No. 11-1265

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICANS FOR SAFE ACCESS, *et al.*,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

PETITIONERS' OPENING BRIEF

JOSEPH D. ELFORD (CA SBN 189934)
AMERICANS FOR SAFE ACCESS
1322 Webster Street, Suite 402
Oakland, CA 94612
(415) 573-7842

Counsel for Petitioners

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28, petitioners report that they consist of Americans for Safe Access ("ASA"), William Britt ("Britt"), the Coalition to Reschedule Cannabis ("CRC"), Kathy Jordan ("Jordan"), Michael Krawitz ("Krawitz"), and Patients Out of Time ("POT"), Rick Steeb ("Steeb") (collectively "petitioners").

Respondents are the Drug Enforcement Administration ("DEA") and Eric Holder, United States Attorney General ("Holder") (collectively "respondents").

There are no rulings under review or related cases pending at this time; however, the administrative order under review to deny marijuana rescheduling was prompted by an action in this Court for unreasonable delay filed by petitioners. *See In re: Coalition to Reschedule Cannabis*, No. 11-5121 (D.C. Cir. 2011). Petitioners respecfully request that this case be assigned to that panel.

DATED: January 23, 2012

/s/ Joseph D. Elford
Joseph D. Elford

Counsel for Petitioners

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, petitioners report that they are non-profit corporations and individuals that do not have parent corporations.

DATED: January 23, 2012

/s/ Joseph D. Elford
Joseph D. Elford

Counsel for Petitioners

INTRODUCTION

The federal government has sought and obtained a patent for the medical use of cannabinoids; yet, it claims in these proceedings that marijuana has *no* medical use. There are numerous peer-reviewed studies establishing that marijuana is effective in treating AIDS wasting syndrome, muscle spasticity, emesis, appetite loss, negative side effects of chemotherapy, and chronic pain, as several of the government's own Commissions and Administrative Law Judges 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. It does not require an expert in marijuana to recognize, although there are many of them, such obvious untruths.

The Drug Enforcement Administration ("DEA") and the Department of Health and Human Services ("HHS"), the federal decisionmakers in this process, will, no doubt, argue that their decisionmaking is entitled to extreme deference, which insulates them from this Court's scrutiny. Deference to agency decisionmaking, however, extends only so far. It does not give the DEA or HHS an unfettered license to apply different criteria to marijuana than to other drugs, ignore critical scientific data, misrepresent social science research, or rely upon unsubstantiated assumptions, as the DEA has done in this case. The CSA and the Administrative Procedures Act ("APA"), as well as due process and fundamental fairness, require the DEA to analyze the scientific data objectively and evenhandedly. Its failure to do so with regard to marijuana is arbitrary and capricious, requiring a remand to the DEA for a hearing and the issuance of findings based on the scientific record.

JURISDICTIONAL STATEMENT

This Court's jurisdiction arises from its statutory authority under 21 U.S.C. § 877 to review "[a]ll final determinations, findings, and conclusions" of the government in relation to rescheduling petitions. On October 9, 2002, petitioners Americans for Safe Access ("ASA"), William Britt ("Britt"), Coalition to Reschedule Cannabis ("CRC"), Cathy Jordan ("Jordan"), Patients Out of Time ("POT"), Rick Steeb ("Steeb"), and Michael Krawitz ("Krawitz") (collectively

"petitioners") petitioned the Drug Enforcement Administration ("DEA") to intiate rulemaking proceedings to reschedule marijuana, pursuant to 21 U.S.C. § 811(a). AR (A.1). After the DEA denied this petition by letter dated June 21, 2011, as published at 76 Fed.Reg. 40552 (July 8, 2011), petitioners timely filed a Petition for Review in this Court on July 21, 2011, pursuant to 21 U.S.C. § 877. Venue is proper in this Court under 21 U.S.C. § 877.

STANDING

Petitioners have Article III standing to seek judicial review of the findings of the DEA both as individuals and based on principles of organizational standing. To establish organizational standing to sue on its own behalf under Article III, an organization needs to show that it has suffered an actual or threatened injury in fact that is fairly traceable to the alleged illegal action and is likely to be redressed by a favorable court decision. *See Valley Forge Christian College v. Americans United for Separation of Church and State*, *Inc.*, 454 U.S. 464, 572 (1982). One way that an organization meets the requisites for Article III injury is if it alleges that purportedly illegal action increases the resources the group must devote to its substantive programs, excluding the costs of its suit challenging the defendants' actions. *See Havens Realty Corp. v. Coleman*, 455 U.S. 362, 379 (1982); *Fair Housing of Marin v. Combs*, 285 F.3d 899, 905 (9th Cir. 2002). ASA has established such injury here, as it has submitted evidence that it has expended

significant resources combatting the DEA's positions respecting marijuana's medical use and abuse potential, which would be redressed by a favorable decision. *See* Sherer Aff.; *cf. Fair Housing*, 285 F.3d at 905 (holding such injury sufficient to confer Article III standing). Reversal of the DEA's denial of the rescheduling Petition would reduce ASA's expenditure of funds and foster its mission, so it has Article III standing. *See Havens*, 455 U.S. at 379; *cf. Central Alabama Fair Housing Center, Inc. v. Lowder Realty Co., Inc.*, 236 F.3d 629, 643 (11th Cir. 2000) (holding that fair housing organization had standing to recover in its own right for the diversion of its resources to combat defendant's discrimination). ASA also has standing on behalf of its members because they are deterred from cultivating the medicine they need for fear of a federal criminal proseuction, but they would not feel so deterred if marijuana were rescheduled. Britt Aff.; Krawitz Aff. Sherer Aff.; Steeb Aff.; *see Brady Campaign to Prevent Gun Violence v. Salazar*, 612 F.Supp.2d 1, 28 (D.D.C. 2009); *cf. United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) (holding that medical marijuana patients may not interpose medical necessity defense because it is a Schedule I substance).

The individually named petitioners, who are members of ASA and POT, also have standing on their own. *See* Britt Aff.; Krawitz Aff.; Sherer Aff.; Steeb Aff. Each of these individually named petitioners suffers from serious medical

conditions that could be aided by the use of marijuana for medical purposes, but they are deterred from obtaining the medicine they need by the government's arbitrary and capricious scheduling determination. *See* Britt Aff.; Krawitz Aff.; Sherer Aff.; Steeb Aff.. A recheduling of marijuana in accordance with the provisions of CSA would allow these patients an opportunity to obtain a sufficient amount of marijuana to treat their medical conditions. *See* Britt Aff.; Krawitz Aff.; Steeb Aff. They would no longer be deterred from culivating their own medicine by draconian federal penalties, since they would likely be afforded a medical necessity defense in federal court. *See* Britt Aff.; Krawitz Aff.; Sherer Aff.; Steeb Aff. *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). They would also no longer be deterred by the government's false statements that marijuana lacks any medical efficacy, as many do now. *See* Sherer Aff. All of these organizational and individual interests are within the intersts served by the CSA, as this Act was designed to promote the "health and general welfare of the American people," 21 U.S.C. § 801(1), and allows "any interested party" to file for relief in this Court, *see* 21 U.S.C. § 877.

ISSUES PRESENTED FOR REVIEW

1. Did the DEA act arbitrarily and capriciously, and without substantial evidence, in deviating from its own regulatory criteria and ignoring numerous

studies submitted by petitioner demonstrating that marijuana has various accepted medical uses to conclude that it does not?

2. Did the DEA act arbitrarily and capriciously, and without substantial evidence, in failing to perfrom the required relative comparisons to other scheduled substances to conclude that marijuana has a "high" abuse potential that is even higher than methamphetamine and cocaine?

3. Did the DEA act arbitrarily and capriciously in failing to hold a hearing or take additional evidence after it delayed for nearly eleven years in denying the rescheduling Petition?

STATEMENT OF THE CASE

The CRC filed the instant rescheduling Petition 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. AR (A.1); 76 Fed.Reg. 40552, 40566 (July 8, 2011). The DEA accepted the Petition for filing on April 3, 2003. AR (A.3); 76 Fed.Reg. 40552, 40566 (July 8, 2011). 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). AR (A.9); 76 Fed.Reg. 40552, 40566 (July 8, 2011). HHS provided its scientific and

medical evaluation to DEA on December 6, 2006. AR (A.10); 76 Fed.Reg. 40552, 40566 (July 8, 2011). Based on HHS' scientific evaluation and recommendation and its consideration of additional evidence it selected, the DEA denied the Petition to reschedule marijuana on July 8, 2011. 76 Fed. Reg. 40522, 40567 (July 8, 2011). Petitioners timely filed the instant petition under 21 U.S.C. § 877 on July 21, 2011, to challenge this erroneous determination.

