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REPORT OF THE COMMISSION ON NARCOTIC DRUGS ON ITS  
THIRTY-FOURTH SESSION\*

(Vienna, 29 April to 9 May 1991)

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\* The present document is a mimeographed version of the report of the Commission on Narcotic Drugs on its thirty-fourth session. It will be issued subsequently in final form as Official Records of the Economic and Social Council, 1991, Supplement No. 4 (E/1991/24, Supp. No. 4).

## Chapter II

### IMPLEMENTATION OF INTERNATIONAL DRUG CONTROL TREATIES

2. At its 1045th meeting, on 30 April 1991, the Commission considered agenda item 3, which related to: (a) the possible rescheduling of one substance and its stereochemical variants under the provisions of the Convention on Psychotropic Substances, 1971 <sup>1/</sup> (E/CN.7/1991/17, paras. 1-6, and Add.2, paras. 1-2); (b) the possible descheduling of one substance under the provisions of the 1971 Convention (E/CN.7/1991/17, paras. 7-16, and Add.2, paras. 3-4); (c) the possible termination of the exemption by one Government of 55 preparations under the provisions of the 1971 Convention (E/CN.7/1991/17, paras. 17-24, and Add.2, paras. 5-6); and (d) the indexing of the E/NL. series of national laws and regulations (E/CN.7/1991/17/Add.1 and E/CN.7/1991/CRP.11). For its consideration of this agenda item, the Commission also had before it the twenty-seventh report of the WHO Expert Committee on Drug Dependence. <sup>2/</sup>

A. Consideration of recommendations for rescheduling, for descheduling and for terminating exemption under the Convention on Psychotropic Substances, 1971

1. Recommendation for rescheduling delta-9-tetrahydrocannabinol and its stereochemical variants

3. The Commission had before it a notification from the Director-General of the World Health Organization (WHO) recommending that delta-9-tetrahydrocannabinol (delta-9-THC) and its stereochemical variants should be rescheduled from Schedule I to Schedule II of the 1971 Convention, together with the comments received by the Secretary-General from Governments on the possible rescheduling of delta-9-THC and its stereochemical variants (E/CN.7/1991/17 and Add.2).

4. The observer for WHO made a statement on the notifications before the Commission. He drew attention to the fact that, in recommending the transfer of delta-9-THC and its stereochemical variants, there would be no need to make a technically difficult differentiation between its stereochemical variants in enforcing the regulation.

5. Some representatives expressed their support for the WHO recommendation and mentioned that the substance was under national control in that it was subject to the same control as substances listed in Schedule I of the Single Convention on Narcotic Drugs, 1961, and that Convention as amended by the 1972 Protocol; <sup>3/</sup> others expressed the view that stricter controls could always be applied at the national level. One representative stated that, while his Government could accept the transfer of delta-9-THC and its stereochemical variants, it should not be used as a precedent to review the 1961 Convention with regard to cannabis or cannabis resin. Several representatives emphasized that the flexibility provided by such a transfer would be highly desirable, in view of the therapeutic usefulness of the substance, and that to keep it under control in Schedule I of the 1971 Convention might limit its availability to patients undergoing chemotherapy. Several representatives stated that in

their opinion there was no link between the therapeutic use of delta-9-THC and the abuse of cannabis. Some representatives did not agree with the WHO recommendation. One said that another drug had proved to be quite effective in the treatment of cancer and that, for that reason, rescheduling the substance did not seem to offer any therapeutic advantage and might even be interpreted as an attempt to legalize cannabis.

6. The Commission, by a vote of 33 in favour and 5 against, with no abstentions, decided to transfer delta-9-THC and its stereochemical variants from Schedule I to Schedule II of the 1971 Convention. The five States voting against the decision were Colombia, Côte d'Ivoire, Egypt, France and Pakistan. For the text of the decision drafted by the Secretariat at the request of the Commission to reflect the results of the vote, see chapter XIV, section B, decision 2 (XXXIV).

2. Recommendation for descheduling of propylhexedrine

7. The Commission also had before it a notification from WHO (E/CN.7/1991/17 and Add.2) recommending that propylhexedrine (N, -dimethylcyclohexaneethylamine) should be deleted from Schedule IV of the 1971 Convention and should not be transferred to any other Schedule.

8. Several representatives expressed their agreement with the WHO recommendation. One, however, expressed concern about making frequent changes in the scope of control of substances, adding that it might result in regulatory and administrative instability within member States.

9. The Commission unanimously decided to remove propylhexedrine from Schedule IV of the 1971 Convention. For the text of the decision drafted by the Secretariat at the request of the Commission to reflect the results of the vote, see chapter XIV, section B, decision 3 (XXXIV).

