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

In re COALITION TO RESCHEDULE CANNABIS,

PETITION FOR WRIT OF MANDAMUS TO THE DRUG ENFORCEMENT ADMINISTRATION AND THE UNITED STATES ATTORNEY GENERAL

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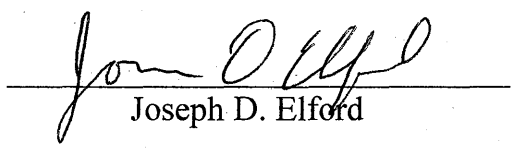
CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

Respondents are the Drug Enforcement Administration ("DEA"), Michelle Leonhart, Administrator for the DEA ("Leonhart"); and Eric Holder, United States Attorney General ("Holder").

There are no rulings under review or related cases, as this is a petition to compel agency action that has been unreasonably delayed.

DATED: May 23, 2011

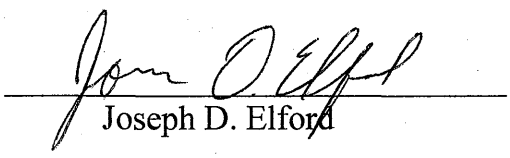


Joseph D. Elford

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: May 23, 2011



Joseph D. Elford

INTRODUCTION

Despite numerous peer-reviewed scientific studies establishing that marijuana is effective in treating AIDS wasting syndrome, muscle spasticity, emesis, appetite loss, chronic pain, and negative side effects of chemotherapy, the Drug Enforcement Administration ("DEA"), at the behest of the Department of Health and Human Services ("HHS"), continues to deprive seriously ill persons of this needed, and often life-saving therapy by maintaining marijuana as a Schedule I substance under the Controlled Substances Act 21 U.S.C. § 801 *et seq.* ("CSA"). To rectify this, petitioners and others filed a Petition with the DEA to reschedule marijuana under 21 U.S.C. § 811 more than eight years ago. To date, however, despite the DEA's public pronouncement that marijuana does not have an accepted medical use through an Inter-Agency Advisory with HHS and NIDA, it has failed to issue a final determination on, or even state whether it will initiate rulemaking proceedings with respect to the pending Petition. To put an end to this unreasonable delay, which harms tens, if not hundreds of thousands of seriously ill persons every day, petitioners Coalition to Reschedule Cannabis ("CRC"), Americans for Safe Access ("ASA"), Patients Out of Time ("POT"), Rick Steeb ("Steeb"), William Britt ("Britt"), Kathy Jordan ("Jordan"), and Michael Kravitz ("Kravitz") (collectively "petitioners") respectfully petition this Court for a writ of mandamus directing the DEA and the Attorney General to issue a full and final determination on petitioners' Petition to reschedule marijuana, or, alternatively, state whether it will initiate rulemaking proceedings, within 60 days.

ISSUE PRESENTED FOR REVIEW

Whether the DEA's delay of nearly nine years in providing a substantive response to petitioners' marijuana rescheduling petition—and almost five years after receiving a 41-page memorandum from HHS stating its scientific evaluation and recommendations—constitutes unlawful withholding or unreasonable delay of agency action, thereby warranting relief under Section 706(1) of the Administrative Procedure Act and the All Writs Act, 28 U.S.C. § 1651(a).

JURISDICTION AND VENUE

The Court's jurisdiction arises from the All Writs Act, 28 U.S.C. § 1651(a), which provides that "the Supreme Court and all courts established by an Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions." *See Telecommunications Research & Action Ctr. v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984); *see also Sierra Club v. Thomas*, 828 F.2d 783, 795-96 (D.C. Cir. 1987). This Court's jurisdiction arises from its statutory authority to review findings on rescheduling petitions under the CSA, 21 U.S.C. § 877, and, since this authority may be thwarted an an agency failing to act, "a Circuit Court may resolve claims of unreasonable delay in order to protect its future jurisdiction." *TRAC*, 750 F.2d at 76. Venue is proper in this Court because the District of Columbia is where respondents DEA; Michelle Leonhart, Administrator, DEA; and Eric Holder, United States Attorney General (collectively "respondents") maintain their principal offices.

