS also concludes that, to date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a "currently accepted

medical use" or a "currently accepted medical use with severe restrictions."

5. The scientific evidence must be widely available

DHHS states that the scientific evidence regarding the safety or efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. As such, there is no opportunity for adequate scientific scrutiny of whether the data demonstrate safety or efficacy. Furthermore, as stated before, there have only been a limited number of small clinical trials and no controlled, large-scale clinical trials have been conducted with marijuana on its efficacy for any indications or its safety.

In summary, from DHHS's statements on the five cited elements required to make a determination of "currently accepted medical use" for marijuana, DEA has determined that none has been fulfilled. A complete scientific analysis of all the chemical components found in marijuana is still missing. There has been no NDA-quality study that has assessed the efficacy and full safety profile of marijuana for any medical use. At this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana. To date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a "currently accepted medical use" or even a "currently accepted medical use with severe restrictions." 21

U.S.C. 812(b)(2)(B)). Additionally, scientific evidence as to the safety or efficacy of marijuana is not widely available.

- *Petitioner's claim of increased recognition by health care professionals and the medical community, including the Institute of Medicine (IOM)*

The petitioner states (pg. 15 line 2), "Cannabis's accepted medical use in the United States is increasingly recognized by healthcare professionals and the medical community, including the Institute of Medicine."

DHHS describes that in February 1997, a National Institutes of Health (NIH)-sponsored workshop analyzed available scientific evidence on the potential utility of marijuana. In March 1999, the Institute of Medicine (IOM) issued a detailed report on the potential medical utility of marijuana. Both reports concluded that there need to be more and better studies to determine potential medical applications of marijuana. The IOM report also recommended that clinical trials should be conducted with the goal of developing safe delivery systems (NIH, 1997; IOM, 1999).

DEA notes that in its recommendations, the 1999 IOM report states,

> If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures.

> Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug but rather to serve as a first step toward the development of nonsmoked rapid-onset cannabinoid delivery systems.

Thus, while the IOM report did support further research into therapeutic uses of cannabinoids, the IOM report did not "*recognize marijuana's accepted medical use*" but rather the potential therapeutic utility of cannabinoids.

DEA notes that the lists presented by the petitioner (pg. 16-18) of "Organizations Supporting *Access* to Therapeutic Cannabis" (emphasis added) and "[Organizations Supporting] No Criminal Penalty" contain a majority of organizations that do not specifically represent medical professionals. By contrast, the petitioner also provides a list of "Organizations Supporting Research on the Therapeutic Use of Cannabis" (emphasis added), which does contain a majority of organizations specifically representing medical professionals.

The petitioner discusses (pg. 20, line 11) the results of a United States survey presented at the annual meeting of the American Society of Addiction Medicine, and states that the study's results, indicate that physicians are divided on the medical use of cannabis (Reuters of 23 April 2001). Researchers at Rhode Island Hospital in Providence asked 960 doctors about their attitude towards the statement, "Doctors should be able to legally prescribe marijuana

as medical therapy." 36 percent of the responders agreed, 38 percent disagreed and 26 percent were neutral.

DEA notes that the results of the study, later published in full (Charuvastra et al., 2005) show that a slight majority of medical doctors polled were opposed to the legalization of medical prescription of marijuana. This supports the finding that there is a material conflict of opinion among medical professionals.

• *Patients' experience in which they reported benefits from smoking marijuana (Exh. C, Section I(3), pg. 22)*;

Under the petition's section C. I. 3., the petitioner proposes both anecdotal self-reported effects by patients and clinical studies. The petitioner states (pg. 22, line 2), [. . .] an increasing number of patients have collected experience with cannabis. Many reported benefits from its use. Some of this experience has been confirmed in reports and clinical investigations or stimulated clinical research that confirmed these patients' experience on other patients suffering from the same disease.

