Both bills contain authority to evaluate programs under this Act. Such evaluation should include examination of individual training grants and contracts to assure that desired results are being achieved.

Title II of bill (national materials policy)

Title II of the Senate amendment provided for the establishment of a presidentially appointed National Commission on Materials Policy to make recommendations on the supply, use, recovery, and disposal of materials and to report thereon by June 30, 1973. The House bill had no comparable provision. The House receded with an amendment which requires the Commission to determine which Federal agency would have continuing responsibility in the materials policy area.

HARLEY O. STAGGERS,
JOHN JARMAN,
PAUL G. ROGERS,
WILLIAM L. SPRINGER,
ANCHER NELSEN,
Managers on the Part of the House.

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

P.L. 91-513, see page 1437

House Report (Interstate and Foreign Commerce Committee) No. 91-1444, Sept. 10, 1970 [To accompany H.R. 18583]

Senate Report (Judiciary Committee) No. 91-613, Dec. 16, 1969 [To accompany S. 3246]

Conference Report No. 91-1603, October 13, 1970 [To accompany H.R. 18583]

Cong. Record Vol. 116 (1970)

DATES OF CONSIDERATION AND PASSAGE

House September 24, October 14, 1970

Senate October 7, 14, 1970

The House bill was passed in lieu of the Senate bill. The House Report and the Conference Report are set out.

HOUSE REPORT NO. 91-1444

THE Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 18583) to amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse, having considered the same,

ILLEGAL POSSESSION FOR PERSONAL USE

The bill also provides that illegal possession of controlled drugs by an individual for his own use is a misdemeanor, with a sentence of up to 1 year imprisonment and a fine of not more than $5,000 or both. The possession involved here is possession for one's own use; possession with intent to manufacture, distribute, or dispense controlled substances is subject to the penalties prescribed for the act of manufacture, distribution, or dispensing itself. The quantity of a drug found in the possession of a person, of course, bears upon the question of whether or not his possession is for his own use, or is for the purpose of illicit transactions involving others, for which much more severe penalties are provided.

In the case of a first prosecution for the offense of possession, the bill provides that if the defendant is found guilty or pleads guilty, the judge may, in lieu of entering a judgment of guilty place the accused person upon probation. The period of probation may not exceed 1 year and shall be subject to such conditions as the court may prescribe. After the defendant has completed his probation, the court shall discharge the defendant and dismiss the proceedings against him without entering a judgment of guilty. This procedure is only available to a defendant one time, and a nonpublic record is to be retained by the Department of Justice of this discharge or dismissal for the purpose of insuring that this lenient treatment is provided only once to a defendant.

The bill further provides that in the case of a person below the age of 21 years who is found guilty, or pleads guilty, to a charge of simple possession, the court may, after dismissal or discharge and upon application, issue an order expunging from all official records all recordation relating to the arrest, indictment, or information, trial, finding of guilty, and dismissal or discharge (except for the nonpublic record retained by the Department of Justice). This expunging of all records restores the defendant to the status he occupied before his arrest and he may not thereafter be held guilty of perjury or giving a false statement for failure to reveal or acknowledge his arrest, indictment, or trial in response to any inquiry made to him for any purpose.

MARIHUANA

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. During the hearings, Dr. Stanley F. Yolles, who was the Director of the National Institute of Mental Health, submitted a chart of fable and fact concerning marihuana. That chart is as follows:

MARIHUANA

FABLE	FACT
1. Marihuana is a narcotic.	1. Marihuana is not a narcotic except by statute. Narcotics are opium or its derivations (like some synthetic chemicals with opium-like activity).

FABLE	FACT
2. Marihuana is addictive.	2. Marihuana does not cause physical addiction, since tolerance to its effects and symptoms on sudden withdrawals does not occur. It can produce habituation (psychological dependence).
3. Marihuana causes violence and crime.	3. Persons under the influence of marihuana tend to be passive. It is true that sometimes a crime may be committed by a person while under the influence of marihuana. However, any drug which loosens one's self-control is likely to do the same and relates primarily to the personality of the user.
4. Marihuana leads to increase in sexual activity.	4. Marihuana has no aphrodisiac property.
5. Marihuana is harmless.	5. Instances, of acute panic, depression, and psychotic states are known, although they are infrequent. Certain kinds of individuals can also become over-involved in marihuana use and can lose their drive. We do not know the effects of long-term use.
6. Occasional use of marihuana is less harmful than occasional use of alcohol.	6. We do not know. Research on the effects of various amounts of each drug for various periods is underway.
7. Marihuana use leads to heroin.	7. We know of nothing in the nature of marihuana that predisposes to heroin abuse. It is estimated that less than 5% of chronic users of marihuana go on to heroin use.
8. Marihuana enhances creativity.	8. Marihuana might bring *fantasies* of enhanced creativity but they are illusory, as are "instant insights" reported by marihuana users.
9. More severe penalties will solve the marihuana problem.	9. Marihuana use has increased enormously in spite of the most severely punitive laws.
10. It is safe to drive while under the influence of marihuana.	10. Driving under the influence of any intoxicant is hazardous.

In the bill as recommended by the administration and as reported by the committee, marihuana is listed under schedule I, as subject to the

most stringent controls under the bill, except that criminal penalties applicable to marihuana offenses are those for offenses involving non-narcotic controlled substances.

The committee requested recommendations from the Department of Health, Education, and Welfare concerning the appropriate location of marihuana in the schedules of the bill, and by letter of August 14, 1970 (printed in this report under the heading "Agency Reports"), the Assistant Secretary for Health and Scientific Affairs recommended "that marihuana be retained within schedule I at least until the completion of certain studies now underway."

In addition, section 601 of the bill provides for establishment of a Presidential Commission on Marihuana and Drug Abuse. The recommendations of this Commission will be of aid in determining the appropriate disposition of this question in the future.

REHABILITATION

The reported bill would provide increased authority for Federal agencies dealing with problems of drug abuse. Title I would provide increased research, training, education, and rehabilitation authority for the Secretary of Health, Education, and Welfare. That title would also provide increased authority for rehabilitation efforts through community mental health centers and through special projects in areas having more serious drug abuse problems for rehabilitation efforts directed to narcotic addicts and drug dependent persons. A total of $164 million in additional appropriations over a 3-year period is authorized in this title for these increased rehabilitation efforts and activities.

COMMUNITY MENTAL HEALTH CENTERS AMENDMENTS AND SPECIAL PROVISIONS FOR NARCOTIC ADDICTS

In 1963 the Congress enacted the Community Mental Health Centers Act, authorizing Federal matching grants for the construction of community mental health centers, designed to provide for the treatment of the mentally ill in facilities close to their homes, where through intensive care they could be returned to their families and jobs at an earlier date than generally is the case where patients are cared for in State institutions. In 1965 this legislation was amended to authorize Federal grants to pay a portion of the costs of staffing of these facilities.

In 1968, this legislation was further amended to authorize specially earmarked funds for the construction and staffing of facilities affiliated with community mental health centers for the treatment of alcoholics or narcotic addicts.

The reported bill would further expand the authority contained in the 1968 amendments to provide funds for construction or staffing of facilities for the treatment and rehabilitation of drug dependent persons, in addition to narcotic addicts. There are approximately 350 community mental health centers in operation in the United States today, and the purpose of the amendments made by the reported bill is to provide increased activities at these centers to provide for persons within the centers' catchment areas suffering from drug problems.

Public Law 91-513

AN ACT

October 27, 1970
[H. R. 18583]

To amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Comprehensive Drug Abuse Prevention and Control Act of 1970".

Comprehensive Drug Abuse Prevention and Control Act of 1970.

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(b) Moneys expended from appropriations of the Bureau of Narcotics and Dangerous Drugs for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Bureau.

Funds, advancement, authority of Attorney General.

(c) The Attorney General is authorized to direct the advance of funds by the Treasury Department in connection with the enforcement of this title.

PART F—ADVISORY COMMISSION

ESTABLISHMENT OF COMMISSION ON MARIHUANA AND DRUG ABUSE

SEC. 601. (a) There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the "Commission"). The Commission shall be composed of—

Membership.

(1) two Members of the Senate appointed by the President of the Senate;

(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

Quorum.

(b) (1) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

Travel expenses, etc.

(2) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission.

Compensation.

Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties.

Meetings.

(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

Personnel.

(c) (1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

80 Stat. 443, 467.
5 USC 5101, 5331.

Ante, p. 198-1.
Experts and consultants.
80 Stat. 416.

(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including traveltime. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

Travel expenses, etc.

80 Stat. 499; 83 Stat. 190.

Information, availability.

(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to

carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

Marihuana, study.

(d)(1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas:

(A) the extent of use of marihuana in the United States to include its various sources, the number of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

(B) an evaluation of the efficacy of existing marihuana laws;

(C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;

(D) the relationship of marihuana use to aggressive behavior and crime;

(E) the relationship between marihuana and the use of other drugs; and

(F) the international control of marihuana.

Report to President and Congress.

(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations.

Drug abuse, study and investigation.

(e) The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

Interim reports, final report to President and Congress.

Termination.

Expenditures, limitation.

(f) Total expenditures of the Commission shall not exceed $1,000,000.

PART G—CONFORMING, TRANSITIONAL AND EFFECTIVE DATE, AND GENERAL PROVISIONS

REPEALS AND CONFORMING AMENDMENTS

Repeals.

SEC. 701. (a) Sections 201(v), 301(q), and 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(v), 331(q), 360(a) are repealed.

79 Stat. 227, 232, 228; 82 Stat. 1361.

Penalties.

(b) Subsections (a) and (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) are amended to read as follows:

82 Stat. 1361.

"SEC. 303. (a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

79 Stat. 232.

(c) Section 304(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is amended (1) by striking out clauses (A) and (D), (2) by striking out "of such depressant or stimulant

National Commission on Marihuana and Drug Abuse
801 19th Street N.W.
Washington, D.C. 20006

March 22, 1972

To The President and Congress of the United States:

As Chairman of the National Commission on Marihuana and Drug Abuse, I am pleased to submit to you our first year Report in conformance with the mandate contained in Section 601 of Public Law 91-513, The Comprehensive Drug Abuse Prevention and Control Act of 1970.