STATEMENT OF FACTS

I. THE CONTROLLED SUBSTANCES ACT - 21 U.S.C. § 801 *et. seq.*

In enacting the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA"), in 1970, Congress 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). 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 classifies marijuana as a Schedule I substance. *See* 21 C.F.R. § 1308.11.

When Congress initially placed marijuana in Schedule I when 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, 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 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); *Alliance for Cannabis Therapeutics*, 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).

II. PAST RESCHEDULING PETITIONS

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

In 1972, NORML, later joined by the Alliance for Cannabis Therapeutics ("ACT"), filed the first marijuana rescheduling petition. 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 Alliance for Cannabis Therapeutics v. DEA,* 15 F.3d 1131, 1133-34 (D.C. Cir. 1994); *ACT*, 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).

Early in the rescheduling 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 the substance. *See NORML v. DEA*, 559 F.2d at 749. This Court, however, 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.* "[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. *Id.* at 149-50.

After repeated delays by the Administrator and HHS, the DEA conducted two years of administrative hearings before Administrative Law Judge ("ALJ") Francis L. Young ("Young"), which featured the testimony of patients, physicians, and researchers, as well as voluminous scientific and medical data. At the conclusion of these lengthy hearings, 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, denied the rescheduling petition after it had been pending for 22 years. *See Alliance for Cannabis Therapeutics,* 15 F.3d at 1133-34.

B. The Gettman Petition (1995)

Three years later, in July of 1995, Jon Gettman,filed an administrative petition with the DEA claiming that marijuana lacks the requirements necessary for Schedule I or

Schedule II status. Unlike the previous petition challenging marijuana's placement in Schedule I on grounds of medical efficacy, Dr. Gettman's 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).

C. The Instant Rescheduling Petition (2002)

1. The Coalition to Reschedule Cannabis

The instant marijuana rescheduling petition ("Petition") [found at http://www.safeaccessnow.org/downloads/CRC_Petition.pdf], was filed in 2002 by the Coalition to Reschedule Cannabis ("CRC"), which is comprised of medical marijuana patients, medical marijuana patient organizations, physicians, and other advocacy organizations, *see* Letter from Michael Kennedy to DEA, dated October 9, 2002 [found at found at http://www.safeaccessnow.org/downloads/CRC_Letter.pdf]. The membership of these organizations and the individual citizen petitioners have several interests in the appropriate scheduling of marijuana under federal law, including an interest in legal access to marijuana for therapeutic use. *See id.* For instance, petitioner Rick Steeb ("Steeb") is a 60-year-old glaucoma patient who has successfully used marijuana to reduce his interocular pressure. *See* Steeb Decl. The failure of the federal government to reschedule marijuana has reduced his access to the medicine he needs to treat his glaucoma. *Id.* Petitioner Dr. Jay Cavanaugh has passed away since the filing of the rescheduling petition.

Drawing on advances in science since the filing of the 1995 rescheduling petition and the experiences of medical marijuana patients, the CRC filed the instant rescheduling Petition on October 9, 2002, in order to ease federal restrictions on medical and therapeutic research into medical treatment programs and protocols involving marijuana and to allow access to patients to medical marijuana.

2. Americans for Safe Access

One of the non-profit advocacy organization members of the CRC is Americans for Safe Access ("ASA"), which is largest grassroots organization of patients and physicians working to expand and protect the rights of seriously ill persons who use marijuana for medical purposes. ASA's members and constituents include seriously ill persons who would have benefited from the use of marijuana for medical purposes, but who have been deprived its medical benefits by DEA's continued placement of marijuana in Schedule I of the CSA. *See* Sherer Decl. ASA has devoted significant resources to combat this position of the federal government, spending more than one hundred thousand dollars and hundreds of staff man-hours producing and disseminating educational materials explaining and demonstrating the effectiveness of marijuana in treating medical conditions and symptoms, including: cancer, HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders and chronic pain. *See* Sherer Decl. ASA is headquartered in Oakland, California, and includes Rick Steeb and William Britt ("Britt") as members. *See* Steeb Decl.; Britt Decl. Britt uses marijuana to treat symptoms associated with polio. *See* Britt Decl.