STATEMENT OF FACTS

I. THE CONTROLLED SUBSTANCES ACT

A. The Initial Placement of Marijuana in Schedule I

When Congress enacted the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA"), in 1970, it explicitly recognized that "[m]any 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." 21 U.S.C. § 801(1). It also sought to "control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. 1, 12-13 (2005); *see* 21 U.S.C § 801. To these ends, Congress classified substances under the CSA into five schedules based on their: (1) relative abuse potential, (2) medical utility, 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 (1) that have the highest potential for abuse, (2) no currently accepted medical use and (3) lack safe use

under medical supervision. 21 U.S.C. § 812(b)(1); *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937 (D.C. Cir. 1991) ("Schedule I drugs are subject to the most severe controls and give rise to the harshest penalties for violations of these controls; they are deemed to be the most dangerous substances, possessing no redeeming value as medicines"). These most restricted substances may only be used for research purposes under strict guidelines. 21 U.S.C. § 823. The government classifies marijuana as a Schedule I substance. 21 U.S.C. § 812(b); 21 C.F.R. § 1308.11.

In initially placing marijuana in Schedule I when enacting the CSA in 1970, Congress did not make any specific findings regarding marijuana as medicine or its relative abuse potential. To the contrary, the House Report recommending marijuana's initial placement in Schedule I reveals Congress' uncertainty about the harms associated with marijuana and its medical benefits -- "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[1] be retained within

[1] "Marihuana" is the older spelling for "marijuana." Unless used in a title or quotation, the more conventional spelling "marijuana" will be used throughout this brief. Also, "marijuana" and "cannabis" are the same and will be used interchangeably.

Schedule I at least until the completion of certain studies now underway to resolve this issue." H.R. Rep. No. 91-1444, Pub. L. No. 91-513, 1970 U.S.C.C.A.N. 4566, 4629 (quoting letter from Roger Egeberg, M.D.O. to Hon. Harley O. Staggers, dated August 14, 1970); *NORML v. Ingersoll*, 497 F.2d 654, 657 (D.C. Cir. 1974); *see also Gonzales v. Raich*, 545 U.S. 1, 14 & n.22 (2005). Congress recognized at that time that "[t]he extent to which marihuana should be controlled is a subject upon which opinions diverge widely." H.R. Rep. No. 91-1444, Pub. L. NOo 91-513, 1970 U.S.C.C.A.N. 4566, 4629

As an interim solution, Congress tentatively 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, Pub. L. No. 91-513, 1970 U.S.C.C.A.N. 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"). Furthermore, just prior to the passage of the CSA, Congress enacted the "Marihuana and Health Reporting Act," Pub. L. No. 91-296,

§§ 501-503, 1970 U.S.C.C.A.N. at p. 418, which directed the Secretary of the Department of Health, Education and Welfare ("HEW") to prepare a report within 90 days and annually thereafter "containing current information on the health consequences of using marihuana." *Id.; see also NORML v. DEA*, 559 F.2d 735, 737-38 (D.C. Cir. 1977) ("Recognizing that the results of continuing research might cast doubt on the wisdom of initial classification assignments, Congress created a procedure by which changes in scheduling could be effected") (footnote omitted); *Ingersoll*, 497 F.2d at 656 ("Congress contemplated that the classification set forth in the [CSA] as originally passed would be subject to continuing review by executive officials").

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 use. *See* AR (B.112 at 152-53). Despite Congress' expectation when it passed the CSA that the "Commission's recommendations 'will be of aid in determining the appropriate disposition of this question in the future," *Ingersoll*, 497 F.2d at 657 (quoting H.R.Rep. No. 91-1444 (Part 1), 91st Cong., 2d Sess. (1970) at p. 13 U.S.C.C.AN. at p. 4579 (1970)), this recommendation by an impartial committee convened by the government would, as would become a distirbing pattern, be simply ignored by the federal government. *See also NORML v. DEA*, 559 F.2d at 752 ("A recent report of a federal panel

representing, *inter alia*, HEW, DEA, the State Department, and the White House, concluded that marihuana use entails a 'relatively low social costs,' and suggested that decriminalization be considered") (citation omitted).[2]

B. The Rescheduling Process

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. §

[2] 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., Watson, Stanley J. and Benson, Jr., John A. (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 AR (B.112)). 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).

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 substance 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 substance in accordance with 21 U.S.C. § 811(a), the DEA 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). The evaluation and recommendations of HHS are binding on the DEA Administrator with respect to scientific and medical matters. *See* 21 U.S.C. § 811(b).

Following 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); *see* 21 C.F.R. § 1308.43(e).

II. PAST RESCHEDULING PETITIONS

A. The NORML and Alliance for Cannabis Therapeutics Petition (1972)

Soon after the enactment of the CSA, in 1972, the National Organization for the Reform of Marijuana Laws ("NORML"), later joined by the Alliance for Cannabis Therapeutics ("ACT"), filed the first marijuana rescheduling petition, requesting that marijuana either be removed entirely from the CSA or transferred to Schedule V. That petition, which remained in the DEA's bureaucratic grasp for approximately 22 years, required this Court's review no less than five times. *See ACT v. DEA,* 15 F.3d 1131, 1133-34 (D.C. Cir. 1994); *ACT v. DEA*, 930 F.2d 936 (D.C. Cir. 1991); *NORML v. DEA & Dep't of Health Education and Welfare,* No. 79-1660 (D.C. Cir. Oct. 16, 1980); *NORML v. DEA*, 559 F.2d 735 (D.C. Cir. 1977). This Court added in one of those cases: "We regrettably find it necessary to remind respondents of an agency's obligation on remand not to 'do anything which is contrary to either the letter or spirit of the mandate construed in the light of the opinion of [the] court deciding the case.'" *NORML v. DEA & Dep't of*

Health Education and Welfare, No. 79-1660 (D.C. Cir. Oct. 16, 1980) (quotation omitted).

Initially, the government refused even to accept the petition for filing, contending that it "was not authorized to institute proceedings for the rule requested" because of the Single Convention on Narcotic Drugs. *NORML v. Ingersoll*, 497 F.2d at 656 (citing 18 U.S.C. § 1407). This Court held that that this rejection of the rescheduling petition was erroneous and it remanded the matter to the DEA for a decision on the merits. *Id.* at 661.

Early in that process, the Administrator took the position that "no matter the weight of the scientific or medical evidence which petitioners might adduce, the Attorney General could not remove marihuana from Schedule I." *NORML v. DEA*, 559 F.2d at 743 (quoting 40 Fed. Reg. 44167 (1975)). Relying on a conclusory one-page letter from the Acting Secretary of HHS that there "is currently no accepted medical use of marihuana in the United States," the Administrator declined to reclassify marijuana. *See id.* at 749. This Court, though, was not satisfied and it acknowledged the possible uses of marijuana to treat glaucoma, asthma, epilepsy, as well as the provision of "needed relief for cancer patients undergoing chemotherapy" -- all of which this Court described as "promising." *Id.; see also* 76 Fed. Reg. 40552, 40579 (July 8, 2011) ("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'") (quoting 66 Fed. Reg. 20038 (2001)). "[R]ecognizing that it is our obligation as a court to ensure that the agency acts within statutory bounds," this Court remanded the case for further findings from the Secretary of HHS consistent with his statutory obligations. *NORML v. DEA*, 559 F.2d at 749 & n.64 ("Courts must be vigilant to ensure that the agency's procedures and underlying standards are in accord with the law: 'Reviewing courts are not obliged to stand aside and rubber-stamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute'") (quoting NLRB v. Brown, 380 U.S. 278, 291 (1965)).

After repeated delays by the DEA and HEW, which prompted this Court to order both the DEA and HEW to file quarterly progress reports with the Court, *id.* at 750, the DEA conducted two years of administrative hearings before Administrative Law Judge ("ALJ") Francis L. Young ("Young") commencing in 1986. These court-ordered hearings featured the testimony of patients, physicians, and researchers, as well as voluminous scientific and medical data. At their conclusion, ALJ Young strenuously recommended that marijuana be reclassified, declaring as follows:

> The evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very

> ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.