This Report "Marihuana, A Signal of Misunderstanding" is an all-inclusive effort to present the facts as they are known today, to demythologize the controversy surrounding marihuana, and to place in proper perspective one of the most emotional and explosive issues of our time. We on the Commission sincerely hope it will play a significant role in bringing uniformity and rationality to our marihuana laws, both Federal and State, and that it will create a healthy climate for further discussion, for further research and for a continuing advance in the development of a public social policy beneficial to all our citizens.

Whatever the facts are we have reported them. Wherever the facts have logically led us, we have followed and used them in reaching our recommendations. We hope this Report will be a foundation upon which credibility in this area can be restored and upon which a rational policy can be predicated.

By Direction of the Commission

Raymond P. Shafer

Raymond P. Shafer
Chairman

The President
The President of the Senate
The Speaker of the House

of existing regulatory schemes, together with an uncertainty about the permanence of social interest in marihuana and the approval inevitably implied by adoption of such a scheme, all impel us to reject the regulatory approach as an appropriate implementation of a discouragement policy at the present time.

Future policy planners might well come to a different conclusion if further study of existing schemes suggests a feasible model; if responsible use of the drug does indeed take root in our society; if continuing scientific and medical research uncovers no long-term ill-effects; if potency control appears feasible; and if the passage of time and the adoption of a rational social policy sufficiently desymbolizes marihuana so that availability is not equated in the public mind with approval.

PARTIAL PROHIBITION

The total prohibition scheme was rejected primarily because no sufficiently compelling social reason, predicated on existing knowledge, justifies intrusion by the criminal justice system into the private lives of individuals who use marihuana. The Commission is of the unanimous opinion that marihuana use is not such a grave problem that individuals who smoke marihuana, and possess it for that purpose, should be subject to criminal procedures. On the other hand, we have also rejected the regulatory or legalization scheme because it would institutionalize availability of a drug which has uncertain long-term effects and which may be of transient social interest.

Instead we recommend a partial prohibition scheme which we feel has the following benefits:

- Symbolizing a continuing societal discouragement of use;
- Facilitating the deemphasis of marihuana essential to answering dispassionately so many of the unanswered questions;
- Permitting a simultaneous medical, educational, religious, and parental effort to concentrate on reducing irresponsible use and remedying its consequences;
- Removing the criminal stigma and the threat of incarceration from a widespread behavior (possession for personal use) which does not warrant such treatment;
- Relieving the law enforcement community of the responsibility for enforcing a law of questionable utility, and one which they cannot fully enforce, thereby allowing concentration on drug trafficking and crimes against persons and property;
- Relieving the judicial calendar of a large volume of marihuana possession cases which delay the processing of more serious cases; and
- Maximizing the flexibility of future public responses as new information comes to light.

No major change is required in existing law to achieve all of these benefits. In general, we recommend only a decriminalization of possession of marihuana for personal use on both the state and federal levels. The major features of the recommended scheme are that: production and distribution of the drug would remain criminal activities as would possession with intent to distribute commercially; marihuana would be contraband subject to confiscation in public places; and criminal sanctions would be withdrawn from private use and possession incident to such use, but, at the state level, fines would be imposed for use in public.*

Specifically, we recommend the following statutory schemes.

RECOMMENDATIONS FOR FEDERAL LAW

Under the Comprehensive Drug Abuse Prevention and Control Act of 1970, Congress provided the following scheme with respect to marihuana, by which was meant only the natural plant and its various parts, not the synthetic tetrahydrocannabinol (THC):

- Cultivation, importation and exportation, and sale or distribution for profit of marihuana are all felonies punishable by imprisonment for up to five years for a first offense and by up to 10 years for a second offense (the available penalty is doubled for sale to a minor).
- Possession of marihuana with intent to distribute is a felony punishable by imprisonment for up to five years for the first offense and by up to 10 years for a second offense.
- Possession of marihuana for personal use is a misdemeanor punishable by up to one year in jail and a $1,000 fine for first offense and by up to two years in jail and a $2,000 fine for second offense (expungement of criminal record is available for first offenders).

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*Commissioners Rogers, Congressman from Florida, and Carter, Congressman from Kentucky, agree with the Commission's selection of a discouragement policy and also agree that criminalization and incarceration of individuals for possessing marihuana for their own use is neither necessary nor desirable as a means of implementing that policy.

At the same time, both Commissioners feel that the contraband concept is not a sufficiently strong expression of social disapprobation and would recommend in addition a civil fine for possession of any amount of marihuana in private or in public.

Both Commissioners feel that the civil fine clearly symbolizes societal disapproval and is a simple mechanism for law enforcement authorities to carry out. If a person is found by a law enforcement officer to be in possession of marihuana, the officer would issue such person a summons to appear in court on a fixed day. Although a warrant would not issue for search of a private residence unless there were probable cause to believe a *criminal* offense was being committed, a police officer legitimately present for other reasons could issue a civil summons for violation of the "possession" proscription.

456-964 O - 72 - 11

- Transfer of a small amount of marihuana for no remuneration is a misdemeanor punishable by up to one year in jail and a $1,000 fine for first offense and by up to two years in jail and a $2,000 fine for second offense (Congress singled out marihuana in this way to allow misdemeanor treatment of casual transfers and permitted first offender treatment, as allowed for possession for personal use).

The Commission recommends *only* the following changes in federal law:

- POSSESSION OF MARIHUANA FOR PERSONAL USE WOULD NO LONGER BE AN OFFENSE, BUT MARIHUANA POSSESSED IN PUBLIC WOULD REMAIN CONTRABAND SUBJECT TO SUMMARY SEIZURE AND FORFEITURE.
- CASUAL DISTRIBUTION OF SMALL AMOUNTS OF MARIHUANA FOR NO REMUNERATION, OR INSIGNIFICANT REMUNERATION NOT INVOLVING PROFIT WOULD NO LONGER BE AN OFFENSE.

The Commission further recommends that federal law be supplemented to provide:

- A PLEA OF MARIHUANA INTOXICATION SHALL NOT BE A DEFENSE TO ANY CRIMINAL ACT COMMITTED UNDER ITS INFLUENCE, NOR SHALL PROOF OF SUCH INTOXICATION CONSTITUTE A NEGATION OF SPECIFIC INTENT.

Commissioners Rogers and Carter believe that the legal system must be utilized directly to discourage *the person* from using marihuana rather than being utilized only indirectly as in the case of contraband.

This civil fine would not be reflected in a police record, nor would it be considered a criminal act for purposes of future job consideration, either in the private sector or for government service.

Agreeing with the other Commissioners that the casual transfers of marihuana for no profit should be treated in the same manner as possession for one's own use, Congressmen Rogers and Carter do not agree that it should extend to transfers involving remuneration. They prefer the limiting language of the Comprehensive Drug Abuse Prevention and Control Act of 1970 which does not include the term "or insignificant remuneration not involving a profit."

Apart from the addition of the civil fine to the contraband recommendation in the respects set out above, Congressmen Carter and Rogers are in complete agreement with the statutory recommendations set out in the Report.

Commissioner Ware concurs completely with the statements made by Congressmen Rogers and Carter but wishes to reemphasize that the social policy and legal scheme adopted is applicable only to marihuana and should not be construed to embrace other psychoactive drugs. The policy set forth in this Report, subject to the already noted comments of the two Congressional Commissioners, makes sense for marihuana on the basis of what is known about the drug and in the absence of any conclusive showing which would verify

RECOMMENDATIONS FOR STATE LAW

Under existing state marihuana laws, cultivation, distribution and possession with intent to distribute are generally felonies and in most states possession for personal use is a misdemeanor. The Commission strongly recommends uniformity of state laws and, in this regard, endorses the basic premise of the Uniform Controlled Substances Act, drafted by the National Conference of Commissioners on Uniform State Laws. The following are our recommendations for a uniform statutory scheme for marihuana, by which we mean, as under existing federal law, only the natural cannabis plant and its various parts, not the synthetic tetrahydrocannabinol (THC):

Existing Law

- CULTIVATION, SALE OR DISTRIBUTION FOR PROFIT AND POSSESSION WITH INTENT TO SELL WOULD REMAIN FELONIES (ALTHOUGH WE DO RECOMMEND UNIFORM PENALTIES).

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some of the anecdotal law enforcement testimony heard by the Commission regarding criminal behavior exhibited while under the influence of marihuana.

Commissioner Ware feels that some penalty short of criminalizing the user, such as a civil fine or some type of intensive drug education, will act as a positive deterrent toward minimizing the incidence of marihuana use especially among the young. Further, he is opposed to the use of *any* drug for the express purpose of getting intoxicated, and includes alcohol within this category. The Commissioner feels that what is needed is an internalizing of discipline among our citizenry, with the legal system assisting this process through the use of disincentives.

Commissioners Hughes, Senator from Iowa, and Javits, Senator from New York, feel that the Commission has taken a major, highly laudable step in recommending that the private use of marihuana be taken out of the criminal justice system. They concur in its threshold judgment that overall social policy regarding this drug should seek to discourage use, while concentrating primarily on the prevention of irresponsible use. They disagree, however, with three specific recommendations relating to the implementation of this discouragement policy.

First, they would eliminate entirely the contraband provision from the partial prohibitory model adopted by the Commission. They want it eliminated first because its legal implications are confusing and the subject of disagreement even among lawyers. Whether or not possession of a given substance is criminal, possession of material designated as contraband makes that possession *unlawful.* Also, marihuana designated as contraband would be subject to government search and seizure, even though the underlying possession is no longer criminal. The provision—which does not apply to marihuana held for personal use within the home—is considered by both Commissioners to be an unnecessary "symbol" of the discouragement policy. It will not foster elimination of the misunderstanding and mistrust which is a hallmark of our current marihuana policy.