3. Patients Out of Time

Another non-profit advocacy organization member of the CRC is Patients Out of Time ("POT"), which is a non-profit corporation headquartered in the Commonwealth of Virginia. The goal of POT is to educate health care professionals in all disciplines and organizations, as well as the public at large, about medical marijuana. POT represents patients, organizations, and caregivers who administer medical cannabis in those areas where medical marijuana has been accepted as part of medical treatments and protocols. Its members include Kathy Jordan ("Jordan") who uses marijuana to treat symptoms associated with Lou Gehrig's disease, *see* Jordan Decl., and Michael Kravitz ("Kravitz") who is a disabled veteran who uses marijuana to treat chronic pain, *see* Kravitz Decl.

4. The Instant Rescheduling Petition

On October 9, 2002, petitioners and others filed with the DEA the rescheduling Petition that is the subject of this suit. *See* Petition [found at http://www.safeaccessnow.org/downloads/CRC_Petition.pdf]; Letter from Michael Kennedy to DEA, dated October 9, 2002 [found at found at http://www.safeaccessnow.org/downloads/CRC_Letter.pdf]. The Petition seeks a rescheduling of marijuana from its Schedule I designation to a less restrictive class under the CSA on the grounds that: (1) marijuana does have accepted medical uses in the United States; (2) it 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. The DEA forwarded the Petition to the Secretary of HHS in July of 2004 for a scientific and medical evaluation and recommendation.

In August, 2004, the soon-to-be-named Secretary of HHS, Michale Levitt, stated in response to an inquiry from a Senator in his confirmation hearing that he "would make every attempt to complete the [scientific] evaluation by August 2005." *See* Letter from James Jeffords to Michael Leavitt, dated October 10, 2006 [found at http://www.safeaccessnow.org/downloads/jeffords_reschedule.]. That timeline, however, was not met. *Id.* Two months after additional prompting from Senator Jeffords, on December 6, 2006, the HHS Secretary sent a 41-page recommendation to the DEA, which appears to have been completed much earlier. *See* Letter from John O. Agwunobi to David C. Holland, dated August 2, 2010 [found at http://www.safeaccessnow.org/downloads/HHS_Rescheduling_Recommendation]. That recommendation, authored by John O. Agwunobi, Assistant Secretary of Health, recommended against the rescheduling of marijuana, stating that it "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." *Id.* Despite that binding recommendation as to scientific matters to the DEA in 2006, *see* 21 U.S.C. § 811(b), the DEA has failed to respond to it in any way or state whether it will initiate rulemaking proceedings after more than four years.

Meanwhile, on April 20, 2006, the DEA joined HHS and NIDA in issuing an Inter-Agency Advisory stating that "marijuana . . . has no currently accepted medical use in treatment in the United States. . . ." *See* http:/www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html.

Three years later, on October 19, 2009, Deputy Attorney General David Ogden

issued an advisory memorandum to Assistant United States Attorneys instructing them on the Department of Justice's stance on marijuana prosecutions in States that have decriminalized marijuana for medical purposes. *See* Memorandum for Selected United States Attorneys, dated October 19, 2009 [found at http://blogs.usdoj.gov/blog/archives/192]. The memorandum advised prosecutors to conserve their investigative and enforcement resources in those districts found within states that have legalized the use of marijuana in medical treatments, regimes, and protocols. *Id.*

No excuse or justification has been offered by DEA or the Attorney General for this unreasonable delay in rendering a final determination on the rescheduling petition.

SUMMARY OF THE ARGUMENT

The DEA has a long history of dragging its feet in responding to marijuana rescheduling petitions. One was pending for approximately 22 years before it was denied. *See Alliance for Cannabis Therapeutics v. DEA,* 15 F.3d 1131, 1133-34 (D.C. Cir. 1994). Another was pending for six years before it, too, was denied. *See Gettman v. DEA,* 290 F.3d 430 (D.C. Cir. 2002). The instant rescheduling Petition has been languishing in the administrative process for more than eight years, with no end in sight. This delay prompted petitioners, who filed a rescheduling Petition with the DEA in 2002, to file the instant petition for writ of mandamus to compel respondents to issue a final determination with respect to the Petition, or, at a minimum, to determine whether to initiate rulemaking proceedings.

