No. 09-1162

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

CARL ERIC OLSEN,
Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION,
Respondent.

Petition for Review
from the Drug Enforcement Administration

BRIEF FOR PETITIONER

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SUMMARY OF THE CASE

This is a petition for review from a final determination of the Drug Enforcement Administration rejecting a petition to remove marijuana from Schedule I of the Controlled Substances Act under 21 U.S.C. § 812(b)(1)B).

The unlawful scheduling of marijuana interferes with the Petitioner's right to use cannabis as a religious sacrament.

Oral argument is necessary in order that the legal principles controlling Petitioner's fundamental rights are thoroughly considered.

Oral argument should be held in this case because it involves novel issues relating to the application of a recent Supreme Court decision affirming the fundamental right of states to determine accepted medical practice. Twenty minutes should be allotted for argument.

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JURISDICTIONAL STATEMENT

The Drug Enforcement Administration (hereafter "DEA") had jurisdiction over this action under 21 U.S.C. § 811(a) and 21 C.F.R. § 1308.43, as the claims set forth in the Petition arise under the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 et seq.

Carl Olsen (hereafter "Olsen"), Petitioner below, sought the removal of marijuana from Schedule I of the CSA because marijuana no longer meets the finding required by the CSA of having no "accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B).

This Court has jurisdiction over this petition under 21 U.S.C. § 877, as it is from the December 19, 2008, final determination of the DEA received by the Petitioner on January 5, 2009. The Petition for Review was timely mailed to this Court on January 16, 2009, and docketed on January 21, 2009. This petition is from a final determination of the DEA that disposes of all the parties' claims.

ISSUE PRESENTED FOR REVIEW

1. Does the Controlled Substances Act ("CSA") bar the states from enacting laws accepting the medical use of marijuana?

Gonzales v. Oregon, 546 U.S. 243 (2006);
21 U.S.C. § 903;
City of Garden Grove v. Superior Court, 157 Cal.App.4th 355, 68 Cal.Rptr.3d 656 (Cal. App. 4th Dist., 2007), ***cert. denied***, ___ U.S. ___, 129 S.Ct. 623, 172 L.Ed.2d 607 (2008).

2. Does the Controlled Substances Act ("CSA") recognize the authority of state lawmakers to determine whether a substance has "accepted medical use" as that phrase is used in the phrase "Placement on schedules; findings required" in the CSA?

Gonzales v. Oregon, 546 U.S. 243 (2006);
21 U.S.C. § 812(b);
21 U.S.C. §§ 812(b)(1)(B), (2)(B), (3)(B), (4)(B), (5)(B);
Grinspoon v. DEA, 828 F.2d 881 (1st Cir. 1987).

STATEMENT OF THE CASE

The instant case is a petition brought by the Petitioner, Carl Olsen (hereafter "Olsen"), against the Respondent, Drug Enforcement Administration (hereafter "DEA"), who is responsible for the enforcement and administration of the Controlled Substances Act (hereafter "CSA"). Olsen's petition (May 12, 2008), memorandum of law (May 25, 2008), and notice to cease and desist (August 5, 2008), sought the removal of marijuana from the CSA because marijuana no longer meets the required findings for inclusion in Schedule I of the CSA.

Olsen was instructed to petition the DEA to remove marijuana from the CSA by the United States District Court for the Southern District of Iowa in ***Carl Eric Olsen v. Alberto R. Gonzales, et al.***, No. 4:07-cv-0023-JAJ, ORDER entered on July 16, 2007 (docket number 49, at page 17):

> **3. Other Claims**
>
> **a. Count V: Iowa Controlled Substance Act**
>
> Olsen asserts that Defendants have criminally prosecuted him in the past and have threatened to criminally prosecute him in the future due to the "erroneous and unlawful determination that Cannabis is a controlled substance under the CSA." Defendants assert that this court lacks jurisdiction to remove marijuana from the CSA and that the "CSA provides "an administrative remedy for any interested

> party to request that a substance be deleted entirely from the CSA or be transferred to a less restrictive schedule." citing 21 U.S.C. § 811(a). This court agrees and dismisses Count V as to all Defendants.

Olsen v. Gonzales (S.D. Ia., July 16, 2007), ***aff'd sub nom. Olsen v. Mukasey***, 541 F.3d 827 (8th Cir. 2008). Olsen has petitioned the United States Supreme Court for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit, ***Carl Eric Olsen v. Eric H. Holder, Jr., et al.***, No. 08-777. On January 29, 2009, the Supreme Court requested that the Attorney General of the United States respond to Olsen's petition by March 2, 2009.

Because Olsen's May 12, 2008, petition, May 25, 2008, memorandum, and August 5, 2008, notice were all based on the plain language of the statute and the only evidence presented by Olsen consisted entirely of 12 state medical marijuana laws which federal courts may notice under Federal Rule of Evidence 201, Olsen believed that he was entitled to immediate declaratory and injunctive relief under 28 U.S.C. § 1331 and 28 U.S.C. §§ 2201-2202 without waiting for a response to his petition from the DEA. See ***Monson v. DEA***, 522 F. Supp. 2d 1188 (D.N.D. 2007); ***Monson v. DEA***, No. 07-3837 (8th Cir., Argued and Submitted November 12, 2008).

On September 15, 2008, Olsen filed a civil complaint for declaratory and injunctive relief against the Attorney General of the United States, the DEA, and the United States Secretary of State which is currently pending in the United States District Court for the Southern District of Iowa, ***Carl Eric Olsen v. Eric H. Holder, Jr., et al.***, No. 4:08-cv-00370-RP-RAW.

Olsen is not an attorney and respectfully requests a liberal interpretation of all pleadings under ***Haines v. Kerner***, 404 U.S. 519 (1972).

STATEMENT OF FACTS

In enacting the CSA, Congress classified marijuana as a Schedule I controlled substance. 21 U.S.C. § 812(c) – Schedule I (c)(10). This preliminary classification was based, in part, on the recommendation of the Assistant Secretary of HEW "that marihuana be retained within schedule I at least until the completion of certain studies now underway." House Report No. 91-1444, at 61, September 10, 1970, 1970 U.S.C.C.A.N. 4566, at 4578-4579 (quoting letter from Roger E. Egeberg, M. D. to Hon. Harley O. Staggers (Aug. 14, 1970)). *See* ***Gonzales v. Raich***, 545 U.S. 1, 14 (2005) (hereafter "Raich").

> Schedule I controlled substances are categorized as such because of their high potential for abuse, lack of any accepted medical use, and absence of any accepted safety for use in medically supervised treatment. § 812(b)(1). These three factors, in varying gradations, are also used to categorize drugs in the other four schedules. For example, Schedule II substances also have a high potential for abuse which may lead to severe psychological or physical dependence, but unlike Schedule I drugs, they have a currently accepted medical use. § 812(b)(2). By classifying marijuana as a Schedule I drug, as opposed to listing it on a lesser schedule, the manufacture, distribution, or possession of marijuana became a criminal offense, with the sole exception being use of the drug as part of a Food and Drug Administration pre-approved research study. §§ 823(f), 841(a)(1), 844(a); see also *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 490 (2001).

Raich, at 14.