Anecdotal self-reported effects by patients are not adequate evidence for the determination of a drug's accepted medical use. DEA previously ruled in its final order denying the petition of the National Organization for Reform of Marijuana Laws (NORML) to reschedule marijuana from Schedule I to Schedule

II of the Controlled Substances Act (57 FR 10499, 1992) that,

> Lay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in details they cannot be scientifically evaluated, and all other forms of anecdotal proof are entirely irrelevant.

DEA further explained in the same ruling that,

> Scientists call [stories by marijuana users who claim to have been helped by the drug] anecdotes. They do not accept them as reliable proofs. The FDA's regulations, for example, provide that in deciding whether a new drug is a safe and effective medicine, "isolated case reports will not be considered." 21 CFR 314.126(e). Why do scientists consider stories from patients and their doctors to be unreliable?
>
> First, sick people are not objective scientific observers, especially when it comes to their own health. [. . .] Second, most of the stories come from people who took marijuana at the same time they took prescription drugs for their symptoms. [. . .] Third, any mind-altering drug that produces euphoria can make a sick person think he feels better. [. . .] Fourth, long-time abusers of marijuana are not immune to illness.
>
> [. . .] Thanks to scientific advances and to the passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1906, 21 U.S.C. 301 et seq., we now rely on

rigorous scientific proof to assure the safety and effectiveness of new drugs. Mere stories are not considered an acceptable way to judge whether dangerous drugs should be used as medicines.

Thus, patients' anecdotal experiences with marijuana are not adequate evidence when evaluating whether marijuana has a currently accepted medical use.

In summary, marijuana contains some 483 natural constituents and exists in several forms, including dried leaves and flowering tops, hashish and hashish oil. It is generally smoked as a cigarette. Research with marijuana is being conducted in humans in the United States under FDA-authorized IND applications, and using marijuana cigarettes provided by NIDA. Adequate studies have not been published to support the safety and efficacy of marijuana as a medicine. No NDA for marijuana has been submitted to the FDA for any indication and thus no medicinal product containing botanical cannabis has been approved for marketing. DEA notes that state laws do not establish a currently accepted medical use under federal law. Furthermore, DEA previously ruled that anecdotal self-reported effects by patients are not adequate evidence of a currently accepted medical use under federal law. A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At present, there is no consensus of medical opinion concerning medical applications of marijuana. In short, the limited number of clinical trials involving marijuana

that have been conducted to date – none of which have progressed beyond phase 1 of the three phases needed to demonstrate safety and efficacy for purposes of FDA approval – fails by a large measure to provide a basis for any alteration of the prior conclusions made by HHS and DEA (in 1992 and in 2001) that marijuana has no currently accepted medical use in treatment in the United States.

FACTOR 4: ITS HISTORY AND CURRENT PATTERN OF ABUSE

Marijuana use has been relatively stable from 2002 to 2009, and it continues to be the most widely used illicit drug. According to the NSDUH, there were 2.4 million new users (6,000 initiates per day) in 2009 and 16.7 million current (past month) users of marijuana aged 12 and older. Past month use of marijuana was statistically significantly higher in 2009 (16.7 million) than in 2008 (15.2 million), according to NSDUH. An estimated 104.4 million Americans age 12 or older had used marijuana or hashish in their lifetime and 28.5 million had used it in the past year. In 2008, most (62.2 percent) of the 2.2 million new users were less than 18 years of age. In 2008, marijuana was used by 75.7 percent of current illicit drug users and was the only drug used by 57.3 percent of these users. In 2008, among past year marijuana users aged 12 or older, 15.0 percent used marijuana on 300 or more days within the previous 12 months. This translates into 3.9 million people using marijuana on a daily or almost daily basis over a 12-month

period. In 2008, among past month marijuana users, 35.7 percent (5.4 million) used the drug on 20 or more days in the past month.

Marijuana is also the illicit drug with the highest rate of past year dependence or abuse. According to the 2009 NSDUH report, 4.3 million persons were classified with marijuana dependence or abuse based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV).