Commissioner Hughes and Javits seek to eliminate it also because as a practical matter it serves no useful law enforcement purpose within the overall partial prohibitory model. If marihuana held for personal use within the home is not contraband, why should marihauna held for personal use within one's

Private Activities

- POSSESSION IN PRIVATE OF MARIHUANA FOR PERSONAL USE WOULD NO LONGER BE AN OFFENSE.
- DISTRIBUTION IN PRIVATE OF SMALL AMOUNTS OF MARIHUANA FOR NO REMUNERATION OR INSIGNIFICANT REMUNERATION NOT INVOLVING A PROFIT WOULD NO LONGER BE AN OFFENSE.

Public Activities

- POSSESSION IN PUBLIC OF ONE OUNCE OR UNDER OF MARIHUANA WOULD NOT BE AN OFFENSE, BUT THE MARIHUANA WOULD BE CONTRABAND SUBJECT TO SUMMARY SEIZURE AND FORFEITURE.
- POSSESSION IN PUBLIC OF MORE THAN ONE OUNCE OF MARIHUANA WOULD BE A CRIMINAL OFFENSE PUNISHABLE BY A FINE OF $100.
- DISTRIBUTION IN PUBLIC OF SMALL AMOUNTS OF MARIHUANA FOR NO REMUNERATION OR INSIGNIFICANT REMUNERATION NOT INVOLVING A PROFIT WOULD BE A CRIMINAL OFFENSE PUNISHABLE BY A FINE OF $100.
- PUBLIC USE OF MARIHUANA WOULD BE A CRIMINAL OFFENSE PUNISHABLE BY A FINE OF $100.
- DISORDERLY CONDUCT ASSOCIATED WITH PUBLIC USE OF OR INTOXICATION BY MARIHUANA WOULD BE A MISDEMEANOR PUNISHABLE BY UP TO 60 DAYS IN JAIL, A FINE OF $100, OR BOTH.

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automobile be contraband? The area of operation of the contraband provision is extremely narrow. If one possesses *more* than one ounce of marihuana in public, it may be seized without regard to the contraband doctrine since such possession is a criminal violation.

Since the contraband provision does not apply to marihuana possession and use in private, the only effective area covered by the contraband provision is the area of possession in public of *less* than one ounce. The Commission has chosen to remove the stigma of the criminal sanction in this kind of case. To impose instead a contraband provision, which it is argued is in the nature of a civil "in rem" seizure which does not operate against the person, is to cloud the issue and to weaken the force of the basic decriminalization. A persuasive justification simply has not been made.

Both Commissioners seek to eliminate it also because they believe that the voice of the Commission should be loud and clear that the preservation of the right of privacy is of paramount importance and cannot be casually jeopardized in the pursuit of some vague public or law enforcement interest which has not been defined and justified with clarity and precision.

The second area of disagreement with the Commission's recommendations concerns the casual distribution of marihuana and the not-for-profit sale. As understood:

- OPERATING A VEHICLE OR DANGEROUS INSTRUMENT WHILE UNDER THE INFLUENCE OF MARIHUANA WOULD BE A MISDEMEANOR PUNISHABLE BY UP TO ONE YEAR IN JAIL, A FINE OF UP TO $1,000, OR BOTH, AND SUSPENSION OF A PERMIT TO OPERATE SUCH A VEHICLE OR INSTRUMENT FOR UP TO 180 DAYS.
- A PLEA OF MARIHUANA INTOXICATION SHALL NOT BE A DEFENSE TO ANY CRIMINAL ACT COMMITTED UNDER ITS INFLUENCE NOR SHALL PROOF OF SUCH INTOXICATION CONSTITUTE A NEGATION OF SPECIFIC INTENT.
- A PERSON WOULD BE ABSOLUTELY LIABLE IN CIVIL COURT FOR ANY DAMAGE TO PERSON OR PROPERTY WHICH HE CAUSED WHILE UNDER THE INFLUENCE OF THE DRUG.

DISCUSSION OF FEDERAL RECOMMENDATIONS

The recommended federal approach is really a restatement of existing federal policy. From official testimony and record evaluation, we know that the federal law enforcement authorities, principally the Federal Bureau of Narcotics and Dangerous Drugs and the Bureau of Customs, do not concentrate their efforts on personal possession cases. The avowed purpose of both Bureaus is to eliminate major traffickers and sources of supply. For the most part, the federal

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(1) The totally donative transfer is not subject to criminal penalty, regardless of where it takes place.

(2) The transfer of *small* amounts for *insignificant* remuneration *not involving a profit* is not subject to criminal penalty (except if it is accomplished in public, in which case it is subject to criminal sanction), but

(3) The transfer of "*large* amounts" for "*significant*" remuneration not involving a profit is subject to criminal penalty.

Footnote 4 on page 158 of the Report, the Commission refers to a Report of The Senate Judiciary Committee on the Comprehensive Drug Abuse Prevention and Control Act of 1970. In substance, it implies that within the meaning of the Act, transfers of more than one or two marihuana cigarettes in return for 50 cents or one dollar to cover cost are not intended to be covered as casual transfers, but rather are to be treated as unlawful sales.

Commissioners Hughes and Javits feel that the Commission has failed to set forth a clear standard which will adequately inform the public of their obligations under the law. The recommendation and its discussion in the Report are confusing and fail to provide the individual with sufficient guidance to allow him to act without having to dodge in and out of illegality. It also undermines a basic, stated objective of the Commission i.e., to concentrate the weight of the criminal sanction upon significant supply and distribution activities, rather than upon casual consumption.

Moreover, proscribing even the most casual not-for-profit transfers when they occur in public is, in their opinion, wrong. Such transfers are necessarily inci-

National Commission on Marihuana and Drug Abuse
801 19th Street N.W.
Washington, D.C. 20006

March 22, 1973

To The President and Congress of the United States:

As Chairman of the National Commission on Marihuana and Drug Abuse, I am pleased to submit to you our second and final Report in conformance with the mandate contained in Section 601 of the Public Law 91-513, The Comprehensive Drug Abuse Prevention and Control Act of 1970.

Our final Report, "Drug Use in America: Problem in Perspective," is an effort to examine the roots of the drug problem in the United States, to analyze the assumptions upon which present policy is based, and to recommend policy directions for both the public and private sectors. We on the Commission believe that policy should be focused on the behavioral concomitants of drug use rather than on the drugs themselves. By so doing, policy makers can refine national objectives and devise more effective strategies for reducing the social costs of drug misuse.

This Report describes the phenomena of drug use, drug-induced behavior and drug dependence and establishes a process for assessing their social impact. We have also submitted concrete recommendations for the present and have speculated about the policies which may prove useful in the future. We sincerely hope that our Report will enhance the efforts of the American people to understand and respond effectively to this most troublesome social concern.

By Direction of the Commission

Raymond P. Shafer

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Chairman

The President
The President of the Senate
The Speaker of the House

INDEX OF FIRST YEAR RECOMMENDATIONS

Marihuana: A Signal of Misunderstanding

(First Report of the National Commission on Marihuana and Drug Abuse [1])

PRINCIPAL RECOMMENDATIONS

Federal

1. Possession of marihuana for personal use would no longer be an offense, but marihuana possessed in public would remain contraband subject to summary seizure and forfeiture.

2. Casual distribution of small amounts of marihuana for no re-

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[1] The 13 Commissioners are in basic agreement with the Report and its recommendations. However, several Commissioners differ with specific recommendations and their opinions are presented in a footnote on pages 151–156 of the First Report. A brief summary of this footnote follows:

Commissioners Rogers and Carter agree with the discouragement policy and the decriminalization aspects of the recommendations, but feel that the contraband concept is not a sufficiently strong expression of societal disapproval of the use of marihuana. They would recommend, in addition, a civil fine for possession of any amount of marihuana in private or in public. This civil fine would not be reflected in a police record.

Commissioner Ware agrees completely with the statements of Congressmen Rogers and Carter but wishes to reemphasize that the social policy and legal scheme adopted is applicable only to marihuana and should not be construed to embrace other psychoactive drugs. He advocates some penalty short of criminalizing the users, such as a civil fine or some type of extensive drug education. Further, he is opposed to the use of *any* drug, including alcohol, for the express purpose of becoming intoxicated.

Commissioners Hughes and Javits, while agreeing with the Commission's recommendation that the private use of marihuana be taken out of the criminal justice system, disagree with three specific recommendations relating to the implementation of the discouragement policy.

First, they would eliminate the contraband provision from the partial prohibition scheme adopted by the Commission. Second, believing the Commission has not set forth a clear standard as to what constitutes the casual not-for-profit sale, they recommend that all not-for-profit sales be excluded from criminal sanction. Third, they feel there is no need to retain criminal sanction on public possession of more than one ounce of marihuana and would permit public possession of "some reasonable amount" for personal use.

muneration, or insignificant remuneration not involving profit, would no longer be an offense.

3. A plea of marihuana intoxication shall not be a defense to any criminal act committed under its influence, nor shall proof of such intoxication constitute a negation of specific intent.

State

1. Cultivation, sale or distribution for profit and possession with intent to sell would remain felonies (although we do recommend uniform penalties).

2. Possession in private of marihuana for personal use would no longer be an offense.

3. Distribution in private of small amounts of marihuana for no remuneration, or insignificant remuneration not involving a profit, would no longer be an offense.

4. Possession in public of one ounce or under of marihuana would not be an offense, but the marihuana would be contraband subject to summary seizure and forfeiture.

5. Possession in public of more than one ounce of marihuana would be a criminal offense punishable by a fine of $100.

6. Distribution in public of small amounts of marihuana for no remuneration or insignificant remuneration not involving a profit would be a criminal offense punishable by a fine of $100.

7. Public use of marihuana would be a criminal offense punishable by a fine of $100.

8. Disorderly conduct associated with public use of or intoxication by marihuana would be a misdemeanor punishable by up to 60 days in jail, a fine of $100, or both.

9. Operating a vehicle or dangerous instrument while under the influence of marihuana would be a misdemeanor punishable by up to one year in jail, a fine of up to $1,000, or both, and suspension of a permit to operate such a vehicle or instrument for up to 180 days.