Francis L. Young, DEA Administrative Law Judge, *Marijuana Rescheduling Petition*, No. 86-22 (DEA Sept. 6, 1988) [found at www.ukcia.org/pollaw/lawlibrary/young.php]. The DEA, nevertheless, rejected the ALJ's recommendation and denied the rescheduling petition. *See ACT,* 15 F.3d at 1133-34. The DEA has made it clear that it will not be swayed by the judgment of medical professionals.

B. The Gettman Petition (1995)

Three years after the DEA denied the NORML petition, in July of 1995, Jon Gettman ("Gettman") filed an administrative petition with the DEA claiming that marijuana lacks the requirements necessary for Schedule I or Schedule II classification. Unlike the previous petition challenging marijuana's placement in Schedule I on grounds of medical efficacy, Gettman's 1995 petition challenged the classification of marijuana in Schedule I based on its relative abuse potential. That rescheduling petition took more than six years to work its way through the rescheduling process before it, too, was finally denied. *See Gettman v. DEA,* 290 F.3d 430 (D.C. Cir. 2002). This Court refused to review the substance of this petition on standing grounds. *Id.*

C. The Instant CRC Rescheduling Petition (2002)

The instant marijuana rescheduling petition ("Petition") (AR (A.1)), was filed on October 9, 2002 by the Coalition to Reschedule Cannabis ("CRC"), which is comprised of medical marijuana patients, medical marijuana patient organizations, physicians, other advocacy organizations, and several of the individually named petitioners. *See* 76 Fed. Reg. 40552, 40566 (July 8, 2011). Drawing on advances in science since the filing of the 1995 rescheduling petition, the CRC filed the instant rescheduling Petition, which cites more than two hundred studies emerging since 1994, to enable current and potential medical marijuana patients to obtain the medicine they need to alleviate their suffering. *See* AR (A.2). The Petition requested that marijuana be rescheduled to Schedule III, IV, or V under the CSA on the grounds that: (1) marijuana does have accepted medical uses in the United States; (2) is safe for use under medical supervision and has an abuse potential lower than Schedule I and II drugs; and (3) it has a dependence liability that is also lower than Schedule I or II drugs. 76 Fed. Reg. 40552, 40566 (July 8, 2011). For some unknown reason, the DEA waited four months before it accepted the Petition for filing on April 3, 2003. *See* AR (A.2 & A.3).

After years of evasion and delay, HHS' sub-agency, the Food and Drug Administration ("FDA"), issued its scientific and medical evaluation and scheduling recommendation to the DEA on January 12, 2007. AR (A.10). The

DEA, however, did not give a final determination on the rescheduling Petition at that time or any time soon thereafter, which propted the petitioners to file a petition for unreasonable agency delay in this Court on May 23, 2011. *See In re: Coalition to Reschedule Cannabis*, No. 11-5121 (D.C. Cir. 2011). Rather than respond to this lawsuit, the DEA denied the rescheduling petition by letter dated June 21, 2011, as published at 76 Fed. Reg. 40552 (July 8, 2011). It concluded that "[l]ittle has changed since 1992" and the "existing clinical evidence is not adequate to warrant rescheduling under the CSA." 76 Fed. Reg. 40552, 40567 (July 8, 2011). This Petition to challenge the merits of those determinations followed.

SUMMARY OF THE ARGUMENT

Numerous peer-reviewed scientific studies demonstrate that marijuana is efffective in treating various medical conditions, but the DEA simply ignores them to conclude that marijuana should remain in Schedule I. Aside from its contention that marijuana has no medical use, the DEA also claims that marijuana has a high potential for abuse, even higher than that of methamphetamine and cocaine. Several federal commissions and administrative law judges have recommended that marijuana be rescfheduled, but the DEA nad HHS choose, instead, to disregard their informed evaluations and maintain marijuana in Schedule I. To obtain this seemingly preordained outcome, the DEA and HHS deviate from the criteria they ordinarily apply to assess medical efficacy and abuse potential. This is arbitrary

and capricious. *Ee, e.g., Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C.Cir.1996) (collecting cases).

Making matters worse, the DEA inexplacably dragged its feet in ruling upon the instant rescheduling Petition, and issued its denial of this Petition only after petitioners compelled it to do so by filing a lawsuit in this Court contending unreasonable agency delay. *See In re: Coalition to Reschedule Cannabis*, No. 11-5121 (D.C. Cir. 2011). This inexplicable delay by the DEA and HHS deprived petitioners a meaningful opportunity to respond to new evidence presented in HHS' scheduling determination, so a remand is necessary to restore due process.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews the DEA's interpretation of the CSA pursuant to the two-step analysis set forth in *Chevron U.S.A., Inc. v. Naurual Resources Defense Council, Inc.,* 467 U.S. 837 (1984). *See Doe v. DEA*, 484 F.3d 561, 570 (D.C. Cir. 2007). *First*, if the intent of Congress is clear, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. In other words, a reviewing court does not defer to an agency's interpretation of its own regulation when an alternative interpretation "is compelled by the regulation's plain language." *Thomas Jefferson Univ. v. Shalala,* 512 U.S. 504, 512 (1994).

Second, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. In the latter case, the court defers to the agency's interpretation of the statute only if the interpretation is "'reasonable' and not otherwise 'arbitrary, capricious, or manifestly contrary to the statute'" and reflects "fair and considered judgment." *Motion Picture Ass'n of Am., Inc. v. FCC,* 309 F.3d 796, 801 (D.C. Cir. 2002) (quoting *Chevron,* 467 U.S. at 842-43)); *Akzo Nobel Salt, Inc. v. Fed. Mine Safety & Health Review Comm'n,* 212 F.3d 1301, 1304 (D.C. Cir. 2000). "[W]here an agency departs from established precedent without a reasoned explanation, its decision will be vacated as arbitrary and capricious." *ANR Pipeline Co. v. FERC*, 71 F.3d 897, 901 (D.C. Cir. 1995); *accord Northern California Power Agency v. FERC*, 37 F.3d 1517, 1522 (D.C. Cir. 1994). "Courts must be vigilant to ensure that the agency's procedures and underlying standards are in accord with the law: 'Reviewing courts are not obligated to stand aside and rubber-stamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute.'" *NORML v. DEA*, 559 F.2d at 750 (quotation and citation omitted).

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II. THE DEA ACTED ARBITRARILY AND CAPRICIOUSLY, AND WITHOUT SUBSTANTIAL EVIDENCE, IN CONCLUDING THAT MARIJUANA DOES NOT HAVE A "CURRENTLY ACCEPTED MEDICAL USE IN TREATMENT IN THE UNITED STATES"

To warrant placement of a substance in the most restrictive of schedules, Schedule I, the CSA requires that a substance not have a "currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B) *see NORML v. DEA*, 559 F.2d 753 (1977). The CSA, however, does not define the phrase "currrently accepted," which the DEA and HHS have seized upon to ignore medical acceptance by the medical community and scientific evidence because these seemingly obvious indications of accepted medical use do not fit neatly into the agencies' overly rigid criteria. Making matters worse, when this distortion of the administrative review process does not serve the DEA's goal of maintaning marijuana in Schedule I, the agency simply deviates from the criteria it has applied to other substances to reach its predetermined outcome. Numerous authorities have held that such deviation from established criteria is arbitrary and caricious. *See infra*.

