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No. 09-1162

IN THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

CARL OLSEN,

Petitioner,

v.

Drug Enforcement Administration,

Respondent.

ON PETITION FOR REVIEW FROM THE DRUG ENFORCEMENT ADMINISTRATION

BRIEF FOR THE RESPONDENT

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### SUMMARY OF THE CASE AND STATEMENT REGARDING ORAL ARGUMENT

This case involves a petition to the Drug Enforcement Administration. Petitioner seeks an initiation of rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act to remove marijuana from schedule I of that Act. The DEA found that the grounds upon which petitioner relied did not justify the initiation of rulemaking proceedings, and accordingly denied the petition. In this petition for review, petitioner seeks an instruction that the Drug Enforcement Administration must remove marijuana from schedule I of the Controlled Substances Act.

Because petitioner's arguments are without merit and present no novel questions of law, the Drug Enforcement Administration does not believe oral argument is necessary in this case.

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Drug Enforcement Administration

Respondent.

ON PETITION FOR REVIEW FROM THE DRUG ENFORCEMENT ADMINISTRATION

BRIEF FOR THE RESPONDENT

### STATEMENT OF JURISDICTION

Petitioner invoked the Drug Enforcement Administration's jurisdiction under 21 U.S.C. § 811(a) and 21 C.F.R. § 1308.43. The DEA issued a final determination dated December 19, 2009 on the petition to initiate rulemaking proceedings. Petitioner's petition for review was docketed in this Court on January 21, 2009. Petitioner invokes this Court's jurisdiction under 21 U.S.C. § 877.

# STATEMENT OF THE ISSUES

1. Whether petitioner has Article III standing to challenge the Drug Enforcement Administration's denial of his petition to reschedule marijuana.

21 U.S.C. § 811

21 U.S.C. § 877

<u>Gettman</u> v. <u>Drug Enforcement Administration</u>, 290 F.3d 430 (D.C. Cir. 2002)

Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992)

2. Whether the Drug Enforcement Administration's conclusion that petitioner presented no grounds to initiate rulemaking procedures to reschedule marijuana was arbitrary, capricious, or otherwise contrary to law.

21 U.S.C. § 811

21 U.S.C. § 812(b)

<u>Alliance for Cannabis Therapeutics</u> v. <u>Drug Enforcement</u> <u>Admin.</u>, 15 F.3d 1131 (D.C. 1994)

## STATEMENT OF THE CASE

In enacting the Controlled Substances Act (CSA), Congress placed marijuana in schedule I, which includes substances with a "high potential for abuse," without a "currently accepted medical use in treatment in the United States," and for which "[t]here is a lack of accepted safety for use ... under medical supervision." 21 U.S.C. § 812(b)(1)(A-C). The statute establishes criteria to be applied by the Attorney General in rescheduling drugs, <u>see</u> 21 U.S.C. § 811.

Pursuant to 21 U.S.C. § 811(a), Carl Olsen filed a petition to reschedule marijuana. Certified Record (Rec.) Tab 1. Petitioner urged that various states have adopted laws decriminalizing medical uses of marijuana and that, as a matter of law, marijuana could thus not be deemed to have no currently accepted medical use.

The DEA denied the petition, and petitioner filed a petition for review in this Court under 21 U.S.C. § 877.

### STATEMENT OF FACTS

#### A. <u>Statutory Background</u>.

The CSA categorizes all controlled substances into five schedules based on whether they have an accepted medical use, potential for abuse, the risk for psychological and/or physical dependence, and accepted safety for use. 21 U.S.C. § 812. "Each schedule is associated with a distinct set of controls regarding

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the manufacture, distribution, and use of the substances listed therein." <u>Gonzales</u> v. <u>Raich</u>, 545 U.S. 1, 14 (2005).

In enacting the CSA, Congress classified marijuana as a schedule I drug. <u>See</u> 21 U.S.C. § 812(c)(C)(10). "Schedule I drugs 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." <u>Raich</u>, 545 U.S. at 14 (citing 21 U.S.C. § 812(b)(1)).

The CSA delegates authority to the Attorney General, after consultation with the Secretary of Health and Human Services, to change classifications based on specified criteria. <u>See</u> 21 U.S.C. § 811.<sup>1</sup> The statute provides that proceedings for a rule to reschedule substances may be initiated, <u>inter alia</u>, "on the petition of any interested party." 21 U.S.C. § 811(a). <u>See also</u> 21 C.F.R. § 1308.43 (setting forth procedures to petition the DEA).