"The CSA provides for the periodic updating of schedules and delegates authority to the Attorney General, after consultation with the Secretary of Health and Human Services, to add, remove, or transfer substances to, from, or between schedules. § 811." ***Raich***, at 14-15. The current scheduling of marijuana is found at 21 C.F.R. § 1308.11(d)(22).

Prior to the enactment of the first state medical marijuana law in California in 1996, courts consistently deferred to the DEA's determination that marijuana had no currently accepted medical use of marijuana in the United States. ***NORML v. DEA***, 559 F.2d 735, 743

n.41 (D.C. Cir. 1977), quotes from a letter reproduced at 40 Fed. Reg. 44,165 (1975) – Theodore Cooper, M.D., Acting Assistant Secretary for Health wrote, "There is currently no accepted medical use of marihuana in the United States."

In 1989, the DEA rejected a petition to transfer marijuana from Schedule I to Schedule II, 54 Fed. Reg. 53,767 (1989). The administrative record did not include evidence of any state law accepting the medical use of marijuana. The only evidence presented in the administrative record was that some patients and some physicians considered marijuana to have therapeutic value. ***Alliance for Cannabis Therapeutics v. DEA***, 930 F.2d 936, 938 (D.C. Cir. 1991):

> The Administrator rejected the ALJ's recommendation, however, determining that the phrase "currently accepted medical use" required a greater showing than that a minority – even a respectable minority – of physicians accept the usefulness of a given drug.

On remand, the DEA administrator determined that the second two findings required by the CSA for inclusion of a substance in Schedule I are analytically the same, 21 U.S.C. §§ 812(b)(1)(B), 812(b)(1)(C). DEA Docket No. 86-22, 57 Fed. Reg. 10,499, at 10,504 (March 26, 1992):

> It must be emphasized that while the existence of adequate safety tests is a separate analytical question, the ultimate determination of whether a drug is safe for a specific use is

> not a distinct issue. Safety and effectiveness are inextricably linked in a risks-benefits calculation. A determination that a drug is ineffective is tantamount to a determination that it is unsafe. *United States v. Rutherford*, 442 U.S. 544 (1970).
>
> The scheduling criteria of the Controlled Substances Act appear to treat the lack of medical use and lack of safety as separate considerations. Prior rulings of this Agency purported to treat safety as a distinct factor. 53 FR 5156 (February 22, 1988). In retrospect, this is inconsistent with scientific reality. Safety cannot be treated as a separate analytical question.

The DEA administrator also determined that the CSA does not give the DEA administrator the authority to determine whether or not a drug should be used as medicine. DEA Docket No. 86-22, 57 Fed. Reg. 10,499, 10,506 (March 26, 1992):

> Clearly, the Controlled Substances Act does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he is limited to determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word "accepted" out of the statutory standard.

The last ruling of the DEA administrator on the rescheduling of marijuana specifically mentions a logical flaw in the 1995 petition filed by Jon Gettman and High Times Magazine. The DEA administrator noted the absence in the administrative record of any evidence of "accepted medical use" of marijuana in the United States. The DEA

administrator's final ruling on the petition to reschedule marijuana, 66 Fed. Reg. 20,038, at pages 20,038-20,039 (April 18, 2001), states:

> DEA's denial of your petition is based exclusively on the scientific and medical findings of HHS, with which DEA concurs, that lead to the conclusion that marijuana has a high potential for abuse. Nonetheless, independent of this scientific and medical basis for denying your petition, there is a logical flaw in your proposal that should be noted.
>
> You do not assert in your petition that marijuana has a currently accepted medical use in treatment in the United States or that marijuana has an accepted safety for use under medical supervision. Indeed, the HHS scientific and medical evaluation reaffirms expressly that marijuana has no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision.

See ***Gettman v. DEA***, 290 F.3d 490 (D.C. Cir. 2003). The first state medical marijuana law was enacted in California in 1996. Mr. Gettman filed his petition in 1995. There was no evidence that marijuana had any currently accepted medical use in the United States in 1995 when the Gettman petition was filed.

Since 1996, a total of 13 states have enacted laws accepting the medical use of marijuana. Olsen's petition gave statutory citations to 12 states statutes accepting the medical use of marijuana. Alaska Statutes § 17.37.070(8) (2008); California Health & Safety Code § 11362.5 (2008); Colorado Constitution Article XVIII, Section 14(b)

(2007); Hawaii Revised Statutes § 329-121(3)(paragraph 3) (2008); 22 Maine Revised Statutes § 2383-B(5) (2008); Montana Code Annotated § 50-46-102(5) (2007); Nevada Revised Statutes Annotated § 453A.120 (2007); New Mexico Statutes Annotated § 26-2B-2 (2008); Oregon Revised Statutes § 475.302(8) (2007); Rhode Island General Laws § 21-28.6-3(4) (2008); 18 Vermont Statutes Annotated § 4472(10) (2007); Revised Code Washington (ARCW) § 69.51A.010(2) (2008).

In November of 2008, Michigan became the 13th state to accept the medical use of marijuana (by voter initiative, Proposal 08-1). http://miboecfr.nictusa.com/election/results/08GEN/90000001.html, last accessed February 14, 2009.

PETITIONER'S STANDING

Olsen has consistently been denied his Constitutional and statutory right to establish and freely exercise his religion. Courts have repeatedly cited the scheduling of marijuana in Schedule I of the CSA as an overriding and compelling governmental interest that outweighs Olsen's religious freedom. ***Olsen v. DEA***, 878 F.2d 1458, 1459 (D.C. Cir. 1989), ***cert. denied***, 495 U.S. 906 (1990):

> [Olsen's] federal convictions were based on the Controlled Substances Act, 21 U.S.C. §§ 801-904 (1982), which lists

> marijuana as a "Schedule I" controlled substance with a "high potential for abuse." Id. § 812(b)(1)(A) & (c) [sic].

Because Olsen is being denied rights secured by the First Amendment to the Constitution of the United States, as well as the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb et seq., Olsen has Article III standing to bring this action before this Court. ***Elrod v. Burns***, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury").

This Court rejected Olsen's establishment and free exercise of religion claim in ***Olsen v. Mukasey***, 541 F.3d 827, 831 (8th Cir. 2008), based on the scheduling of marijuana in Schedule I cited as a compelling governmental interest overriding Olsen's establishment and free exercise of religion in all of Olsen's previous cases:

> The pre-*Smith* standard applicable in *Olsen*, *Rush*, and *DEA* is the same standard applicable to Olsen's current claim. There is no difference in the controlling law. Olsen's federal RFRA claim is barred by collateral estoppel.

