

CASE BEING CONSIDERED FOR TREATMENT  
PURSUANT TO RULE 35(j) OF THE GENERAL RULES

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

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No. 94-1605

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CARL ERIC OLSEN

Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION

Respondent.

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Petition for Review of an order of the  
Drug Enforcement Administration

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Petitioner's Reply Brief

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**ARGUMENT**

The Drug Enforcement Administration (DEA) claims that the issue of whether (-)-delta-9-(trans)-tetrahydrocannabinol (also known as levo-trans-delta-9-tetrahydrocannabinol) has been, or should have been, rescheduled to Schedule II of the Controlled Substances Act is being raised for the first time in this petition for judicial review. This objection is without merit. The matter of the scheduling of (-)-delta-9-(trans)-tetrahydrocannabinol<sup>1</sup> was implicit in the original petition for rescheduling of marijuana.

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<sup>1</sup> Throughout the remainder of this brief, the abbreviation "THC" will be used in place of the term "tetrahydrocannabinol."

There are four isomers of delta-9-THC: (1) levo-(trans)-delta-9-THC; (2) levo-(cis)-delta-9-THC; (3) dextro-(trans)-delta-9-THC; and (4) dextro-(cis)-delta-9-THC. Of these four, only one is found naturally occurring in the marijuana plant: levo-(trans)-delta-9-THC (also known as (-)-delta-9-(trans)-THC).<sup>2</sup> Levo-(trans)-delta-9-THC is also the only one of the four isomers that is active (or psychoactive). This isomer is the same isomer found in the commercial product Marinol®. This isomer has also been given the U.S. Adopted Name (USAN) of dronabinol.

In the petitioner's brief which accompanied the original petition to the DEA, A. 3-4,<sup>3</sup> a substance by the name of dronabinol was clearly identified. A DEA proposal to reschedule dronabinol to Schedule II of the Controlled Substances Act was also cited in the original brief filed with the DEA by the petitioner. 50 Fed. Reg. 42,186 (Oct. 18, 1985). According to the DEA and the Physician's Desk Reference, this substance is clearly identified as "the principle psychoactive substance in Cannabis sativa L., marijuana." 1989 Physician's Desk Reference, page 1859. In other words, dronabinol can be made synthetically or extracted from marijuana, the plant in which it occurs naturally. Dronabinol is exactly the same no matter whether it is produced synthetically in a test tube, or extracted from a marijuana plant. This is an important distinction, because

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<sup>2</sup> Another name for this isomer is levo-(trans)-delta-1-THC, or (-)-delta-1-(trans)-THC.

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

dronabinol is not exclusively a semi-synthetic substance like heroin,<sup>4</sup> or a synthetic substance like alphacetylmethadol.<sup>5</sup>

Of course, the actual substance which was later rescheduled was not dronabinol, but rather "dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule." 51 Fed. Reg. 17,476 (1986). However, this combination of drug and food substances was not mentioned in the petitioner's brief which was attached to the original petition filed with the DEA. The reason this combination was not mentioned was because sesame oil and soft gelatin capsules are foods. Sesame oil is not added for purpose of diluting dronabinol, nor does encapsulation in gelatin capsules change the strength or potency of dronabinol.

The original brief filed with the DEA also referred to an international treaty, the Convention on Psychotropic Substances, February 21, 1971, 32 U.S.T. 543, T.I.A.S. 9725, 1019 U.N.T.S. 175, which was amended at the request of the United States in 1991, and which included the rescheduling of all the stereochemical variants of THC.<sup>6</sup> E/1991/24 E/CN.7/1991/26, 24 May 1991. The United States is bound by this treaty and the

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<sup>4</sup> Pursuant to a telephone conversation of November 27, 1995, with John P. Morgan, Professor of Pharmacology, City University of New York, Medical School, Room J903, 138th Street at Convent Avenue, New York, New York 10031; telephone (212) 650-8255. Professor Morgan stated that heroin does not occur naturally in the opium poppy. Heroin is a semi-synthetic derivative of morphine.

<sup>5</sup> Id. Professor Morgan, footnote 4, supra. Professor Morgan also stated that alphacetylmethadol is not a naturally occurring substance. It is made synthetically.

