
CASE BEING CONSIDERED FOR TREATMENT
PURSUANT TO RULE 34(j) OF THE GENERAL RULES

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

No. 94-1605

CARL ERIC OLSEN,

Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

PETITION FOR REVIEW OF AN ORDER OF THE
DRUG ENFORCEMENT ADMINISTRATION

BRIEF FOR THE RESPONDENT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

All parties, intervenors, and amici appearing before the agency and in this court are listed in the Petitioner's Brief.

B. Rulings Under Review

References to the ruling at issue appear in the Petitioner's Brief. The ruling is reproduced on pages 17-25 of the Petitioner's Appendix.

C. Related Cases

This matter was previously before this court in Olsen v. Drug Enforcement Admin., No. 93-1109 (D.C. Cir. Dec. 9, 1993). In that case, the court granted DEA's motion for remand.

References to related cases in the Petitioner's Brief accurately identify cases before this court that previously addressed the scheduling of marihuana. Another case addressing the scheduling of marihuana is National Org. for the Reform of Marijuana Laws v. Bell, 488 F. Supp. 123 (D.D.C. 1980) (three judge court).

GLOSSARY

CSA - Controlled Substances Act, 21 U.S.C. 801 et seq.

DEA - U.S. Drug Enforcement Administration

FDA - U.S. Food and Drug Administration

HEW - U.S. Department of Health, Education, and Welfare

THC - tetrahydrocannabinol

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BRIEF FOR THE RESPONDENT

STATEMENT OF THE ISSUE

Whether the Drug Enforcement Administration properly rejected the petitioner's theory that marihuana plants should be moved from Schedule I to Schedule II of the Controlled Substances Act because marihuana plants are a source of an accepted and useful medication when the petitioner's theory was based solely upon language in an informal letter and was contradicted directly by the plain language of the Controlled Substances Act.

STATUTES AND REGULATIONS

Except for those already included in the Addendum to the Petitioner's Brief, the pertinent statutes and regulations are set forth in an addendum bound with this brief.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

In response to the growing drug problem in the United States, Congress in 1970 passed the Controlled Substances Act, 21 U.S.C. 801 et seq. ("CSA"). The CSA classifies various hazardous drugs into five schedules. Id. 812. Restrictions upon use and access to a particular drug vary based upon the drug's schedule status in the CSA. Drugs in Schedule I are subject to more severe restrictions than drugs in the other schedules. See Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., 930 F.2d 936, 937 (D.C. Cir. 1991). Congress placed marihuana in Schedule I of the CSA.¹ 21 U.S.C. 812(c), Schedule I(c)(10).

Although Congress made the initial scheduling decisions, the CSA specifically permits the Attorney General to add a substance to a schedule, transfer a substance from one schedule to another or remove a substance from the schedules entirely. Id. 811(a). The Attorney General may only transfer a substance to a different schedule if she "finds that such drug or other substance has a potential for abuse" and makes findings that the drug or substance meets the requirements for the new schedule. Id. The findings required for placing a substance in a particular schedule are listed in 21 U.S.C. 812(b). The Attorney General has delegated the authority to reschedule controlled substances

¹ The substance is called "marihuana" in the CSA and the respondent will use that spelling throughout this brief. However, where the spelling "marijuana" is used in a quoted passage, the spelling has not been changed.

to the Administrator of the Drug Enforcement Administration ("DEA"). 28 C.F.R. 0.100(b). The Drug Enforcement Administrator ("Administrator") has further delegated this authority to the Deputy Administrator. 28 C.F.R. 0.104.

For over 20 years, various groups and individuals have asked DEA to exercise its authority to move marihuana from Schedule I to a less restrictive schedule or to remove marihuana from the CSA schedules entirely. See Alliance for Cannabis Therapeutics v. Drug Enforcement Admin., 15 F.3d 1131 (D.C. Cir. 1994); Alliance for Cannabis Therapeutics, 930 F.2d at 937; National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d 735 (D.C. Cir. 1977); National Org. for the Reform of Marijuana Laws v. Ingersoll, 497 F.2d 654 (D.C. Cir. 1974). Despite these efforts, in March of 1992, the Administrator issued a final order denying a petition to reschedule marihuana from Schedule I to Schedule II of the CSA. See 57 Fed. Reg. 10,499 (1992).²