3. Recommendation for terminating the exemption of 55 preparations containing butalbital by the Government of the United States of America

10. The Commission also had before it a notification from WHO recommending the termination of the exemption by the Government of the United States of America of 55 preparations containing butalbital from certain control measures, under the provisions of article 3 of the 1971 Convention (E/CN.7/1991/17 and Add.2).

11. The Commission decided unanimously to terminate the exemption by the Government of the United States of the 55 preparations containing butalbital, so that the requirements of article 12, paragraph 2, of the 1971 Convention should apply to those preparations. For the text of the decision drafted by the Secretariat at the request of the Commission to reflect the results of the vote, see chapter XIV, section B, decision 4 (XXXIV).

B. Cumulative index of laws and regulations relating to the control of narcotic drugs and psychotropic substances published in the E/NL. series

12. For its consideration of the cumulative index of laws and regulations relating to the control of narcotic drugs and psychotropic substances published in the E/NL. series, the Commission had before it a note by the Secretariat (E/CN.7/1991/17/Add.1) containing an explanation of the improvements on the format of the cumulative index for the period 1987-1990, that would make it a more useful tool for legislative research in connection with the provisions of the 1988 Convention. The Commission took note of the cumulative index for the period 1987-1990 (E/CN.7/1991/CRP.11) and agreed that it should be issued as a United Nations sales publication.

13. One speaker emphasized the quality and usefulness of the cumulative index. He suggested that, while the Secretariat should continue to distribute it to Governments, it should leave it to them to request the texts of laws and regulations that they required.

## B. Decisions

292. The Commission, at its thirty-fourth session, adopted the following decisions:

### Decision 1 (XXXIV)

#### Adoption of revised part B of the annual reports questionnaire\*

At its 1059th meeting, on 9 May 1991, the Commission on Narcotic Drugs decided to replace part B of the annual reports questionnaire with its revised version, 1/ beginning with the annual reports questionnaire for the calendar year 1991.

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1/ E/CN.7/1991/CRP.10.

### Decision 2 (XXXIV)

#### Transfer of delta-9-THC and its stereochemical variants from Schedule I to Schedule II of the Convention on Psychotropic Substances, 1971\*\*

At its 1045th meeting, on 29 April 1991, the Commission on Narcotic Drugs, in accordance with article 2, paragraphs 5 and 6, of the Convention on Psychotropic Substances, 1971, decided that delta-9-tetrahydrocannabinol (also referred to as delta-9-THC) and its stereochemical variants should be transferred from Schedule I to Schedule II of that Convention.

### Decision 3 (XXXIV)

#### Deletion of propylhexedrine from Schedule IV of the Convention on Psychotropic Substances, 1971\*\*\*

At its 1045th meeting, on 29 April 1991, the Commission on Narcotic Drugs, in accordance with article 2, paragraphs 1 and 6, of the Convention on Psychotropic Substances, 1971, decided that N, dimethylcyclohexaneethylamine (also referred to as propylhexedrine) should be deleted from Schedule IV of that Convention.

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\* See paragraph 133 above.

\*\* See paragraph 6 above.

\*\*\* See paragraph 9 above.

(m) *Primary protective barrier for mammography x-ray systems.* For mammography x-ray systems manufactured after September 30, 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed  $2.58 \times 10^{-8}$  C/kg (0.1 mR) for each activation of the tube.

(4) Compliance for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

Dated: June 16, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy Coordination.*

[FR Doc. 99-16835 Filed 7-1-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Parts 1308, 1312

[DEA-180F]

#### **Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [(-)- $\Delta^9$ -(trans)-Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This is a final rule of the Deputy Administrator of the Drug Enforcement Administration (DEA) transferring a drug between schedules of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811. With the issuance of this final rule, the Deputy Administrator transfers from schedule II to schedule III of the CSA the drug containing synthetic dronabinol [(-)- $\Delta^9$ -(trans)-tetrahydrocannabinol] in sesame oil and encapsulated in soft gelatin capsules in a product approved by the Food and Drug Administration (FDA). This rule also designates this drug as a schedule III non-narcotic substance requiring an import/export permit. As a result of this rule, the regulatory controls and criminal sanctions of schedule III will be applicable to the manufacture, distribution, importation and exportation of this drug.

**EFFECTIVE DATE:** July 2, 1999.

**FOR FURTHER INFORMATION CONTACT:**

Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, 202-307-7183.