10. A plea of marihuana intoxication shall not be a defense to any criminal act committed under its influence nor shall proof of such intoxication constitute a negation of specific intent.

11. A person would be absolutely liable in civil court for any damage to person or property which he caused while under the influence of the drug.

ANCILLARY RECOMMENDATIONS

In addition to these legal recommendations for federal and state action, the Commission believes certain other ancillary recommendations should be presented for action.

Legal and Law Enforcement Recommendations

Federal

1. Federal law enforcement agencies, especially the Bureau of Narcotics and Dangerous Drugs and the Bureau of Customs, should improve their statistical reporting systems so that policies may be planned and resources allocated on the basis of accurate and comprehensive information.

2. The Federal Bureau of Narcotics and Dangerous Drugs should increase its training programs of state and local police with special emphasis on the training in the detection of trafficking cases.

3. Increased border surveillance, a tightening of border procedures, and a realistic eradication program to diminish the supply of drugs coming into the country, coupled with a more effective program for diminishing the domestic production and distribution of marihuana, are required.

State

1. All states should adopt the Uniform Controlled Substances Act to achieve uniformity with regard to marihuana and other drug laws, with the exception that the legal response to possession for one's own use be uniformly adopted in accordance with our recommendation in Chapter V of this report.

2. Each state should establish a centralized compulsory reporting and record-keeping authority so that adequate and accurate statistics of arrests, sentences and convictions on a statewide basis are available.

3. Those states requiring physicians to report drug users seeking medical assistance should change such requirements to insure the confidentiality of the drug user's identity, so that persons needing medical help will feel free to seek it.

International

If the United States should become a signatory of the proposed Psychotropic Convention, we recommend that cannabis be removed from the existing Single Convention and consideration be given to listing it in the proposed Psychotropic Convention among drugs which have similar effects.

Medical Recommendations

1. Fuller coordination of the marihuana research conducted by governmental and private agencies is needed to reduce the duplication of effort, assure a diversity of new approaches and new objectives, and

to provide efficient integration of findings into the available body of knowledge.

2. Research efforts to develop an inexpensive, easy method for detecting and quantifying the presence of marihuana in the blood, breath or urine of a person suspected of being intoxicated should be accelerated.

3. An accelerated program for funding foreign research should be undertaken immediately.

4. Increased support of studies which evaluate the efficacy of marihuana in the treatment of physical impairments and disease is recommended.

5. Community-based treatment facilities should be promoted in caring for problem drug users utilizing existing health centers when possible and appropriate.

6. Public health courses on the social aspects of drug use should be included in the curricula of the schools of the health professions.

Other Recommendations

1. The Commission recognizes that several state legislatures have improperly classffied marihuana as a narcotic, and recommends that they now redefine marihuana according to the standards of the recently adopted Uniform Controlled Substances Act.

2. A single federal agency source should disseminate information and materials relating to marihuana and other drugs. The National Clearinghouse for Drug Abuse Information should be charged with this responsibility.

3. The Special Action Office for Drug Abuse Prevention in the White House should be responsible for the coordination, development and content review of all federally-supported drug educational materials and should issue a report as soon as possible, evaluating existing drug education materials.

4. The Commission notes the significant role played by the voluntary sector of the American community in influencing the social, religious and moral attitudes of our nation's citizens and recommends that the voluntary sector be encouraged to take an active role in support of our recommended policy of discouraging the use of marihuana.

drug use in america: problem in perspective

Second Report of the National Commission on Marihuana and Drug Abuse

March 1973

Public Law 91-513
91st Congress, H. R. 18583
October 27, 1970

An Act

To amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Comprehensive Drug Abuse Prevention and Control Act of 1970".

PART F—ADVISORY COMMISSION

ESTABLISHMENT OF COMMISSION ON MARIHUANA AND DRUG ABUSE

SEC. 601. (a) There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the "Commission"). The Commission shall be composed of—

(1) two Members of the Senate appointed by the President of the Senate;

(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

(b)(1) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

(2) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties.

(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

(c)(1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including traveltime. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

(d)(1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas:

(A) the extent of use of marihuana in the United States to include its various sources, the number of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

(B) an evaluation of the efficacy of existing marihuana laws;

(C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;

(D) the relationship of marihuana use to aggressive behavior and crime;

(E) the relationship between marihuana and the use of other drugs; and

(F) the international control of marihuana.

(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations.

(e) The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

(f) Total expenditures of the Commission shall not exceed $1,000,000.

National Commission on Marihuana and Drug Abuse
801 19th Street N.W.
Washington, D.C. 20006

March 22, 1973

To The President and Congress of the United States:

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welfare system. The obvious negative aspects of heroin dependence for the community are offset to some extent by unexpected benefits. The need to steal creates a second illicit market, in which persons in the lower socio-economic strata of our society can purchase stolen goods, such as televisions, radios, food, clothing, automobile tires, at reduced prices. The compulsive drive of a large heroin-dependent population assures a constant supply of goods.

While a stolen goods market existed before widespread heroin use, and certainly would continue after use subsides, the extent of the current heroin problem has increased both the size of the market and the certainty of its supply. While the underground system is deplorable, society must recognize that it exists and seek to replace it with something better. Disregard of a phenomenon upon which, rightly or wrongly, a segment of our society relies could create problems in other social areas which seem logically unrelated to heroin dependence.

The Commission does believe that increased and improved enforcement of availability restrictions is a necessary part of dealing with the drug use problem. In the following pages, we have set forth a number of specific recommendations to enhance present efforts. The Commission urges policy makers and public agencies, however, not to overstate the possible outcome. The public must appreciate what enforcement can do and what it cannot; no program or policy should be advertised as a panacea.

The Role of International Agreements

The present system of international drug treaties and conventions is not self-enforcing; how well international controls work depends solely on how well each member nation enforces them in its own territory. With agricultural products, such as the opium poppy, the coca bush and the cannabis plant, the difficulties of keeping drug products out of illicit channels are great, regardless of whether or not a government registers and supervises its domestic growers pursuant to international law. In countries whose economies are primitive and whose central governments often have little actual power in the hinterlands, control of supply becomes impossible.

In our visits to 36 countries, the Commission observed that in some nations, the production of opium, coca leaves and cannabis, though illegal, is an integral part of the domestic economy. Moreover, for parts of these populations, smuggling is a way of life, and the official bribe is simply a cost of doing business. Where such conditions exist, multi-national or bi-national efforts to eradicate illicit cultivation, transshipment and exportation will have limited utility.

As one of our consultants noted in discussing opium controls, "It is obvious that problems of this kind cannot be solved by treaty pro-

visions nor by national laws controlling or prohibiting opium production" (Lande, 1973). He felt the same way with respect to coca leaves:

> The cultivation of the coca bush and the production of coca leaves are nowhere effectively controlled. Clandestine manufacturers of cocaine have no difficulty whatsoever in obtaining the coca leaves which they need (Lande, 1973).

With marihuana, there is no hope whatsoever of extinguishing cultivation. The plant grows wild almost everywhere and is cultivated in many countries for non-medical purposes (for example, India) and industrial uses (for example, in 1970, European countries cultivated 94,000 hectares, yielding 82,800 metric tons of hemp fiber). "It is submitted that it would be unduly optimistic to assume that one could in the foreseeable future suppress the illicit traffic by a universally accepted and applied international regime adequate for this purpose" (Lande, 1973).

In reality, the present system of international controls, principally the Single Convention on Narcotic Drugs, deals most effectively not with the illicit traffic, but with the lawful production and manufacture of these substances. This aspect of international control depends more on economics than on prohibitions and appears to work reasonably well. Yet, many public spokesmen give the impression that treaties such as the Single Convention suppress *illicit* trafficking. Such misrepresentations should cease since they raise false expectations and detract from the actual value of international agreements.

The Commission supports continued multilateral international efforts to control the production and manufacture of drugs, such as opium, cocaine and cannabis; however, we believe that strengthened bilateral agreements with individual source nations will prove more useful in reducing the illicit traffic. **In this regard, the Commission recommends that the State Department, in conjunction with the Department of Justice, immediately undertake a comprehensive review of existing extradition treaties dealing with drug offenses with a view toward expanding the scope of extraditable offenses and facilitating the extradition process.** Drug traffickers must not be able to flee to "safe" countries and avoid prosecution for acts committed here. Recently, the State and Justice Departments have succeeded in bringing several major traffickers to this country for prosecution, but more needs to be done. The Commission feels this is a high priority item, requiring vigorous diplomatic efforts.

The Commission further recommends that the United States encourage law enforcement agencies in all concerned countries to increase both formal and informal exchanges of information concerning drug traffic and traffickers. At the present time, investi-

gative agencies share information only on a case-specific basis. The Office of National Narcotics Intelligence of the Department of Justice should encourage all foreign law enforcement agencies to share information routinely, perhaps on a regional basis.

In terms of day-to-day enforcement policy by the United States in other countries, lines of responsibility should be more clearly defined. Since enforcement efforts may have ramifications in other spheres, including commerce, finance and agriculture, the State Department should coordinate all enforcement activity by BNDD, Customs, AID and other agencies on foreign soil. The ambassador should have final authority over day-to-day tactical decisions which have diplomatic overtones, while Washington should define overall enforcement strategy.

In framing enforcement strategies overseas, federal enforcement officials should recognize that no eradication program will successfully eliminte opium, cocaine or marihuana. At best, the United States may reduce somewhat the supply of drugs entering the international illicit market and, therefore, reduce the supply entering this country. Some law enforcement resources may be profitably spent in improving police and drug enforcement capabilities in indigenous drug-producing countries in order to reduce the amount of drugs entering the international traffic and, therefore, finding their way into our domestic market. The interception of a pound of heroin in Thailand or a pound of cocaine in Peru is simply a more cost-effective way of reducing the illicit supply for our country than by trying to seize that same pound after it has been cut and "retailed" to users in New York City or Chicago.