In ***Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal***, 546 U.S. 418, 432-434 (2006), the U.S. Supreme Court found that the scheduling of a controlled substance is an important factor to be considered in the balancing of harms a court must weigh in applying

the compelling interest test of ***Sherbert v. Verner***, 374 U.S. 398 (1963), and ***Wisconsin v. Yoder***, 406 U.S. 205 (1972), required by the Religious Freedom Restoration Act ("RFRA"):

> Under the more focused inquiry required by RFRA and the compelling interest test, the Government's mere invocation of the general characteristics of Schedule I substances, as set forth in the Controlled Substances Act, cannot carry the day. It is true, of course, that Schedule I substances such as DMT are exceptionally dangerous. See, *e.g.*, *Touby v. United States*, 500 U.S. 160, 162, 111 S. Ct. 1752, 114 L. Ed. 2d 219 (1991). Nevertheless, there is no indication that Congress, in classifying DMT, considered the harms posed by the particular use at issue here -- the circumscribed, sacramental use of *hoasca* by the UDV. The question of the harms from the sacramental use of *hoasca* by the UDV was litigated below. Before the District Court found that the Government had not carried its burden of showing a compelling interest in preventing such harms, the court noted that it could not "ignore that the legislative branch of the government elected to place materials containing DMT on Schedule I of the [Act], reflecting findings that substances containing DMT have 'a high potential for abuse,' and 'no currently accepted medical use in treatment in the United States,' and that 'there is a lack of accepted safety for use of [DMT] under medical supervision.'" 282 F. Supp. 2d, at 1254. But Congress' determination that DMT should be listed under Schedule I simply does not provide a categorical answer that relieves the Government of the obligation to shoulder its burden under RFRA.
>
> This conclusion is reinforced by the Controlled Substances Act itself. The Act contains a provision authorizing the Attorney General to "waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety." 21 U.S.C. § 822(d). The fact that the Act itself contemplates

that exempting certain people from its requirements would be "consistent with the public health and safety" indicates that congressional findings with respect to Schedule I substances should not carry the determinative weight, for RFRA purposes, that the Government would ascribe to them.

And in fact an exception has been made to the Schedule I ban for religious use. For the past 35 years, there has been a regulatory exemption for use of peyote – a Schedule I substance – by the Native American Church. See 21 CFR § 1307.31 (2005). In 1994, Congress extended that exemption to all members of every recognized Indian Tribe. See 42 U.S.C. § 1996a(b)(1). Everything the Government says about the DMT in *hoasca* – that, as a Schedule I substance, Congress has determined that it "has a high potential for abuse," "has no currently accepted medical use," and has "a lack of accepted safety for use . . . under medical supervision," 21 U.S.C. § 812(b)(1) – applies equal measure to the mescaline in peyote, yet both the Executive and Congress itself have decreed an exception from the Controlled Substances Act for Native American religious use of peyote. If such use is permitted in the face of the congressional findings in § 812(b)(1) for hundreds of thousands of Native Americans practicing their faith, it is difficult to see how those same findings alone can preclude any consideration of a similar exception for the 130 or so American members of the UDV who want to practice theirs. See *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 547, 113 S. Ct. 2217, 124 L. Ed. 2d 472 (1993) ("It is established in our strict scrutiny jurisprudence that 'a law cannot be regarded as protecting an interest 'of the highest order' . . . when it leaves appreciable damage to that supposedly vital interest unprohibited'" (quoting *Florida Star v. B. J. F.*, 491 U.S. 524, 541-542, 109 S. Ct. 2603, 105 L. Ed. 2d 443 (1989) (SCALIA, J., concurring in part and concurring in judgment))).

The Government responds that there is a "unique relationship" between the United States and the Tribes,

> Brief for Petitioners 27; see *Morton v. Mancari*, 417 U.S. 535, 94 S. Ct. 2474, 41 L. Ed. 2d 290 (1974), but never explains what about that "unique" relationship justifies overriding the same congressional findings on which the Government relies in resisting any exception for the UDV's religious use of *hoasca*. In other words, if any Schedule I substance is in fact always highly dangerous in any amount no matter how used, what about the unique relationship with the Tribes justifies allowing their use of peyote? Nothing about the unique political status of the Tribes makes their members immune from the health risks the Government asserts accompany any use of a Schedule I substance, nor insulates the Schedule I substance the Tribes use in religious exercise from the alleged risk of diversion.
>
> The Government argues that the existence of a congressional exemption for peyote does not indicate that the Controlled Substances Act is amenable to judicially crafted exceptions. RFRA, however, plainly contemplates that courts would recognize exceptions – that is how the law works. See 42 U.S.C. § 2000bb-1(c) ("A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government"). Congress' role in the peyote exemption – and the Executive's, see 21 CFR § 1307.31 (2005) – confirms that the findings in the Controlled Substances Act do not preclude exceptions altogether; RFRA makes clear that it is the obligation of the courts to consider whether exceptions are required under the test set forth by Congress.

This Court's determination in ***Olsen v. Mukasey***, 541 F.3d 827 (8th Cir. 2008), that collateral estoppel bars Olsen's RFRA claim rests on an assumption that marijuana is correctly scheduled in the CSA. Olsen is irreparably injured by the failure of the DEA to obey the plain

statutory language of the CSA and remove marijuana from Schedule I of the CSA.

The U.S. District Court in ***Carl Eric Olsen v. Alberto R. Gonzales, et al.***, No. 4:07-cv-0023-JAJ, ORDER entered on July 16, 2007 (docket number 49, at page 17), clearly told Olsen to bring this matter to the attention of the DEA. Olsen has brought this matter to the attention of the DEA. This Court must now determine whether the DEA has lawfully refused to remove marijuana from 21 C.F.R. § 1308.11 now that marijuana has been accepted for medical use by 13 states in the United States.

The accepted medical use of marijuana and the manner in which the states have accepted it (allowing personal cultivation, or cultivation by a caregiver, for a patient's personal medical use), shows there is no compelling governmental interest in preventing Olsen from practicing his religion. The fact that federal law recognizes the authority of the states to make these medical determinations and the DEA is unlawfully regulating marijuana in the wrong schedule proves the irreparable injury that gives Olsen standing to bring this Petition for Review.

ARGUMENT

I. STANDARD OF REVIEW

The standard of review in ***Grinspoon v. DEA***, 828 F.2d 881, 884-885 (1st Cir. 1987), is as follows:

> The Administrator argues correctly that we must review his interpretation of the CSA in light of the guidelines set forth by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984). In *Chevron* the Court explained that a reviewing court must employ a two-step analysis that focuses initially on the intentions of Congress:
>
> > First, always, is the question whether Congress had directly spoken to the precise question at issue. If *the intent of Congress is clear*, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.
>
> *Id.* at 842-43 (emphasis supplied). In the absence of congressional intent, however, the court must proceed to a second inquiry:
>
> > If . . . the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, 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 (footnote omitted; emphasis supplied).

II. ACCEPTED MEDICAL USE

Congress enacted the CSA as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. P. L. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801-904). The purpose of the CSA is to regulate the use of controlled substances for legitimate medical purposes and to prevent those substances from being diverted for illegal manufacture, distribution, and use. Controlled substances are categorized into five schedules, ranging from Schedule I substances that have no currently accepted medical use in treatment and can only be used in very limited circumstances, to substances in Schedules II, III, IV, and V that have accepted medical uses and may be manufactured, distributed, and used in accordance with the CSA. *See* 21 U.S.C. § 812.