**SUPPLEMENTARY INFORMATION:**

#### **Background**

Dronabinol is the United States Adopted Name (USAN) for the (-)-isomer of  $\Delta^9$ -(trans)-tetrahydrocannabinol [(-)- $\Delta^9$ -(trans)-THC], which is believed to be the major psychoactive component of *Cannabis sativa L.* (marijuana). On May 31, 1985, FDA approved for marketing the product Marinol<sup>®</sup>—which contains synthetic dronabinol in sesame oil and encapsulated in soft gelatin capsules—for the treatment of nausea and vomiting associated with cancer chemotherapy. Following this FDA approval, DEA issued a final rule on May 13, 1986, transferring FDA-approved products of the same formulation as Marinol<sup>®</sup> from schedule I to schedule II of the CSA in accordance with 21 U.S.C. 811(a). (For simplicity within this document, the term “Marinol<sup>®</sup>” will be used hereafter to refer to Marinol<sup>®</sup> and any other products, which may be approved by FDA in the future, that have the same formulation as Marinol<sup>®</sup>.) The 1986 rescheduling of Marinol<sup>®</sup> was based on a medical and scientific evaluation and scheduling recommendation from the Assistant Secretary for Health in accordance with 21 U.S.C. 811(b). The transfer of Marinol<sup>®</sup> to schedule II did not affect the CSA classification of pure dronabinol, which—as a tetrahydrocannabinol with no currently accepted medical use in treatment in the United States—remains a schedule I controlled substance. On December 22,

1992, FDA expanded Marinol<sup>®</sup>'s indications to include the treatment of anorexia associated with weight loss in patients with AIDS.

#### **The Petition To Reschedule Marinol<sup>®</sup>**

On February 3, 1995, UNIMED Pharmaceuticals, Inc. petitioned the Administrator of DEA to transfer Marinol<sup>®</sup> from schedule II to schedule III. In response to this petition, and in view of supplemental information that UNIMED provided to DEA on December 11, 1996, DEA had to determine whether this proposed rescheduling of Marinol<sup>®</sup> would comport with United States obligations under the Convention on Psychotropic Substances, 1971 (Psychotropic Convention). See 21 U.S.C. 811(d). Under the Psychotropic Convention, dronabinol and all dronabinol-containing products, such as Marinol<sup>®</sup>, are listed in schedule II. As a result, the United States is obligated under the Psychotropic Convention to impose certain restrictions on the export and import of Marinol<sup>®</sup>. DEA has concluded that, in order for the United States to continue to meet its obligations under the Psychotropic Convention, DEA will continue to require import and export permits for international transactions involving Marinol<sup>®</sup>, even though Marinol<sup>®</sup> will be transferred to schedule III of the CSA. (As set forth below, to accomplish this, DEA is hereby amending 21 CFR 1312.30 to require import and export permits for international transactions involving Marinol<sup>®</sup>.)

After determining that Marinol<sup>®</sup> could be transferred to schedule III while maintaining the controls required by the Psychotropic Convention, and after gathering the necessary data, on August 7, 1997, DEA requested from the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), a scientific and medical evaluation, and recommendation, as to whether Marinol<sup>®</sup> should be rescheduled, in accordance with 21 U.S.C. 811(b).

On September 11, 1998, the Acting Assistant Secretary for Health sent to DEA a letter recommending that Marinol<sup>®</sup> be transferred from schedule II to schedule III of the CSA. Enclosed with the September 11, 1998, letter was a document prepared by the FDA entitled “Basis for the Recommendation for Rescheduling Marinol<sup>®</sup> Capsules from schedule II to schedule III of the Controlled Substances Act (CSA).” In this document, the FDA defines the Marinol<sup>®</sup> product as “an FDA-acting drug product containing synthetically produced dronabinol dissolved in sesame oil and encapsulated in soft

gelatin capsules (2.5 mg, 5 mg, and 10 mg per dosage unit)." The document contained a review of the factors which the CSA requires the Secretary to consider, which are set forth in 21 U.S.C. 811(c).

### The Proposed Rule

On November 7, 1998, the then-Acting Deputy Administrator of DEA published a notice of proposed rule making in the **Federal Register** (63 FR 59751), proposing to transfer Marinol® from schedule II to schedule III of the CSA. The proposed rule was based on the DHHS scientific and medical evaluation and scheduling recommendation and DEA's independent evaluation. Also under the proposed rule, 21 CFR 1312.30 would be amended to include Marinol® as a schedule III non-narcotic controlled substance specifically designated as requiring import and export permits pursuant to 21 U.S.C. 952(b)(2) and 953(e)(3). As discussed above, this proposed amendment to 21 CFR 1312.30 is necessary for the United States to continue to meet its obligations under the Psychotropic Convention. The notice of proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing in writing to DEA on or before December 7, 1998.

### Comments From the Public

DEA received comments regarding the proposed rule from ten persons. Nine of the commenters supported the proposed rule. One commenter objected to the proposed rule and requested a hearing thereon. The comments are briefly summarized below.