Under the APA, federal agencies have the legal duty to "conclude a matter

presented to it" "within a reasonable time," 5 U.S.C. § 555(b), which is "typically counted in weeks or months, not years," *In re American Rivers and Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004). The DEA's delay here of more than eight years since the rescheduling Petition was filed -- and more than four years since it received HHS' binding evaluation and recommendations -- is inexcusable, especially since it announced publicly in 2006 in an Inter-Agency Advisory that "marijuana has no currently accepted medical use in the United States." *See Inter-Agency Advisory Regarding Claims that Smoked Marijuana Is Medicine* (April 20, 2006) [found at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108643.htm]. Under the factors announced by this Court in *Telecommunications Research & Action Ctr. v. FCC* (*"TRAC"*), 750 F.2d 70, 80 (D.C. Cir. 1984), this agency delay in acting on the rescheduling Petition is unreasonable, requiring this Court to intervene.

STANDING

Petitioners have standing to assert their claim of unreasonable agency delay both as individuals and based on the principle of organizational standing. Petitioner Rick Steeb is a medical marijuana patient member of the CRC who petitioned the DEA to reschedule marijuana in 2002. *See* Steeb Decl. He uses marijuana to treat symptoms associated with glaucoma, but the federal government's refusal to reschedule marijuana impairs his ability to obtain the medicine he needs. *See* Steeb Decl. This gives him standing to assert a claim of unreasonable delay. Petitioner Dr. Jay Cavanaugh was a medical marijuana patient who passed away while the rescheduling petition was pending. *See* http://en.wikipedia.org/wiki/Jay_Cavanaugh.

Petitioners CRC, ASA, and POT are membership organizations seeking to expand the access of medical marijuana patients to the medicine they need to treat multiple symptoms. *See* Sherer Decl; Britt Decl.; Jordan Decl.; Kravitz Decl.; Steeb Decl. They have organizational standing to assert the instant claim for unreasonable delay for this very purpose, since this delay by respondents impairs their membership's ability to obtain the medicine they need. *See Brady Campaign to Prevent Gun Violence v. Salazar*, 612 F.Supp.2d 1, 28-29 (D.D.C. 2009).

ARGUMENT

I. LEGAL STANDARDS

This Court has the authority to grant a writ of mandamus compelling the DEA to act formally on the 2002 Petition in order to safeguard its prospective jurisdiction to review the DEA's ultimate findings under the CSA. *See* 21 U.S.C. § 877; *In re American Rivers and Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004) (citing *TRAC*, 750 F.2d at 76); *TRAC*, 750 F.2d at 76 ("Because the statutory obligation of a Court of Appeals to review on the merits may be defeated by an agency that fails to resolve disputes, a Circuit Court may resolve claims of unreasonable delay in order to protect its future jurisdiction.") Although the issuance of a writ of mandamus "is an extraordinary remedy reserved for extraordinary circumstances[,] [a]n administrative agency's unreasonable delay presents such a circumstance because it signals the 'breakdown of the regulatory processes.'" *In re American Rivers*, 372 F.3d at 418 (citations omitted). "Through § 706 [of the APA] Congress has stated unequivocally that courts must compel agency action unlawfully withheld of unreasonably delayed." *Forest Guardians v.*

Babbit, 174 F.3d 1178, 1187 (10th Cir. 1999) ("This conclusion accords with the Tenth Circuit's established approach under the APA to requests for writs of mandamus to compel agency action unlawfully withheld."); *Mt. Emmons Mining Co. v. Babbit,* 117 F.3d 1167, 1170 (10th Cir. 1997) ("[A]s a reviewing court, we must compel agency action unlawfully withheld or unreasonably delayed."); *see* 5 U.S.C. § 706(1); *In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992) (per curiam). "[T]he primary purpose of the writ in circumstances like these is to ensure that an agency does not thwart our jurisdiction by withholding a reviewable decision." *In re American Rivers*, 372 F.3d at 419 (citing *TRAC*, 750 F.2d at 76).