The "finding" required by the CSA for inclusion of a substance in Schedule I is that it must have no "accepted medical use in treatment in the United States". 21 U.S.C. § 812(b)(1)(B). The meaning of this requirement has previously been interpreted in ***Grinspoon v. DEA***, 828 F.2d 881, 886 (1st Cir. 1987), to mean accepted medical use in "any" state in the United States regardless of approval by the Food and Drug Administration (hereafter "FDA") for interstate marketing:

> The CSA's definition of "United States" plainly does not require the conclusion asserted by the Administrator simply because section 802(28) defines "United States" as "all places subject to the jurisdiction of the United States." 21 U.S.C. § 802(28) (emphasis supplied). Congress surely intended the reference to "all places" in section 802(28) to delineate the broad jurisdictional scope of the CSA and to clarify that the CSA regulates conduct occurring any place, as opposed to every place, within the United States. As petitioner aptly notes, a defendant charged with violating the CSA by selling controlled substances in only two states would not have a defense based on section 802(28) if he contended that his activity had not occurred in "all places" subject to United States jurisdiction. We add, moreover, that the Administrator's clever argument conveniently omits any reference to the fact that the pertinent phrase in section 812(b)(1)(B) reads "in the United States," (emphasis supplied). We find this language to be further evidence that the Congress did not intend "accepted medical use in treatment in the United States" to require a finding of recognized medical use in every state or, as the Administrator contends, approval for interstate marketing of the substance.

The meaning of "accepted medical use" was considered again in ***Alliance for Cannabis Therapeutics v. DEA***, 930 F.2d 936, 939 (D.C. Cir. 1991):

> The difficulty we find in petitioners' argument is that neither the statute nor its legislative history precisely defines the term "currently accepted medical use"; therefore, we are obliged to defer to the Administrator's interpretation of that phrase if reasonable.
> . . .
> We certainly have no grounds, on this record, to dispute the Administrator's premise that without much more complete

> scientific data American physicians will not "accept" marijuana.

In 1991, and again in 1994 when ***Alliance for Cannabis Therapeutics v. DEA***, 15 F.3d 1131 (D.C. Cir. 1994) was decided, the record submitted by the petitioners contained no evidence that any state in the United States had accepted the medical use of marijuana. Prior to 1996, the question of whether state medical marijuana laws were controlling was not asked nor answered by federal courts (other than the explanation given by the Circuit Court in ***Grinspoon v. DEA***). The first state to accept the medical use of marijuana was California in 1996.

In the absence of any state law accepting the medical use of marijuana, it is entirely appropriate for the court to accept the DEA administrator's definition of "accepted medical use", if reasonable. New drugs, such as Marinol, 21 C.F.R. § 1308.13(g)(1) ("Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7369"), were not accepted by state lawmakers or widely accepted by a majority of physicians before they were accepted as having accepted medical use by the DEA administrator or for marketing approval by the FDA. The

CSA gives the DEA administrator the "limited" authority to determine accepted medical use of new drugs that have not been accepted by state lawmakers or a majority of physicians. ***Gonzales v. Oregon***, 546 U.S. 243, 258 (2006), discusses the limited authority of the DEA administrator:

> The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.

Gonzales v. Oregon, 546 U.S. 243, 259 (2006):

> The CSA gives the Attorney General limited powers, to be exercised in specific ways. His rulemaking authority under the CSA is described in two provisions: (1) "The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals," 21 U.S.C. § 821 (2000 ed. and Supp. V); and (2) "The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter," 21 U.S.C. § 871(b). As is evident from these sections, Congress did not delegate to the Attorney General authority to carry out or effect all provisions of the CSA. Rather, he can promulgate rules relating only to "registration" and "control," and "for the efficient execution of his functions" under the statute.

Gonzales v. Oregon, 546 U.S. 243, 262 (2006):

> By this logic, however, the Attorney General claims extraordinary authority. If the Attorney General's argument were correct, his power to deregister necessarily would include the greater power to criminalize even the actions of registered physicians, whenever they engage in conduct he deems illegitimate. This power to criminalize – unlike his power over registration, which must be exercised only after considering five express statutory factors – would be unrestrained. It would be anomalous for Congress to have so painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside "the course of professional practice," and therefore a criminal violation of the CSA.

The statutory factors for scheduling a substance, approved in ***Alliance for Cannabis Therapeutics v. DEA***, 15 F.3d 1131 (D.C. Cir. 1994), allow the DEA administrator to accept the medical use of a substance without any evidence in the record that any state in the United States has accepted the medical use of the substance. The marijuana rescheduling petition in ***Alliance for Cannabis Therapeutics*** would never have been accepted for filing if acceptance by state lawmakers was the only way a substance could be found to have accepted medical use. ***Gonzales v. Oregon***, 546 U.S. 243, 265 (2006) (emphasis added):

> The CSA allocates decisionmaking powers among statutory actors so that ***medical judgments, if they are to be***

> ***decided at the federal level*** and for the limited objects of the statute, are placed in the hands of the Secretary.

Marijuana is the only controlled substance in Schedule I that has ever been accepted for medical use by any state in the United States, so the question of whether state laws accepting the medical use of marijuana trigger automatic removal from Schedule I has never been presented to a federal court before. This is a legal question of first impression in the federal courts.

III. FEDERAL PREEMPTION

The CSA does not require that marijuana remain in Schedule I and expresses no value judgment as to whether marijuana should or should not have an accepted medical use in treatment in the United States. In placing marijuana in Schedule I, Congress was not telling the states they could not accept the medical use of marijuana. Congress was simply making an observation that marijuana had no currently accepted medical use in treatment in the United States when the CSA was enacted in 1970. *See* ***City of Garden Grove v. Superior Court***, 157 Cal. App. 4th 355, 68 Cal. Rptr. 3d 656 (Cal. App. 4th Dist., 2007), ***cert. denied***, ___ U.S. ___, 129 S. Ct. 623, 172 L. Ed. 2d 607 (2008).

Gonzales v. Oregon, 546 U.S. 243, 251 (2006):

> The CSA explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its pre-emption provision.
>
> "No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together." § 903.

IV. FEDERAL SUPREMACY

Not surprisingly, numerous court decisions have rejected making exceptions to the CSA for individual medical users. Because the CSA specifically contemplates methods for approving medical use, courts have been unwilling to carve out exceptions for individual medical users.

Gonzales v. Raich, 545 U.S. 1 (2005), rejected a claim that application of the CSA to purely intrastate, non-commercial, medical use of marijuana exceeds Congress' Commerce Clause powers. ***Raich*** did not consider whether marijuana was correctly scheduled in the CSA, because Raich did not contest the scheduling of marijuana in Schedule I of the CSA. The Court specifically mentioned that

marijuana may in fact not be correctly scheduled. ***Gonzales v. Raich***, 545 U.S. 1, 28 n.37 (2005):

> We acknowledge that evidence proffered by respondents in this case regarding the effective medical uses for marijuana, if found credible after trial, would cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I.

United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001), rejected a claim of medical necessity because the CSA specifically contemplates medical use. As in ***Raich***, the plaintiffs in ***Oakland*** did not contest the scheduling of marijuana in Schedule I of the CSA. The Court noted that the Attorney General could not put marijuana in Schedule I if it has any accepted medical use in the United States. ***United States v. Oakland Cannabis Buyers' Cooperative***, 532 U.S. 483, 492 (2001).

Similar cases rejecting exceptions for terminally ill patients from FDA regulations are ***United States v. Rutherford***, 442 U.S. 544 (1979), and ***Abigail Alliance v. FDA***, 495 F.3d 695 (D.C. Cir. 2007).