The Administrator relied upon the language of the CSA in

² DEA's review of the rescheduling petition was quite extensive. DEA issued a notice of a hearing on the rescheduling petition in 1986. See 51 Fed. Reg. 22,946 (1986). After hearings before an administrative law judge, the Administrator issued findings of fact and conclusions of law that determined that marihuana should not be moved from Schedule I because the marihuana plant has no currently accepted medical use and because it is not safe for use, even under medical supervision. See 54 Fed. Reg. 53,767, 53,784 (1989). On appeal, this court generally upheld the Administrator's decision but remanded the matter for clarification. See Alliance for Cannabis Therapeutics, 930 F.2d at 940-941. On remand, the Administrator again found that marihuana plants should remain in Schedule I. See 57 Fed. Reg. at 10,507-10,508. The latter decision was affirmed by this Court in Alliance for Cannabis Therapeutics, 15 F.3d at 1137.

making his determination. Under the CSA, a drug or substance may not be placed in Schedule II absent findings that:

- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

21 U.S.C. 812(b)(2)(A)-(C).

In the Administrator's final order, he concluded that the marihuana plant had no currently accepted medical use and thus could not be placed in schedule II. 57 Fed. Reg. at 10,499. The Administrator applied a five-part test for determining whether a substance had a currently accepted medical use:

- (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.

57 Fed. Reg. at 10,504-10,507. After reviewing the evidence in the record, the Administrator found that marihuana could not satisfy a single one of these criteria. *Id.* at 10,507. These findings, as well as other findings of fact and conclusions of law, resulted in the denial of the marihuana rescheduling petition.

II. THE CURRENT PROCEEDINGS

On July 21, 1992, the petitioner sent a letter to then-Administrator Robert C. Bonner in which he raised several questions about the Administrator's final order. In the letter, the petitioner appeared to agree with the Administrator's finding that marihuana, as a plant, failed to satisfy the first part of the test for determining a currently accepted medical use because a plant such as marihuana is not a scientifically established compound capable of reproduction in standard dosages. A. 1.³ The petitioner's letter then asked why coca and opium plants (the sources of cocaine, morphine, and heroin) were placed in Schedule II. Id. If, the petitioner reasoned, coca and opium plants are subject to the same scientific variances as marihuana plants, then DEA is "treating marijuana unfairly." Id. The petitioner suggested either removing all plants from the CSA schedules because they "will never fit into your definition of drugs" or changing the definition to account for the inconsistency in the treatment of the different plants. Id.

On August 17, 1992, Administrator Bonner sent the petitioner a response to his letter. A. 5. In the response, the Administrator rejected the petitioner's attempt to analogize marihuana plants to coca and opium plants. Id. The Administrator explained that when Congress placed coca leaves and opium plant materials in Schedule II, it was aware that these

³ "A." references are to the bound appendix submitted by the petitioner with his brief.

plants had been recognized historically as the source for a variety of accepted and useful medications. Id. The plants contain medically active alkaloids that can be extracted and used to produce pharmaceutical compounds capable of reproduction in standardized doses. Id. In contrast, the Administrator pointed out that the recent attempts to reschedule marihuana were not grounded on claims that medically useful compounds could be extracted from marihuana, but rather that smoking marihuana itself produced medical benefits. Id. Thus, the Administrator found the scheduling decisions to be reconcilable. Id. at 5-6.

The petitioner, proceeding pro se, then filed a formal request for the rescheduling of marihuana pursuant to 21 U.S.C. 811 and 21 C.F.R. 1307.03.⁴ A. 2-4. In his petition, he drew an analogy from language in the Administrator's letter of August 17, 1992. He reasoned that if coca leaves and opium plants could be placed in Schedule II because they are sources of accepted and