II. THE DEA'S DELAY IN RESPONDING TO THE MARIJUANA RESCHEDULING PETITION IS UNREASONABLE

This case presents a paradigmatic example of unreasonable delay under *Telecommunications Research & Action Ctr. v. FCC* (*"TRAC"*), 750 F.2d 70, 80 (D.C. Cir. 1984). Although Congress did not expressly provide a timetable for responses to rescheduling petitions, it directed the Secretary of HHS to submit his scientific and medical evaluation and recommendations to the Administrator "within a reasonable time." The APA, in turn, requires the DEA to "conclude a matter presented to it" "within a reasonable time." *See* 5 U.S.C. § 555(b) ("within a reasonable time, each agency *shall* proceed to conclude a matter presented to it"); *In re American Rivers,* 372 F.3d at 418 (holding that, under the APA, federal agency must respond to rulemaking proceedings); Richard J. Pierce, Jr., Administrative Law Treatise § 6.10 (4th ed. 2002) ("At a minimum, the right to petition for rulemaking entitles a petitioning party to a response to

the merits of the petition."). The DEA, therefore, had a duty to adjudicate the rescheduling Petition "within a reasonable time."

Seemingly recognizing this duty, the Secretary of HHS stated in response to an inquiry from a Senator in his confirmation hearing in August, 2004, that he "would make every attempt to complete the [scientific] evaluation [of the 2002 Petition] by August 2005." *See* Letter from James Jeffords to Michael Leavitt, dated October 10, 2006 [found at http://www.safeaccessnow.org/downloads/jeffords_reschedule.pdf.]. That evaluation, however, was not completed for more than a full year. *See id.*; *cf. Center for Biological Diversity v. Abraham*, 218 F.Supp.2d 1143, 1164 (N.D. Cal. 2002) ("This order finds it significant that DOE has now missed two sets of deadlines—the statutory deadlines, and the ones it set for itself."). Meanwhile, on April 20, 2006, the DEA, along with HHS, disseminated on the FDA's website an Inter-Agency Advisory stating that "marijuana . . . has no currently accepted medical use in treatment in the United States. . . ." *See* http:/www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html.

The facts, therefore, demonstrate unambiguously that HHS completed its review and transmitted this review to the DEA in 2006, yet the DEA has inexplicably failed to do anything with it in nearly five years. There is no basis to say that agency resources are inadequate or that an order to provide a final response to the rescheduling Petition would prevent the DEA from carrying out other priorities, since it has the time to make public statements expressing its conclusions with respect to the rescheduling Petition. An order to act within 60 days is necessary and appropriate under these circumstances.

TRAC provides the standards in this Circuit for determining whether agency delay warrants mandamus relief, which is based on a "rule of reason." *Telecommunications Research & Action Ctr. v. FCC ("TRAC")*, 750 F.2d 70, 80 (D.C. Cir. 1984). The non-exhaustive six *TRAC* factors are as follows:

> (1) [T]he time agencies take to make decisions must be governed by a "rule of reason;" (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, the statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is "unreasonably delayed."

750 F.2d at 79-80 (internal citations omitted); *see In re American Rivers*, 372 F.3d at 418 (*quoting TRAC*, 750 F.2d at 80); *see also In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000). Analysis of these factors shows that the DEA has unreasonably delayed issuing its rescheduling determination "within a reasonable time," warranting mandamus relief.

A. The DEA Has Not Acted Consistently with the "Rule of Reason"

No legitimate reason justifies the DEA's failure to issue the rescheduling determination it has already prepared. While courts have sometimes held that the complexity of the issues facing an agency, or the work and resources required to address these issues, justifies an agency's delay, *see Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987), those factors are unavailing in this case, since the DEA and HHS have already completed all the work required for the DEA to make its rescheduling determination, or,

at least, state whether it will initiate rulemaking proceedings. *See* 21 U.S.C. § 811. As discussed above, HHS has already issued a 41-page memorandum stating that marijuana does not have a currently accepted medical use and it has issued an Inter-Agency Advisory, together with the DEA, confirming this. *See* from John O. Agwunobi to David C. Holland, dated August 2, 2010 [found at http://www.safeaccessnow.org/downloads/HHS_Rescheduling_Recommendation].