V. FEDERALISM

In its decision in ***Oregon v. Ashcroft***, 368 F.3d 1118, 1124 (9th Cir. 2004), the Ninth Circuit noted that in our system of federalism,

> [S]tate lawmakers, not the federal government, are "the primary regulators of professional [medical] conduct." *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002); see also *Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring). The Supreme Court has made the constitutional principle clear: "Obviously, direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18, 69 L. Ed. 819, 45 S. Ct. 446 (1925); see also *Barsky v. Bd. of Regents*, 347 U.S. 442, 449, 98 L. Ed. 829, 74 S. Ct. 650 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power.").

Oregon v. Ashcroft, 368 F.3d 1118, 1124-1125 (9th Cir. 2004):

> By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders and therefore "alters the 'usual constitutional balance between the States and the Federal Government.'" *Gregory v. Ashcroft*, 501 U.S. 452, 461, 115 L. Ed. 2d 410, 111 S. Ct. 2395 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242, 87 L. Ed. 2d 171, 105 S. Ct. 3142 (1985)). Under these circumstances, "it is incumbent on the federal courts to be certain of Congress' intent" before finding that federal authority supercedes state law. *Gregory*, 501 U.S. at 460 (quotation marks and citation omitted).
>
> Unless Congress' authorization is "unmistakably clear," the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care. *Id*. at 460-61 (quoting *Atascadero State Hosp*., 473 U.S. at 242); see also *Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173, 148 L. Ed. 2d 576, 121 S. Ct. 675 (2001) ("This concern is heightened where an administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power."); *United*

States v. Bass, 404 U.S. 336, 349, 30 L. Ed. 2d 488, 92 S. Ct. 515 (1971) ("Unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance."). In divining congressional intent, it is a "cardinal principle" of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems, [federal courts shall] construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575, 99 L. Ed. 2d 645, 108 S. Ct. 1392 (1988).

The Ashcroft Directive is invalid because Congress has provided no indication – much less an "unmistakably clear" indication – that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide. By attempting to regulate physician assisted suicide, the Ashcroft Directive invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice. See *Linder*, 268 U.S. at 18; *Conant*, 309 F.3d at 639. Because Congress has not clearly authorized such an intrusion, the Ashcroft Directive violates the clear statement rule. See *Solid Waste Agency*, 531 U.S. at 172-73; *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208-09, 141 L. Ed. 2d 215, 118 S. Ct. 1952. We need not, and therefore do not, decide whether the Ashcroft Directive actually exceeds Commerce Clause boundaries, but only that it "invokes the outer limits of Congress' power" without explicit authority from Congress. *Solid Waste Agency*, 531 U.S. at 172 (citing *Edward J. DeBartolo Corp.*, 485 U.S. at 575); see also *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208-09, 141 L. Ed. 2d 215, 118 S. Ct. 1952 (1998) ("Absent an unmistakably clear expression of intent to alter the usual constitutional balance between the States and the Federal Government, we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers.") (quotation marks and citations omitted).

Congress intended to limit that CSA to problems associated with drug abuse and addiction. The preamble to the CSA states its purpose: "to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse." Comprehensive Drug Abuse Prevention and Control Act of 1970, P. L. 91-513, 84 Stat. 1236 (1970) (preamble).

City of Garden Grove v. Superior Court, 157 Cal. App. 4th 355, 383, 68 Cal. Rptr. 3d 656, 675 (2007):

> Congress enacted the CSA to combat recreational drug abuse and curb drug trafficking. (*Gonzales v. Oregon*, supra, 546 U.S. at p. 271; *Gonzales v. Raich*, supra, 545 U.S. at pp. 10-13.) Its goal was not to regulate the practice of medicine, a task that falls within the traditional powers of the states. (Gonzales v. Oregon, supra, 546 U.S. at p. 269.)

City of Garden Grove v. Superior Court, 157 Cal. App. 4th 355, 383-384, 68 Cal. Rptr. 3d 656, 676 (2007):

> The [Compassionate Use Act] does not authorize doctors to use their prescription-writing powers "to engage in illicit drug dealing and trafficking as conventionally understood." Instead, the act grants doctors the authority to recommend marijuana to their patients for medicinal purposes. No other use is contemplated. As a matter of fact, the CUA provides that it shall not "be construed to supersede legislation prohibiting persons from engaging in conduct that endangers

> others, nor to condone the diversion of marijuana for nonmedical purposes." (§ 11362.5, subd. (b)(2).) Similarly, nothing in the MMP "shall authorize the individual to smoke or otherwise consume marijuana unless otherwise authorized by this article, nor shall anything in this section authorize any individual or group to cultivate or distribute marijuana for profit." (§ 11362.765.)
>
> These restrictions are consistent with the goals of the CSA. Irrespective of Congress's prohibition against marijuana possession, "[i]t is unreasonable to believe that use of medical marijuana by [qualified users under the CUA] for [the] limited purpose [of medical treatment] will create a significant drug problem" (*Conant v. McCaffrey* (N.D.Cal. 1997) 172 F.R.D. 681, 694, fn. 5, affd. *Conant v. Walters*, supra, 309 F.3d 629), so as to undermine the stated objectives of the CSA. (Cf. *Gonzales v. Oregon*, supra, 546 U.S. at p. 273 [state initiative allowing doctors to prescribe controlled substances for the purpose of facilitating a patient's suicide is not inconsistent with the CSA's objective to prevent recreational drug use].)

CONCLUSION

WHEREFORE, Carl Olsen respectfully moves this Court to instruct DEA to immediately remove marijuana from Schedule I of the CSA as required by the CSA.

Respectfully submitted,

By: _____

CARL OLSEN
Post Office Box 4091
Des Moines, Iowa 50333
(515) 288-5798

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing Brief for Petitioner complies with the type-volume limitation provided in Fed. R. App. P. 32(a)(7)(B). The foregoing brief contains 6,752 words of Century Schoolbook (14 point) proportional type. The word processing software used to prepare this brief was Microsoft Office Word 2007.

_____

Carl Olsen

CERTIFICATE OF SERVICE

Service of 2 copies of this brief were mailed by first class mail on the 27th day of February, 2009, to the following parties:

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Springfield, VA 22152

Ms. Michele Leonhart
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By: _____

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ADDENDUM

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JUN 25 2008

Mr. Carl Olsen
130 East Aurora Avenue
Des Moines, Iowa 50313-3654

Dear Mr. Olsen:

This letter pertains to the May 12, 2008, petition you submitted to the Drug Enforcement Administration (DEA) to amend 21 CFR § 1308.11(d)(22), to remove marijuana from schedule I of the Controlled Substances Act. The petition complies procedurally with the requirements of 21 CFR § 1308.43(b), and the DEA is therefore accepting the petition for filing.

If you should have further questions relating to your petition, please feel free to contact Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, at (202) 307-7183.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Deputy Chief of Operations
Office of Diversion Control

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

December 19, 2008

Mr. Carl Olsen
130 E Aurora Avenue
Des Moines, Iowa 50313-3654

Dear Mr. Olsen:

On May 12, 2008, you petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). You requested that DEA remove marijuana from schedule I of the CSA based on your assertion that the federal definition for a schedule I controlled substance no longer applies to it. You contend that federal drug law gives states the authority to determine accepted medical use and that marijuana, therefore, has a "currently accepted medical use in treatment in the United States" because 12 states have passed laws relating to the use of marijuana for medical purposes. Based on these same assertions, on August 5, 2008, you filed a "Notice and Deadline to Cease and Desist Illegal Enforcement of Fraudulant [sic] Marijuana Regulation." The notice states that the DEA must "cease and desist enforcement of the illegal regulation of marijuana" within 30 days or you will file a federal civil injunction.