⁴ The petitioner has frequently litigated issues related to the legal treatment of marihuana. He challenged several criminal convictions by arguing that marihuana smoking was protected by the free exercise clause of the First Amendment and the equal protection clause of the Fourteenth Amendment. See Olsen v. Iowa, 808 F.2d 652, 653 (8th Cir. 1986); United States v. Rush, 738 F.2d 497, 511-513 (1st Cir. 1984), cert. denied, 470 U.S. 1004 (1985); State v. Olsen, 315 N.W.2d 1, 7-9 (Iowa 1982). Additionally, the petitioner has brought numerous civil actions seeking to obtain judicial authorization to use marihuana. See Olsen v. Drug Enforcement Admin., 878 F.2d 1458, 1461-1465 (D.C. Cir. 1989), cert. denied, 495 U.S. 906 (1990); Olsen v. Drug Enforcement Admin., 776 F.2d 267, 268 (11th Cir. 1985), cert. denied, 475 U.S. 1030 (1986); Olsen v. State, Civ. No. 83-301-E, 1986 WL 4045, at *1 (S.D. Iowa March 19, 1986). The petitioner also participated in the administrative proceedings where the DEA considered a petition to reschedule marihuana from Schedule I to Schedule II of the CSA. See 54 Fed. Reg. at 53,767.

useful medications, then marihuana plants could be placed in schedule II if marihuana is shown to be "a source for an accepted and useful medication." A. 3. The petitioner then noted that dronabinol, a synthetic equivalent of the isomer which is the principle psychoactive substance in marihuana, has been rescheduled to Schedule II. Id. Because marihuana is the source of an accepted and useful medication, dronabinol, the petitioner reasoned that marihuana must be moved to Schedule II of the CSA. Id. at 4. The petitioner then requested that the Administrator reschedule marihuana from Schedule I to Schedule II of the CSA. Id. at 2.⁵

The Administrator initially refused to accept the rescheduling petition because dronabinol is a wholly synthetic substance and is not obtained from marihuana. A. 7. However, after the petitioner appealed, DEA voluntarily asked this court to remand the petition for a ruling. This court remanded the petition in an Order dated December 9, 1993. See Olsen v. Drug Enforcement Admin., No. 93-1109 (D.C. Cir. Dec. 9, 1993).

On May 16, 1994, Deputy Administrator Stephen H. Greene issued a nine-page final order denying the petition. A. 17. The final order explained that Congress placed marihuana in Schedule I. A. 19-20. It rejected the petitioner's analogy, finding that marihuana can only be moved from Schedule I if there is a finding that marihuana has a "currently accepted medical use in treatment

⁵ The petitioner did not ask DEA to reschedule any other substances.

in the United States." A. 22. The order acknowledged that (-) delta-9-trans-THC isomer, the principal psychoactive ingredient in marihuana, is also the ingredient in a pharmaceutical product that has proven to be a safe and effective anti-emetic for patients receiving cancer chemotherapy. Id. However, the order noted that only a very specific synthetic dronabinol product was rescheduled to Schedule II -- "dronabinol ("synthetic) in sesame oil and encapsulated in a soft gelatin capsule" in a drug product approved by the Food and Drug Administration ("FDA"). A. 23.

The order further stated that the regulation of plants and chemicals under the CSA is distinct and that the CSA requires the independent evaluation of each individual controlled substance.

A. 24. The final order reaffirmed that marihuana plants have no currently accepted medical use in treatment and found that the rescheduling of one pharmaceutical product did not require DEA to transfer marihuana plants or any other substance to Schedule II.

A. 24-25.

The petitioner has appealed the final order to this court pursuant to 21 U.S.C. 877.

SUMMARY OF THE ARGUMENT

Congress placed marihuana in Schedule I of the CSA and this decision has been consistently approved by the courts. The petitioner is incorrect in asserting that marihuana must be moved from Schedule I to Schedule II if it is a source of an accepted and useful medication. The plain language of the CSA requires that a substance itself must have a currently accepted medical

use before it may be moved from Schedule I to Schedule II. The petitioner has failed to provide any evidence to suggest that the marihuana plant itself has a currently accepted medical use. Under the CSA, the rescheduling of synthetic dronabinol in a pharmaceutical product has no effect on the scheduling of the marihuana plant. Thus, the petitioner's request for rescheduling failed to raise any issue that justified the initiation of rescheduling proceedings.

The petitioner is also incorrect in asserting that dronabinol was moved from Schedule I to Schedule II. Only one specific pharmaceutical product containing synthetic dronabinol has been moved to Schedule II: synthetic dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a FDA-approved drug product. Although the petitioner now seeks to challenge the legality of the rule rescheduling this pharmaceutical product and argues that dronabinol should have been rescheduled in its entirety, he did not raise these issues before DEA. These issues should not be considered for the first time by this court.