A. The DEA Deviated from the Statutory Language and Its Own Regulation When It Erroneously Found that Marijuana Does Not Have a "Currently Accepted" Medical Use Because There Is Not a "Consensus" of Medical Opinion

Inexplicably, the DEA and HHS deviate from their own regulations when they found that "[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." 76 Fed. Reg. 40552, 40562 (July 8, 2011); *accord* 76 Fed. Reg. 40552, 40585 (July 8, 2011) (DEA concluding: "At this time, it is clear there is no consensus of opinion among experts concerning medical applications of marijuana."). This is not the standard announced by the DEA and HHS for accepted medical use, which requires only that "[t]he drug must be accepted by qualified experts." 76 Fed. Reg. 40552, 40579 (July 8, 2011); 57 Fed. Reg. 10,499, 10,506 (1992), see *ACT*, 15 F.3d at 1135. The agencies' application of a much more rigorous standard for medical acceptance when it comes to marijuana than is stated in the HHS regulations is arbitrary and capricious as a matter of law -- "A long line of precedent has established that an agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently." *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C.Cir.1996) (collecting cases); *see Airmark Corp.,* 758 F.2d at 692 (vacating exemption rulings as arbitrary due to failure of agency to provide consistent criteria to all petitioners; "At the very least, 'an agency ... must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored'") (quotation omitted); *cf. D&F Afonso Realty Trust v. Garvey,* 216 F.3d 1191, 1195 (D.C. Cir. 2000) ("we conclude that the FAA acted arbitrarily by issuing a hazard

determination inconsistent with established standards"); *see also Northern California Power Agency v. FERC,* 37 F.3d 1517, 1522 (D.C.Cir.1994) ("agency acts arbitrarily when it departs from its precedent without giving any good reason"); *United States v. Diapulse Corporation of America*, 748 F.2d 56, 62 (D.C. Cir. 1984) ("we must insist that the FDA apply its scientific conclusions evenhandedly"); *Etelson v. Office of Pers. Mgmt*., 684 F.2d 918, 926 (D.C. Cir. 1982) (noting that varying treatments of similarly situated people occur when the government acts arbitrarily); Friendly, Henry, J., *Indiscretion About Discretion*, 31 EMORY L.J. 747, 758 (1982) (referring to the above requirement to treat similar cases alike as "the most basic principle of jurisprudence").[3]

As noted, the CSA requires that a substance have a "currently accepted" medical use, which means "generally approved" or "generally agreed upon." *See*

[3] One legal scholar described the importance of consistency in administrative decisionmaking as follows:

> Consistency is widely regarded as being of great importance in legal systems in general and in administrative law in particular. The requirement that administrative agencies act consistently is related to the prerequisite under which similar cases should be treated alike; to due process requirements; to the fundamental values of equality, fairness, impartiality and evenhandedness in law enforcement; and to the integrity of legal systems under the idea of the rule of law. It is also intertwined with the need to protect the reliance interests of those who are influenced by governmental actions.

Dotan, Yoav, *Making Consistency Consistent*, 57 ADMIN. L. REV. 995, 996 (2005).

Grinspoon v. DEA, 828 F.2d 881, 886 (1st Cir. 1987). Based on this statutory language, HHS' own regulations require only that a "drug is accepted by qualified experts" to qualify for acceptance in the medical community, 66 Fed. Reg. 20037, 20052 (April 18, 2001), not that there must be a unanimity, or "consensus," of opinion, as the DEA has required here. *Cf. United States v. Articles of Drug Consisting of Following: 5,906 Boxes*, 745 F.2d 105, 120 n.22 (1st Cir. 1984) ("It is by now clear that unanimity among experts is not required to demonstrate 'general' recognition' in the scientific community") (citing *United States v. Articles of Food and Drug Consisting of Coli-Trol 80,* 618 F.2d 743, 746 (5th Cir. 1975); *United States v. Articles of Drag Labeled "Quick-O-Ver"*, 274 F.Supp. 443, 448 n.7 (D. Md. 1967)). The DEA acted arbitrarily and capriciously in engrafting upon § 812(b)(1)(B) a requirement that there must be a consensus of medical opinion not found in its own regulations. Numerous authorities have held such differential administrative treatmnet to be arbitrary and unreasonable. *See* cases cited *supra*; *cf.* Davis, Kenneth Culp & Pierce, Jr., Richard J., *Administrative Law Treatise*, § 11.5, at 204 (3d ed. 1994) (noting that agencies that fail to adequately explain their departure from precedent act in an "arbitrary and capricious [manner]"); Dotan, *supra* at 996 ("Under the idea of the rule of law, administrative decisions are expected to be made with reference to a system of clearly stated, previously established, and publicly promulgated set of legal rules and principles--

in a fashion that preserves the coherence and predictability of the process of decisionmaking. [Footnote omitted] Inconsistency in administrative decisionmaking (that is, where agencies fail to treat similar cases alike) defies the values of the rule of law."); *see also INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) ("An agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view.") (quoting *Watt v. Alaska*, 451 U.S. 259, 273 (1981)); *PDK Labs, Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) (remanding the agency decision for an unexplained departure from precedent); *Freeman Eng'g Assocs., Inc. v. FCC,* 103 F.3d 169, 178-80 (D.C. Cir. 1997) (rejecting agency's "newly developed (and questionable) interpretation" of a rule which was not applied equally to all parties).

B. Qualified Experts Accept Marijuana for Medical Use

If the DEA or HHS had applied their own criteria for medical use evenhandedly, they would have been compelled by the data presented to conclude that there is widespread agreement in the scientific community that marijuana has medical use. No less an authority than the Institute of Medicine ("IOM") Report cited by HHS states "there is substantial consensus among experts in the relevant disciplines on the scientific evidence about potential medical uses of marijuana." IOM Report at 2; *see also* IOM Report at 14 ("the study team found substantial

consensus, among experts in the relevant disciplines, on the scientific evidence bearing on potential medical use"). The DEA and HHS acted arbitrarily and capriciously, and without substantial evidence, to deny the widespread opinion of experts that marijuana has medical use.

C. The DEA Acted Arbitrarily and Capriciously in Ignoring, Without Explanation, Numerous Peer-Reviewed Studies, Including the Institute of Medicine Study Commissioned by the Federal Government to Review the Medical Efficacy of Marijuana, that Establish that Marijuana Is Accepted as Effective in Treating Various Medical Conditions

1. Legal Standards

Administrative agencies have an obligation to consider all relevant evidence and arguments presented or, at the very least, provide a reasoned explanation for their failure to do so. *See, e.g, Dickson v. Sec'y of Defense,* 68 F.3d 1396, 1404 (D.C. Cir. 1995). As stated by this Court, an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Tourus Records, Inc. v. DEA,* 259 F.3d 731, 736 (D.C. Cir. 2001) (citations and internal quotations omitted); *Public Service Comm'n of Kentucky v. FERC,* 397 F.3d 1004, 1008 (D.C. Cir. 2005) (agencies must "consider relevant data and 'articulate a rational connection between the facts found and the choices made'") (quotation and citations omitted); *see also Rominger v. United States,* 72 Fed. Cl. 268, 273 (2006). "[I]n reviewing an administrative body's decision, the court must examine whether

or not the agency has considered all of the evidence before it, and if so, if it has stated why evidence contrary to the final decision was 'disregarded or given less weight.'" *Smith v. Dalton,*927 F. Supp. 1, 5 (D.D.C. 1996) (citation omitted). When an agency fails to address key arguments and evidence, its decision is arbitrary and capricious and cannot be upheld. *See Golden Spread Electric Cooperative v. FERC,* 319 F.3d 522, 524 (D.C. Cir. 2003) (directing agency to address arguments of party before it); *see also Frizelle v. Slater,* 111 F.3d 172, 177 (D.C. Cir. 1997) (reversing grant of summary judgment because agency failed to provide "a reason that a court can measure" to support its decision to ignore certain arguments).

2. *The DEA Acted Arbitrarily and Capriciously, and Without Substantial Evidence, in Ignoring More than Two Hundred Studies Demonstrating the Medical Efficacy of Marijuana Presented to It by Petitioner Without Explanation*

As is explained in the Petition, numerous published peer-reviewed studies have assessed and confirmed the efficacy of marijuana with respect to muscle spasms 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. AR (A.1.). The Petition cites more than two hundred such peer-reviewed published studies, but the DEA, without explanation, ignores all but ten of them. For instance, in a

comprehensive review of the therapeutic uses of marijuana prepared in 1999 by the Institute of Medicine ("IOM") commissioned by the White House's Office of National Drug Control Policy -- *Marijuana as Medicine: Assessing the Science Base* -- the IOM found that marijuana does have accepted medical use. *See* 66 Fed. Reg. 20037, 20047 (April 18, 2001). Specifically, with respect to pain management, the IOM report cited three double-blind, placebo-controlled studies on treating cancer pain, which found marijuana's primary psychoactive component to be comparable to codeine in effectiveness, but without the nausea and other debilitating side effects. *Marijuana as Medicine: Assessing the Science Base* (1999). The IOM also reports that an experimental study on pain showed that "cannabinoids were comparable with opiates in potency and efficacy. . . ." IOM Report at 54 (citing Borison et al. 1983 & Hanigan et al. 1986). "In conclusion, the available evidence from animal and human studies indicates that cannabinoids can have substantial analgesic effect." IOM Report at 145.