The Deputy Administrator finds, for the reasons stated herein, that the grounds upon which you rely are not sufficient to justify the initiation of proceedings for the removal of marijuana from schedule I of the CSA. Accordingly, your petition is hereby denied. For the same reasons, the Deputy Administrator finds that the notice to cease and desist also lacks merit. Accordingly, to the extent you seek action based on this filing, this request also is hereby denied.

Legal Background

When the CSA was created, Congress specified the initial scheduling of controlled substances and the criteria by which controlled substances could be rescheduled. 21 U.S.C. §§ 811-812 (2008). Congress placed marijuana into schedule I. *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513, § 202(c), schedule I (c)(10), 84 Stat. 1247.

The Attorney General "may by rule" transfer a drug or other substance between schedules if he finds that such drug or other substance has a potential for abuse and

makes with respect to such drug or other substance the findings prescribed by subsection (b) of Section 812 for the schedule in which such drug is to be placed. 21 U.S.C. § 811(a)(1). In order for a substance to be placed in schedule I, the Attorney General must find that:

> (A) The drug or other substance has a high potential for abuse;
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States; and
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

21 U.S.C. § 812(b)(1)(A)-(C). To be classified in one of the other schedules (II through V), a drug of abuse must have a "currently accepted medical use in treatment in the United States."[1]

The CSA provides that, in making any rescheduling determination, the Attorney General shall consider the following eight factors:

> (1) The drug's actual or relative potential for abuse;
> (2) Scientific evidence of its pharmacological effect, if known;
> (3) The state of current scientific knowledge regarding the drug;
> (4) Its history and current pattern of abuse;
> (5) The scope, duration, and significance of abuse;
> (6) What, if any, risk there is to the public health;
> (7) The drug's psychic or physiological dependence liability; and
> (8) Whether the substance is an immediate precursor of a substance already controlled under the CSA.

21 U.S.C. § 811(c). The Attorney General has delegated this authority to the Administrator of DEA, who has redelegated it to the Deputy Administrator. *See* 28 C.F.R. §§ 0.100(b) & 0.104, Appendix to Subpart R, sec. 12 (2008).

The CSA further provides that, before initiating proceedings to reschedule a drug, the Administrator must gather the necessary data and request from the Secretary of Health and Human Services (HHS) a scientific and medical evaluation and recommendations as to whether the controlled substance should be rescheduled

[1] A controlled substance in schedule II must have either "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B); *see also* Notice of Denial of Petition, 66 Fed. Reg. 20,038, 20,038 (Apr. 18, 2001) ("Congress established only one schedule – schedule I – for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and a 'lack of accepted safety for use . . . under medical supervision.'").

as the petitioner proposes. 21 U.S.C. § 811(b); 21 C.F.R. § 1308.43(d); *Gettman v. DEA*, 290 F.3d 430, 432 (D.C. Cir. 2002). In making such evaluation and recommendations, the Secretary must consider the factors listed in paragraphs (2), (3), (6), (7), and (8) above, and any scientific or medical considerations involved in paragraphs (1), (4), and (5) above. 21 U.S.C. § 811(b). The Secretary has delegated this function to the Assistant Secretary for Health.[2] If the Administrator determines that the evaluations and recommendations of the Assistant Secretary and "all other relevant data" constitute substantial evidence that the drug that is the subject of the petition should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings to reschedule the drug or remove it from the schedules as the evidence dictates. 21 U.S.C. § 811(b); 21 C.F.R. § 1308.43(e).

Basis for Denial of Your Petition and Notice

Your petition and notice rest on your contention that federal drug law gives states the authority to determine, for purposes of the CSA, whether a drug has a "currently accepted medical use in treatment in the United States," and that marijuana has such a currently accepted medical use because 12 states have passed laws relating to the use of marijuana for medical purposes. *See* Carl Olsen Petition for Marijuana Rescheduling (May 12, 2008) ("Pet."); Carl Olsen Memorandum of Law in Support of Petition for Marijuana Rescheduling (May 25, 2008) ("Mem."); Notice and Deadline to Cease and Desist Illegal Enforcement of Fraudulant [sic] Marijuana Regulation (Aug. 5, 2008) ("Notice").[3] For the following reasons, your contention is not in accordance with law.

A. The CSA's Statutory Scheme

The CSA's statutory scheme disproves your contention that federal drug law gives states the authority to determine whether a drug has a "currently accepted medical use" within the meaning of the CSA. You rely on Section 903 of the CSA, *see* Pet. at 2; Mem. at 16; Notice at 1, which provides that: "No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any state law on

---

[2] As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. Memorandum of Understanding with the Nat'l Inst. on Drug Abuse, 50 Fed. Reg. 9,518 (Mar. 8, 1985).

[3] You do not, in this petition or notice, dispute whether marijuana meets the first criterion for schedule I or schedule II, *i.e.*, that the substance has a high potential for abuse. Nor do you purport to present new scientific or medical evidence – beyond that previously considered by DEA in its prior denial of another petition to reschedule marijuana, *see* Notice of Denial of Petition, 66 Fed. Reg. at 20,038 – regarding whether marijuana has a currently accepted medical use. *See generally* Pet.; Mem.; Notice. Finally, you do not raise any religious use arguments such as those you previously raised and recently had rejected in the United States Court of Appeals for the Eighth Circuit. *See Olsen v. Mukasey*, 541 F.3d 827 (8th Cir. 2008) (rejecting Olsen's religious use claims under the Religious Freedom Restoration Act and the Religious Land Use and Institutionalized Persons Act and rejecting Olsen's free exercise and equal protection claims).

the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together." 21 U.S.C. § 903 (2008).

As a threshold matter, 21 U.S.C. § 903 merely reaffirms, for purposes of the CSA, what is inherent in the supremacy clause of the United States Constitution: that any state law that actually conflicts with federal law is preempted by federal law and therefore invalid under the supremacy clause.[4] Section 903 also provides that, so long as the states do not enact a law relating to controlled substances that creates a positive conflict with the CSA, the states are free to enact laws regulating controlled substances which would otherwise be within their authority that will operate alongside the CSA. Thus, it would be antithetical to the text of section 903 to cite it for the proposition that state controlled substance laws that conflict with the CSA can override or frustrate the purposes of the CSA. As the Supreme Court stated in the context of marijuana possession and cultivation taking place in purported compliance with California law: "The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail."[5]

Furthermore, the CSA plainly does not assign to the states the authority to make findings relevant to CSA scheduling determinations. Rather, the CSA expressly delegates the task of making such findings – including whether a substance has any currently accepted medical use – to the Attorney General. 21 U.S.C. § 811(a). The CSA also expressly tasks the Secretary of HHS to provide a scientific and medical evaluation and scheduling recommendations to inform the Attorney General's findings. 21 U.S.C. § 811(b).[6] That Congress explicitly provided scheduling authority to these two federal entities further precludes your argument that Section 903 reserves this authority to the states.