ARGUMENT

I. STANDARD OF REVIEW

Any interested person may submit a petition to DEA requesting that DEA reschedule a controlled substance. 21 U.S.C. 811(a); 21 C.F.R. 1308.44(a). However, a petition that is accepted for filing "may be denied by the Administrator within a reasonable time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of

proceedings." 21 C.F.R. 1308.44(c). The Administrator relied upon this provision in denying the petition in the instant case. A. 18-19.

In reviewing the Administrator's decision, findings of fact, "if supported by substantial evidence, shall be conclusive." 21 U.S.C. 877. Additionally, DEA's action may be set aside if it was arbitrary, capricious, an abuse of discretion or contrary to law. 5 U.S.C. 706. However, when reviewing an administrative agency's interpretation of a statute, the court must give effect to the unambiguously expressed intent of Congress. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-843 (1984). If the statute is silent or ambiguous, the court is to determine whether the agency's interpretation is based upon a permissible construction of the statute. Id. at 843. The court may not substitute its own judgment for a reasonable interpretation made by the administrator of an agency. Id. at 844.

II. CONGRESS, DEA, AND THE COURTS HAVE ALL FOUND THAT MARIHUANA IS PROPERLY IN SCHEDULE I OF THE CSA AND MUST REMAIN THERE UNTIL IT SATISFIES THE CRITERIA IN 21 U.S.C. 812(b).

Congress made the initial decision to place marihuana in Schedule I. 21 U.S.C. 811(c). This decision was made after careful consideration. The legislative history of the CSA demonstrates that Congress was sensitive to the arguments of

those who advocated the deregulation of marihuana.⁶ See H. Rep. No. 1444, 81st Cong., 2d Sess. 12-13, reprinted in 1970 U.S.C.C.A.N. 4566, 4577-4578. Congress also sought the advice of the Department of Health, Education, and Welfare ("HEW") before making a scheduling determination for marihuana.⁷ After considering this information, Congress placed marihuana in Schedule I so that the drug would be subject to the CSA's "most stringent controls." Id. at 14, reprinted in 1970 U.S.C.C.A.N.

⁶ The House Report on the CSA contains several pages of discussion about the proper treatment of marihuana under the CSA. The House Report noted that:

The extent to which marihuana should be controlled is a subject upon which opinions diverge widely. There are some who not only advocate its legalization but would encourage its use; at the other extreme there are some States which have established the death penalty for distribution of marihuana to minors.

H. Rep. No. 1444, 81st Cong., 2d Sess. 12, reprinted in 1970 U.S.C.C.A.N. 4566, 4577.

⁷ The Assistant Secretary for Health and scientific Affairs wrote to Chairman Harley O. Staggers that:

Some question has been raised whether the use of the plant itself produces "severe psychological or physical dependence" as required by a schedule I or even schedule II criterion. Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marihuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue. If those studies make it appropriate for the Attorney General to change the placement of marihuana to a different schedule, he may do so in accordance with the authority provided under section 201 of the bill.

Letter from Dr. Roger O. Egeberg, Assistant Secretary for Health and Scientific Affairs, Dep't of HEW, to Hon. Harley O. Staggers, Chairman, House Comm. on Interstate and Foreign Commerce, reprinted in id. at 61, reprinted in 1970 U.S.C.C.A.N. at 4629.

at 4579.

Since the passage of the CSA, numerous individuals have attempted to challenge the decision of Congress to place marihuana in Schedule I as being irrational or unconstitutional. These challenges have been uniformly rejected by the federal courts. See, e.g., United States v. Greene, 892 F.2d 453, 455-456 (6th Cir. 1989), cert. denied, 495 U.S. 935 (1990); United States v. Fogarty, 692 F.2d 542, 547 (8th Cir. 1982), cert. denied, 460 U.S. 1040 (1983); United States v. Middleton, 690 F.2d 820, 823 (11th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); National Org. for the Reform of Mariiуana Laws v. Bell, 488 F. Supp. 123, 139-141 (D.D.C. 1980) (three judge court).