The nine commenters who supported the proposed rule included organizations, physicians, and one individual. Eight of the nine commenters who supported the proposed rule expressed the opinion that Marinol® is a safe and effective alternative to smoking marijuana for treatment of nausea and loss of appetite and has low abuse potential.

One commenter who supported the proposed rule expressed the view that the rescheduling of Marinol® should not serve as a substitute for making marijuana legally available for medical use. This commenter stated that it supported the use of marijuana for medical purposes and, therefore, wished to emphasize that the proposed rule affected the CSA status of Marinol®—not that of marijuana, which remains a schedule I controlled substance.

The one commenter who objected to the proposed rule, and requested a hearing thereon, asserted that Marinol®

should not be transferred to schedule III unless and until marijuana and all other THC-containing drugs are simultaneously and likewise rescheduled. This commenter asserted that Marinol® has the same potential for abuse as marijuana and all other THC-containing drugs. This commenter agreed with the proposed rule that Marinol®'s potential for abuse is less than the "high potential for abuse" commensurate with schedules I and II of the CSA. Accordingly, this commenter agreed that Marinol® should be transferred to a less restrictive schedule than schedule II. However, this commenter disagreed with what would be the resultant status of Marinol® vis-à-vis marijuana and THC if the NPRM becomes final: Marinol® would be in schedule III while marijuana and THC would remain in schedule I. This commenter asserted that the CSA prohibited transferring Marinol® to a less restrictive schedule unless marijuana and all THC-containing drugs are simultaneously transferred to the same schedule. DEA has determined that this commenter's objections are based on a misinterpretation of the CSA, which can be addressed, as a matter of law, without conducting a fact-finding hearing. Accordingly, as this commenter presented no material issues of fact, DEA denied this commenter's request for a hearing.

### Findings

Relying on the scientific and medical evaluation and scheduling recommendations of the Assistant Secretary for Health, and based on DEA's independent review thereof, the Deputy Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on information now available, Marinol® has a potential for abuse less than the drugs or other substances in schedules I and II.

(2) Marinol® is a FDA-approved drug product and has a currently accepted medical use in treatment in the United States; and

(3) Abuse of Marinol® may lead to moderate or low physical dependence or high psychological dependence.

### Rescheduling Action

Based on the above findings, the Deputy Administrator of the DEA concludes that Marinol® should be transferred from schedule II to schedule III. Schedule III regulations will, among other things, allow five prescription refills in six months and lessen record keeping requirements and distribution restrictions. The schedule III control of Marinol® will become effective July 2,

1999, except that certain regulatory provisions governing registrants who handle Marinol will take effect as indicated below. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the schedule III regulations regarding Marinol®. The applicable regulations are as follows.

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports Marinol® or who engages in research or conducts instructional activities with Marinol®, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations.

2. *Security.* Marinol® must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All commercial containers of Marinol®, which are packaged on or after January 3, 2000 must have the appropriate Schedule III labeling as required by §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations. Commercial containers of Marinol® packaged before January 3, 2000. After April 3, 2000, all commercial containers of Marinol must bear the CIII labels as specified in §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. *Inventory.* Registrants possessing Marinol® are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

5. *Records.* All registrants must keep records pursuant to §§ 1304.03, 1304.04 and 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

6. *Prescriptions.* All prescriptions for Marinol® are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations. All prescriptions for Marinol® issued on or after July 2, 1999, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after January 2, 2000.

7. *Importation and Exportation.* Due to its international control status, import and export permits for Marinol® will be required in accordance with 21 CFR 1312.30. All importation and exportation of Marinol® shall be in compliance with part 1312 of Title 21 of the CFR.

8. *Criminal Liability.* Any activity with Marinol® not authorized by, or in violation of, the CSA or the Controlled

Substances Import and Export Act shall continue to be unlawful.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rule making "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1). The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Marinol® is a prescription drug used to treat nausea due to cancer chemotherapy and AIDS wasting. Handlers of Marinol® are likely to handle other controlled substances used to treat cancer or AIDS which are already subject to the regulatory requirements of the CSA. Further, placement of Marinol® in schedule III of the CSA will mean a significant decrease in the regulatory requirements for persons handling Marinol®.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule, if finalized, will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

## List of Subjects

### 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

### 21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Narcotics, Reporting requirements.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR parts 1308 and 1312 as follows:

### PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

#### § 1308.12 [Amended]

2. Section 1308.12 is amended by removing paragraph (f)(1) and redesignating the existing paragraph (f)(2) as (f)(1).

3. Section 1308.13 is amended by adding a new paragraph (g) to read as follows:

#### § 1308.13 Schedule III.

\* \* \* \* \*

(g) *Hallucinogenic substances.*

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7369.