As another example, Colombia, with a coastline on two oceans, is a natural transit point for illicit drugs originating in South America destined for the United States. Yet, Colombia's Customs Service has only 12 patrol boats, six of which are not operational, five more of which have only one of two motors operational. From a cost-effectiveness standpoint, increasing the Colombian capability to intercept the drugs in Colombian waters might well repay the cost to this country by eliminating the need to find the same drugs after their arrival in New Orleans, Miami or New York.

Additionally, the Commission observed in its travel overseas the intense interest on the part of foreign police agencies for more drug law enforcement training assistance. Presently such training is being conducted by the Federal Bureau of Narcotics and Dangerous Drugs. Since it benefits the overall national drug enforcement effort to offer such technical assistance, the Commission feels that the training being performed by BNDD is useful and should be continued and, if possible, expanded.

A major deficiency in the present system of international regulation is that little attention is given to measures which might be taken, internationally, to reduce demand for psychoactive substances. That the United Nations Commission on Narcotic Drugs is comprised primarily of representatives of law enforcement agencies reflects its supply-only orientation. The Commission feels that problems of drug use prevention and education, treatment and rehabilitation also merit discussion and consideration at the international level. **The Commission recommends that the membership of the Commission on Narcotic Drugs be expanded to permit representatives of the health authorities of member nations equal participation in its deliberations and decisions. In this regard, the Commission further recommends that the United States, in cooperation with the United Nations, convene a worldwide conference to consider the issues surrounding prevention of demand for drugs.**

If international controls do too little in some areas, they do too much in others, intruding upon national sovereignty. The international control system should not dictate how participating nations deal with the use of drugs within their own borders. Too often treaties and conventions have been consciously utilized as a method of foreclosing policy options at home and circumventing the usual and proper legislative processes. In the future, treaties and conventions should not contain provisions which infringe upon national sovereignty in this manner, and such provisions in present agreements should be removed.

In particular, the Commission recommends that the Single Convention and the proposed Psychotropic Convention be redrafted to make clear that each nation is free to determine for itself which domestic uses for controlled substances it will allow, provided only that each nation prevent diversion, prohibit exportation and production for exportation for illegal use in other countries.

The current restriction on availability of controlled drugs to medical and scientific purposes should be replaced by a broader provision which would permit each nation to define what kinds of domestic use are legitimate. Provided every national regulatory scheme prevents diversion and exportation for illicit uses to other nations, international obligations should be considered satisfied.

To maintain the current medical use limitation is to prepetuate a charade, for even now each nation can define its lawful uses as "medical," though others do not concur in its judgment. For example, Great Britain has employed opiate maintenance as a form of medical treatment for many years while the United States consistently rejected it on several grounds, including its putative inconsistency with the Single Convention. Now, this country has adopted a methadone maintenance system, which it has also defined as a "medical use."

Further, the Single Convention recognizes the validity of non-medical use of drugs by exceptions which permit use of certain substances for recreational purposes. For example, *bangh*, a cannabis beverage, is lawful in India, as is *mate de coca*, or coca leaf tea, in Bolivia and Peru; as long as these products are not diverted or exported into other countries, where similar use is illicit, the international community accepts such uses.

It is particularly important that international controls not interfere with legitimate scientific and medical research. Certain drugs, for example, have become difficult to obtain for research purposes; recently representatives of several countries complained they were unable to secure enough legitimate opium to satisfy their scientific needs. The Commission urges that the international system of controls *promote* needed research and establish an environment in which the responsible researcher can function unimpaired by needless restrictions.

Measured by these principles, the Psychotropic Convention, adopted in Geneva in March 1972, has a number of important defects and should not be ratified in its present form. First, the new Convention goes beyond the Single Convention in placing undue restrictions on legitimate research. Second, it would demean the role of the World Health Organization by providing that the International Commission on Narcotic Drugs could completely ignore the advice of the World Health Organization in scheduling decisions; this is again contrary to the structure of the Single Convention which allows the Commission on Narcotic Drugs to accept or reject the World Health Organization's recommendations but not to adopt courses of action contrary to them. Third, and most important, the Convention would interfere improperly with United States domestic law, imposing record-keeping requirements contrary to those in the Comprehensive Drug Abuse Prevention and Control Act of 1970 and possibly placing drugs under domestic control without the approval of the Secretary of Health, Education, and Welfare.

The Commission strongly recommends that the United States not ratify the Psychotropic Convention in its present form. If, however, for diplomatic or other reasons, the United States government does adopt the Convention, the Commission urges that the instrument of ratification include the following declarations:

- **That it is the understanding of the United States that scheduling decisions adopted by the Commission on Narcotic Drugs and ratified by the membership are not effective within the United States until and unless the procedures established by Section 201 of the Comprehensive Drug Abuse Prevention**

and Control Act (PL 91–513) are complied with and the Secretary of Health, Education, and Welfare and the Attorney General of the United States agree that the substance is subject to control.

- **That it is the understanding of the United States that the provisions of the Convention do not affect the manner in which the United States restricts availability of substances included in the Convention to medical and scientific purposes.**
- **That it is the understanding of the United States that the definition of punishable offenses in Article XXII, paragraph 1, sub-paragraph (a) does not include possession of substances in Schedule I for personal consumption.**
- **That it is the understanding of the United States that in Article VII, paragraph (a), the word "establishments" contained in the phrase "in medical and scientific establishments which are directly under the control of their government or specifically approved by them," includes the offices of physicians licensed to practice under the law of the United States.**

The Commission also feels that the Department of Health, Education and Welfare has so far played too insignificant a role in the international drug control system. Too often, the Department's only contribution has been to comment on actions proposed by agencies directly participating, the Bureau of Narcotics and Dangerous Drugs and recently, the Department of State. We encourage the Department of Health, Education, and Welfare to develop the necessary legal expertise in the area to exercise a meaningful and coordinate role with the other departments involved.

Finally, the Commission recommends that the United States take the necessary steps to remove cannabis from the Single Convention on Narcotic Drugs (1961), since this drug does not pose the same social and public health problems associated with the opiates and coca leaf products. Moreover, if the Psychotropic Convention is adopted, retention of the natural plant products of cannabis in the Single Convention, while its synthesized and concentrated active ingredient, tetrahydrocannabinol, is controlled under another system, would be an anomaly. **Accordingly, the Commission further recommends that the proposed Psychotropic Convention be revised to include all cannabis substances, but not under Schedule I, since cannabis products are used for medicinal or self-medicating purposes in many parts of the world.**

appendix

drug use in america: problem in perspective

The Technical Papers
of the Second Report of
the National Commission
on Marihuana and
Drug Abuse

March 1973

VOLUME III: The Legal System and Drug Control

THE INTERNATIONAL DRUG CONTROL SYSTEM

by

Adolph Lande*

CONTENTS

THE NATIONAL INTEREST IN INTERNATIONAL CONTROL OF DANGEROUS DRUGS

It was largely due to the initiative of President Theodore Roosevelt that the International Opium Commission met in Shanghai in 1909 and thus set in motion international efforts which led to the gradual establishment of the present international narcotics regime. Since then the United States of America has undoubtedly been the most important protagonist of international action for the control of "narcotic" drugs [1] and has generally favoured the strictest control measures,[2] including often some provisions which proved to be unacceptable to many other States. For the purpose of determining whether this attitude was justified in the past and what policies our country should adopt in the future in regard to problems of international drug control it may first be appropriate to establish the interest which the United States has in the international drug treaty system, this is to say what advantages it has obtained from this system and what additional benefits it could expect from a more effective functioning of the international drug regime in the future.

Probably the most important factor which induced governments to establish a system of international

* Attorney, New York, New York

[1] The term "narcotic drugs" is used for referring to those drugs which are subject to the Single Convention on Narcotic Drugs, 1961, while the term "psychotropic substances" is applied to the drugs which would be controlled by the Vienna Convention of 1971 on Psychotropic Substances. If the words "narcotic" and "psychotropic" are used in their normal meaning and not in that employed by these two treaties all drugs falling under the 1961 Convention are psychotropic substances and not all of them are narcotic (e.g. Cocaine). Moreover, many of the substances which would be subject to the 1971 Convention are in this sense narcotic drugs.

[2] The only notable exception was the proposed International Opium Monopoly which would have applied only to

Footnote continued on next page.

necessary in accordance with a national policy adopted by the two departments.[644]

Despite important differences the procedures of the two conventions for effecting changes in their respective Schedules also show considerable similarities. In both cases the procedure can be initiated only by a notification either of the Party to the Convention concerned or by the World Health Organization to the Secretary General. A party or the World Health Organization is required to make such a notification if it has information which in its opinion may require an amendment to any of the Schedules of the treaty in question.

The Commission on Narcotic Drugs may require parties to subject a substance, not yet controlled by the Convention, to provisional control pending its final decision on the control status of that substance while it would not have this power under the Vienna Convention.[645] Parties to the Vienna Convention would however be required to examine the possibility of the provisional application to a substance which is a subject of the procedure pursuant to article 2, of all measures of control applicable to substances in Schedule I or Schedule II, as appropriate, if the information transmitted to them together with the notification of a party or the World Health Organization which would have initiated the procedure, would indicate that the substance involved would be suitable for inclusion in Schedule I or Schedule II. This requirement of examining the possibility of applying such provisional control would apply to substances which would not yet be controlled by the Vienna Convention as well as to substances which would already be in Schedule II, III or IV, of that Convention. The parties would have to make this examination "in the light of all information available to them." [646]

[644] The writer is inclined to believe that the Commission on Narcotic Drugs, in view of its composition, would be more ready to extend control to additional drugs or psychotropic substances than was the Conference of 1971 which adopted the Vienna Convention. It is of course assumed that the drug or substance would constitute an *international* problem.

[645] Article 3, paragraph 3, sub-paragraph (ii); the provisional control to be applied would have to be that control which must be applied to drugs in Schedule I of the Single Convention.

[646] Article 2, paragraph 3 of the Vienna Convention; see also article 3, paragraph 3, sub-paragraph (i) of the Single Convention.