In rejecting constitutional challenges to the initial classification of marihuana, courts frequently have pointed out that 21 U.S.C. 811(a) provides the Attorney General with the authority to reclassify marihuana if scientific information later demonstrates that Schedule I is not the appropriate schedule. See, e.g., Greene, 892 F.2d at 456; Fogarty, 692 F.2d at 548; Middleton, 690 F.2d at 823; National Org. for the Reform of Mariiуana Laws, 488 F. Supp. at 141. DEA, on behalf of the Attorney General, recently conducted lengthy proceedings pursuant to 811(a) and found that marihuana should not be moved from Schedule I because the plant has no currently accepted medical use and because it is not safe for use, even under medical supervision. These decisions were approved by this court. See footnote 2, supra.

III. DEA PROPERLY FOUND THAT THE PETITION WAS NOT SUFFICIENT TO JUSTIFY ADDITIONAL RESCHEDULING PROCEEDINGS BECAUSE THE PETITION WAS PREMISED ON THE INCORRECT BELIEF THAT A SCHEDULE I DRUG MUST BE RESCHEDULED IF IT IS THE SOURCE OF AN ACCEPTED AND USEFUL MEDICATION.

In seeking to reschedule marihuana from Schedule I to Schedule II, the petitioner made a rather creative argument based upon several flawed premises. DEA properly detected the flaws in the petitioner's logic and found that the petition raised no credible issue that would justify additional proceedings to reschedule marihuana.

A. THE PETITIONER'S ARGUMENT

The petitioner's argument was based entirely upon his construction of language contained in then-Administrator Bonner's response to an earlier letter sent by the petitioner. In response to the petitioner's query about why marihuana plants are in Schedule I while coca leaves and opium plants are in Schedule II, the Administrator stated that:

In placing coca leaves and opium plant material in Schedule II, Congress was very much aware that these plant materials have historically been recognized as the source for a variety of accepted and useful medications.

A. 5. The petitioner then seized upon the Administrator's language as "general rules of statutory construction." Pet. Br. 9. Using the newly created rules of statutory construction as his springboard, the petitioner took an additional logical leap by inferring that if marihuana were found to be a "source for an accepted and useful medication," it must be moved from Schedule I to Schedule II. A. 3-4.

Having created a new theory of statutory construction, the petitioner proceeded to apply it with apparently successful results. He noted that a synthetic equivalent of the principal psychoactive ingredient in marihuana recently had been moved from Schedule I to Schedule II. Since marihuana was the source of this "accepted and useful medication," the petitioner concluded that marihuana "must now be moved from Schedule I to Schedule II of the CSA." A. 4.

B. THE CSA DOES NOT MANDATE THAT A SCHEDULE I DRUG MUST BE RESCHEDULED IF IT IS THE SOURCE OF AN ACCEPTED AND USEFUL MEDICATION BUT REQUIRES DEA TO MAKE INDIVIDUAL FINDINGS ABOUT A PARTICULAR DRUG PRIOR TO RESCHEDULING IT.

The premise of the petitioner's argument is that if a Schedule I controlled substance is the source of an accepted and useful medication, the Schedule I substance must be placed into the schedule that contains the accepted and useful medication. This premise is in direct conflict with the language of the CSA.

As discussed previously, Congress itself decided to place marihuana in Schedule I. See National Org. for the Reform of Mariiuanu Laws, 488 F. Supp. at 141. Although marihuana may be rescheduled:

[t]he clear meaning of section 812(c) is that Congress intended marijuana to remain in Schedule I until such time as it might be reclassified by the Attorney General on the basis of more complete scientific information about the drug. In such a reclassification hearing, the statutory criteria would be the guides to determining the most appropriate schedule for marijuana.

Id. Thus, under the CSA, marihuana plants should remain in

Schedule I unless and until more complete information indicates that placement in a different schedule is more appropriate.

The CSA's language concerning the rescheduling of a controlled substance does not suggest that a substance should be rescheduled merely because it is the source for an accepted and useful medication. The CSA states that in order to transfer a controlled substance from one schedule to another, the Attorney General must make "with respect to such drug or other substance the findings prescribed by" 21 U.S.C. 812(b) "for the schedule in which such drug is to be placed." 21 U.S.C. 811(a)(1)(B) (emphasis added). Under 812(b), "a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance." 21 U.S.C. 812(b) (emphasis added). Thus, contrary to the petitioner's representations, the plain language of the CSA states that in order for DEA to reschedule marijuana plants from Schedule I to Schedule II, DEA must make the appropriate findings with respect to marijuana plants.⁸

The CSA states that DEA cannot move a drug from Schedule I to Schedule II unless it finds, inter alia, that the "drug or other substance" to be rescheduled has a currently accepted