[Some other names for dronabinol: (6a*R*-*trans*)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo [*b*,*d*]pyran-1-ol) or (-)-delta-9-(*trans*)-tetrahydrocannabinol]

(2) [Reserved]

### PART 1312—[AMENDED]

1. The authority citation for part 1312 continues to read as follows:

**Authority:** 21 U.S.C. 952, 953, 954, 957, 958.

2. Section 1312.30 is amended by adding a new paragraph (a) and reserving paragraph (b) to read as follows:

#### § 1312.30 Schedule III, IV and V non-narcotic controlled substances requiring an import and export permit.

\* \* \* \* \*

(a) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin

capsule in a U.S. Food and Drug Administration approved product.

(b) [Reserved]

Dated: June 28, 1999.

**Donnie R. Marshall,**

*Deputy Administrator, Drug Enforcement Administration.*

[FR Doc. 99-16833 Filed 7-1-99; 8:45 am]

BILLING CODE 4410-09-M

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[LA-29-1-7403; FRL-6370-8]

### Approval and Promulgation of Air Quality Implementation Plans; Louisiana: Reasonable-Further-Progress Plan for the 1996-1999 Period, Attainment Demonstration, Contingency Plan, Motor Vehicle Emission Budgets, and 1990 Emission Inventory for the Baton Rouge Ozone Nonattainment Area; Louisiana Point Source Banking Regulations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** In this action, the EPA is finalizing its approval of revisions to the Louisiana State Implementation Plan (SIP) for the Baton Rouge ozone nonattainment area. These revisions were submitted by the State of Louisiana for the purpose of satisfying the Post-1996 Rate-of-Progress (RÖP), Attainment Demonstration, and Contingency Plan requirements of the Federal Clean Air Act (the Act), which will aid in ensuring the attainment of the National Ambient Air Quality Standard (NAAQS) for ozone. The EPA is also approving the associated 1999 Motor Vehicle Emissions Budgets (MVEBs) for the area.

The EPA is also taking final action to approve additional SIP revisions submitted by Louisiana including codifying revisions that were made to the 1990 base year emission inventory and submitted to the EPA as part of the Baton Rouge 15% Rate-of-Progress Plan approved on October 22, 1996. Furthermore, the EPA is approving additional revisions to the 1990 base year emissions inventory submitted as part of the Post-1996 RÖP Plan. The EPA is also approving the State's point source banking regulations. This rulemaking action is being taken under sections 110, 301, and part D of the Act. **EFFECTIVE DATE:** This action is effective on August 2, 1999.



IN THE SUPREME COURT OF IOWA

STATE OF IOWA,

) Filed July 18, 1984

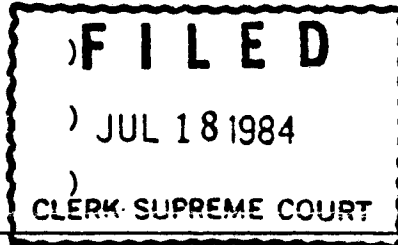
Appellee,

)

vs.

CARL ERIC OLSEN,

Appellant.



171  
69079

Appeal from the Iowa District Court for Muscatine County, R. K. Stohr, Judge.

Defendant appeals from a judgment convicting him of unlawful possession of marijuana with intent to deliver, a violation of Iowa Code section 204.401(1). AFFIRMED.

Carl Eric Olsen, Miami Beach, Florida, pro se.  
James R. Cook of Cook & Waters, Des Moines, on the brief.

Thomas J. Miller, Attorney General, Joseph P. Weeg, Assistant Attorney General, and Stephen J. Petersen, County Attorney, for appellee.

Considered by Reynoldson, C.J., and Uhlenhopp, Larson, Schultz, and Wollé, JJ.

PER CURIAM.

Defendant, Carl Eric Olsen, appeals from a judgment convicting him of unlawful possession of marijuana with intent to deliver, a violation of Iowa Code section 204.401(1). This case was before us in State v. Olsen, 293 N.W.2d 216 (Iowa), cert. denied, 449 U.S. 993, 101 S. Ct. 530, 66 L. Ed. 2d 290 (1980), in which we reversed and remanded when a State's witness was permitted to testify beyond the scope of the minutes of testimony. Following his conviction on a second trial, defendant again appeals and we affirm.

Olsen admits that when stopped by the West Liberty police in May of 1978, he was transporting 129 pounds of marijuana and \$10,915 in cash. His sole defense is that his possession and use of the marijuana are protected by the first amendment's guarantee of religious freedom.