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

> (1) The drug's actual or relative potential for abuse;
> (2) Scientific evidence of its pharmacological effect, if known;
> (3) The state of current scientific knowledge regarding the drug;
> (4) Its history and current pattern of abuse;
> (5) The scope, duration, and significance of abuse;
> (6) What, if any, risk there is to the public health;
> (7) The drug's psychic or physiological dependence liability; and

[4] *See, e.g., California Fed. Sav. & Loan Assoc. v. Guerra*, 479 U.S. 272, 280-281 (1987).
[5] *Gonzales v. Raich*, 545 U.S. 1, 29 (2005).
[6] DEA regulations echo this statutory scheme. *See* 21 C.F.R. § 1308.43.

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

21 U.S.C. § 811(c). These factors do not include state law. The CSA's statutory text evidences that Congress did not envision such a role for state law in establishing the schedules of controlled substances under the CSA.[7]

B. Gonzales v. Oregon and Other Recent Supreme Court Cases

You further rely on *Gonzales v. Oregon*, 546 U.S. 243 (2006). *See* Pet. at 2-3; Mem. at 13; Notice at 4. This reliance also is misplaced. You argue that *Oregon* supports your petition by requiring federal authorities to defer to states' determinations on issues of medical practice. To the contrary, *Oregon* affirms the core federal authority of the Attorney General, in consultation with the Secretary of HHS, as to drug scheduling.

In *Oregon*, the United States Supreme Court considered the Attorney General's Interpretive Rule prohibiting doctors from prescribing controlled substances for use in physician-assisted suicide under an Oregon state law that permitted the procedure. *Id.* at 248. The Court held that the Rule was not entitled to deference because it was not issued pursuant to an explicit delegation of rulemaking authority. *Id.* at 258-69. The Court did not find the Attorney General's interpretation persuasive and invalidated the Rule because the CSA "manifests no intent to regulate the practice of medicine generally." *Id.* at 270.

In so holding, however, the Court repeatedly cited by contrast – as a valid and explicit delegation of authority – the Attorney General's power as to drug scheduling.[8] The Court observed that, by the text of the CSA itself, Congress had delegated "control" authority to the Attorney General to add, remove, or reschedule substances.[9] The Court further cited the CSA's detailed scheduling procedures, including the requirement to request a scientific and medical evaluation by the Secretary of HHS. *Id.* at 260. *Oregon* thus confirmed that, in contrast to the invalidated Rule, drug scheduling authority and the

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[7] DEA previously conducted lengthy proceedings to review a petition to reschedule marijuana from 1995 through 2001. After requesting and reviewing a scientific and medical evaluation from HHS, the Administrator denied the petition on the grounds that marijuana has no currently accepted medical use and because it is not safe for use even under medical supervision. Notice of Denial of Petition, 66 Fed. Reg. at 20,038, *pet. for review dismissed, Gettman*, 290 F.3d at 436. As you note, the Coalition for Rescheduling Cannabis filed a petition with the DEA in October 2002 discussing scientific and medical findings relating to the medical use of marijuana. That petition remains pending.

[8] *See Oregon*, 546 U.S. at 262 ("It would be anomalous for Congress to have painstakingly described the Attorney General's limited authority to . . . schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside 'the course of professional practice' and therefore a criminal violation of the CSA.").

[9] The Court noted that the term "control" is a term of art in the CSA, meaning to "add a drug or other substance . . . to a schedule . . . whether by transfer from another schedule or otherwise." *Oregon*, 546 U.S. at 260 (quoting 21 U.S.C. § 802(5)).

corresponding scheduling procedures are an appropriate exercise of the federal power granted in the CSA.

The Court also approvingly cited the CSA's explicit allocation of medical judgments in the scheduling context – not, as you argue, to states – but rather, to the Secretary: "The CSA allocates decision making powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary." *Id.* at 265. Whereas the invalidated Rule involved an overly broad assertion of authority, the drug scheduling context exemplified the "CSA's consistent delegation of medical judgments to the Secretary and its otherwise careful allocation of powers." *Id.* at 272. Thus, far from giving authority to the states, *Oregon* instead confirms the Attorney General's explicit authority, in conjunction with the Secretary's recommendations on scientific and medical matters, as to drug scheduling.

The two other recent Supreme Court cases you cite, *see* Mem. at 15-16; Notice at 3, likewise affirmed the primacy of federal law over state marijuana laws. In *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) ("*OCBC*"), the Court held that no medical necessity exception existed to the CSA's prohibition on manufacturing and distributing marijuana. Notwithstanding California state law authorizing possession and cultivation of marijuana for claimed medical purposes, Congress' clear determination that all schedule I controlled substances, including marijuana, have no currently accepted medical use forecloses any argument as to whether such drugs can be dispensed and prescribed for medical use. *Id.* at 493. The Court in *OCBC* was explicit in stating that "for purposes of the [CSA], marijuana has 'no currently accepted medical use' at all. § 812." *Id.* at 491. Similarly, in *Raich*, 545 U.S. 1, the Court held that, even in a state that had legalized marijuana activity for claimed medical use, Congress' federal commerce clause power extended to prohibit purportedly intrastate cultivation and use of marijuana in compliance with the state law. "Limiting the activity to marijuana possession and cultivation 'in accordance with state law' cannot serve to place respondents' activities beyond congressional reach." *Id.* at 29.

C. Whether A Drug Has A "Currently Accepted Medical Use in Treatment in the United States"

Your argument that there is no federal definition of "currently accepted medical use" also fails. In order to determine whether a substance has a "currently accepted medical use," the Administrator applies a five-part test:

1) The drug's chemistry must be known and reproducible;
2) There must be adequate safety studies;
3) There must be adequate and well-controlled studies proving efficacy;
4) The drug must be accepted by qualified experts; and
5) The scientific evidence must be widely available.

Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994) ("*ACT II*"). This test was approved by the United States Court of Appeals for the D.C. Circuit as a reasonable interpretation of the statutory language. *See id.* at 1134-5, 1137 (approving the Administrator's Final Order applying these five criteria); *see also Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991) ("*ACT I*"). Significantly, with respect to your petition, this test includes no reference to state law.

D. Other Arguments as to Currently Accepted Medical Use

A substantial portion of the remainder of your memorandum in support of your current petition and your notice merely rehash arguments as to "currently accepted medical use" that you unsuccessfully asserted when you petitioned DEA to reschedule marijuana in 1992 and when you sought review of DEA's denial of that petition by the United States Court of Appeals for the District of Columbia Circuit. The United States Court of Appeals, in declining your petition for review in a *per curiam* order issued October 3, 1996, stated that the arguments you raised "occasion no need for an opinion." *Olsen v. DEA*, No. 94-1605, 1996 WL 590870 (D.C. Cir. Oct. 3, 1996). It is, therefore, unnecessary for DEA to revisit these same arguments yet again in 2008.