Because the DEA cannot show that any significant work or any complex decisionmaking remains to be done with regard to the rescheduling determination, its delay fails the "rule of reason." *See In re American Rivers*, 372 F.3d at 419 (finding agency delay unreasonable because "none of its reasons comports with the specific considerations outlined in *TRAC*" and because "a reasonable time for agency action is typically counted in weeks or months, not years."); *see also Community Nutrition Inst. v. Young,* 773 F.2d 1356, 1361 (D.C. Cir. 1985) (quoting *MCI Telecomms. Corp. v. FCC*, 627 F.2d 322, 340 (D.C. Cir. 1980)) ("While there is no absolute definition of what is a reasonable time, we know that it may encompass 'months, occasionally a year or two, but not several years or a decade."). As this Court stated in *Public Citizen Health Research Group v. Brock*, 823 F.2d 626 (D.C. Cir. 1987): "[W]e have seen it happen time and time again, . . . action . . . for the protection of public health all too easily becomes hostage to bureaucratic recalcitrance, factional infighting, and special interest politics. At some point, we must lean forward from the bench to let an agency know, in no uncertain terms, that enough is enough." *Id.* at 627. The DEA's more than eight-year delay is nothing less than egregious. *Cf. In re American Rivers*, 372 F.3d at 419 ("FERC's six-year-plus

delay is nothing less than egregious"); *Air Line Pilots Ass'n v. Civil Aeronautics Bd.*, 750 F.2d 81, 86 (D.C. Cir. 1984) (five-year delay unreasonable); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983) (holding that OSHA's delay of three years in issuing standard regulating industrial exposure to ethylene oxide was unreasonable and compelling agency to act); *Sandoz, Inc. v. Leavitt*, 427 F.Supp.2d 29, 41 & n.13 (D.D.C. 2006) (holding that HHS's delay in acting on a new drug application for nearly 1000 days was unreasonable; "The defendant's briefing is particularly troubling in that it seems to take *TRAC* and *In Re Barr*[, 930 F.2d 72, 75 (D.C. Cir. 1991)] as *de facto* invitations for the FDA to not comply with Congress' mandates." "The plaintiff is entitled to an end to this 'marathon round' of 'keep-away and soon.'") (quoting *In re American Rivers and Idaho Rivers United,* 372 F.3d at 420); *Raymond Proffitt Foundation v. EPA*, 930 F.Supp. 1088, 1103 (E.D. Pa. 1996) (holding that nineteen month delay by EPA in preparing and publishing proposed regulations setting forth revised or new water quality standard for state was unreasonable and compelling agency to act); *MCI Telecomms. Corp.*, 627 F.2d at 338-42 (four-year delay unreasonable); *see also In re American Rivers*, 372 F.3d at 419 ("We are not concerned here with what answer FERC might ultimately give the petitioners; rather, we are reviewing its failure to give them *any* answer for more than six years") (emphasis in original); *Public Citizen Health Research Group*, 823 F.2d at 628 (six-year delay "tread[ed] at the very lip of the abyss of unreasonable delay").

B. Human Health and Welfare Are at Stake

As discussed above, HHS and NIDA have already completed their review of the medical efficacy and dangerousness of marijuana. *See* Letter from John O. Agwunobi to David C. Holland, dated August 2, 1010 [found at http://www.safeaccessnow.org/downloads/HHS_Rescheduling_Recommendation]. They disagree vehemently with numerous health organizations, as well as this Court, who have recognized the possible health benefits of marijuana. It is, therefore, clear that extremely significant health and welfare concerns are at stake here. Numerous courts, including this one, have recognized that "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." *See, e.g., Brower v. Evans*, 257 F.3d 1058, 1068-69 (9th Cir. 2001) (quoting *TRAC*, 750 F.2d at 80); *Independence Mining Co. v. Babbitt*, 105 F.3d 502, 507 (9th Cir. 1997) (same); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983).

C. Ordering Issuance of the Rescheduling Determination Will Not Hamper Agency Activities of Higher or Competing Priority

Because the DEA has already completed nearly all of the work necessary to rule on the rescheduling Petition, an order directing the agency to issue this determination within sixty days will not affect other agency activities of higher or competing priority. As shown above, HHS has submitted a fully-documented determination of the scientific review to the DEA and it has issued an Inter-Agency Advisory with HHS and NIDA stating that marijuana has no currently accepted medical use. Compelling the DEA to

rule upon the rescheduling Petition or initiate rulemaking proceedings will cause the agency to expend little or no additional agency resources.

