UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of PETITION OF CARL ERIC OLSEN	On Remand From the United States Court of Appeals for the District of Columbia Circuit, No. 93-1109

FINAL ORDER

This order is issued pursuant to an Order dated December 9, 1993, from the United States Court of Appeals for the District of Columbia Circuit which remanded the matter of a petition from Carl Eric Olsen to the Drug Enforcement Administration (DEA) for a ruling by the agency.

On September 6, 1992, Carl Eric Olsen (Petitioner) of Des Moines, Iowa, submitted a petition requesting that the controlled substance marijuana, be rescheduled from Schedule I to Schedule II of the Controlled Substances Act of 1970 (CSA). The Petitioner's grounds were based on his evaluation of two prior rescheduling actions by the Administrator. See Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules, 51 Fed. Reg. 17476 (1986) and Marijuana Rescheduling Petition, 57 Fed. Reg. 10499 (1992). On October 23, 1992, then-Administrator of Drug Enforcement, Robert C. Bonner, declined to accept his petition. The Petitioner subsequently filed for review of then-Administrator Bonner's decision with the United States Court of Appeals for the District of Columbia

Circuit. The matter was remanded by Order of that Court to the DEA for a ruling. Pursuant to that Court's Order, and 21 C.F.R. § 1308.44(c), the Deputy Administrator of the Drug Enforcement Administration has considered the matters before him and hereby renders his final decision.

In his Petition for rescheduling, the Petitioner alleged that marijuana need not have an accepted medical use in treatment in the United States in order to be rescheduled from Schedule I, but "it only needs to be shown that marijuana is a source for an accepted and useful medication". This contention was based on Petitioner's own analogies drawn from an earlier DEA marijuana rescheduling case, 57 Fed. Reg. 10499 (1992), and subsequent written statements made to the Petitioner by then-Administrator Bonner regarding coca leaves and opium plant material; and the Petitioner's incorrect contention that the DEA proposed to reschedule dronabinol in a proposed rulemaking. See Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules, 50 Fed. Reg. 42186 (1985). It appears that Petitioner contends that this rescheduling action included delta-9-tetrahydrocannabinol (delta-9-THC), an ingredient in marijuana, and concluded that "since marijuana is now a source for an accepted and useful medication, it must now be rescheduled from Schedule I to Schedule II of the CSA".

The Deputy Administrator finds, for the reasons stated herein, that the grounds upon which the Petitioner relies are not

sufficient to justify the initiation of proceedings for the transfer of marijuana from Schedule I to Schedule II of the CSA.

In July 1992, the Petitioner wrote then-Administrator Bonner regarding his final order of March 26, 1992, (57 Fed. Reg. 10499), in which the Administrator declined to reschedule marijuana to Schedule II, and the apparent "unfair" classification of the marijuana plant as a Schedule I substance, while coca and opium plants remained in Schedule II. Then-Administrator Bonner replied by letter on August 17, 1992, and distinguished the pharmaceuticals or derivative compounds from each plant. Apparently, the Petitioner then created a theory, that given that the Schedule II opium and coca plants were a source for an accepted medication, then if marijuana plants were a source for accepted medications it should also be a Schedule II substance. To further his argument, the Petitioner pointed to the rescheduled drug, which he called dronabinol, as having its source in marijuana. The Petitioner also alluded to inconsistencies of scheduling of delta-9-THC, a component of marijuana, between the CSA and certain multilateral international agreements.

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. The DEA is bound, by law, to follow this mandate. Congress placed both the tetrahydrocannabinols, which includes delta-9-THC, and the plant marijuana into Schedule I when it enacted the

CSA. See Pub. L. 91-513, § 202(c), Schedule I (c)(17) and (c)(10). Similarly, Congress placed opium poppy and straw and coca leaves into Schedule II. See Pub. L. 91-513, § 202(c), Schedule II (a)(3) and (a)(4). The legislative history indicates that marijuana was placed into Schedule I on its own merits and not because delta-9-THC could be extracted from it. H.R. Rep. No. 1444, 91st Cong., 2d Sess., pt. 1, at 12 (1970).

Whether or not marijuana is a source of delta-9-THC is irrelevant to the status of marijuana under the CSA. With regard to the classification of controlled substances, the Attorney General may, by rule, add to the established schedules or transfer between such schedules any drug or other substance if [s]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). The Attorney General has delegated this authority to the Administrator, who has redelegated it to the Deputy Administrator. See 28 C.F.R. §§ 0.100(b) and 0.104. (59 Fed. Reg. 23637 (May 6, 1994)).

In order for a substance to be placed into Schedule II, 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 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).

Then-Administrator John C. Lawn previously determined that marijuana does not have a currently accepted medical use in treatment in the United States and as a result must remain in Schedule I. See Marijuana Rescheduling Petition, 54 Fed. Reg. 53767 (1989). Then-Administrator Lawn's final order was appealed to the United States Circuit Court of Appeals for the D.C. Circuit which returned the matter to the DEA for an explanation of the factors relied upon in determining "currently accepted medical use". See Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936 (D.C. Cir. 1991).