<sup>6</sup> This international rescheduling included all four isomers of delta-9-THC, along with all other forms of THC found in the plant, e.g., those found in 21 C.F.R. § 1308.11(d)(25).

amendment pursuant to the Psychotropic Substances Act, Pub. L. 95-633, November 10, 1978. This international rescheduling procedure allowed the United States to reschedule dronabinol, although the DEA is claiming that only the specific isomer dronabinol (and only when made synthetically) in sesame oil and encapsulated in a soft gelatin capsule was actually rescheduled.

The petitioner's original petition and brief did not tell the DEA that rescheduling of dronabinol was being sought, because it was implicit in the argument that marijuana should be rescheduled. The petitioner argued that dronabinol had already been rescheduled to Schedule II, and, therefore, marijuana is now the source of a Schedule II substance, dronabinol. Contrary to the DEA's assertions, this issue is not being raised for the first time on judicial review. The DEA could have asked for clarification, if it was unsure of the grounds for the petition.

The fact that no cite case law was cited in the Petitioner's original brief does not mean that none existed. All of the ideas expressed in the petitioner's original petition and brief were taken from prior decisions of this court in United States v. Walton, 514 F.2d 201 (D.C. Cir. 1975), National Organization for the Reform of Marijuana Laws v. Drug Enforcement Administration, 559 F.2d. 735 (D.C. Cir. 1977), and Alliance for Cannabis Therapeutics v. Drug Enforcement Administration, 930 F.2d 936 (D.C. Cir. 1991). There is nothing original about these arguments, as they were all presented by this court in these three cases.

On page 3 of its brief, the DEA talks about 20 years of rescheduling petitions, all of which have been appealed and denied. The DEA fails to mention that none of these previous petitions raised the issue presented here. In all of the cases cited by the DEA, the petitioners were seeking either recreational, medical, or sacramental use of the marijuana plant, in its natural form. The matter presently before this court seeks none of these, and that's why the issue presented here has never been raised before, even though it was invited by this court in National Organization for the Reform of Marijuana Laws v. Drug Enforcement Administration, 559 F.2d 735, 748 (D.C. Cir. 1977).

If this case is successful in transferring marijuana from Schedule I to Schedule II of the Controlled Substances Act (CSA), the most that could be hoped for is that dronabinol could be extracted from marijuana, rather than being made entirely synthetically. Both cocaine and morphine can be made synthetically, but neither of them are commonly made that way. It is more economical to extract cocaine and morphine from their natural sources (the plants they come from, coca and opium poppy).<sup>7</sup> The trend is to go with extraction, rather than synthesis.

The United States government currently grows marijuana under contract with the University of Mississippi, and it could easily

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<sup>7</sup> Id. Professor Morgan, footnote 4, supra. Professor Morgan also stated that aspirin is not even made synthetically, because it's cheaper to extract it from its natural plant source.

license others to manufacture marijuana for the purpose of extracting dronabinol. In 1942, the federal government actually exempted farmers from military service if they agreed to grow marijuana for the production of hemp fiber during World War II. Marijuana is still mentioned as a strategic military resource in Section 901(e) of the Executive Order 12919 of June 3, 1994 (National Defense Industrial Resources Preparedness).

The penalties for illegal possession of a Schedule II substance are no different from those for illegal possession of a Schedule I substance. Therefore, there is no valid enforcement concern for the Drug Enforcement Administration, because the DEA's mission is strictly one of enforcement. United States v. Moore, 423 U.S. 122, 135 (1972). As the DEA Administrator stated in 1992, "Clearly, the Controlled Substances Act does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate decision as to whether a drug should be used as medicine." 57 Fed. Reg. 10,499, 10,505 (March 26, 1992). Rescheduling marijuana from Schedule I to Schedule II would not set any precedent for further rescheduling, nor would it lead to increased drug diversion when the strict Schedule II requirements for manufacture are met.<sup>8</sup>

Although the DEA in its brief continually refers to the statutory criteria for scheduling set forth in 21 U.S.C. § 812(b)(2) Schedule II, and is quick to point out that marijuana

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<sup>8</sup> Manufacturers would be required to meet the same standards as those currently employed by the federal government's marijuana farm at the University of Mississippi.

fails to satisfy any of them, it completely sweeps under the rug the fact that coca and opium poppy, both Schedule II substances, also fail to satisfy any of them. The DEA refers to the plain meaning of the statute, but fails to explain this obvious inconsistency between its argument and the plain wording of the statute. Congress was clearly using other factors to determine scheduling, which this court properly recognized in 1977. Id. NORML v. DEA, 559 F.2d at 748.