As for treating nausea, the IOM reported on numerous clinical studies – including "a carefully controlled double-blind study" and "a double-blind, cross-over, placebo-controlled study" – showing that both marijuana and select cannabinoids are effective antiemetics for patients suffering nausea and lack of appetite related to both cancer treatment and HIV/AIDS. *See* IOM Report at 148 (citations omitted). Not only did the IOM report conclude that marijuana is

effective, but also that "[f]or 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." IOM Report at 177. Thus, "[i]t is possible that the harmful effects of smoking marijuana for a limited period of time might be outweighed by the antiemetic benefits of marijuana, at least for patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis." IOM Report at 154; *see also* IOM Report at 179 ("Until a nonsmoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting."). The IOM Report concluded: "Nausea, appetite loss, pain, and anxiety are all afflictions of wasting, and all can be mitigated by marijuana." IOM Report at 159.[4]

Moreover, since the release of the IOM report, additional clinical studies on the medical efficacy of marijuana were published in peer-reviewed journals and included in the Petition. *See* AR (A.1) at pp. 44-56.

[4] The IOM Report also noted: "Since 1996, five important reports pertaining to the medical uses of marijuana have been published, each prepared by deliberative groups of medical and scientific experts (Appendix E). . . . With the exception of the report by the Health Council of the Netherlands, each concluded that marijuana can be moderately effective in treating a variety of symptoms." IOM Report at 180.

In the face of these scientific studies, many of which are funded and approved by the federal government, but simply ignored by its administrative agencies without explanation, the DEA and HHS acted arbitrarily and without substantial evidence in concluding that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition." *See* 76 Fed. Reg. 40552, 40567 (July 8, 2011); *cf. Frizelle*, 111 F.3d at 177; *Robinson v. Dalton,* 45 F. Supp.2d 1 (D.D.C. 1998) (failure to respond to applicant's argument renders decision arbitrary; remanded for ""more fully reasoned explanation''); *see also Calloway,* 366 F. Supp. 2d at 55; *Dickson,* 68 F.3d 1396, 1405 (D.C. Cir. 1995). "[T]here must be satisfactory indication that a correction board's decision is based 'upon a balanced *consideration of all the evidence* available and presented." *Buchanan v. United States,* 223 Ct. Cl. 291,311-312 (Ct. Cl. 1980) (quoting *Smith v. United States,* 168 Ct Cl. 545, 553 (1964)) (emphasis added)); *Six v. United States,*71 Fed. Cl. 671, 679 (Fed. Cl. 2006) (remand ordered because the BCNR "did not consider or address evidence before it that may have had the effect of changing the result"); *see also* The Hon Juan Juan R. Torruella, *Déjà vu: A Federal Judge Revisits the War on Drugs or Life in a Balloon*, 20 B.U. PUB. INT. L.J. 167, 205 n.211 ("These reports and assertions [by various federal agencies] border on scientific obscurantism by totally ignoring, if not outright suppressing, the abundant credible scientific evidence worldwide, which is

contrary to these reports and statements"); *see also id.* ("As masterfully argued by Professor David M. Helfeld in his article, Narcotics, Puerto Rico, Public Policy: In Search of Truth and Wisdom, 75 Rev. Jur. U.P.R. 1029 (2006), there has been a misuse of federal power in the debate over the legalization of drugs, particularly regarding marijuana and its use for medical purposes").

D. The DEA Deviates from the Statutory Language of the CSA and Its Own Regulation When It States That There Has Not Been Sufficient Analysis of Marijuana's Chemistry, as Peer-Reviewed Studies Establish that Marijuana's Chemistry Is Known and Reproducible

Whereas the DEA and HHS found that marijuana does not have a currently accepted medical use because "a complete scientific analysis of all the chemical components found in marijuana has not been conducted," 76 Fed. Reg. 40552, 40584 (July 8, 2011), the known chemistry requirement published in the *Federal Register* requires only that the "drug's chemistry is known and reproducible," not that every one of its components be scientifically evaluated and analyzed. *See* 66 Fed. Reg. 20037, 20051 (April 18, 2001).[5] Marijuana easily meets the published criterion. The active components of marijuana are well known and well described, as are the mechanisms of its biologic action in humans. Research on marijuana

[5] If it were otherwise, no botanical could qualify as having an "accepted medical use." Congress has implicitly rejected this view by placing cocoa leaves, the opium poppy, and poppy straw in Schedule II, which means that these botanicals have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." *See* 21 U.S.C. §§ 812(b)(2)(B) & (c), Schedule II(a)(3) & (4).

chemistry cited in the Petition was inexplicably overlooked. Only by ignoring these peer-reviewed studies and deviating from its announced criteria can HHS continue to disseminate to the public the statement that "a complete scientific analysis of all the chemical components found in marijuana has not been conducted." 76 Fed. Reg. 40552, 40584 (July 8, 2011). Both reveal bias on the DEA and HHS's part, rendering their actions arbitrary and capricious and without substantial evidence.

E. The DEA Acted Arbitrarily and Capriciously in Failing to Consider "All Relevant Data" in Its Scheduling Determination

The DEA admits that it has has an obligation to consider "all other relevant data" in its scheduling determination, 76 Fed. Reg. 40552, 40566, (July 8, 2011) (quoting 21 U.S.C. § 811(b)), yet it failed to do this. Perhaps the DEA did not conduct the searching inquiry required by the CSA because it believes "[a] drug will be deemed to have a currently accepted medical use for CSA purposes only if all five [criteria it uses to assess currently accepted medical use] are demonstrated." 76 Fed. Reg. 40552, 40567 (July 8, 2011). This interpretation of the CSA is arbitrary and capricious, as the CSA does not provide that scheduling determinations should be based on such absolutist criteria. *Cf. Grinspoon*, 828

F.2d at 891 (holding that DEA cannot treat lack of FDA marketing approval as conclusive evidence that substance has no currently accepted medical use).[6]

Aside from the peer-reviewed studies cited by petitioners *infra at xx* and *supra at xx*, the DEA expressly disregarded the medical judgment of sixteen states and the District of Columbia that marijuana has medical use.[7] In *Gonzales v. Oregon*, 546 U.S. 243 (2006), the United States Upreme Court held that states have

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[6] Notably, the DEA does not require that a substance meet all of the factors it considers regarding abuse potential to conclude it has a high abuse potential. *Cf.* 76 FR 40552, 40568 (DEA and HHS conceding that marijuana has a limited potential of diversion from legitimate channels).

[7] *See* Alaska (Medical Uses of Marijuana for Persons Suffering from Debilitating Medical Conditions Act, Alaska Stat. Ann. §§ 17.37.010-17.37.080 (West 2005)); Arizona (Drug Medicalization, Prevention and Control Act, Ariz. Rev. Stat. Ann. §§ 13-3412 (2005) (West)); California (Compassionate Use Act, Cal. Health & Safety Code. § 11362.5 (West 2005)); Colorado (Col. Const. art. XVIII, § 14; Colo. Rev. Stat. Ann. § 18-18-406.3 (West 2006)); Delaware (The Delaware Medical Marijuana Act) 49A Del. Code § 4901A (2011)**;** Hawaii (Medical Use of Marijuana Act, Haw. Rev. Stat. § 329-121-329-128 (West 2005)); Maine (Maine Medical Marijuana Act, Me. Rev. Stat. Ann. 22 § 2383-B(5) (2005)); Massachusetts (Massachusetts Medical Marijuana Act); Michigan (Michigan Medical Marijuana Act, Mich. Comp. Laws §§ 33.26421-333.26430 (2008)); Montana (Montana Medical Marijuana Act, Mont. Code Ann. §§ 50-46-101-50-46-210 (2005)); Nevada (Medical Use of Marijuana Act, Nev. Rev. Stat. §§ 453A.010-453A.810 (2005)); New Jersey (New Jersey Compassionate Use Medical Marijuana Act, N.J. Stat. Ann. § 24:61-1-Pub. L. (West 2010)); New Mexico (Lynn and Erin Compassionate Use Act, N.M. Stat. Ann. §§ 26-2B-1-26-2B-7 (West 2007)); Oregon (Oregon Medical Marijuana Act, Or. Rev. Stat. Ann. §§ 475.300-475.346 (West 2005)); Rhode Island (The Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act, R.I. Gen. Laws Ann. § 28.6 (West 2005)); Vermont (Marijuana Use by Persons with Severe Illness Act, Vt. Stat. Ann. 18 §§ 4472-4474d (West 2005)); and, Washington (Washington Medical Use of Marijuana Act, Was. Rev. Code Ann. §§ 69.51A.005-69.51A.092 (West 2005)), as well as the District of Columbia (Legalization of Marijuana for Medical

the authority to define general standards of medical practice. *Id.* at 275. And, in that case, the government relied upon "the judgment of the 49 States that have not legalized physician-assisted suicide as further support for the proposition that the practice is not legitimate medicine," *id.* at 272, which is a complete about face of its current position that "[t]he CSA does not assign to the states the authority to make findings relevant to CSA scheduling determinations," 76 Fed. Reg. 40552, 40579 (July 8, 2011).[8] Given the traditional and well-recognized constitutional authority of states and medical practitioners to define the legitimate practice of medicine, *Gonzales*, 546 U.S. at 269, and the CSA's express command that the DEA consider all relevant data, *see* 21 U.S.C. § 811(b), the DEA acted arbitrarily and capriciously in disregarding the views of states and physicians in concluding that marijuana has no "currently accepted" medical use. *See also* Brown, Melissa, *The Garden State Just Got Greener: New Jersey Is the Fourteenth State to Legalize Medical Marijuana*, 41 SETON HALL L. REV. 1519, 1520 (2011) (noting the "widely accepted therapeutic value of marijuana")