Olsen is a member and priest of the Ethiopian Zion Coptic Church. Testimony at his trial revealed the bona fide nature of this religious organization and the sacramental use of marijuana within it. Testimony also revealed church members use marijuana continuously and publicly, commencing at an early age. Olsen admitted to smoking marijuana while driving and to using the drug a few hours before testifying in his second trial. Nonetheless, he asks us on this appeal to afford his religious use of marijuana unlimited constitutional protection.

I. This court dealt at length with Olsen's first amendment claim in State v. Olsen, 315 N.W.2d 1, 7-9 (Iowa

1982), a case involving this defendant but based on a different automobile stop and arrest. We find no reason to retreat from our holding there that "[a] compelling state interest sufficient to override Olsen's free exercise clause argument is demonstrated in this case." In fact, since our last Olsen decision, we have been joined in our analysis by yet another court, see Whyte v. United States, 471 A.2d 1018 (D.C. 1984).

Olsen now contends we must make an independent finding of a compelling state interest rather than defer to the legislature's decision to regulate marijuana. The cases do not support Olsen's assertion. See Leary v. United States, 383 F.2d 851, 860-61 (5th Cir. 1967), rev'd on other grounds, 395 U.S. 6, 89 S. Ct. 1532, 23 L. Ed. 2d 57 (1969); Whyte, 471 A.2d at 1021; State v. Rocheleau, 142 Vt. 61, 68, 451 A.2d 1144, 1148 (1982).

II. Defendant also raises an equal protection challenge, based on the legislative exemption granted the peyote ceremonies of the Native American Church. See Iowa Code § 204.204(8) (1983). This statutory exemption may be derived from the California Supreme Court's decision in People v. Woody, 61 Cal. 2d 716, 394 P.2d 813, 40 Cal. Rptr. 69 (1964). The Woody court noted in granting the prosecution exemption that peyote was used only in a desert enclosure and only during a special Saturday sundown to Sunday sunrise ceremony. The participants were fed breakfast at the close of the ceremony and were kept isolated from the general population

until the drug's effects had dissipated. Defendant can point to no such safeguards in the Coptic Church's indiscriminate use of marijuana; the drug is smoked publicly and continuously and made available to church members regardless of age or occupation. These significant distinctions render meritless defendant's equal protection argument.

We affirm the judgment of the district court.

AFFIRMED.

Not Reported in F.Supp., 1986 WL 4045 (S.D.Iowa)  
(Cite as: Not Reported in F.Supp.)

**H**

Olsen v. State of Iowa  
S.D.Iowa,1986.

Only the Westlaw citation is currently available.

United States District Court, S.D. Iowa, Central  
Division.

Carl Eric OLSEN and the Ethiopian Zion Coptic  
Church, Plaintiffs,

v.

STATE OF IOWA, Defendant.

Civ. No. 83-301-E

March 19, 1986.

James R. Cook, Des Moines, Iowa, for plaintiffs.  
Joseph P. Weeg, Asst. Atty. Gen., Des Moines,  
Iowa, for defendant.

**ORDER**

DONALD E. O'BRIEN, District Judge.

\*1 This matter is before the Court on defendant's resisted motion for summary judgment. A hearing was held on November 25, 1985. After careful consideration of the parties' briefs and arguments, this Court grants defendant's motion.

Plaintiff is a priest of the Ethiopian Zion Coptic Church. This religion uses marijuana as an integral part of its religious doctrine. *United States v. Rush*, 738 F.2d 497, 512 (1st Cir.1984), *cert. denied*, --- U.S. ---, 105 S.Ct. 1355 (1984). In 1978, plaintiff was convicted of possession of a controlled substance (marijuana) with intent to deliver in violation of Iowa Code Section 204.401(1) (1977). The Iowa Supreme Court reversed plaintiff's conviction on appeal. *State v. Olsen*, 293 N.W.2d 216 (Iowa), *cert. denied*, 449 U.S. 993 (1980). Olsen was retried, convicted, and appealed. The Iowa Supreme Court affirmed, finding that plaintiff's right to equal protection was not violated by the Iowa laws on marijuana usage. No. 171-69079 (July 18, 1984) at 3-4 (unreported opinion attached). On May 9, 1985, plaintiff filed

a Petition for Declaratory Judgment, claiming that the Iowa criminal statutes regarding controlled substances discriminated against his religious beliefs, thereby denying him equal protection of the laws.

The Iowa Supreme Court has already upheld the constitutionality of Iowa Code Section 204.401(1) against plaintiff's equal protection attack. *State v. Olsen*, *supra*, at 3-4. The federal declaratory judgment statute, 28 U.S.C. §§ 2201-2202 does not give this Court the power to review a state court decision. *Travelers Insurance Co. v. Davis*, 490 F.2d 536, 644 (3rd Cir.1974). Plaintiff cites *Peyote Way Church of God, Inc. v. Smith*, 742 F.2d 193 (5th Cir.1984), for the proposition that this Court can enter a declaratory judgment on the constitutionality of the Iowa controlled substance laws. However, the *Peyote Way* decision is distinguishable from the instant case because in the former, there was no prior state court decision involving the constitutionality of the criminal statute in the religious context.