⁸Thus, the Deputy Administrator was correct in stating that "[w]hether or not marijuana is a source of delta-9-THC is irrelevant to the status of marijuana under the CSA." A. 20. Despite the petitioner's assertions, this statement is not inconsistent with United States v. Walton, 514 F.2d 201 (D.C. Cir. 1975). The statement simply indicates that each drug is evaluated under 21 U.S.C. 812(b) based upon an independent assessment of its features, not based upon other possible uses of the chemicals contained within the drug.

medical use.⁹ 21 U.S.C. 812(b)(2)(B). The CSA's language does not state or imply that this criterion can be satisfied by a substance that is the source of a drug with a currently accepted medical use. Additionally, the petitioner has produced no authority to indicate that any controlled substance being considered for rescheduling ever has been found to have a currently accepted medical use merely because it was the source of an "accepted and useful medication."¹⁰ Thus, marihuana

⁹ There are some instances in which courts have suggested that the statutory criteria in 21 U.S.C. 812 are not mandatory, but are factors to be used in a balancing process. See, e.g., Fogarty, 692 F.2d at 548 ("the three statutory criteria for Schedule I classification set out in S 812(b)(1) - high potential for abuse, no medically accepted use, and no safe use even under medical supervision - should not be read as being either cumulative or exclusive"); National Org. for the Reform of Mariiuanas Laws, 559 F.2d at 748 ("placement in Schedule I does not appear to flow inevitably from lack of a currently accepted medical use"); National Org. for the Reform of Mariiuanas Laws, 488 F. Supp. at 140 ("statutory criteria of section 812(b)(1) are guides in determining the schedule to which a drug belongs, but are not dispositive"). Although the meaning of these dicta is somewhat unclear, DEA has interpreted the CSA to require that a controlled substance placed by Congress in Schedule I may not be rescheduled into Schedule II unless it has a currently accepted medical use. See 54 Fed. Reg. at 53,773; 57 Fed. Reg. at 10,499. Nothing in this court's recent marihuana rescheduling cases suggests that DEA's interpretation is incorrect. See Alliance for Cannabis Therapeutics, 15 F.3d at 1133; Alliance for Cannabis Therapeutics, 930 F.2d at 938-940. If there is a tension between some language in older cases and DEA's interpretation of the CSA, DEA's reasonable interpretation of the CSA is entitled to deference under Chevron, 467 U.S. at 843-845.

¹⁰ In fact, there is authority to the contrary. In 1993, the DEA proposed to reschedule the levo isomer of alphacetylmethadol while leaving all other isomers of alphacetylmethadol in Schedule I because the levo isomer had been approved by the FDA for treatment of narcotic addiction. See 58 Fed. Reg. 25,790 (1993). Levo-alphacetylmethadol was subsequently placed in Schedule II. See 21 C.F.R. 1308.12(c)(11). Despite the petitioner's "rules of statutory construction," alphacetylmethadol (the source of this accepted

plants themselves must have a "currently accepted medical use" in order to satisfy the rescheduling criterion in 21 U.S.C. 812(b)(2)(B). Because the petitioner's request raised no doubts about DEA's recent findings that marihuana plants have no currently accepted medical use, DEA acted properly when it declined to initiate proceedings to reschedule marihuana plants.¹¹

The petitioner's novel theory that a source of an accepted and useful medication must be moved out of Schedule I is rooted in a misinterpretation of the then-Administrator's letter. Although the letter attempted to explain why Congress may have chosen to place coca leaves and opium plants in Schedule II, nothing in the letter states or even suggests that Congress, the Attorney General, DEA or the courts have adopted a general rule of statutory construction that whenever a plant is the source of an accepted and useful medication, it must be rescheduled. Further, nothing in the letter suggests that its text was intended to serve as some type of binding administrative interpretation of the CSA. The letter was simply an informal response to a citizen's question about DEA's recent refusal to

and useful medication) remains in Schedule I. See 21 C.F.R. 1308.11(b)(4).