Underscoring the unreasonableness of the DEA's delay is the time it usually takes the agency to issue a final determination on drug rescheduling petitions. *Cf In re American Rivers*, 372 F.3d at 420 (noting that agency's dilatoriness was uncharacteristic of time agency typically expends on similar petitions). With respect to other drug rescheduling petitions under the CSA since 2002, the DEA has issued its final determination, on average, within six months after it receives the HHS evaluation. *See* Elford Decl. In particular, with respect to the last rescheduling Petition filed in 1995, the DEA took only four months in issuing its final determination after receiving the HHS evaluation. *See Gettman v. DEA,* 290 F.3d 430 (D.C. Cir. 2002). This comparative evidence establishes that the DEA has no impediments in moving forward with the instant rescheduling Petition, but is, instead, dragging its feet intentionally.

D. Delay Is Causing Significant Harm to the Public

What is most troubling about the DEA's evasiveness and delay in responding to the rescheduling Petition is that the information involved is vital to the health of thousands of Americans. Numerous Americans are being deprived the medical benefits of marijuana with each passing day that the DEA fails to act on the marijuana rescheduling Petition, since such findings may challenged by an interested party in court under the CSA. *See* 21 U.S.C. § 877; Britt Decl.; Jordan Decl; Kravitz Decl.; Steeb Decl. The DEA's pattern of delay and evasion suggests that, unless this Court intervenes and

requires a response within a time certain, the DEA will delay providing a final response to the rescheduling Petition indefinitely.

That the DEA's delay in responding to the rescheduling Petition has extremely detrimental health consequences is demonstrated by the fact that, after two years of hearings involving the testimony of patients, physicians and researchers, ALJ Young found in 1988:

> 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, *Marijuana Rescheduling Petition*, No. 86-22 (DEA Sept. 6, 1988). The DEA's refusal to reschedule marijuana in light of this evidence is no less arbitrary today than it was 23 years ago. In fact, it is far more arbitrary now because there is voluminous additional evidence that marijuana is safe and effective in treating various ailments. Thousands of people are needlessly suffering from the DEA's inexcusable delay. *Cf.* 21 U.S.C. § 801(1) (noting that purpose of the CSA is to improve "the health and general welfare of the American people"); *Cutler v. Hayes*, 818 F.2d at 897-98 (in assessing whether delay is unreasonable, court "must also estimate the extent to which [the] delay may be undermining the statutory scheme") (internal quotations omitted) .

E. Although Petitioners Need Not Show Agency Impropriety to Make Out a Case for Mandamus, There is Ample Evidence that the DEA Has Acted, and Continues to Act, Improperly

As if this were not enough, it is clear that the DEA has acted in bad faith in its treatment of the rescheduling Petition. Although a finding of bad faith is not necessary for this Court to hold that the DEA's delay in providing a definitive response to the rescheduling petition is unreasonable, *TRAC*, 750 F.2d at 80 (quotation omitted), it is one factor that courts may consider, *see Independence Mining Co. v. Babbitt*, 105 F.3d 502, 510 (9th Cir. 1997); *Chevron U.S.A. Production Co. v. O'Leary*, 958 F.Supp. 1485, 1498 (E.D. Cal. 1997). Indeed, as this Court has declared, "[i]f the court determines that the agency [has] delay[ed] in bad faith, it should conclude that the delay is unreasonable." *Cutler v. Hayes,* 818 F.2d at 898; Chevron, 958 F.Supp at 1498; see also *McGrail & Rowley, Inc. v. Babbitt*, 986 F.Supp. 1386, 1391 (S.D. Fla. 1997), *aff'd* 226 F.3d 646 (11th Cir. 2000) (noting that the court may go beyond the administrative record where agency may have acted in bad faith).