Assuming for purposes of discussion that *Peyote Way* applies, the equal protection issue has already been decided adverse to plaintiff by another federal circuit. In *United States v. Rush*, 738 F.2d 497 (1st Cir.1984), *cert. denied*, --- U.S. ---, 105 S.Ct. 1355 (1984), the Court held that, "the Ethiopian Zion Coptic Church cannot be deemed similarly situated to the Native American Church for equal protection purposes." *Id.* at 513. In *Rush*, the Ethiopian Zion Coptic Church claimed it should be afforded a religious exemption from the marijuana laws on the same terms as the peyote exemption granted to the Native American Church. *Id.* The Court reasoned that the Native American Church's exemption was a product of congressional findings and legislative history underlying the American Indian Religions Freedom Act, and that the Ethiopian Zion Coptic Church had not received similar congressional dispensation for marijuana use. *Id.*

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\*2 While this Court is not bound by another circuit's decision, the Eighth Circuit has recently spoken of the need for deference to other circuits: [a]lthough we are not bound by another circuit's decision, we adhere to the policy that a sister circuit's reasoned decision deserves great weight and precedential value. As an appellate court, we strive to maintain uniformity in the law among our circuits, wherever reasoned analysis will allow ... [t]his duty applies to the district courts in this circuit.

*Keasler v. United States*, 766 F.2d 1227, 1233 (8th Cir.1985), (footnote and citations omitted). Thus, even were this Court to consider granting plaintiff a declaratory judgment, such relief is foreclosed by the *Rush* decision.

Plaintiff's equal protection issue is also barred by collateral estoppel, or issue preclusion. "Under collateral estoppel, once a court has decided an issue of law or fact necessary to its judgment, that decision may preclude relitigation of the issue in a suit on a different cause of action involving a party to the first case." *Montana v. United States*, 440 U.S. 147, 153 (1979). The Supreme Court faced a similar problem in *Allen v. McCurry*, 449 U.S. 90 (1980). In that case, plaintiff brought a § 1983 action against the officers who entered his home seizing evidence used against him in his state criminal trial. *Id.* at 91. The Court noted that 28 U.S.C. § 1738 requires federal courts to give preclusive effect to state court judgments whenever the courts of the state where the judgments were issued would do so. *Id.* at 96.

Justice Stewart's majority opinion held that as the state court had already decided the search and seizure issue, and because petitioner did not assert that the state court failed to provide him with a full and fair opportunity to litigate the issue, collateral estoppel barred relitigation in federal court on the same issue in a § 1983 action. *Id.* at 101. Justice Stewart wrote, "the Court's view of § 1983 in *Monroe* lends no strength to any argument that Congress intended to allow relitigation of federal issues decided after a full and fair hearing in a state court simply because the state court's decision may have been erroneous." *Id.*

Thus, the only issue remaining is whether the Iowa Supreme Court's order can be given collateral estoppel effect under the test announced in *In re Piper Aircraft Litigation*, 551 F.2d 213 (8th Cir.1977). Four elements must be satisfied under the collateral estoppel test:

(1) [T]he issue sought to be precluded must be the same as that involved in the prior action; (2) that issue must have been actually litigated; (3) it must have been determined by a valid and final judgment; and (4) the determination must have been essential to the prior judgment.

*Id.* at 218-219.

Applying the above elements to the facts of the instant case, this Court concludes that collateral estoppel effect must be given to the Iowa Supreme Court's judgment. Plaintiff here challenges the statute on equal protection grounds, which is the same issue decided by the Iowa Supreme Court. (see attached unreported opinion at 3-4). The issue was also actually litigated at the state level. The Iowa Supreme Court based its' decision on testimony regarding the Church's indiscriminate use of marijuana, indicating that this issue was fully litigated. *Id.* at 4. The equal protection issue was also determined in a judgment by the Iowa Supreme Court, and plaintiff has failed to produce any reason why the decision should not be considered valid and final. Finally, the determination of the equal protection issue was essential to the prior judgment, for had the Iowa Supreme Court ruled otherwise, plaintiff's conviction would have been reversed.