Before discussing the descriptions, in the two Conventions, of the conditions under which a substance could be placed under the control regime of the treaty concerned three general observations may be made:

- Only a substance which would not yet be "under international control" could be placed under the control regime of the Vienna Convention.[647] What is meant by "international control" is *control by the Single Convention,* and not control by a preceding narcotics treaty. All drugs covered by control provisions of the earlier treaties are at present also controlled by the Single Convention. It is submitted that removal of a drug from the control of the Single Convention would under the conditions of article 2 of the Vienna Convention make it possible to subject it to an appropriate regime of the latter treaty although that drug might continue to be controlled by provisions of earlier narcotics treaties. There is on the other hand no provision of the Single Convention which would make it impossible to place under the regime of that treaty a substance which would be and continue to be controlled by the Vienna Convention. However, such an arrangement would hardly be practicable although the application of the provisions of both treaties to the same substance would be possible since they would not be incompatible with each other.

- Under the Single Convention not only dangerous substances which it defines for this purpose can be placed under international control but also those which are "convertible" into drugs already under the control of that treaty. The Vienna Convention would not provide for the control of substances which would be "convertible" into psychotropic substances already under its control or into substances which would have the dangerous properties which under the provisions of article 2 would render it possible to place them under that control.[648]

- The definitions in the two Conventions, of the dangerous substances which may be placed under their respective regime are *overlapping.*

[647] Article 2, paragraph 1.

[648] Article 2, paragraph 4. It is submitted that it would be impossible to consider the definition of this paragraph as covering such "convertible" substances. The provision of article 2, paragraph 9 refers to a different matter. It corresponds to article 2, paragraph 8 of the Single Convention. For various proposals to bring precursors within the scope of the Vienna Convention see e.g. United Nations documents E/CONF. 58/C. 3/L. 8, L. 10/Add. 4, L. 14–19 and E/CONF. 58/C. 4/L. 61.

party render the prohibition of the manufacture of narcotic drugs and/or of psychotropic substances the most suitable measure for preventing the diversion of narcotic drugs and/or psychotropic substances into the illicit traffic, the party should be required to prohibit the manufacture of such drugs and substances. Such a treaty provision would of course have to be carried out in good faith and the party's real rather than its alleged opinion would be relevant. Such a provision could be used to exercise pressure on the party not to commence manufacture, to improve its controls if it has already started manufacture and finally to prohibit manufacture

- Introduction into the Single Convention and into the Vienna Convention of a provision that in countries in which the manufacture of, wholesale trade in, export and import of, narcotic drugs and psychotropic substances is not carried out by State enterprises, the number of manufacturing, wholesale, export and import licenses [863] should be limited to such a minimum as would be compatible with some degree of competition and with promotion of research. An oligopolitical system of the trade in narcotic drugs and psychotropic substances is advantageous from the viewpoint of control.

QUESTION OF TREATY PROVISIONS PREVENTING POLICY OPTIONS ON CERTAIN CONTROVERSIAL QUESTIONS

- Punishment of the Acquisition (including Purchase) and Possession of Narcotic Drugs or Psychotropic Substances for Personal Consumption

The terms "possession" and "purchase" used in the penal provisions of the Single Convention [864] mean only possession and purchase for the purpose of illicit traffic. Consequently unauthorized possession and acquisition (purchase) of narcotic drugs for personal consumption need not be treated under the Single Convention either as punishable offenses or as serious offenses. If a government does not accept this view, they may consider purchase and possession for personal use to be offenses punishable by fines, censure or the confiscation of the drugs, or to be serious offenses punishable by deprivation of liberty, including imprisonment.[865]

The provisions of the Protocol of 1972 permitting the substitution of treatment and rehabilitation for conviction or punishment of addicted offenders will remain ineffective for the United States at least for a very long time.[866]

However, nothing in the Single Convention would prevent the United States from imposing on illegal purchase and possession of narcotic drugs for personal consumption penalties it considers advisable.

The Vienna Convention does not require parties to prohibit the possession of psychotropic substances in Schedules II, III or IV without legal authority,[867] but only to provide that the possession of substances in Schedule I should be prohibited without a special license or prior authorization.[868] The penal provisions of the Vienna Convention [869] are patterned after those of the Single Convention although the former define the punishable offenses in general terms instead of using the largely enumerative method of the latter. The penal provisions of the Vienna Convention aim at the illicit traffic; illicit acquisition (purchase) and possession of *all* psychotropic substances for personal consumption are not punishable offenses under the Vienna Convention, even though the government concerned might not permit the possession of substances in Schedules II, III and IV without legal authority. Here again a government which does not share this view, could in any event treat such purchase and possession as offenses which are not serious and which are punishable by fines, censure or even only by confiscation of the substances involved. The liberty of governments to impose heavy penalties would not be restricted by the Vienna Convention.

These legal considerations are of less importance in the Vienna Convention than in the Single Convention because the provision of the former, permitting the substitution of measures of treatment and rehabilitation for offenders who abuse psychotropic substances for their conviction or punishment, could be applied by the United States.

- Distribution and Sale of Narcotic Drugs and Psychotropic Substances

Illicit distribution and sale of narcotic drugs and

[863] Article 29, paragraph 1, article 30, paragraph 1, sub-paragraph (a) and article 31, paragraph 3, sub-paragraph (a) of the Single Convention; article 7, paragraphs (b) and (f) and article 8, paragraph 1 of the Vienna Convention.

[864] Article 36, paragraph 1 of the unamended version and paragraph 1, sub-paragraph (a) of the amended version.

[865] Article 33 and (if considered to be punishable offenses) article 37.

[866] Article 36, paragraph 1, sub-paragraph (b) of the amended text.

[867] Article 5, paragraph 3.

[868] Article 7, paragraph (b).

[869] Article 22.

psychotropic substances would be treated as serious punishable offenses subject to appropriate punishment, particularly by deprivation of liberty, including imprisonment. However, governments would be permitted to treat them as non-serious offenses and to punish them by fines, by censure or by confiscation. Such a case would include possession or distribution of a small amount of a relatively less dangerous drug for distribution to a friend without consideration or without profit.

Under the Vienna Convention, treatment and rehabilitation of all distributors of psychotropic substances, who abuse such substances, could be substituted for their conviction or punishment.

The corresponding provision of the amended Single Convention would remain ineffective for the United States, at least for a very long time.

- Legalization of the Non-Medical Use of Cannabis and Cannabis Resin

As long as cannabis and cannabis resin remain in the Schedules I and IV of the Single Convention, or are removed only from Schedule IV or are transferred to Schedule II, which involves deletion from Schedule IV, the United States is bound by the Single Convention to prohibit their non-medical use.

In accordance with a recommendation of the World Health Organization, the Commission, by a simple majority of its members present and voting, could remove cannabis and cannabis resin from the Schedules of the Single Convention. Cannabis and cannabis resin would thus cease to be drugs within the meaning of this Convention and would be freed from all drug control provisions.[870] No longer considered drugs, cannabis and cannabis resin could be produced, exported, imported, distributed, traded, used and possessed for non-medical purposes without any controls, except those which the United States would wish to maintain or establish. However, a somewhat anomalous situation would exist because article 28, paragraph 1 of the Single Convention would continue to be in force, except if deleted by an amendment of this treaty. It would continue to require that the cultivation of the cannabis plant for the production of cannabis and cannabis resin be controlled as is the cultivation of the poppy for the production of opium; but despite these controls the cannabis and cannabis resin could be produced for any purpose, including non-medical consumption.

The legalization of the non-medical use of cannabis and cannabis resin presupposes that these substances would not be included in a Schedule of the Vienna Convention.

- The Non-Medical Use of the Leaves of the Cannabis Plant.

The Single Convention[871] does not prohibit the non-medical use of the leaves of the cannabis plant if they are not accompanied by the tops of the plant.[872] Parties are required to adopt such measures as might be necessary to prevent the misuse of and illicit traffic in the leaves. The measures required to prevent misuse might include the prohibition of the sale of very potent leaves, of the sale of excessive quantities to one individual and of the sale to persons below a certain age. These are only a few examples of what parties might have to do under the vague provision of the Convention. The obligation to prevent the illicit traffic in the leaves may be carried out by limiting the trade in the leaves to government shops or licensed traders. Generally speaking such measures as are adopted in many countries to prevent excessive consumption of alcohol and illegal trade in alcohol may be sufficient.

- Maintenance Programs

The treaty provision limiting the use of drugs "to medical and scientific purposes"[873] has always been interpreted by some governments to permit consumption by persons whose addiction has proved to be incurable of the minimum quantities of addictive drugs required to prevent painful withdrawal symptoms and to make it possible for these addicts to lead a "normal" life. No party to the drug treaties has objected to this interpretation. However, the use of drugs in maintenance programs must in all cases be determined by *medical considerations*, which include the desire to *help* the addicts or other abusers of controlled drugs.[874]

MEASURES WHICH WOULD BE POSSIBLE WITHOUT TREATY AMENDMENT AND WHICH MIGHT BE DESIRABLE

- Opium

Opium producing countries which have an effective administration and which apply the provisions of the

[870] Article 1, paragraph 1, sub-paragraph (j) and article 2, paragraphs 1–5; see also article 4, paragraph (c).

[871] Nor the Vienna Convention as long as the leaves are not included in one of its Schedules.

[872] Article 1, paragraph 1, sub-paragraph (b) and article 28, paragraph 3.

[873] The first drug treaty which uses this term is the 1925 Convention; the 1912 Convention uses the phrase "medical and legitimate purposes".

[874] The same would apply to the Vienna Convention, when in force, which also limits the use of psychotropic substances to "medical and scientific purposes".

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In The Matter Of MARIJUANA RESCHEDULING PETITION	Docket No. 86-22

OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF ADMINISTRATIVE LAW JUDGE

FRANCIS L. YOUNG, Administrative Law Judge

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DATED: SEP 6 1988

VIII.

ACCEPTED SAFETY FOR USE UNDER MEDICAL SUPERVISION

With respect to whether or not there is "a lack of accepted safety for use of [marijuana] under medical supervision", the record shows the following facts to be uncontroverted.