¹¹ Even if the statutory language were not clear, DEA's interpretation of the CSA certainly would be permissible. The petitioner can point to nothing in the statute, the legislative history or elsewhere that would suggest that the interpretation is not reasonable. Accordingly, even if the CSA is ambiguous, this court should affirm DEA's interpretation. See Chevron, 467 U.S. at 843-844.

reschedule marihuana. Such an informal unpublished letter that does not even purport to be a final agency action cannot have a binding effect on DEA. See Independent Ins, Agents of Am., Inc. v. Ludwig, 997 F.2d 958, 962 (D.C. Cir. 1993) (finding that six unpublished letters of Comptroller of the Currency provided no reliable evidence of Comptroller policy); USAA Fed. Sav. Bank v. McLaughlin, 849 F.2d 1505, 1508-1509 (D.C. Cir. 1988) (finding that informal unpublished letter in response to individuals specific inquiry did not constitute definitive statement of Department of Labor policy).

Although there may be some arguable inconsistency between the scheduling of marihuana plants and the scheduling of coca leaves and opium plant material, such would not be irrational or contrary to the CSA. Congress placed all of these substances in their CSA schedules. These scheduling decisions have been upheld as rational and constitutional. See, e.g., United States v. Whitley, 734 F.2d 1129, 1141 (6th Cir. 1984) (not irrational or unreasonable for Congress to classify cocaine as narcotic substance under Schedule II of CSA even though cocaine is non-narcotic central nervous system stimulant); National Org. for the Reform of Marijuana Laws, 488 F. Supp. at 140 (even if marihuana does not fall within literal reading of Schedule I, classification in Schedule I is rational and furthers regulatory purposes of Congress). DEA and the courts have conducted reviews of the scheduling decision and have determined that marihuana should remain in Schedule I. See Alliance for Cannabis

Therapeutics, 15 F.3d at 1137. Since the petitioner presented no new medical, scientific or other information to suggest that circumstances have changed since DEA's last review, DEA acted properly when it refused to conduct additional hearings in response to the petitioner's request to move marihuana from Schedule I to Schedule II.

IV. THE ADMINISTRATOR PROPERLY DENIED THE PETITION BECAUSE IT RELIED ON THE INCORRECT ASSUMPTION THAT DRONABINOL HAS BEEN MOVED TO SCHEDULE II WHEN IN FACT ONLY A SINGLE PHARMACEUTICAL PRODUCT HAS BEEN MOVED TO SCHEDULE II.

In addition to relying on a mistaken interpretation of the CSA, the petitioner also appeared to rely incorrectly upon the premise that all forms of dronabinol have been rescheduled from Schedule I to Schedule II. DEA did not promulgate such a sweeping rule. Rather, DEA has merely rescheduled one particular pharmaceutical product that has been approved by the FDA.

In May of 1985, the FDA approved a new drug application for Marinol Capsules, which was submitted by Unimed Incorporated. Marinol Capsules contain specified quantities of synthetic dronabinol in sesame oil and encapsulated in round soft gelatin capsules. See 50 Fed. Reg. 42,186 (1985). DEA then issued a notice of proposed rulemaking seeking to move this pharmaceutical product (and no other Schedule I substance) to Schedule II. Id. After following appropriate rulemaking procedures, on May 13, 1986, the Administrator issued a rule:

to transfer U.S. Food and Drug Administration (FDA) approved drug products that consist of synthetic dronabinol in sesame oil encapsulated in soft gelatin capsules from Schedule I into Schedule II of the

Controlled Substances Act (CSA). Dronabinol is the synthetic equivalent of the isomer of delta-9-tetrahydrocannabinol (THC) which is the principal psychoactive substance in Cannabis sativa L., marijuana. This action is based on a finding that U.S. Food and Drug Administration approved drug products which contain dronabinol fit the statutory criteria for inclusion in Schedule II of the CSA. . . . This rule does not affect the Schedule I status of any other substance, mixture or preparation which is currently included in 21-CFR 1308-11(d)(21), Tetrahydrocannabinols.