To be fair, the DEA has admitted there is an inconsistency in its argument. In footnote 9, on page 16 of its brief, the DEA admits that some courts, including this one, have found that the scheduling criteria in 21 U.S.C. § 812 are neither cumulative nor exclusive. However, the DEA gives two reasons why these doubts should be resolved in its favor.

First, the DEA claims that the dicta in these cases were overruled by this court's decisions in Alliance for Cannabis Therapeutics v. Drug Enforcement Administration, 15 F.3d 1131, 1133 (D.C. Cir. 1991), and Alliance for Cannabis Therapeutics v. Drug Enforcement Administration, 930 F.2d 936, 938-940 (D.C. Cir. 1994). The problem with the DEA's reasoning is that the issue in this case was not raised by the Alliance for Cannabis Therapeutics cases, and, therefore, it is not res judicata in this matter.

The second argument given by the DEA is that this court should give deference to the DEA's interpretation of the statute because of the guidelines for statutory interpretation articulated by the U.S. Supreme Court in Chevron , U.S.A, Inc. v.

Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

Again, the problem with this reasoning is that Chevron requires this court to first look at the plain meaning of the statute. This court must first resolve the inconsistency of the scheduling of coca and opium poppy under the statute. According to the DEA's reasoning, neither coca and opium poppy could be scheduled in Schedule II of the statute. The DEA has never moved to correct this inconsistency by attempting to reschedule coca and opium poppy to Schedule I. Therefore, it is obvious that the DEA has failed to properly interpret the statute in this matter.

The DEA admits that, in drafting the statute, Congress was aware that coca and opium poppy were the sources of accepted medicines, but fails to acknowledge that this creates an additional scheduling criterion (being the natural plant source of an accepted medicine), and that Congress was equally aware that marijuana was not the source of any accepted medicine at the time the Controlled Substances Act was written. Things have changed. Marijuana is now the source of an accepted medicine, even though the DEA makes an artificial distinction between the synthetic and the naturally extracted equivalent of the drug. Coca and opium poppy are the evidence that Congress did not consider the scheduling of plants and their included chemicals to be distinct, and the DEA half-heartedly admits as much.<sup>9</sup>

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<sup>9</sup> It is important to note that coca, opium, and marijuana plants are not only the source of accepted medicines, but those medicines are all the principle psychoactive drugs contained within those plants. In other words, these plants are only medically active (psychoactive) to the extent they contain these drugs. Of course, that is not to say that these plants have no

There is no difference between a synthetic drug and its naturally extracted twin. By definition, a synthetic molecule must be identical to its natural equivalent. The Food and Drug Administration verifies this fact. A. 16. Synthetic dronabinol and the (-)-delta-9-(trans)-THC found in the marijuana plant are the same thing. The DEA is saying that only synthetic dronabinol in sesame oil and encapsulated in soft gelatin capsules has been rescheduled, and the Code of Federal Regulations actually distinguishes (wrongly) synthetic from naturally occurring dronabinol (as if synthetic and naturally occurring drugs were not the exact same thing). 21 C.F.R. § 1308.11(f)(1). However, the DEA is saying that dronabinol itself was not transferred from Schedule I to Schedule II of the CSA. The DEA claims that only a pharmaceutical product, dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules, was transferred to Schedule II.

On page 21 of its brief, the DEA briefly mentions Grinspoon v. Drug Enforcement Administration, 828 F.2d 881, 891-892 (1st Cir. 1987), but completely fails to mention its subsequent approval by this court in Alliance for Cannabis Therapeutics v. Drug Enforcement Administration, 930 F.2d 936, 939-940 (D.C. Cir. 1991). The Grinspoon court held that the DEA cannot rely on FDA marketing approval in making scheduling decisions. While it is true, as the DEA points out in footnote 13, on page 21 of its brief, that FDA marketing approval is sufficient to establish

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other medicinal qualities, just none that are presently recognized by the medical profession.

accepted medical use, the DEA fails to acknowledge that lack of FDA marketing approval does not necessitate a finding that the substance has no medical use. Alliance, 930 F.2d at 939; Grinspoon, 828 F.2d at 891. As this court wrote in 1977,

If, as respondent contends, a determination that the substance has no accepted medical use ends the inquiry, then presumably Congress would have spelled that out in its procedural guidelines. Its failure to do so indicates an intent to reserve to HEW a finely tuned balancing process involving several medical and scientific considerations.