Findings of Fact

1. Richard J. Gralla, M.D., an oncologist and Professor of Medicine who was an Agency witness, accepts that in treating cancer patients oncologists can use the cannabinoids with safety despite their side effects.

2. Andrew T. Weil, M.D., who now practices medicine in Tucson, Arizona and is on the faculity of the College of Medicine, University of Arizona, was a member of the first team of researchers to perform a Federal Government authorized study into the effects of marijuana on human subjects. This team made its study in 1968. These researchers determined that marijuana could be safely used under medical supervision. In the 20 years since then Dr. Weil has seen no information that would cause him to reconsider that conclusion. There is no question in his mind but that marijuana is safe for use under appropriate medical supervision.

3. The most obvious concern when dealing with drug safety is the possibility of lethal effects. Can the drug cause death?

4. Nearly all medicines have toxic, potentially lethal effects. But marijuana is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality.

5. This is a remarkable statement. First, the record on marijuana encompasses 5,000 years of human experience. Second, marijuana is now used daily by enormous numbers of people throughout the world. Estimates suggest that from twenty million to fifty million Americans routinely, albeit illegally, smoke marijuana without the benefit of direct medical supervision. Yet, despite this long history of use and the extraordinarily high numbers of social smokers, there are simply no credible medical reports to suggest that consuming marijuana has caused a single death.

6. By contrast aspirin, a commonly used, over-the-counter medicine, causes hundreds of deaths each year.

7. Drugs used in medicine are routinely given what is called an LD-50. The LD-50 rating indicates at what dosage fifty percent of test animals receiving a drug will die as a result of drug induced toxicity. A number of researchers have attempted to determine marijuana's LD-50 rating in test animals, without success. Simply stated, researchers have been unable to give animals enough marijuana to induce death.

8. At present it is estimated that marijuana's LD-50 is around 1:20,000 or 1:40,000. In layman terms this means that in order to induce death a marijuana smoker would have to consume 20,000 to 40,000 times as much marijuana as is contained in one marijuana cigarette. NIDA-supplied marijuana cigarettes weigh approximately .9 grams. A smoker would theoretically have to consume nearly 1,500 pounds of marijuana within about fifteen minutes to induce a lethal response.

9. In practical terms, marijuana cannot induce a lethal response as a result of drug-related toxicity.

10. Another common medical way to determine drug safety is called the therapeuic ratio. This ratio defines the difference between a therapeutically effective dose and a dose which is capable of inducing adverse effects.

11. A commonly used over-the-counter product like aspirin has a therapeutic ratio of around 1:20. Two aspirins are the recommended dose for adult patients. Twenty times this dose, forty aspirins, may cause a lethal reaction in some patients, and will almost certainly cause gross injury to the digestive system, including extensive internal bleeding.

12. The therapeutic ratio for prescribed drugs is commonly around 1:10 or lower. Valium, a commonly used prescriptive drug, may cause very serious biological damage if patients use ten times the recommended (therapeutic) dose.

13. There are, of course, prescriptive drugs which have much lower therapeutic ratios. Many of the drugs used to treat patients with cancer, glaucoma and multiple sclerosis are highly toxic. The therapeutic ratio of some of the drugs used in antineoplastic therapies, for example, are regarded as extremely toxic poisons with therapeutic ratios that may fall below 1:1.5. These drugs also have very low LD-50 ratios and can result in toxic, even lethal reactions, while being properly employed.

14. By contrast, marijuana's therapeutic ratio, like its LD-50, is impossible to quantify because it is so high.

15. In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating ten raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death.

16. Marijuana, in its natural form, is one of the safest therapeutically

active substances known to man. By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care.

17. Some of the drugs most widely used in chemotherapy treatment of cancer have adverse effects as follows:

> Cisplatin, one of the most powerful chemo-therapeuic agents used on humans - may cause deafness; may lead to life-threatening kidney difficulties and kidney failure; adversely affects the body's immune system, suppressing the patient's ability to fight a host of common infections.
>
> Nitrogen Mustard, a drug used in therapy for Hodgkins disease - nauseates; so toxic to the skin that, if dropped on the skin, this chemical literally eats it away along with other tissues it contacts; if patient's intravenous lead slips during treatment and this drug gets on or under the skin the patient may suffer serious injury including temporary, and in extreme cases, permanent, loss of use of the arm.
>
> Procarbizine, also used for Hodgkins disease - has known psychogenic, i.e., emotional, effects.
>
> Cytoxin, also known as Cyclophosphanide - suppresses patient's immune system response; results in serious bone marrow depletion; studies indicate this drug may also cause other cancers, including cancers of the bladder.
>
> Adriamycan, has numerous adverse effects; is difficult to employ in long term therapies because it destroys the heart muscle.

While each of these agents has its particular adverse effects, as indicated above, they also cause a number of similar, disturbing adverse effects. Most of these drugs cause hair loss. Studies increasingly indicate all of these drugs may cause other forms of cancer. Death due to kidney, heart or respiratory failure is a very real possibility with all of these agents and the margin for error is minimal. Similarly, there is a danger of overdosing a patient weakened by his cancer. Put simply, there is very great risk associated with the medical

use of these chemicals agents. Despite these high risks, all of these drugs are considered "safe" for use under medical supervision and are regularly administered to patients on doctor's orders in the United States today.

18. There have been occasional instances of panic reaction in patients who have smoked marijuana. These have occurred in marijuana-naive persons, usually older persons, who are extremely anxious over the forthcoming chemotherapy and troubled over the illegality of their having obtained the marijuana. Such persons have responded to simple person-to-person communication with a doctor and have sustained no long term mental or physical damage. If marijuana could be legally obtained, and administered in an open, medically-supervised session rather than surreptitiously, the few instances of such adverse reaction doubtless would be reduced in number and severity.

19. Other reported side effects of marijuana have been minimal. Sedation often results. Sometimes mild euphoria is experienced. Short periods of increased pulse rate and of dizziness are occasionally experienced. Marijuana should not be used by persons anxious or depressed or psychotic or with certain other health problems. Physicians could readily screen out such patients if marijuana were being employed as an agent under medical supervision.

20. All drugs have "side effects" and all drugs used in medicine for their therapeutic benefits have unwanted, unintended, sometimes adverse effects.

21. In medical treatment "safety" is a relative term. A drug deemed "safe" for use in treating a life-threatening disease might be "unsafe" if prescribed for a patient with a minor ailment. The concept of drug "safety" is relative. Safety is measured against the consequences a patient would confront in the absence of therapy. The determination of "safety" is made in terms of

whether a drug's benefits outweigh its potential risks and the risks of permitting the disease to progress.

22. In the context of glaucoma therapy, it must be kept in mind that glaucoma, untreated, progressively destroys the optic nerve and results in eventual blindness. The danger, then, to patients with glaucoma is an irretrievable loss of their sight.

23. Glaucoma is not a mortal disease, but a highly specific, selectively incapacitating condition. Glaucoma assaults and destroys the patient's most evolved and critical sensory ability, his or her vision. The vast majority of patients afflicted with glaucoma are adults over the age of thirty. The onset of blindness in middle age or later throws patients into a wholely alien world. They can no longer do the work they once did. They are unable to read a newspaper, drive a car, shop, walk freely and do all the myriad things sighted people take for granted. Without lengthy periods of retaining, adaptation and great effort these individuals often lose their sense of identity and ability to function. Those who are young enough or strong-willed enough will regain a sense of place, hold meaningful jobs, but many aspects of the life they once took for granted cannot be recaptured. Other patients may never fully adjust to their new, uncertain circumstances.

24. Blindness is a very grave consequence. Protecting patients from blindness is considered so important that, for ophtholmologists generally, it justifies the use of toxic medicines and uncertain surgical procedures which in other contexts might be considered "unsafe." In practice, physicians often provide glaucoma patients with drugs which have many serious adverse effects.

25. There are only a limited number of drugs available for the

treatment of glaucoma. All of these drugs produce adverse effects. While several government witnesses lightly touched on the side effects of these drugs, none provided a full or detailed description of their known adverse consequences.

26. The adverse physical consequences resulting from the chronic use of commonly employed glaucoma control drugs include a vast range of unintended complications from mild problems like drug induced fevers, skin rashes, headaches, anorexia, asthma, pulmonary difficulties, hypertension, hypotension and muscle cramps to truly serious, even life-threatening complications including the formation of cataracts, stomach and intestinal ulcers, acute respiratory distress, increases and decreases in heart rate and pulse, disruption of heart function, chronic and acute renal disease, and bone marrow depletion.

27. Finally, each FDA-approved drug family used in glaucoma therapy is capable of producing a lethal response, even when properly prescribed and used. Epinephrine can lead to elevated blood pressure which may result in stroke or heart attack. Miotic drugs suppress respiration and can cause respiratory paralysis. Diuretic drugs so alter basic body chemistry they cause renal stones and may destroy the patient's kidneys or result in death due to heart failure. Timolol and related beta-blocking agents, the most recently approved family of glaucoma control drugs, can trigger severe asthma attacks or cause death due to sudden cardiac arrhythmias often producing cardiac arrest.

28. Both of the FDA-approved drugs used in treating the symptoms of multiple sclerosis, Dantrium and Lioresal, while accepted as "safe" can, in fact, be very dangerous substances. Dantrium or dantrolene sodium carries a boxed warning in the Physician's Desk Reference (PDR) because of its very high toxicity. Patients using this drug run a very real risk of developing sympto-

matic hepatitis (fatal and nonfatal). The list of sublethal toxic reactions also underscores just how dangerous Dantrium can be. The PDR, in part, notes Dantrium commonly causes weakness, general malaise and fatigue and goes on to note the drug can also cause constipation, GI bleeding, anorexia, gastric irritation, abdominal cramps, speech disturbances, seizure, visual disturbances, diplopia, tachycardia, erratic blood pressure, mental confusion, clinical depression, renal disturbances, myalgia, feelings of suffocation and death due to liver failure.

29. The adverse effects associated with Lioresal baclofen are somewhat less severe, but include possibly lethal consequences, even when the drug is properly prescribed and taken as directed. The range of sublethal toxic reactions is similar to those found with Dantrium.