According to the 2010 Monitoring the Future (MTF) survey, marijuana is used by a large percentage of American youths. Among students surveyed in 2010, 17.3 percent of eighth graders, 33.4 percent of tenth graders, and 43.8 percent of twelfth graders reported lifetime use (i.e., any use in their lifetime) of marijuana. In addition, 13.7, 27.5 and 34.8 percent of eighth, tenth and twelfth graders, respectively, reported using marijuana in the past year. A number of high-schoolers reported daily use in the past month, including 1.2, 3.3 and 6.1 percent of eighth, tenth and twelfth graders, respectively.

The prevalence of marijuana use and abuse is also indicated by criminal investigations for which drug evidences were analyzed in DEA and state laboratories. The National Forensic Laboratory System (NFLIS), which compiles information on exhibits analyzed in state and local law enforcement laboratories, showed that marijuana was the most frequently identified drug from January 2001 through December 2010: In 2010, marijuana accounted for 36.3 percent

(464,059) of all drug exhibits in NFLIS. Similar findings were reported by the System to Retrieve Information from Drug Evidence (STRIDE), a DEA database which compiles information on exhibits analyzed in DEA laboratories, for the same reporting period. From January 2001 through December 2010, marijuana was the most frequently identified drug. In 2010, there were 11,293 marijuana exhibits associated with 7,158 law enforcement cases representing 16.7 percent of all exhibits in STRIDE.

The high consumption of marijuana is being fueled by increasing amounts of domestically grown marijuana as well as increased amounts of foreign source marijuana being illicitly smuggled into the United States. In 2009, the Domestic Cannabis Eradication and Suppression Program (DCE/SP) reported that 9,980,038 plants were eradicated in outdoor cannabis cultivation areas in the United States. Major domestic outdoor cannabis cultivation areas were found in California, Kentucky, Tennessee and Hawaii. Significant quantities of marijuana were also eradicated from indoor cultivation operations. There were 414,604 indoor plants eradicated in 2009 compared to 217,105 eradicated in 2000. Most foreign-source marijuana smuggled into the United States enters through or between points of entry at the United States-Mexico border. However, drug seizure data show that the amount of marijuana smuggled into the United States from Canada via the United States-Canada border has risen to a significant level. In

2009, the Federal-wide Drug Seizure System (FDSS) reported seizures of 1,910,600 kg of marijuana.

While most of the marijuana available in the domestic drug markets is lower potency commercial-grade marijuana, usually derived from outdoor cannabis grow sites in Mexico and the United States, an increasing percentage of the available marijuana is high potency marijuana derived from indoor, closely controlled cannabis cultivation in Canada and the United States. The rising prevalence of high potency marijuana is evidenced by a nearly two-fold increase in average potency of tested marijuana samples, from 4.87 percent $\triangle^9$-THC in 2000 to 8.49 percent $\triangle^9$-THC in 2008.

In summary, marijuana is the most commonly used illegal drug in the United States, and it is used by a large percentage of American high-schoolers. Marijuana is the most frequently identified drug in state, local and federal forensic laboratories, with increasing amounts both of domestically grown and of illicitly smuggled marijuana. An observed increase in the potency of seized marijuana also raises concerns.

* * *

DETERMINATION

After consideration of the eight factors discussed above and of DHHS's recommendation, DEA finds that marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1):

1. Marijuana has a high potential for abuse

Marijuana is the most highly abused and trafficked illicit substance in the United States. Approximately 16.7 million individuals in the United States (6.6 percent of the United States population) used marijuana monthly in 2009. A 2009 national survey that tracks drug use trends among high school students showed that by 12th grade, 32.8 percent of students reported having used marijuana in the past year, 20.6 percent reported using it in the past month, and 5.2 percent reported having used it daily in the past month. Its widespread availability is being fueled by increasing marijuana production domestically and increased trafficking from Mexico and Canada.