As the Supreme Court noted in <u>Raich</u>, "[d]espite considerable efforts to reschedule marijuana, it remains a Schedule I drug." 545 U.S. at 15; <u>see also id</u>. n.23 (noting that "[t]he Court of Appeals for the District of Columbia Circuit has reviewed the petition to reschedule marijuana on five separate occasions over the course of 30 years, ultimately upholding the Administrator's

<sup>&</sup>lt;sup>1</sup> The Attorney General has delegated that authority to the Drug Enforcement Administration. <u>See</u> 28 C.F.R. §§ 0.100, 0.104.

final order") (citing <u>Alliance for Cannabis Therapeutics</u> v. <u>DEA</u>, 15 F.3d 1131, 1133 (1994)).

### B. <u>Prior Proceedings</u>.

On May 12, 2008, Carl Olsen petitioned the DEA to reschedule marijuana. Rec. Tab 1.<sup>2</sup> Petitioner argued that marijuana no longer fit the statutory criterion that schedule I substances have no "currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B). Asserting that "federal law defines accepted medical use to be whatever the states say it is," petitioner claimed that various states' enactment of laws decriminalizing marijuana for medical use obliged the DEA to reschedule marijuana out of schedule I. Rec. Tab 1 at 4; see also Rec. Tab 4 (petitioner's "Notice and Deadline to Cease and Desist Illegal Enforcement of Fraudulant [<u>sic</u>] Marijuana Regulation," reiterating that states' decriminalization of medical marijuana use should have "automatically triggered" the rescheduling of marijuana, and asserting that the DEA's failure to "cease and desist enforcement" of marijuana's status as a schedule I substance

<sup>&</sup>lt;sup>2</sup> Petitioner's assertion that the District Court for the Southern District of Iowa "instructed" him to file such a petition is without basis. Pet. Br. 3. Rather, that court simply noted that it lacked the authority to reschedule substances given 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." <u>Olsen v. Gonzales</u>, et al., No. 4:07-cv-0023, Docket #49, page 17 (July 16, 2007).

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"will result in a federal civil injunction being filed" against the DEA).

As indicated in his "Notice and Deadline," petitioner on September 15, 2008 filed a separate action in the United States District Court for the Southern District of Iowa seeking declaratory and injunctive relief from enforcement of marijuana as a schedule I substance. <u>See Olsen v. Mukasey</u>, No. 4:08-cv-00370 (S.D. Iowa). As of the filing date of this brief, the government's motion to dismiss this case for, <u>inter alia</u>, lack of jurisdiction was still pending.

In a decision dated December 19, 2008, the DEA denied the petition to reschedule marijuana, and denied any request for action based on the "Notice to Cease and Desist." Rec. Tab 5. DEA explained that federal law does not give states the authority to determine whether a drug has a "currently accepted medical use" within the meaning of the CSA. Rec. Tab 5 at 3. The statute on which petitioner rested this argument, the DEA stated, provided that states were free to enact laws regulating controlled substances that did not create a "positive conflict with the CSA." Rec. Tab 5 at 4 (citing 21 U.S.C. § 903). DEA also explained that the CSA expressly gives the authority to make scheduling determinations to the Attorney General, based on statutory factors that do not include reference to state law. Rec. Tab 5 at 4-5 (citing 21 U.S.C. § 811(c)).

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The agency noted that its five-part test for determining whether a substance has a "currently accepted medical use" within the meaning of the CSA, which does not reference state law, has been approved by the D.C. Circuit as a reasonable interpretation of the statutory criteria. Rec. Tab 5 at 5-7 (citing <u>Alliance</u> <u>for Cannabis Therapeutics</u>, 15 F.3d at 1135).

Noting that much of petitioner's petition included previously rejected arguments from petitioner's last petition to reschedule marijuana in 1992, the DEA nonetheless explained why: (1) previous court decisions related to a superseded version of the DEA's test to determine "currently accepted medical use" were inapposite; (2) marijuana's status as a plant rather than a chemical was irrelevant to marijuana's status under the CSA; (3) a congressionally appointed commission's 1972 report on marijuana was irrelevant given Congress' failure to amend the CSA in any respect based on that report; (4) a limited program of compassionate use was not grounds for rescheduling marijuana; and (5) a 1988 Administrative Law Judge's opinion which had been rejected by the DEA Administrator was not a basis for rescheduling marijuana. Rec. Tab 5 at 7-9.