Treatment Initiative Amendment Act of 2010, D.C. Res. 18-399).

[8] No less an authority than the American Medical Association has called for a review of marijuana as a Schedule I substance alongside LSD and PCP. Tourella *supra,* at 205 & fn,215 (citing Kevin B. O'Reilly, AMA Meeting: Delegates Support Review of Marijuana's Schedule I Status, American Medical News, Nov. 23, 2009, http:// www.ama-assn.org/amednews/2009/11/23/prse1123.htm). The Petition cites 87 medical organizations that have concluded that marijuana should be rescheduled, all of which were inexplicably ignored by the DEA. *See* AR (A.1 at 15-19).

III. THE DEA ACTED ARBITRARILY AND CAPRICIOUSLY, AND WITHOUT SUBSTANTIAL EVIDENCE, IN CONCLUDING THAT MARIJUANA HAS A "HIGH POTENTIAL FOR ABUSE"

A. The CSA Requires the DEA to Compare a Substance with Other Scheduled Substances to Determine Where to Schedule that Substance

To warrant placement in the most restrictive of schedules, Schedule I, a substance must have a "high potential for abuse." 21 U.S.C. § 812(b)(1)(A).[9] 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. 40552, 40567 & 40568 (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."

[9] This is so even if the substance does not have a currently accepted medical use. *See NORML v. DEA*, 559 F.2d at 748 ("plcement in Schedule I does not appear to flow inevitably from lack of a currently acccepted medical use"). The DEA errs when it contends otherwise. 76 Fed.Reg. 40552, 40566 (July 8, 2011).

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).[10]

Rather than properly perform this relative analysis by comparing marijuana to other scheduled substances, the DEA relies on four factors from the legislative history of the CSA, which are used to determine whether a substance has a sufficient "potential for abuse" to be scheduled at all, *Grinspoon v. DEA*, 828 F.2d 881, 893 (1st Cir. 1987), to conclude that marijuana has a "high" potential for abuse, 76 Fed. Reg. 40552, 40567-68 (july 8, 2011). The DEA concludes: "In summary, examination of the indicators set forth in the legislative history of the CSA demonstrate that marijuana has a high potential for abuse." 76 Fed. Reg. 40552, 40568 (July 8, 2011); *see also id.* ("marijuana has a high potential for abuse

[10] The CSA allows placement of a substance in Schedule I only if "[t]here is a lack of safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b)(1)(C). Schedule II substances require that "[a]buse of the drug or other substance may lead to servere psychological or physical dependence." 21 U.S.C. § 812(b)(2)(C). Continuing down the continuim, Schedule III substances require that "[a]buse of the drug or other substance may lead to moderate or low physical dependance or has high psychological dependence." 21 U.S.C. § 812(b)(3)(C). Schedule IV substances require that "[a]buse of the drug or other substance may lead to limited physical dependance or psychological dependence relative to the drugs or other substances in schedule III." 21 U.S.C. § 812(b)(4)(C). And Schedule V requires that "[a]buse of the drug or other substance may lead to limited physical dependance or psychological dependence relative to the drugs or other substances in schedule IV." 21 U.S.C. §

as determined using the indicators identified in the CSA's legislative history"). While the presence of one or more of these factors may justify control of that substance, *see supra*; H.R. Rep. No. 91-1444, Pub. L. No. 91-513, 1970 U.S.C.C.A.N. 4566, 4629 ("If the Attorney General determines that the data gathered and the evaluations and recommendations of the Secretary constitute substantial evidence of potential for abuse, he may initiate control proceedings under this section."), they cannot, by themselves, establish a "high" potential for abuse.

In *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), the court held that the DEA had established MDMA's high potential for abuse after it compared MDMA to other Schedule I and II substances and found structural and pharmacological similarities. *See id.* at 893-95. In so holding, the *Grinspoon* court noted that the CSA provides no definition of the phrase "high potential for abuse," and it acknowledged Grinspoon's argument that "the passage from the legislative history quoted above provides guidance only as to the minimum needed to show *any* potential for abuse, in other words, enough to justify a level of CSA control as low as placement in Schedule V." *Id.* at 893. The *Grinspoon* court, then, found that the DEA Administrator had not acted arbitrarily and capriciously in finding that MDMA has a "high" potential for abuse because he had compared this substance

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812(b)(5)(C).

to *other* Schedule I and II substances. *See id.* at 893-95 (citing 51 Fed. Reg. 36,555-57 (1986)).

Here, by sharp contrast, the DEA fails to make any serious comparisons between marijuana and *other* scheduled substances. Instead, the DEA cites HHS for the proposition that "there are two drug products containing cannabinoid compounds that are structurally related to the active components in marijuana." 76 Fed. Reg. 40552, 40568 (July 8, 2011). "Marinol is a schedule III drug product containing synthetic delta-9 THC, known generically as dranabinol, formulated in sesame oil in soft gelatin capsules." 76 Fed. Reg. 40552, 40568 (July 8, 2011). "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." 76 Fed. Reg. 40552, 40568 (July 8, 2011); *see* 76 Fed. Reg. 40552, 40570 (July 8, 2011) ("Marijuana and delta-9-THC produced profiles of behavioral and subjective effects that were similar regardless of whether the marijuana was smoked or taken orally . . . or orally as THC-containing capsules"); *cf. NORML v. DEA*, 559 F.2d at 757 ("Nor does [the DEA] argue that the similarities between synthetic THC and natural marihuana materials are too slight to warrant consolidated consideration"). These comparison by the DEA and HHS to Schedule III and II substances only underscore that none of them should be placed in Schedule I.

Absent the minimally necessary comparisons, the DEA's comparative inquiry is woefully inadequate under *Grinspoon* and represents a radical departure from its treatment of other drugs. In *Grinspoon,* the DEA compared the drug MDMA (ecstasy) to Schedule I and II substances LSD, cocaine, mescaline, amphetamines, methamphetamine, and MDA, and it made 46 detailed findings regarding their similar chemical structures and pharmacological and neurotoxic effects. *See Grinspoon*, 828 F.2d at 893-95. Similarly, when considering butorphanol, the DEA made detailed comparisons with the scheduled substances morphine, codeine, fentanyl, and pentazocine in terms of their physical and psychological dependence and pharmacological effects and concluded that the abuse potential of butorphanol falls somewhere between morphine and pentazocine. 62 Fed. Reg. 37004 (July 10, 1997). And, when HHS applied for and received its own patent for medical uses of cannabinoids, it emphasized marijuana's lack of toxicity. *See* Request for Judicial Notice, Exh. 1. Here, in making criminals out of marijuana users, the DEA does not even consider it.

Instead, in the proceedings below, the DEA only compares marijuana with other cannabinoids, with the exception of very limited comparisons with other scheduled substances in terms of dependence and hospital visits that seriously *undermine* any claim that marijuana has an abuse potential nearly as high as Schedule I substances like heroin and morphine. Its own limited analysis

concludes that marijuana has a "mild" dependence compared to these substances. *See infra*. And marijuana accounts for far fewer hospital visits than other scheduled substances.[11] The DEA acted arbitrarily and capriciously in failing to perform a proper comparative analysis to other scheduled substances, as required by the CSA.