Nevertheless, to ensure completeness of the record, we briefly address and dismiss these contentions. First, you discuss again at length litigation relating to the 1972 petition to reschedule marijuana filed by the National Organization for the Reform of Marijuana Laws (NORML), *see* Mem. at 7-9, and the United States Court of Appeals for the First Circuit's decision in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987). *See* Mem. at 9-12; Notice at 2. These cases are inapposite, however, as they were superseded by the subsequent *ACT I* and *ACT II* decisions approving the present five-factor test. *See ACT II*, 15 F.3d at 1133 (noting "[t]he petition to reschedule marijuana was first filed [by NORML] in 1972 and has been before this court on four prior occasions . . . ."); *ACT I*, 930 F.2d at 939-40 (explicitly distinguishing *Grinspoon*).[10]

Second, you reiterate arguments regarding the Convention on Psychotropic Substances, contending that it was modified in 1991 to allow for the medical use of the pharmaceutically pure primary psychoactive ingredient in marijuana, delta-9-THC, and

[10] The *Grinspoon* court never considered the present five-part test, but rather invalidated only a 1986 version of the "currently accepted medical use" test that depended on FDA approval. 828 F.2d at 884. On administrative remand, the test evolved before being replaced with the present five-part test approved in *ACT I* and *ACT II*. *See* Schedules of Controlled Substances, 53 Fed. Reg. 5,156, 5,157 (Feb. 22, 1988) (formulating alternative eight-factor test following *Grinspoon* remand); Marijuana Scheduling Petition; Denial of Petition, 54 Fed. Reg. 53,767, 53,783 (Dec. 29, 1989) (applying eight-factor test); Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,506 (Mar. 26, 1992) (discarding eight-factor test and applying present five-part test). As to possible duplication of criteria between the 1986 version of the test *Grinspoon* rejected and the present test, the *ACT I* court explicitly distinguished *Grinspoon*, stating that the First Circuit "never suggested the DEA Administrator was foreclosed from incorporating and relying on those standards employed by the FDA that are relevant to the pharmaceutical qualities of the drug." 930 F.2d at 939.

that this ingredient has been rescheduled twice, from schedule I to schedule III. Mem. at 4. You further contend that plants are not typically scheduled in schedules more restrictive than the psychoactive substances that are obtained from them. Mem. at 5. Under the CSA, however, the regulation of chemicals and the plant material are distinct from each other: drugs or other substances are treated and classified differently, according to the enumerated statutory criteria. 21 U.S.C. § 812(b); *see also* Final Order, In the Matter of Petition of Carl Eric Olsen (May 16, 1994) (rejecting petition to reschedule marijuana); *Olsen*, 1996 WL 590870, at *1 (denying Olsen's petition for review). Whether marijuana is a source of delta-9-THC is irrelevant to the status of marijuana under the CSA.

None of your remaining arguments as to whether marijuana has a currently accepted medical use have merit.[11] First, you reference a portion of the 1970 legislative history of the CSA relating to appointment of a commission that issued a report on marijuana in 1972, citing a portion of the 1972 report itself. *See* Mem. at 2-3. In the more than 36 years that have elapsed since these materials were published, however, numerous individuals and marijuana legalization advocates have pointed to the 1972 marijuana report to justify CSA violations involving marijuana, to challenge the constitutionality of the federal marijuana laws, or, as with your latest petition, to argue that marijuana should be deemed to have medical efficacy for purposes of the CSA.[12] None of these efforts have ever succeeded for the simple reason that Congress took no action to alter the CSA in any respect as a result of the 1972 report. The fact that Congress has not rescheduled marijuana speaks for itself.

You also observe that the federal government has supplied marijuana to medical patients through a program of compassionate use. Mem. at 5-6 (citing *Kuromiya v.*

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[11] Your notice in particular exhibits a fundamental misunderstanding of the "currently accepted medical use" standard. You argue that the DEA should have rescheduled marijuana in 1996 as soon as one state (California) passed legislation relating to the medical use of marijuana, citing *Raich*, *OCBC*, and *Grinspoon*. Notice at 2-3. But none of these cases support your argument. First, as you acknowledge, *see* Notice at 3, *Raich* noted that Congress classified marijuana in schedule I, that is, "Congress expressly found that [marijuana] has no acceptable medical uses." 545 U.S. at 27. Second, you ignore that *OCBC* specifically rejected an exception for the medical use of marijuana on the basis that Congress, and not the Attorney General, had placed marijuana in schedule I. The Court held:

> It is clear from the text of the [CSA] that Congress has made a determination that marijuana has no medical benefits worthy of an exception. . . . The statute . . . includes no exception at all for any medical use of marijuana. Unwilling to view this omission as an accident, and unable in any event to override a legislative determination manifest in a statute, we reject the [plaintiff's] argument.

532 U.S. at 493. Third, you misstate the holding of *Grinspoon*. That court did not say, as you argue, that a controlled substance cannot be scheduled in schedule I if it has accepted medical use *anywhere* in the United States; rather, it said only that "Congress did not intend . . . to require a finding of recognized medical use in *every* state." 828 F.2d at 886 (emphasis added).

[12] *See, e.g.*, *United States v. Cannabis Cultivators Club*, 5 F. Supp. 2d 1086, 1105 (N.D. Cal. 1998); *NORML v. Bell*, 488 F. Supp. 123, 128 (D.D.C. 1980); *United States v. LaFroscia*, 354 F. Supp. 1338, 1340 (S.D.N.Y. 1973).

United States, 78 F. Supp. 2d 367 (E.D. Pa. 1999)). The existence of this exception is not a ground for rescheduling. As the federal district court held in *Kuromiya*, the government's decision to continue the program at all was a "means of balancing" the interests of those who had relied on the drug with the government's desire to avoid distributing marijuana. 78 F. Supp. 2d at 370-71. You further claim that one participant's primary care doctor has retired, and that she is not able to find another doctor willing to prescribe marijuana because of the stigma associated with prescribing a schedule I substance. Mem. at 6. You have not provided any evidence to support this contention. Even if you had, one individual's potential hardship to participate in a compassionate use program is not adequate legal grounds for rescheduling. *See* 21 U.S.C. § 811(c).

Finally, you argue that the "DEA's own Administrative Law Judge [ALJ Young] has already determined that marijuana is safe for use under medical supervision." Olsen Petition at 4. As you acknowledge, however, *see* Pet. at 3, the DEA Administrator unambiguously rejected ALJ Young's determination in *In re Marijuana Rescheduling*, DEA Dkt. No. 86-22 (Sept. 6, 1998) (attached as Ex. 1 to Pet.). The D.C. Circuit later affirmed the DEA's final order (Mar. 26, 1992) in *ACT II*, 15 F.3d at 1135 (denying petition to review DEA's final order declining to reschedule marijuana). Nor is it accurate that the Administrator's rejection of ALJ Young's determination depended on the fact that no state had accepted the use of marijuana for medical purposes. In fact, ALJ Young's opinion had noted the efforts of a number of states to pass such legislation. *See, e.g.*, *In re Marijuana Rescheduling*, DEA Dkt. No. 86-22, ¶¶ 21, 22, 28. In any case, for the reasons set forth in detail above, the existence of state legislation is not relevant to a scheduling determination.

Conclusion

Accordingly, there is no statutory basis for DEA to grant your petition to initiate proceedings to reschedule marijuana. Nor is there any basis to initiate any action based on your August 5th notice.

The Petitioner's request is denied.

Sincerely,

Michele M. Leonhart
Deputy Administrator