On January 21, 2009, petitioner filed a petition for review in this Court under 21 U.S.C. § 877.

# SUMMARY OF ARGUMENT

Petitioner lacks standing to challenge the DEA's denial of

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his petition to reschedule marijuana in federal court. The CSA allows any "interested party" to petition the DEA to initiate rulemaking proceedings. To challenge denial of a petition in federal court, however, a petitioner must have standing under Article III. Petitioner's asserted injury here - the denial of a religious exemption from the CSA to use marijuana - would not be redressed by a finding that the DEA erred in concluding that marijuana has no "currently accepted medical use" within the meaning of the CSA.

Assuming that petitioner could establish Article III standing, his petition for review would fail on the merits. Petitioner's sole contention is that marijuana must have a "currently accepted medical use" if one or more states endorse that position. This contention cannot be squared with the governing statutory language, which entrusts such determinations to federal officials, guided by statutory criteria that do not include reference to state law. The five-part test the DEA uses to determine whether a substance has an accepted medical use within the meaning of the CSA is a reasonable interpretation of the statutory language, and has been upheld as such by the District of Columbia Court of Appeals. <u>See Alliance for Cannabis</u> <u>Therapeutics</u>, 15 F.3d at 1134-35. Petitioner's assertion that application of the test is precluded as a matter of law by the

### STANDARD OF REVIEW

This court reviews the DEA's factual findings for substantial evidence, <u>see</u> 21 U.S.C. § 877, and its reasoning to determine whether it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," <u>see Tourus Records, Inc.</u> v. <u>DEA</u>, 259 F.3d 731, 736 (D.C. Cir. 2001) (quoting 5 U.S.C. § 706(2)(A)); <u>see also Hoxie</u> v. <u>Drug Enforcement Admin.</u>, 419 F.3d 477, 482 (6th Cir. 2005). The DEA's interpretation of the CSA is entitled to deference as set out in <u>Chevron U.S.A.</u>, <u>Inc.</u> v. <u>Natural Resources Defense Council, Inc.</u>, 467 U.S. 837 (1984). <u>See</u>, <u>e.q.</u>, <u>Grinspoon</u> v. <u>Drug Enforcement Admin.</u>, 828 F.2d 881, 884 (1st Cir. 1987).

#### ARGUMENT

#### I. Petitioner Lacks Article III Standing.

A. Although 21 U.S.C. § 811(a) allows any "interested party" to petition the DEA to initiate rescheduling proceedings, petitioner's status as such an "interested party" does not establish his Article III standing to bring suit in federal court to review the DEA's denial of his petition. As the D.C. Circuit explained in <u>Gettman v. Drug Enforcement Administration</u>, 290 F.3d 430 (D.C. Cir. 2002), 21 U.S.C. § 811(a) does not provide "`automatic standing' to appeal the DEA's denial of [a] petition" simply because it "permits `any interested party' to file a petition to initiate rulemaking proceedings." <u>Id</u>. at 433.

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"Petitioners may be 'interested part[ies]' under the statute, and therefore able to petition the agency, and yet not have Article III standing to bring [an] action in federal court." <u>Id</u>.;<sup>3</sup> <u>accord Bonds</u> v. <u>Tandy</u>, 457 F.3d 409, 413 (5th Cir. 2006) (concluding that § 877's "person aggrieved" requirement "includes both the constitutional and prudential limits on standing" and that the statute "limits petitions for judicial review to those litigants with Article III standing and who are also arguably within the zone of interests protected by the CSA").