B. The DEA Erroneously Equates Widespread Use with Abuse

In an attempt to compensate for its failure to properly perform the comparative analysis required by the CSA, the DEA seizes on the current illegality of marijuana under federal law to argue that widespread *use* and trafficking of

[11]With respect to hospital visits, the DEA notes that, as estimated by the Drug Abuse Warning Network ("DAWN"), in 2009, marijuana was involved in 376,467 emergency department ("ED") visits out of 1,948,312 drug-related visits. 76 Fed.Reg. 40552, 40571 (July 8, 2011). Even in absolute numbers, this figure is less than 422,896 ED visits reported for cocaine. *Id.* In proportional terms, more importantly, cocaine users are more than ten times as likely as marijuana users to visit the ED and heroin users are more than seventy times as likely to do so. *See* AR (A.1) at p. 99. Emergency room visits provide precious little support for the DEA's position.

The same is true with respect to the social survey data cited by the DEA with respect to drug treatment. *See* 76 Fed.Reg. 40552, 40571 (July 8, 2011). Although the DEA notes that marijuana use accounted for 16 (or 17) percent of all drug treatment admissions in 2007 and 2008, *see id.* at 40571 & 40574, it admits at the same time that 57 percent of these marijuana users were referred to treatment through the criminal justice system, compared to much smaller percentages for heroin and cocaine, *see id.* at 40574. This strongly suggests that marijuana accounts for a significant percentage of drug treatment admissions only because of a trend towards compulsory treatment, rather than incarceration,. Other Schedule I substances, such as heroin and cociane, by sharp contrast, result in drug treatment admissions because their deletarious effects compel this. Again, the DEA's statistics, which reflects involuntary drug treatment due to marijuana's illegality,

marijuana is tantamount to widespread *abuse*. *See* 76 Fed. Reg. 40552, 40567-68 (July 8, 2011) ("Marijuana has a high abuse potential. It is the most widely used illicit substance in the United States" "Marijuana is the most commonly abused illegal drug in the United States"). Congress already implicitly rejected this position when it exempted the most popular drugs, alcohol and tobacco, from the proscriptions of the CSA. *See* 21 U.S.C. § 802(6). Indeed, at one point in its response, the DEA seemingly acknowledged that use is not tantamount to abuse when it discussed the "gateway" theory and noted the inadequacy of tests to support this theory because the "the determinative measure for testing [the gateway theory] . . . is whether marijuana leads to 'any drug use' rather than that marijuana leads to 'drug abuse and dependence' as defined by DSM-IV criteria." 76 FR 40552, 40583.

The best the DEA can muster for its dubious proposition that use is the same as abuse is that one of the criteria described in the legislative history of the CSA for "potential for abuse" involves the use of a substance on one's own initiative, rather than on the basis of medical advice from a physician. 76 Fed. Reg. 40552, 40568 (July 8, 2011) (quotation omitted). In making this contention, the DEA ignores the language of the CSA, its legislative history, and Supreme Court precedent interpreting these.

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does not support a finding of high abuse potential.

As explained above, the factor cited by the DEA above is only one of four factors the DEA is supposed to consider to determine whether a substance should be controlled at all. *See supra.* The language of the CSA, as well as the statutory framework, require a potential for harm, not just use, to justify placement in the controlled substance schedules, as the CSA speaks of "abuse" in terms of psychological and physical dependence. *See* 21 U.S.C. §§ 812(b)(2)(C), (b)(3)(C), (b)(4)(C) & (b)(5)(C); *cf. Consumer Product Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 107 (1980) ("the starting point for interpreting a statute is the language of the statute itself and, absent a clearly expressed legislative intent to the contrary, that language must ordinarily be regarded as conclusive"). Indeed, the first of the four threshold criteria for control requires that "[i]ndividuals 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." H.R. Rep. No. 91-1444, Pub. L. No. 91-513, 1970 U.S.C.C.A.N. 4566, 4601; *see also id.* ("Misuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use are regarded as indicative of a drug's potential for abuse."). The CSA and its legislative history require at least the potential for abuse before use of a substance can be considered abuse. *See Grinspoon*, 828 F.2d at 893-94. Even then, given the CSA's express focus on psychological and physical dependence, widespread use cannot be considered paramount, as the DEA has made it here.

Underscoring this point is *Gonzales v. Oregon*, 546 U.S. 243 (2006), wherein the Supreme Court held that the CSA did not authorize the Attorney General to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide where authorized to do so by state law. Interpreting the structure and legislative history of the CSA, the Court emphasized that "[t]he statutory criteria for deciding what substances are controlled . . . consistently connect the undefined term 'drug abuse' with addiction or abnormal effects on the nervous system." *Id.* at 273. In the view of the Supreme Court, use of a drug in compliance with state law to commit suicide does not constitute "drug abuse" under the CSA based on Congress' "consistent use [of this phrase] throughout the statute, not to mention its ordinary meaning." *Id.* at 274. It would seemingly be apparent that use of marijuana without any apparent harm should not be considered more abusive than suicide.

Indeed, if use alone could justify Schedule I treatment, extremely popular substances, such as caffeine and aspirin, which are not statutorily exempt, would have to join marijuana in Schedule I. Of course, the CSA does not compel such a result. Rather than indicate a high potential for abuse, widespread use reflects individual decisions, which in many cases are made with knowledge of marijuana's relatively low dependence liability. The DEA erred in repeatedly equating use

with abuse to conclude that marijuana has a "high" abuse potential, even more so than methamphetamine.

C. A Proper Comparison of Marijuana to Other Scheduled and Non-Controlled Substances Demonstrates that Marijuana Does Not Have a "High" Potential for Abuse

Had the DEA and HHS performed the proper comparative analysis, as required by the CSA, they would have found that marijuana does not have a sufficiently high abuse potential to warrant placement in Schedule I, even according to the selective data it cites. With respect to dependence, HHS found that "[a]lthough a distinctive marijuana withdrawal syndrome has been identified, indicating that marijuana produces physical dependence, this phenomenon is mild and short-lived. . . ." 76 Fed. Reg. 40552, 40561 (July 8, 2011) (citing Budney et al. 2004); *see also id*. at 40562 (comparing marijuana withdrawal symptoms to those of caffeine and describing them as mild). Both the DEA and HHS recognize that marijuana's physical dependence "is distinct and mild compared to the withdrawal syndromes associated with alcohol and heroin use." *Id.* at 40583 (citing Budney et al., 1999; Haney et al., 1999)); *see id.* at 40562. The DEA also cites a study describing marijuana dependence as only a "mild craving." *Id.* at 40584 (citing Budney, *et al.* (1999)).

Given these concessions regarding this most important indicator of a drug's potential for abuse, as spelled out by the CSA, it was arbitrary and capricious for

the DEA to recognize that marijuana's dependence liability is "mild" compared to other Schedule I drugs, yet place marijuana in Schedule I. As far back as 1973, the National Commission on Marijuana and Drug Abuse found that marijuana "does not pose the same social and public health problems associated with the opiates and coca leaf products." *NORML v. DEA*, 559 F.2d at 752. Far more recently, in 2007, Great Britian commissioned a study with the prestigious *Lancet* scientific journal entitled "**"**Development of a Rational Scale to Assess the Harm of Drugs of Potential Misuse." *See* Torreulla, *supra*, at 200 & n.193 (citing Nutt, David, *et al. Development of a Rational Scale to Assess the Harm of Drugs of Potential Abuse*, 369 LANCET 1047, 1047 (2007)). "The results of the study are not startling, but confirm the general knowledge and experience of anyone with some degree of objective expertise in this field" *Id.* "Ranked first and second in terms of harmfulness, were heroin and cocaine respectively, with alcohol fifth and tobacco ninth, both of which were ranked as substantially more damaging than marijuana, which was ranked eleventh on the list." *Id.* at 200-01. Judge Torreulla concluded that "it makes little sense to prohibit the use of marijuana when its prejudicial effects on our health are minimal when compared to those unquestionably caused by alcohol and tobacco." *Id.* at 202.