NORML, 559 F.2d at 748. It would be ludicrous to assume that dronabinol has no medical value unless it is in sesame oil and encapsulated in soft gelatin capsules, or that it would have no medical value if it were extracted from a marijuana plant.

It is interesting to note in footnote 7, on page 11, and, again on page 14 of the DEA's brief, that the DEA recognizes that Congress had strong doubts about placing marijuana in Schedule I and fully intended that further research would clarify this matter. Further research has indeed revealed that marijuana has at least as much therapeutic value as coca and opium poppy.

It is also disturbing how the DEA ignores the holdings in United States v. Walton, 514 F.2d 201 (D.C. Cir. 1975). This court specifically held that marijuana was illegal only to the extent that it contained THC. This court interpreted the plain meaning of the statute, as well as its history in the Marihuana Tax Act of 1937, and determined that it was plain from the face of the statute that THC<sup>10</sup> was the controlling factor in

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<sup>10</sup> The term "THC", as used by this court, referred to dronabinol, since it is the only isomer of delta-9-THC which is

marijuana's scheduling. The DEA seems to think this holding has been overruled by subsequent decisions in Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936, and Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131. Again, the issues raised were not the same, and neither of the Alliance rulings are res judicata as to the issue presented here.

In footnote 10, on page 16 of its brief, the DEA makes an interesting analogy to a substance by the name of levo-alphaacetylmethadol. This is a great analogy, because it's almost exactly the same situation as we have with levo-(trans)-delta-9-THC. The other three isomers of delta-9-THC are psychoactively inactive. In other words, they have little, if any, medical value, which means that it's highly unlikely they will ever be rescheduled to Schedule II (or below) under the DEA's currently proposed (and faulty) standards. It also means they have practically no abuse potential, which means that it's highly unlikely they would have ever been scheduled in Schedule I (or any schedule) if it had not been for their psychoactive counterpart (dronabinol). As this court noted in Walton, it was the psychoactive isomer of delta-9-THC that caused marijuana to be outlawed in the first place.<sup>11</sup> If none of the isomers of delta-9-THC were psychoactive, it would be highly unlikely that

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present in the marijuana plant, and it is the only form of THC which is psychoactive.

<sup>11</sup> At the time Walton was decided, the term THC was used as if it were the same thing as dronabinol, because the levo-(trans) isomer is the only isomer of delta-9-THC that is actually produced by the plant. The other isomers can only be produced in a chemical laboratory.

Congress would ever have even thought of outlawing marijuana. Without the psychoactive isomer of delta-9-THC, marijuana is just another weed.

Marijuana is the source of dronabinol, and not the source of the other three isomers of delta-9-THC. Practically speaking, it is the levo-(trans) isomer of delta-9-THC that we are speaking of when we refer to delta-9-THC. In the DEA's analogy, alphacetylmethadol would be the equivalent of delta-9-THC, and levo-alphacetylmethadol would be the equivalent of dronabinol.

Alphacetylmethadol doesn't come from a plant, it's made synthetically.<sup>12</sup> If alphacetylmethadol came from a plant, that plant would only be controlled to the extent that it contained the psychoactive substance levo-alphacetylmethadol and not the other isomers of alphacetylmethadol which are psychoactively inactive.<sup>13</sup> The difference between alphacetylmethadol and marijuana is that the former comes from a test tube and the latter comes from a seed. The genesis of alphacetylmethadol is a test tube and the genesis of delta-9-THC is a plant. The precedent for the treatment of plants has already been established by Congress in drafting the Controlled Substances Act. The analogy breaks down, because alphacetylmethadol does not come from a plant. Both alphacetylmethadol and the three non-dronabinol isomers of delta-9-THC can only be made synthetically. However, dronabinol is produced either

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<sup>12</sup> Id. Professor Morgan, footnote 4, supra.

<sup>13</sup> Id. Professor Morgan, footnote 4, supra.

synthetically or by a plant, while levo-alphaacetylmethadol can only be made synthetically.