To establish Article III standing, the Constitution requires that a plaintiff have suffered an "injury in fact," which is: (1) "concrete and particularized," as well as "actual or imminent, not conjectural or hypothetical," (2) "fairly ... traceable to the challenged action of the defendant," and (3) "likely, as opposed to merely speculative, that the injury will

<sup>&</sup>lt;sup>3</sup> As the D.C. Circuit explained "it is not at all anomalous that Congress could permit ... 'interested part[ies]' ... to participate in agency proceedings, and yet they be unable to seek review in the federal courts." Gettman, 290 F.3d at 434. "Because agencies are not constrained by Article III, they may permit persons to intervene in the agency proceedings who would not have standing to seek judicial review of the agency action." Id. (internal quotation marks omitted). "[I]t is perfectly proper, and indeed appropriate and even necessary, for the political branches to respond to the abstract, ideological, philosophical or even idiosyncratic wishes and needs of citizens ... the courts are granted authority only for the purpose delineated in Article III, section 2, clause 1 of the Constitution and 'may exercise power only in the last resort and as a necessity.'" Id. at 433-434 (quoting Allen v. Wright, 468 U.S. 737, 752 (1984) (internal quotation marks omitted)).

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be redressed by a favorable decision." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561 (1992) (internal citations, quotation marks, and alterations omitted). Congress' grant of procedural rights in § 811(a) cannot alone serve as a basis for such an injury because these procedures are not "designed to protect some threatened concrete interest" of a petitioner. Lujan, 504 U.S. at 573 n. 8 (1992); see also Gettman, 290 F.3d at 433-34 (holding that even if petitioners had been interested parties under § 811(a), they lacked standing to appear before an Article III court unless they could "demonstrate an injury in fact, both particularized and concrete, as required by the Constitution").

Nor does Congress' provision in 21 U.S.C. § 877 that "any person aggrieved by a final decision ... may obtain review of the decision in" a court of appeals provide a petitioner with standing where he could not otherwise meet Article III's injury in fact requirement. Congress cannot "convert the undifferentiated public interest ... into an 'individual right' vindicable in the courts" without violating separation of powers principles by "transfer[ring] from the President to the courts the Chief Executive's most important constitutional duty, to 'take Care that the Laws be faithfully executed.'" <u>Lujan</u>, 504 U.S. at 577 (quoting Art. II, § 3).

B. Even assuming that petitioner could demonstrate an

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injury that is fairly traceable to marijuana's placement on schedule I, he cannot establish that a favorable DEA decision would redress his inability to legally consume marijuana. Petitioner argues that the DEA erred in determining that marijuana has no "currently accepted medical use in treatment in the United States" within the meaning of 21 U.S.C. § 812(b)(1). <u>See</u> Rec. Tab 1 at 1. However, petitioner does not assert he has any medical condition that he believes could be treated with marijuana; his sole proposed use of marijuana is for religious purposes.<sup>4</sup> Thus, even were the DEA to conclude that marijuana does have accepted medical uses and reschedule it accordingly, this decision would not allow petitioner to legally use marijuana, and therefore would not redress petitioner's "injury."

Petitioner's suggestion that a DEA determination that marijuana does have a "currently accepted medical use" would allow him to relitigate his claim that he is entitled to use marijuana for religious purposes is without basis. Pet. Br. 11. Although previous judicial determinations that petitioner was not

<sup>&</sup>lt;sup>4</sup> Even if petitioner had alleged such a medical condition, it is unclear that the DEA's transfer of marijuana from schedule I to another schedule would allow him to legally use marijuana. Petitioner does not attempt to explain how marijuana could be legally obtained for medicinal purposes. The Food and Drug Administration has not approved any marijuana drug for marketing in the United States, and an unapproved marijuana drug would run afoul of the Food, Drug, and Cosmetic Act. <u>See</u>, <u>e.q.</u>, 21 U.S.C. §§ 321, 331(d), 355.

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entitled to a religious exemption from the Controlled Substances Act referred to marijuana's status as a schedule I drug, they did not turn on whether marijuana has any accepted medical uses. In Olsen v. Drug Enforcement Administration, 878 F.2d 1458 (D.C. Cir. 1989), the D.C. Circuit determined that "marijuana usage by Olsen and other members of his church can [not] be accommodated without undue interference with the government's interest in controlling the drug." Olsen, 878 F.2d at 1462. This conclusion did not turn in any way on the existence of marijuana's medical uses, accepted or otherwise. See id. ("forecast[ing] a large monitoring burden in light of evidence that in years past, the [petitioner's] church's checks on distribution of cannabis to nonbelievers in the faith were minimal, there was easy access to cannabis for a child who had absolutely no interest in learning the religion, and members partook of cannabis anywhere, not just within the confines of a church facility") (internal quotation marks and alterations omitted); see also Olsen v. Mukasey, 541 F.3d 827 (8th Cir. 2008) (concluding, without reference to schedule I, that petitioner was collaterally estopped from relitigating his constitutional and statutory claim to a religious exemption from the CSA to use marijuana).

