



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 Fraudulent [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 Fraudulent [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

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.*

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. LaFroschia*, 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