Marijuana has dose-dependent reinforcing effects that encourage its abuse. Both clinical and preclinical studies have clearly demonstrated that marijuana and its principle psychoactive constituent, $\triangle^{9}$-THC, possess the pharmacological attributes associated with drugs of abuse. They function as discriminative stimuli and as positive reinforcers to maintain drug use and drug-seeking behavior.

Significant numbers of chronic users of marijuana seek substance abuse treatment. Compared to all other specific drugs included in the 2008 NSDUH survey, marijuana had the highest levels of past year dependence and abuse.

2. Marijuana has no currently accepted medical use in treatment in the United States

DHHS states that the FDA has not evaluated nor approved an NDA for marijuana. The long-established factors applied by DEA for determining whether a drug has a "currently accepted medical use" under the CSA are as follows. A drug will be deemed to have a currently accepted medical use for CSA purposes only if all of the following five elements have been satisfied. As set forth below, none of these elements has been fulfilled:

i. The drug's chemistry must be known and reproducible

Although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted. Furthermore, many variants of the marijuana plant are found due to its own genetic plasticity and human manipulation.

ii. There must be adequate safety studies

Safety studies for acute or sub-chronic administration of marijuana have been carried out through a limited number of Phase I clinical investigations approved by the FDA, but there have been no NDA-quality studies that have scientifically assessed the full safety profile of marijuana for any medical condition. Large, controlled studies have not been conducted to evaluate the risk-benefit ratio of marijuana

use, and any potential benefits attributed to marijuana use currently do not outweigh the known risks.

iii. There must be adequate and well-controlled studies proving efficacy

DHHS states that there have been no NDA-quality studies that have scientifically assessed the efficacy of marijuana for any medical condition. To establish accepted medical use, the effectiveness of a drug must be established in well-controlled, well-designed, well-conducted, and well-documented scientific studies, including studies performed in a large number of patients. To date, such studies have not been performed for any indications.

Small clinical trial studies with limited patients and short duration are not sufficient to establish medical utility. Studies of longer duration are needed to fully characterize the drug's efficacy and safety profile. Scientific reliability must be established in multiple clinical studies. Anecdotal reports and isolated case reports are not sufficient evidence to support an accepted medical use of marijuana. The evidence from clinical research and reviews of earlier clinical research does not meet the requisite standards.

iv. The drug must be accepted by qualified experts

At this time, it is clear that there is no consensus of opinion among experts concerning medical applications of marijuana. To date, research on the medical

use of marijuana has not progressed to the point that marijuana can be considered to have a "currently accepted medical use" or a "currently accepted medical use with severe restrictions.

v. The scientific evidence must be widely available

DHHS states that the scientific evidence regarding the safety and efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. In addition, as noted, there have only been a limited number of small clinical trials and no controlled, large scale, clinical trials have been conducted with marijuana on its efficacy for any indications or its safety.

3. There is a lack of accepted safety for use of marijuana under medical supervision

At present, there are no FDA-approved marijuana products, nor is marijuana under NDA evaluation at the FDA for any indication. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. The Center for Medicinal Cannabis Research in California, among others, is conducting research with marijuana at the IND level, but these studies have not yet progressed to the stage of submitting an NDA. Current data suggest that marijuana use produces adverse effects on the respiratory system, memory and learning.

Marijuana use is associated with dependence and addiction. In addition, very large epidemiological studies indicate that marijuana use may be a causal factor for the development of psychosis in individuals predisposed to develop psychosis and may exacerbate psychotic symptoms in individuals with schizophrenia. Thus, at this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy. In sum, at present, marijuana lacks an acceptable level of safety even under medical supervision.

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 11-1265 **September Term, 2012**

DEA-76FR40552

Filed On: April 15, 2013

Americans for Safe Access, et al.,

Petitioners

v.