Petitioner does not contest here the DEA's determination that marijuana has a "high potential for abuse," a feature of both schedule I and II substances, or that the government's

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interest in controlling substance abuse of marijuana has diminished since the D.C. Circuit's determination. Thus, even if the DEA were to agree with petitioner that marijuana has a currently accepted medical use within the meaning of the CSA, such a determination would not relieve petitioner of the collateral estoppel effects of his previous, failed attempts to win a religious exemption.

Nor does the Supreme Court's decision in <u>Gonzales</u> v. <u>O</u> <u>Centro Espirita Beneficente Uniao do Vegetal</u>, 546 U.S. 418 (2006), in any way suggest that the analysis applied to petitioner's free exercise claims would be altered by a DEA determination that marijuana has medical uses. The Supreme Court in that case held that a substance's classification in schedule I did <u>not</u> establish the government's compelling interest in denying religious exemptions for use of such substances. <u>See O Centro</u>, 546 U.S. at 432. As this Court held in <u>Olsen v. Mukasey</u>, 541 F.3d 827 (8th Cir. 2008), prior judicial determinations that petitioner was not entitled to a religious exemption used the same standard the Court announced in <u>O Centro</u>, a standard that does not allow the government to rely solely on marijuana's schedule I classification, but rather requires an particularized determination explaining why an individual cannot be granted a

religious exemption.<sup>5</sup>

In sum, because petitioner cannot establish that a favorable decision by the DEA would redress his asserted injury, he lacks Article III standing to petition this Court to review the DEA's determination that petitioner had identified no grounds upon which to initiate a rulemaking to reschedule marijuana.<sup>6</sup>

# II. The Petition For Review Lacks Merit.

Assuming that petitioner could establish Article III standing, his challenge to the denial of his petition should be denied on its merits.<sup>7</sup>

Petitioner's sole contention is that a conclusion by any

<sup>6</sup> As the D.C. Circuit recognized, cases in which courts assumed constitutional standing in entertaining petitions for review of DEA orders "create[] no precedent upon which future litigants may rely." <u>Gettman</u>, 290 F.3d at 436 (citing <u>NORML</u> v. <u>DEA</u>, 559 F.2d 735 (D.C. Cir. 1977); <u>Grinspoon</u> v. <u>DEA</u>, 828 F.2d 881 (1st Cir. 1987); <u>Alliance for Cannabis Therapeutics</u> v. <u>DEA</u>, 930 F.2d 936 (D.C. Cir. 1991) ("<u>Alliance I</u>") & 15 F.3d 1131 (D.C. Cir. 1994) ("<u>Alliance II</u>").

<sup>7</sup> Petitioner does not raise any argument on appeal relating to the document styled as a "Notice to Cease and Desist," which he sent to the DEA on August 5, 2008. Rec. Tab. 4. In any event, this document does not conform with the requirements of 21 C.F.R. § 1308.43 to petition the DEA, nor does it assert any basis for DEA action beyond the meritless grounds petitioner put forward in his petition to reschedule.

<sup>&</sup>lt;sup>5</sup> Previous court decisions holding that petitioner was not entitled to a religious use exemption from the CSA employed the analysis applicable to Free Exercise Clause challenges before the Supreme Court's decision in <u>Employment Division</u> v. <u>Smith</u>, 494 U.S. 872 (1990). In <u>Olsen</u>, this Court held that petitioner was collaterally estopped from his religious rights under the Religious Freedom Restoration Act (RFRA) because that pre-<u>Smith</u> standard was identical to that applicable to RFRA claims.

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state that marijuana has an accepted medical use precludes its classification in schedule I. As petitioner notes, "[t]he '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.'" Br. 17. He then declares that "[t]he meaning of this requirement has previously been interpreted ... to mean accepted medical use in 'any' state in the United States." Id. (citing Grinspoon v. DEA, 828 F.2d 881, 886 (1st Cir. 1987)).