51 Fed. Reg. 17,476 (1986) (emphasis added).

This rule clearly indicates that only a very specific substance ("Marinol") was moved from Schedule I to Schedule II. See 21 C.F.R. 1308.12(f)(1). DEA did not transfer any other dronabinol products to Schedule II nor did it transfer all tetrahydrocannabinols or all cannabis products to Schedule II. See 51 Fed. Reg. at 17,476 ("Dronabinol and all mixtures, compounds and preparations thereof, except dronabinol in sesame oil and encapsulated in soft gelatin capsules in a FDA approved product, remain in Schedule I"). Thus, marijuana plants and tetrahydrocannabinols remain listed in Schedule I. See 21 C.F.R. 1308.11(d)(18) and 1308.11(d)(26).¹²

In rejecting the petitioner's request in this case, DEA's final order correctly explained that dronabinol remains in Schedule I of the CSA and that only Marinol was placed in Schedule II in 1986. A. 23. Faced with this explanation and the

¹² Unlike Marinol, marijuana plants contain varying quantities of over 400 chemicals, including THC, that cannot be reproduced in standardized dosages. 57 Fed. Reg. at 10,507. Additionally, no currently approved medicine is administered by smoking. Id. at 10,499.

clear language of DEA's final rule of 1986, the petitioner has changed his argument. He now claims that dronabinol should have been placed in Schedule II when the pharmaceutical product Marinol was rescheduled in 1986. Thus, for the first time on appeal, the petitioner appears to be challenging the propriety of the DEA rule that rescheduled Marinol from Schedule I to Schedule II.¹³ See 51 Fed. Reg. at 17,476.

The petitioner did not seek this relief below. Nothing in his petition to DEA suggested that he was challenging the validity of the rescheduling of Marinol. Similarly, nothing in the petition suggested that he was petitioning DEA to reschedule dronabinol or some other substance to Schedule II. The petition only asked DEA to reschedule marijuana. See A. 2-4. To the extent that petitioner seeks relief that he did not request in the proceedings before DEA or challenges the validity of a rule he did not previously challenge, he should be precluded from raising these issues for the first time on appeal because he has failed to exhaust his administrative remedies. See Cutler v. Hayes, 818 F.2d 879, 890-891 (D.C. Cir. 1987); Randolph-Sheppard

¹³ Contrary to the petitioner's assertions, DEA's actions in rescheduling Marinol were not in conflict with the holding of Grinspoon v. Drug Enforcement Admin., 828 F.2d 881, 891-892 (1st Cir. 1987). In Grinspoon, the court specifically found that FDA approval was sufficient to establish an accepted medical use for rescheduling determinations under the CSA. *Id.* at 890. Thus, DEA properly initiated rescheduling proceedings for Marinol after it received FDA approval. See 50 Fed. Reg. at 42,186. Although the Grinspoon court found that the lack of FDA approval did not preclude a finding of accepted medical use, DEA was not faced with such a case; the 1985 petition only sought to reschedule Marinol, a substance that had been approved by the FDA.

Vendors of America v. Weinberger, 795 F.2d 90, 104-105 (D.C. Cir. 1986). The court should require the petitioner to exhaust his administrative remedies on these additional issues because (1) it is necessary to discourage this prolific petitioner from frequently and deliberately flouting the administrative process by raising new issues for the first time on appeal; (2) DEA should have the first opportunity to consider these issues and apply its technical expertise in order to protect its autonomy from judicial intrusion; (3) the record before this court on these issues is incomplete because the issues were not discussed in the administrative proceeding; and (4) judicial economy will be enhanced if the administrative proceedings obviate the need for judicial involvement. See Fertilizer Institute v. United States Env'tl. Protection Agency, 935 F.2d 1303, 1312-1313 (D.C. Cir. 1991); Cutler, 818 F.2d at 890-891.

The petitioner is free to bring a separate challenge to the validity of the rulemaking that rescheduled Marinol or to petition DEA to reschedule dronabinol or some other substance. However, no purpose would be served by remanding the instant case to address either challenge. Even assuming arguendo that the petitioner could prevail on either challenge, he could not achieve the ultimate relief he sought in this proceeding -- rescheduling of marihuana plants -- because the language of the CSA clearly indicates that the scheduling of other substances has no bearing on the proper scheduling of marihuana plants.

CONCLUSION

For the foregoing reasons, this court should affirm DEA's final order denying the petitioner's request.

Respectfully submitted,

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CERTIFICATE OF SERVICE

It is hereby certified that service of this BRIEF FOR THE RESPONDENT was made on the petitioner on this 6th day of November, 1995, by mailing two copies, postage prepaid, addressed as follows.

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CERTIFICATION PURSUANT TO D.C. CIRCUIT RULE 28(d)(1)

It is hereby certified that this brief contains no more than 12,500 words in accordance with D.C. Circuit Rule 28(d)(1).

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