Drug Enforcement Administration,

Respondent

Carl Eric Olsen,
Intervenor

BEFORE: Garland, Chief Judge, Henderson, Circuit Judge, and Edwards, Senior Circuit Judge

ORDER

Upon consideration of petitioners' corrected petition for panel rehearing filed on March 27, 2013, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Jennifer M. Clark
Deputy Clerk

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v.

Drug Enforcement Administration,

Respondent

Carl Eric Olsen,
Intervenor

BEFORE: Garland, Chief Judge, and Henderson, Rogers, Tatel, Brown, Griffith, and Kavanaugh, Circuit Judges, and Edwards, Senior Circuit Judge

ORDER

Upon consideration of petitioners' corrected petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Jennifer M. Clark
Deputy Clerk

21 U.S.C.A. § 801

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

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21 U.S.C.A. § 811

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule –

(1) add to such a schedule or transfer between such schedules any drug or other substance if he –

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, 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. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed.

The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The 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. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall 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.

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21 U.S.C.A. § 877

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

U.S. Supreme Court Skirts Review of Marijuana's Medical Use, While Millions of Patients Are Still Denied Helpful Treatment

October 10, 2013 | Kris Hermes

Earlier this week, the U.S. Supreme Court refused to review an appeal of marijuana's federal classification as a dangerous drug with no medical value. While this came as no surprise to advocates, including the plaintiff Americans for Safe Access (ASA), the federal government continues to deny millions of Americans legal access to a valuable medicine for political reasons.

ASA, as part of the Coalition for Rescheduling Cannabis (CRC), filed a petition in 2002 to reclassify marijuana for medical use. After 9 years of hearing nothing from the federal government and faced with a lawsuit for unreasonable delay, the Drug Enforcement Administration (DEA) denied the petition based on a purported lack of evidence of medical efficacy. The more than 200 peer-reviewed, double-blind, placebo-controlled studies were apparently not enough for the Obama Administration.

The silver lining in the government's refusal to recognize marijuana's medical value was that for the first time in 20 years, the issue of marijuana's classification was again brought into federal court. The D.C. Circuit, where ASA v. DEA was heard, granted the plaintiffs standing to bring such an appeal but unfortunately denied the case on its merits. In so doing, the D.C. Circuit established a brand new precedent, requiring petitioners to obtain evidence from Phase II and III clinical trials to prove medical efficacy, a ruling that conflicts with the First Circuit in Grinspoon v. DEA, 828 F.2d 881 (1st Cir. 1987). The First Circuit held that the DEA cannot treat a lack of FDA marketing approval as conclusive evidence that a substance has no "currently accepted medical use in treatment in the United States." The Grinspoon Court also held that for some drugs (like smoked marijuana):

[T]here is no economic or other incentive to seek interstate marketing approval ... because [they] cannot be patented and exploited commercially.

This week's refusal by the U.S. Supreme Court to rule on marijuana's federal reclassification comes less than three months after a writ of certiorari was filed with the High Court seeking review. The appeal was not only based on a clear conflict with Grinspoon, but also a failure by the D.C. Circuit to review marijuana's abuse potential, which is currently considered as harmful as heroin and PCP and even more harmful than methamphetamine, cocaine and opium.

Despite the closure of this chapter in the history of rescheduling cannabis, the struggle is far from over. There are a number of ways the federal government can take action to reclassify this important medicine. HR 689, the States' Medical Marijuana Prevention Act, which would move marijuana out of Schedule I, was introduced earlier this year and is currently pending in Congress. The Justice Department, which recently issued its third directive to scale back on federal marijuana enforcement, could at any time reclassify cannabis for medical use. Even President Obama could issue an Executive Order to reschedule marijuana. But, it's going to require the federal government to recognize the mountain of scientific evidence and align with the overwhelming popular support for medical marijuana to make it happen.

In the meantime, the governors of four states -- Colorado, Rhode Island, Vermont and Washington -- have filed their own petitions to reclassify marijuana for medical use. However it happens, though, hundreds of thousands of patients will be on the front lines in the effort to bring sanity to the country's public health policy. We're not going away.