In response to the remand, then-Administrator Bonner issued a final order in which he determined that for a substance to have a "currently accepted medical use" the following must exist:

a. the drug's chemistry must be known and reproducible;

b. there must be adequate safety studies;

c. there must be adequate and well-controlled studies proving efficacy;

d. the drug must be accepted by qualified experts; and

e. the scientific evidence must be widely available.

Then-Administrator Bonner concluded that marijuana failed to meet all elements of the five-part test and, therefore, did not meet the statutorily prescribed criteria for a Schedule II substance. Marijuana Rescheduling Petition, 57 Fed. Reg. 10499 (1992); See

Alliance for Cannabis Therapeutics v. DEA, et al., 15 F.3d 1131 (D.C. Cir. 1994) upholding the Administrator's decision.

Accordingly, the Deputy Administrator concludes that the Petitioner's contention that marijuana need not have an accepted medical use in treatment in the United States in order to be rescheduled from Schedule I to Schedule II of the CSA is not in accordance with law. DEA may only move a drug from Schedule I if there is a finding of "currently accepted medical use in treatment in the United States".

Although delta-9-THC is the principal psychoactive ingredient in marijuana, it can be synthesized and exist as a chemical. Delta-9-THC is a generic term which refers to four separate chemicals and two mixtures of chemicals, i.e., four stereochemical variants of the parent substance and two racemates. One of the stereochemical variants, the (-) delta-9-trans-THC isomer, is the principal psychoactive ingredient in Cannabis sativa, L., or marijuana. That isomer is also the ingredient in a pharmaceutical product which has been shown to be safe and effective as an anti-emetic for certain patients receiving cancer chemotherapy, and is identified chemically as (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]-pyran-1-ol. The International Nonproprietary name (INN) and the U.S. Adopted Name (USAN) for that isomer of delta-9-THC is dronabinol.

With the development of scientific and medical evidence that demonstrated that a pharmaceutical product which contained

dronabinol was safe and effective for the treatment of nausea and vomiting associated with cancer chemotherapy in certain patients, then-Administrator John C. Lawn rescheduled this pharmaceutical product from Schedule I to Schedule II. See 51 Fed. Reg. 17476 (1986). Only the pharmaceutical product was transferred from Schedule I to Schedule II, i.e., "dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product". No rescheduling action was taken with regard to (-) delta-9-trans-THC, i.e., dronabinol, which remains in Schedule I of the CSA. Tetrahydrocannabinols, including delta-9-THC, one of the synthetic equivalents of the substances contained in the plant or resinous extractives of Cannabis (marijuana) are listed at 21 C.F.R. § 1308.11(d)(25).

Tetrahydrocannabinols and all their isomers, including delta-9-THC, are also the subject of control by international agreement under the United Nations Convention on Psychotropic Substances, 1971, February 21, 1971, 32 U.S.T. 543, T.I.A.S. 9725, 1019 U.N.T.S. 175. Cannabis, cannabis resin and extracts and tinctures of cannabis are regulated as Schedule I substances under the United Nations Single Convention on Narcotic Drugs, 1961, March 30, 1961, 18 U.S.T. 1407, T.I.A.S. 6298, 520 U.N.T.S. 204. The United States is a party to both conventions.

Then-Administrator Lawn also discussed the United States international obligations in his Dronabinol in Sesame Oil and Encapsulated in a Soft Gelatin Capsule, rescheduling action.

See 51 Fed. Reg. 17476 (1986). Since Article 7 of the Convention on Psychotropic Substances, 1971 has strict prohibitions on activities involving Schedule I drugs, in 1987, the United States Government initiated an action to have delta-9-THC transferred to Schedule II to allow the pharmaceutical product to be marketed. See U.N. Doc. E/CN.7/1990/4. Such a transfer was not inconsistent with the substance delta-9-THC remaining in the CSA Schedule I. Under Article 23 of the Convention on Psychotropic Substances, 1971, a party may adopt more strict or severe measures of control if desirable or necessary for the protection of the public health and welfare.

Under the CSA, the regulation of chemicals and the plant material are distinct from each other. The classification of delta-9-THC has no bearing on the classification of marijuana. Under the CSA, a proposed change in the schedule of either a tetrahydrocannabinol or the plant marijuana requires the Attorney General to proceed independently.

Petitioner apparently does not wish to look to the clear construct of the Controlled Substances Act, but to pose alternative theories of the Act. Under the CSA, drugs or other substances may be treated and classified differently, according to the enumerated statutory criteria. 21 U.S.C. § 812(b).

The Deputy Administrator reaffirms that marijuana does not have a currently accepted medical use in treatment in the United States and is thus appropriately listed as a Schedule I controlled substance. The Deputy Administrator finds nothing to

support the petitioner's contention that since marijuana, coca, and opium are all plant materials they must be treated alike in the CSA. The Deputy Administrator further finds that the rescheduling of the pharmaceutical product "dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product", which contains the synthetic chemical ingredient (-) delta-9-trans-THC, did not require that either the plant marijuana or substance delta-9-THC be similarly rescheduled. The Petitioner's request is denied.

Stephen H. Greene
Deputy Administrator

Dated: 5-16-94