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D. The DEA and HHS Acted Arbitrarily and Capriciously in Failing to Consider the Effect of Their Failure to Reschedule Marijuana on the Public and the Cost of Enforcement

In assessing abuse, the legislative history of the CSA admonishes the Attorney General (DEA) to "consider the economics of regulation and enforcement attendant to such a decision. In addition, he should be aware of the social significance and impact of such a decision upon those people, especially the young, that would be affected by it." PL 91-513 at p. 4603; *see also NORML v. Ingersoll*, 497 F.2d at 656 ("The [CSA's] five Schedules define classes of drugs and substances pursuant to criteria set in terms of dangers *and benefits* of the drugs") (emphasis added); 21 U.S.C. § 801(1) (describing the purpose of CSA as promoting the "health and general welfare of the American people,"). As stated *supra* at Parts II, tens, if not hundreds, of thousands of putative medical marijuana patients would benefit from the use of marijuana for therapeutic purposes, but are being deprived its pallative benefits by the DEA's arbitrary scheduling determination. Meanwhile, to enforce this arbitrary scheduling decision, the federal government expends approximately $1 billion per year, even without considering the lives lost through imprisonment and unemployment. *See* Kleiman, Mark A. & Saiger, Aaron J., *Drug Legalization: The Importance of Asking the Right Question*, 18 HOFSTRA L. REV. 527, 555 (1990) ("Government expenditures on marijuana enforcement are quite high. It is estimated that the Federal

Government alone has spent $636 million on marijuana enforcement in 1986. Similar calculations suggest that expenditures in 1988 were $968 million") (footnotes omitted). The DEA's failure to consider these negative effects on human lives and its own pursestrings, as the CSA and its legislative history require, was arbitrary and capricious yet again.

IV. THE DEA ACTED ARBITRARILY AND CAPRICIOUSLY BY FAILING TO HOLD A HEARING ON THE PETITION, WHICH IS NEEDED TO RESOLVE FACTUAL AND LEGAL DISPUTES AND AFFORD PETITIONERS A MEANINGFUL OPPORTUNITY TO PRESENT CURRENT SCIENTIFIC AND MEDICAL EVIDENCE IGNORED BY THE DEA AND HHS

"In order to prevent unfair and uniformed decisions on petitions to reschedule sucstances under the CSA, the Act establishes specific procedures that the agency must follow." *NORML v. DEA*, 559 F.2d at 750. In particular, 21 U.S.C. § 811(a) provides that the DEA may engage in rulemaking proceedings to schedule a substance under the CSA, or transfer a substance between schedules, and that such rulemaking proceedings "shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the APA]." The HHS' evaluation and recommendation to the DEA "serve[] to trigger an administrative hearing at which interested persons may introduce evidence to rebut the Secretary's scheduling recommendation." *Grinspoon*, 828 F.2d at 897.

Here, the DEA and HHS deprived petitioners of a meaningful opportunity to present evidence and make (reflective) legal arguments regarding currently

accepted medical use and relative abuse potential, in violation of due process. Whereas petitioners and respondents hotly dispute whether scientific experts, medical practitioners and others recognize the medical efficacy of marijuana, and its relative abuse potential, the DEA and HHS purposely dragged their feet in responding to the Petition, in direct contradiction to the CSA's command that "[t]he evaluations and recommendations of [HHS] shall be . . . submitted to the Attorney General within a reasonable time," 21 U.S.C. § 811(b). *See* AR (A.10). The DEA, then, inexplicably compounded this delay by waiting more than four years from the HHS recommendation to issue its denial of the scheduling Petition, and only did so after petitioners filed a petition in this Court under the APA for unreasonable delay. *See* AR (A.11). In rejecting the rescheduling Petition, the DEA relied repeatedly and selectively on studies published since the filing of the Petition in 2002 supporting only its position, without giving petitioners a meaningful opportunity to respond to them through a hearing or otherwise. This violates due process.

As a result of the DEA's unexplained intransigence, petitioners were deprived a meaningful opportunity to present evidence that has emerged since 2002 demonstrating that marijuana has a currently accepted medical use with a relatively low abuse potential in response to data relied upon by respondents. This new evidenec includes studies that marijuana is effective as an appetitie stimulant,

antiemetic, and sedative, as well as calls from the American Medical Association and the American College of Physicians for marijuana's rescheduling. Brown, *supra*, at 1530. Petitioners could not have anticipated how HHS and the DEA would approach these issues in 2002 when they filed their rescheduling Petition and make responsive legal and scientific arguments accordingly. *Cf. Grinspoon*, 828 F.2d at 897 (quoted *supra*). This failure to conduct a hearing or reopen the record after revealing to petitioners the results of HHS' evaluation and recommendations in 2006 was arbitrary and capricious and violates due process -- "It was not the kind of agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process." *NORML v. Ingersoll,* 497 F.2d at 659; *cf. Esch v. Yeutter*, 876 F.2d 976, 993 (D.C. Cir. 1989), *disapproved on other grounds by Axiom Res. Mgmt., Inc. v. United States,* 564 F.3d 1374, 1379–81 (Fed.Cir.2009), *rev'g* 80 Fed.Cl. 530 (2008) ("Not until very late in the appellate process were appellees informed of the nature of the asserted inadequacies of their applications, a failure severely impairing their right and ability to adduce relevant evidence at all stages of that process") (footnotes omitted); *Coalition of Concerned Citizens v. Damian,* 608 F.Supp. 110, 124 (S.D. Ohio 1984) ("The public hearing requirement is intended to provide a mechanism by which highway planners are publicly confronted with opposing views, to ensure that they take account during the planning process of the desire and objections of

citizens affected by proposed projects") (citing *D.C. Federation of Civic Ass'ns, Inc. v. Volpe,* 434 F.2d 436, 441 (D.C.Cir.1970)); *see also Russo Development Corp. v. Thomas*, 735 F.Supp. 631, 636 (D. N.J. 1989) ("the court does not rule out the possibility that a delay by a government agency may be so excessive as to constitute a deprivation of a party's due process rights").

One clear example of the prejudice suffered by petitioners, and medical marijuana patients generally, by the DEA's failure to hold a hearing or allow petitioners to supplement the record is the heavy reliance the DEA places upon the respiratory effects of marijuana smoking to conlcude that marijuana has a high potential for abuse. *See* 76 Fed. Reg. 40552, 40567, 40568, 40575, 40579, 40582 & 40583 (July 8, 2011) ("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"). This proposition is flatly rejected by a recent study published in *The Journal of the American Medical Association*, concluded that, although marijuana has many of the same constituents as tobacco smoke, it occassional use "was not associated with adverse effets on pulminary function." *See* Request for Judicial Notivce, Exh. 2. Certainly, an objective observer seeking to ascertain the abuse potential of marijuana would want to know and assess this study. The DEA, however, did not. Its refusal to

hold a hearing or open the administrative record after HHS issued its evaluation was arbitrary and capricious and violates due process.

In *NORML v. DEA,* this Court emphasized the need for a hearing or, at the barest minimum, an opportunity to respond to the HHS' response in some way when it reversed the DEA's rescheduling determination and remanded for futher proceedings consist with the CSA -- "Only a formal referral *and hearing* will allow due weight to be given to [HHS'] findings." 559 F.2d at 749 (emphasis added). "The issue could then have been fully litigated at a DEA rulemaking hearing." *Id.* at 754 (footnote omitted). Because the DEA's determination was not made in conformity with the procedures set out in the CSA, "[w]e owe no deference to statutorily invalid exercise of discretion." *Id.* at 754; *see also Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 595 (D.C. Cir. 1971) ("Public hearings bring the public into the decision-making process, and create a record that facilitates judicial review"). A remand is required to ensure compliance with the intent of Congress when it prescribed the procedures set forth in the CSA and is necessary to restore due process.

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CONCLUSION

For the foregoing reasons, petitioners respectfully request that this case be remanded to the DEA for a meaningful evaluation of all the factors concerning relative abuse potential and medical efficacy listed in the CSA.

DATED: January 23, 2012

Respectfully Submitted,

/s/ Joseph D. Elford
Joseph D. Elford

Counsel for Petitioners

CERTIFICATION REGARDING BRIEF FORM

I, Joseph D. Elford, hereby certify pursuant to Fed.R.App.P. 32, that the attached brief is proportionately spaced, has a typeface of 14 points, and contains 12,918 words.

DATED: January 23, 2012

Respectfully Submitted,

/s/ Joseph D. Elford
Joseph D. Elford

Counsel for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing were served via first-class mail upon the United States Attorney General's Office, 950 Pennsylvania, Avenue, N.W., Washington DC, 20530, and upon Carl Olsen, P.O. Box 4091, Des Moines, IA, 50333.

DATED: January 23, 2012 Respectfully Submitted,

/s/ Joseph D. Elford
Joseph D. Elford

Counsel for Petitioners