The DEA's bad faith here is manifested in numerous ways. The DEA has dragged its feet repeatedly when acting on past marijuana rescheduling petitions, *see supra*, which prompted the court in *United States v. Cannabis Cultivators Club*, 5 F.Supp.2d 1086 (N.D. Cal. 1998), to express its frustration with the pace of this process as follows:

> The Court doubts whether a rescheduling petition is a reasonable alternative for all seriously ill patients whose physicians have recommended marijuana for therapeutic purposes. For example, such a petition was filed in 1972 and did not receive a final ruling from the Administrator of the Drug Enforcement Agency until 1992, and a final

> decision on appeal until 1994. *See Alliance for Cannabis Therapeutics v. Drug Enforcement Administrator*, 15 F.3d 1131 (D.C. Cir. 1994). Needless to say, it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to alleviate a current medical problem.

Id. at 1102.

With respect to the instant Petition, the DEA felt confident enough of its knowledge of the state of the science that on April 20, 2006, it joined with HHS in disseminating on the FDA website an Inter-Agency Advisory reaffirming its previously disseminated conclusion that "marijuana . . . has no currently accepted medical use in treatment in the United States. . . ." *See* http:/www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html. And, on August 2, 2010, it received HHS' scientific findings and recommendations. The DEA has taken more than twice as long to act on these recommendations than in other drug rescheduling petitions, *see* Elford Decl., and more than twelve times longer than it took to act on HHS' evaluation with respect to the marijuana rescheduling petition filed in 1995. This all reveals that the DEA has acted in bad faith in its treatment of the instant rescheduling Petition, dragging the process out intentionally solely for the purpose of delay.

III. PETITIONERS HAVE NO OTHER ADEQUATE REMEDY

Mandamus is proper only if "there is no other adequate remedy available to the plaintiff." *Northern States Power Co. v. DOE*, 128 F.3d 754, 758 (D.C. Cir. 1997) (citation omitted). Because the DEA's error is its unreasonable delay in acting, there is no

agency action to review and Petitioners' only avenue for relief is to seek a writ of mandamus.

IV. THE DEA SHOULD BE ORDERED TO ISSUE ITS RESCHEDULING DETERMINATION AND/OR DENIAL OR INITIATION OF RULEMAKING PROCEEDINGS WITHIN 60 DAYS

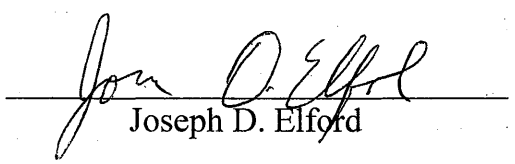
Given that the DEA has already effectively made a rescheduling determination more than four years ago, the Court does not need to wrestle strenuously with the question of how much more time is needed for the DEA to complete its task. Sixty days is more than enough time for the DEA to issue a document it has effectively completed.

CONCLUSION

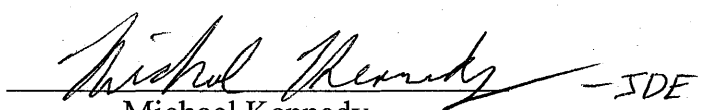
For the reasons set forth above, Petitioners respectfully request that this Court issue a writ of mandamus requiring the DEA to issue within sixty days its determination on the rescheduling Petition, or, alternatively, its decision wither to initiate rulemaking proceedings.

DATED: May 23, 2011

Respectfully Submitted,



Joseph D. Elford



Michael Kennedy
David Holland

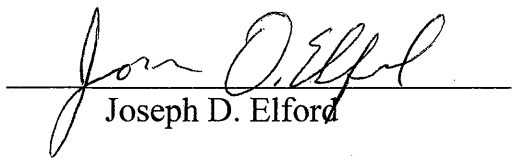
Counsel for Petitioners

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 13 points, and contains 7,145 words.

DATED: May 23, 2011

Respectfully Submitted,



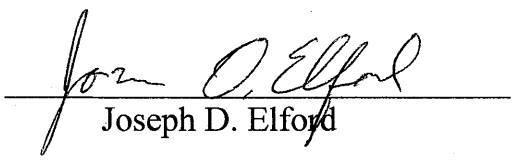
Joseph D. Elford

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.

DATED: May 23, 2011

Respectfully Submitted,



Joseph D. Elford