DEA is not required to defer to the judgment of either state legislatures that conclude marijuana has medical uses or to state legislatures that conclude to the contrary. The CSA provides that the Attorney General shall make findings relevant to CSA scheduling determination, <u>see</u> 21 U.S.C. § 811(a), and that the Secretary of the Department of Health and Human Services shall provide scientific and medical evaluation and scheduling recommendations to inform the Attorney General's findings, <u>see</u> 21 U.S.C. § 811(b). In making these findings, Congress expressly directed the Attorney General to consider a variety of factors, none of which refer to state law in any way. <u>See</u> 21 U.S.C. § 811(c).<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> The factors are:

<sup>(1)</sup> Its actual or relative potential for abuse; (2) Scientific evidence of its pharmacological effect, if known; (3) The state of current scientific knowledge regarding the drug or other substance; (4) Its history and current pattern of abuse; (5) The scope, duration,

The criteria for placing a drug in schedule I or moving it from that schedule are set out in the governing statute and regulations. To place a substance 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). The DEA employs a five-part test to determine whether substances have a "currently accepted medical use":

- 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.

Marijuana Scheduling Petition, 57 Fed. Reg. 10,499, 10,506 (March 26, 1992).

This test is a reasonable interpretation of the CSA's undefined term, "currently accepted medical use," and is entitled to deference. The CSA's language does not define this phrase.

and significance of abuse; (6) What, if any, risk there
is to the public health; (7) Its psychic or
physiological dependence liability; (8) Whether the
substance is an immediate precursor of a substance
already controlled under this subchapter.
21 U.S.C. § 811(c).

<u>See Alliance II</u>, 15 F.3d at 1134-35 (citing <u>Chevron U.S.A. Inc.</u> v. <u>Natural Resources Defense Council</u>, 467 U.S. 837, 843-45 (1984)); <u>see also Alliance I</u>, 930 F.2d at 939 ("[N]either the statute nor its legislative history precisely defines the term 'currently accepted medical use.'").

Petitioner does not argue that the DEA's five-part definition of the phrase "currently accepted medical use" is unreasonable, nor does he articulate any reasons why his preferred test - which would instead look to state law - is the only reasonable interpretation of the CSA's language. Grinspoon v. DEA, 828 F.2d 881 (1st Cir. 1987), relied on by petitioner, in no way suggests that findings of one or more state legislatures compel the conclusion that a substance has a currently accepted medical use. The First Circuit held that the existence of a "currently accepted medical use" presented a different question than the determination made by the Food and Drug Administration in approving a substance for interstate marketing. Id. at 886-As the court observed, approval for interstate approval 87. could be denied on the basis of factors not directly relevant to the drug's medical use. See id. (finding "no necessary linkage between failure to obtain FDA interstate marketing approval and a determination that the substance in question is unsafe and has no medical use").<sup>9</sup> That decision offers no support for petitioner's

<sup>&</sup>lt;sup>9</sup>The <u>Grinspoon</u> court's statement that finding a "currently accepted medical use" did not require "a finding of recognized

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claims, and the DEA regulations at issue in that case have long since been superseded by the five-part test currently applied by DEA. <u>See Rec. Tab 5 at 7 & n.10;</u> Schedules of Controlled Substances, 53 Fed. Reg. 5,156, 5,157 (Feb. 22, 1988) (formulating alternative eight-part test after <u>Grinspoon</u> remand); Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,506 (Mar. 26, 1992) (discarding eight-part test and applying current five-part test).

Petitioner cites a variety of decisions, none of which advance his position. In <u>Gonzales</u> v. <u>Oregon</u>, 546 U.S. 243 (2006), the Supreme Court contrasted the Attorney General's lack of delegated authority to restrict the use of controlled substances for physician-assisted suicide (the issue presented in that case), with the CSA's explicit grant of scheduling authority. <u>See id</u>. at 260, 265 (noting the CSA's explicit delegation of medical judgments in the scheduling context to federal officials).<sup>10</sup> <u>Gonzales</u> v. <u>Raich</u>, 545 U.S. 1 (2005), and

 $^{10}$  Contrary to petitioner's argument in his petition to the DEA, the Supreme Court's citation to 21 U.S.C. § 903 – which specifies that Congress did not intend to occupy the field of substance regulation – in <u>Gonzales</u> v. <u>Oregon</u> did not suggest that Congress intended states to determine whether a substance has a

medical use in every state" was a response to the DEA's argument that the phase required the FDA's "approval for interstate marketing of the substance" through the entire United States. 828 F.2d at 886. The court did not suggest that "any" state's determination necessarily triggered the conclusion that a substance did have a currently accepted medial use, or that the DEA Administrator was statutorily obliged to take into account state law determinations about medical uses.