\*3 The above analysis demonstrates that collateral estoppel applies to bar litigation of the equal protection issue before this Court. These same principles also apply to plaintiff's first amendment issue, as the Iowa Supreme Court decided that aspect of plaintiff's claim in *State v. Olsen*, 315 N.W.2d 1, 7-9 (Iowa 1982). In that case, the court held that "[a] compelling state interest sufficient to override Olsen's free exercise clause argument is demonstrated in this case." *Id.* at 9. Therefore, as the issues plaintiff seeks to litigate before this Court are barred by collateral estoppel, defendant's motion for summary judgment must be granted, and defendant's case dismissed.

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IT IS THEREFORE ORDERED that defendant's motion for summary judgment is hereby granted.

IT IS FURTHER ORDERED that plaintiff's petition for a declaratory judgment is hereby denied, and the case dismissed.

EXHIBIT "A"

IN THE SUPREME COURT OF IOWA

STATE OF IOWA, Appellee,

vs.

CARL ERIC OLSEN, Appellant.

Filed July 18, 1984

171

69079

Appeal from the Iowa District Court for Muscatine County, R.K. Stohr, Judge.

Defendant appeals from a judgment convicting him of unlawful possession of marijuana with intent to deliver, a violation of Iowa Code section 204.401(1). AFFIRMED.

Carl Eric Olsen, Miami Beach, Florida, pro se.  
James R. Cook of Cook & Waters, Des Moines, on the brief.

Thomas J. Miller, Attorney General, Joseph P. Weeg, Assistant Attorney General, and Stephen J. Petersen, County Attorney, for appellee.

Considered by Reynoldson, C.J., and Uhlenhopp, Larson, Schultz, and Wolle, JJ.

PER CURIAM.

Defendant, Carl Eric Olsen, appeals from a judgment convicting him of unlawful possession of marijuana with intent to deliver, a violation of Iowa Code section 204.401(1). This case was before us in *State v. Olsen*, 293 N.W.2d 216 (Iowa), cert. denied, 449 U.S. 993, 101 S.Ct. 530, 66 L.Ed.2d 290 (1980), in which we reversed and remanded when a State's witness was permitted to testify beyond the scope of the minutes of testimony. Following his conviction on a second trial, defendant again appeals and we affirm.

Olsen admits that when stopped by the West Liberty police in May of 1978, he was transporting 129 pounds of marijuana and \$10,915 in cash. His sole defense is that his possession and use of the marijuana are protected by the first amendment's guarantee of religious freedom.

Olsen is a member and priest of the Ethiopian Zion Coptic Church. Testimony at his trial revealed the bona fide nature of this religious organization and the sacramental use of marijuana within it. Testimony also revealed church members use marijuana continuously and publicly, commencing at an early age. Olsen admitted to smoking marijuana while driving and to using the drug a few hours before testifying in his second trial. Nonetheless, he asks us on this appeal to afford his religious use of marijuana unlimited constitutional protection.

I. This court dealt at length with Olsen's first amendment claim in *State v. Olsen*, 315 N.W.2d 1, 7-9 (Iowa 1982), a case involving this defendant but based on a different automobile stop and arrest. We find no reason to retreat from our holding there that "[a] compelling state interest sufficient to override Olsen's free exercise clause argument is demonstrated in this case." In fact, since our last *Olsen* decision, we have been joined in our analysis by yet another court, see *Whyte v. United States*, 471 A.2d 1018 (D.C.1984).

\*4 Olsen now contends we must make an independent finding of a compelling state interest rather than defer to the legislature's decision to regulate marijuana. The cases do not support

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Olsen's assertion. See *Leary v. United States*, 383 F.2d 851, 860-61 (5th Cir.1967), *rev'd on other grounds*, 395 U.S. 6, 89 S.Ct. 1532, 23 L.Ed.2d 57 (1969); *Whyte*, 471 A.2d at 1021; *State v. Rocheleau*, 142 Vt. 61, 68, 451 A.2d 1144, 1148 (1982).

II. Defendant also raises an equal protection challenge, based on the legislative exemption granted the peyote ceremonies of the Native American Church. See Iowa Code § 204.204(8) (1983). This statutory exemption may be derived from the California Supreme Court's decision in *People v. Woody*, 61 Cal.2d 716, 394 P.2d 813, 40 Cal.Rptr. 69 (1964). The *Woody* court noted in granting the prosecution exemption that peyote was used only in a desert enclosure and only during a special Saturday sundown to Sunday sunrise ceremony. The participants were fed breakfast at the close of the ceremony and were kept isolated from the general population until the drug's effects had dissipated. Defendant can point to no such safeguards in the Coptic Church's indiscriminate use of marijuana; the drug is smoked publicly and continuously and made available to church members regardless of age or occupation. These significant distinctions render meritless defendant's equal protection argument.

We affirm the judgment of the district court.

AFFIRMED.

S.D.Iowa, 1986.

Olsen v. State of Iowa

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