One last point that should be mentioned again is that the DEA originally sought to reschedule dronabinol itself. 50 Fed. Reg. 42,186 (Oct. 18, 1985). On page 19 of the DEA's brief, the DEA incorrectly states that this proposal was only for synthetic dronabinol in sesame oil and encapsulated in a soft gelatin capsule. The original proposal was for dronabinol itself, not a U.S. Food and Drug Administration approved product. The actual rescheduling order changed the rescheduling to "dronabinol in sesame oil and encapsulated in soft gelatin capsules." 51 Fed. Reg. 17,476 (1986). This is not difficult to understand, because this action was prior to the 1987 ruling in Grinspoon v. Drug Enforcement Administration, 828 F.2d 881, 891-892 (1st Cir. 1987), where the First Circuit ruled that the DEA could not rely solely on FDA marketing approval in making scheduling decisions. This court approved the holding of the Grinspoon court in Alliance for Cannabis Therapeutics v. Drug Enforcement Administration, 930 F.2d 936, 939-940 (D.C. Cir. 1991).

The DEA's assertion that dronabinol was not rescheduled, along with its assertion that marijuana is not the source of an accepted medicine are false. Evidence of the DEA's error is the list of controlled substances contained in Schedule I and Schedule II in the Code of Federal Regulations at 21 C.F.R. §§ 1308.11 and 1308.12. Dronabinol is the only substance that contains the following added language:

(synthetic) in sesame oil and encapsulated in a soft gelating capsule in a U.S. Food and Drug Administration approved drug product

21 C.F.R. § 1308.11(f)(1). Every other substance in Schedule I and Schedule II is identified only by its chemical name.<sup>14</sup> The addition of sesame oil and gelatin capsules does nothing to change the nature of the substance dronabinol. In the petitioner's brief attached to the original petition filed with the DEA, the substance identified is dronabinol, not a U.S. Food and Drug Administration approved product.

#### **FAILURE TO FOLLOW PROPER ADMINISTRATIVE PROCEDURE**

Since the DEA is concerned about following proper administrative procedure, it should be noted that the DEA has failed to follow proper administrative procedure on numerous occasions, particularly in four cases (three in which the petitioner has been a party). National Organization for the Reform of Marijuana Laws v. Ingersoll, 497 F.2d 654 (D.C. Cir. 1974) (case remanded because DEA refused to accept a rescheduling petition); Carl Eric Olsen v. Drug Enforcement Administration, 776 F.2d 267 (11th Cir. 1985) (DEA scolded for refusing to

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<sup>14</sup> Admittedly, there is some cross-scheduling of substances in the lower schedules (e.g., codeine is in Schedule II, while codeine diluted to "not more than 200 milligrams of codeine per 100 milliliters or per 100 grams" is in Schedule V), but such cross-scheduling involves diluted forms of the same drug. It is important to note that codeine is in Schedule II, not Schedule I, because it has medical use. To suggest that codeine be included in Schedule I unless it is in sesame oil and encapsulated in soft gelatin capsules would be absurd. It is also important to note that there is no cross-scheduling between Schedule I and Schedule II (with the exception of dronabinol).

respond to a rescheduling petition); Carl Eric Olsen v. Drug Enforcement Administration, 878 F.2d 1458 (D.C. Cir. 1989) (petitioner had to file for a writ of mandamus to compel the DEA to accept a rescheduling petition, and case later remanded because DEA failed to properly address the issues raised); Carl Eric Olsen v. Drug Enforcement Administration, No. 93-1109 (D.C. Cir. Dec. 9, 1993) (case remanded because DEA refused to accept a rescheduling petition). This record shows that the DEA has made a consistent effort to obstruct justice and deny petitioners the first amendment constitutional right to petition government for a redress of grievances.

#### CONCLUSION

The regulations of the DEA clearly state that a petition to reschedule can be brought by any interested party. 21 C.F.R. § 1307.03. It is important that citizens be encouraged to keep an eye on government officials; in fact, it is a civil duty. It is not the function of the government to keep the citizen from falling into error; it is the function of the citizen to keep the government from falling into error.

The DEA improperly failed to reschedule marijuana and dronabinol when it rescheduled the pharmaceutical equivalent of dronabinol. The DEA improperly refused to reschedule marijuana when this error was brought to its attention. The appropriate remedy is for this court to order that marijuana and dronabinol are both included within Schedule II of the Controlled Substances Act of 1970.

**REQUEST FOR ORAL ARGUMENT**

The petitioner respectfully requests that he be granted oral argument in this matter.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that two copies of the foregoing Petitioner's Reply Brief were mailed by first class mail on this \_\_\_\_\_ day of November, 1995, to:

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