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<u>United States</u> v. <u>Oakland Cannabis Buyers' Cooperative</u>, 532 U.S. 483 (2001), affirmed the primacy of federal law over state marijuana laws. <u>See Raich</u>, 545 U.S. at 29 (holding that under the Supremacy Clause, "limiting the activity to marijuana possession and cultivation 'in accordance with state law' cannot serve to place respondents' activities beyond congressional reach");<sup>11</sup> <u>see Oakland Cannabis Buyers' Cooperative</u>, 532 U.S. at 491 (stating, despite a California law permitting medical use of marijuana, that "for purposes of the Controlled Substances Act, marijuana has 'no currently accepted medical use' at all"). Petitioner likewise misunderstands the D.C. Circuit's decisions in <u>Alliance I</u> and <u>Alliance II</u>, which approved as reasonable the very test the DEA now employs to determine accepted medical use. Pet. Br. 18-19; <u>see Alliance II</u>, 15 F.3d at 1134-35.

currently accepted medical use within the meaning of the CSA. As the Court noted, although the CSA does not grant federal authorities the ability to regulate all aspects of medical practice, the CSA explicitly entrusts substances scheduling determinations to federal officials. <u>See</u> 546 U.S. at 264-65.

<sup>&</sup>lt;sup>11</sup> Also inapposite to this case is petitioner's citation to the Supreme Court's footnote stating that if found credible "evidence proffered by respondents in this case regarding the effective medical uses for marijuana ... would cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I." <u>Raich</u>, 545 U.S. at 28 n.37. Petitioner's argument here is not based on any putative direct evidence of marijuana's medical uses; rather, the sole basis for petitioner's argument that the DEA Administrator was obliged to remove marijuana from schedule I is that various states have decriminalized marijuana for certain medical uses.

Finally, petitioner's suggestion that the CSA's purpose of preventing drug abuse somehow prevents federal officials from determining medical uses within the meaning of the CSA is difficult to fathom. Pet. Br. 24-28. States' roles as "'the primary regulators of professional [medical] conduct'" in areas where Congress has not exercised its powers does not undermine the authority which Congress clearly extended to federal officials to determine which substances lack an accepted medical use within the meaning of the CSA. Pet. Br. 25 (quoting <u>Oregon</u> v. <u>Ashcroft</u>, 368 F.3d 1118, 1124 (9th Cir. 2004) (alteration in original), <u>affirmed by Gonzales</u> v. <u>Oregon</u>, 546 U.S. 243 (2006)).<sup>12</sup>

<sup>12</sup> Even assuming that petitioner had standing and could establish any error in the DEA's decision declining to initiate rulemaking proceedings, his request that "this Court ... instruct DEA to immediately remove marijuana from Schedule I of the CSA" mistakes the nature of the remedy available in cases of such error. Pet. Br. 28. The CSA sets out the requisite rulemaking procedures by which substances may be rescheduled, and if there were error in the DEA's decision, the proper remedy would be to remand to the DEA for further agency proceedings, including the initiation of these mandatory rulemaking procedures if necessary. See, e.g., N.L.R.B. v. Food Store Employees Union, Local 347, 417 U.S. 1, 9 (1974) (noting the "guiding principle of administrative law" that "an administrative determination in which is imbedded a legal question open to judicial review does not impliedly foreclose the administrative agency, after its error has been corrected, from enforcing the legislative policy committed to its charge") (internal quotation marks omitted).

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### CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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APRIL 2009

### CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief complies with the type-volume limitation of Fed. R. App. Rule 32(a)(7)(C). The brief contains 4,843 words, according to the count of Corel WordPerfect 12.

I also certify that the computer disk containing the full text of the foregoing brief has been scanned for viruses and, to the best of our ability and technology, is virus-free.

Melissa Patterson

### CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of April 2009, I caused ten copies of the foregoing brief, and one electronic copy, to be filed with the Court by Federal Express overnight delivery; and caused two additional copies of the same brief to be served by ordinary mail, and an electronic copy by electronic mail, on:

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