30. Norman E. Zinberg, M.D., one of Dr. Weil's colleagues in the 1968 study mentioned in finding 2, above, accepts marijuana as being safe for use under medical supervision. If it were available by prescription he would use it for appropriate patients.

31. Lester Grinspoon, M.D., practicing psychiatrist, researcher and Associate Professor of Medicine at Harvard Medical School, accepts marijuana as safe for use under medical supervision. He believes its safety is its greatest advantage as a medicine in appropriate cases.

32. Tod H. Mikuriya, M.D., a psychiatrist practicing in Berkley, California who treats substance abusers as inpatients and outpatients, accepts marijuana as safe for use under medical supervision.

33. Richard D. North, M.D., who has treated Robert Randall for glaucoma with marijuana for nine years, accepts marijuana as safe for use by his patient

under medical supervision. Mr. Randall has smoked ten marijuana cigarettes a day during that period without any evidence of adverse mental or physical effects from it.

34. John C. Merritt, M.D., an expert in ophthalmology, who has treated Robert Randall and others with marijuana for glaucoma, accepts marijuana as being safe for use in such treatment.

35. Deborah B. Goldberg, M.D., formerly a researcher in oncology and now a practicing physician, having worked with many cancer patients, observed them, and heard many tell of smoking marijuana successfully to control emesis, accepts marijuana as proven to be an extremely safe anti-emetic agent. When compared with the other, highly toxic chemical substances routinely prescribed to cancer patients, Dr. Goldberg accepts marijuana as clearly safe for use under medical supervision. (See finding 17, above.)

36. Ivan Silverberg, M.D., board certified in oncology and practicing that specialty in the San Francisco area, has accepted marijuana as a safe anti-emitic when used under medical supervision. Although illegal, it is commonly used by patients in the San Francisco area with the knowledge and acquiesence of their doctors who readily accept it as being safe for such use.

37. It can be inferred that all of the doctors and other health care professionals referred to in the findings in Sections V, VI and VII, above, who tolerate or permit patients to self-addminister illegal marijuana for therapeutic benefit, accept the substance as safe for use under medical supervision.

Discussion

The Act, at 21 U.S.C. § 812(b)(1)(C), requires that marijuana be retained in Schedule I if "[t]here is a lack of accepted safety for use of [it] under medical supervision." If there is no lack of such safety, if it is accepted that this substance can be used with safety under medical supervision, then it is unreasonable to keep it in Schedule I.

Again we must ask - "accepted" by whom? In the MDMA proceeding the Agency's first Final Rule decided that "accepted" here meant, as in the phrase "accepted medical use in treatment", that the FDA had accepted the substance pursuant to the provisions of the Food, Drug and Cosmetic Act. 51 Fed. Reg. 36555 (1986). The Court of Appeals held that this was error. On remand, in its third Final Rule on MDMA, the Agency made the same ruling as before, relying essentially on the same findings, and on others of similar nature, just as it did with respect to "accepted medical use." 53 Fed. Reg. 5156 (1988).

The administrative law judge finds himself constrained not to follow the rationale in that MDMA third Final Order for the same reasons as set out above in Section V with respect to "accepted medical use" in oncology. See pages 30 to 33. Briefly, the Agency was looking primarily at the results of scientific tests and studies rather than at what physicians had, in fact, accepted. The Agency was wrongly basing its decision on a judgement as to whether or not doctors ought to have accepted the substance in question as safe for use under medical supervision. The criteria the Agency applied in the MDMA third Final Rule are inappropriate. The only proper question for the Agency here is: Have a significant minority of physicians accepted marijuana as safe for use under medical supervision?

The gist of the Agency's case against recognizing marijuana's acceptance as safe is to assert that more studies, more tests are needed. The Agency has presented highly qualified and respected experts, researchers and others, who hold that view. But, as demonstrated in the discussion in Section V above, it is unrealistic and unreasonable to require unanimity of opinion on the question confronting us. For the reasons there indicated, acceptance by a significant minority of doctors is all that can reasonably be required. This record makes it abundantly clear that such acceptance exists in the United States.

Findings are made above with respect to the safety of medically supervised use of marijuana by glaucoma patients. Those findings are relevant to the safety issue even though the administrative law judge does not find accepted use in treatment of glaucoma to have been shown.

Based upon the facts established in this record and set out above one must reasonably conclude that there is accepted safety for use of marijuana under medical supervision. To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious.

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

No. 79-1660

The National Organization for the Reform of Marijuana Laws (NORML), Petitioner,

v.

U.S. Drug Enforcement Administration (DEA) and U.S. Department of Health and Human Services (DHHS), Respondents.

MEMORANDUM OF FEDERAL RESPONDENTS IN RESPONSE TO NORML'S EMERGENCY MOTION TO COMPEL COMPLIANCE WITH THIS COURT'S PRIOR ORDERS

By emergency motion filed on April 12, 1982, NORML, for the second time, has requested this Court to enjoin federal respondents' ongoing court ordered review of NORML's petition for the rescheduling of synthetic tetrahydrocannabinol (THC) under the Controlled Substances Act (CSA), 21 U.S.C. § 801, et. seq; order federal respondents to hold a hearing, within sixty days, on the rescheduling of the remaining substances in NORML's petition, marijuana cigarettes; issue a declaratory judgment that the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (DHHS) have not complied with this Court's prior order of October 16, 1980, and opinion in NORML v. DEA, 559 F.2d 735 (D.C. Cir.

criteria of both Schedules I and II of the CSA. For sound reasons that are described in detail in the DHHS 1982 Federal Register notice, DHHS' recommendation is that this drug, THC, nevertheless should remain in Schedule I until a new drug application, pursuant to the Federal Food, Drug, and Cosmetic Act, is approved. In making the final determination of the appropriate schedule for THC, DEA will not be precluded from rescheduling THC.

Finally, NORML has failed to exhaust its administrative remedies on THC rescheduling. McKart v. United States, 395 U.S. 185, 194 (1969). The comment period on the proposed findings and recommendation on THC is ongoing. NORML's dissatisfaction with DHHS' tentative conclusions should be expressed in the form of comments on the proposal submitted to DHHS' administrative docket on THC, and not, for the first time, in pleadings filed in Court.

c. DEA Was Not Required To Determine Limitations Of The Psychotropic Convention On The Domestic Scheduling Of THC Before Referring The Matter To DHHS

NORML now asserts, for the first time, that DEA should have received testimony and comments over a year ago on the limitations, if any, that the Psychotropic Convention imposes on the domestic scheduling of THC. DEA should have gone through this procedure, according to NORML, before referring the matter to DHHS for a scientific and medical evaluation.

NORML claims that DEA's failure to do so constitutes a violation of the Court's orders. NORML's Motion at pp. 18-21.

A plain reading of the Court's October 16, 1980, order, however, buttressed by NORML's own actions shortly following the issuance of that order, demonstrate that NORML's assertion is without merit. The Court's October 16, 1980, order directed DEA to refer the matter to DHHS for a scientific and medical reevaluation in light of new scientific evidence on THC. No mention was made in that order of any prior hearings or determinations by DEA of the international treaty issue, and all parties at the time, including NORML, viewed the scientific and medical update as the focus of the remand order. Indeed, that remand order had hardly issued before NORML contacted the Secretary of DHHS by letter, requesting a meeting to discuss the procedures that DHHS would follow in response to the Court's order. Appendix B to current NORML Motion. Such a meeting was held with DHHS representatives, and no mention was made by NORML at that meeting, or at any time thereafter until the current motion, of the need to hold up proceedings under the remand for a prior determination by DEA.

NORML's references to prior decisions of this Court in NORML v. Ingersoll, 497 F.2d 854 (D.C. Cir. 1974), and NORML v. DEA, supra, are misdirected. Those decisions interpret language in section 201(d) of the CSA, 21 U.S.C. § 881(d),

relating to a different treaty, the Single Convention on Narcotic Drugs, the treaty which covers marijuana. Subsequent to those court decisions, Congress passed the Psychotropic Substances Act of 1978, Pub. L. No. 95-633, which amended section 201(d) by adding different procedures regarding the Convention on Psychotropic Substances (Psychotropic Convention), the treaty which covers THC.7/ Accordingly, this Court's directives as to marijuana in those prior decisions are not directly applicable here to the treatment of THC in a subsequent treaty and separate implementing legislation.

DHHS recognizes there are international treaty ramifications under the Psychotropic Convention regarding the domestic scheduling of THC. In the proposed medical and scientific evaluation recently published in the Federal Register for public comment, FDA noted, "FDA is considering with the other interested agencies of government involved in international scheduling whether rescheduling of THC to [CSA] Schedule II could be accomplished without international rescheduling." 47 F.R. 10082 (1982). These other government agencies include DEA, the Department of State, and other

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7/ Under those amendments, former section 201(d) became section 201(d)(1) and the new language appeared in section 201(d)(2)-(5). Sections 201(d)(1) and 201(d)(2)-(5) are mutually exclusive.

constituents of DHHS. The issue is still unresolved because the international law is ambiguous. Contrary to NORML's assertions, domestic rescheduling of THC may be permissible, without international rescheduling, thus obviating the need for a hearing on this issue.8/

Moreover, NORML's avowed cause9/ is aided, not prejudiced, by the procedures being followed. It is prudent for DHHS to provide a complete scientific and medical evaluation on THC at this time, because even if the ultimate

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8/ It is true, as NORML points out, that THC is listed in Schedule I of the Psychotropic Convention, and that Article 7 of that convention restricts use of Schedule I substances to "scientific and very limited medical purposes ...," thereby suggesting that only CSA Schedule I would be appropriate. However, the official Commentary on the Psychotropic Convention, in discussing this restriction, points out that,

> [I]t cannot have been the intention of the 1971 Conference to prohibit or unduly impede any medically justified therapeutic use of substances in Schedule I.... It may sometimes be held in such a case to be advisable to permit such use ..., and consequently not to transfer the substances in question from Schedule I to another Schedule.

Commentary on the Convention on Psychotropic Substances (United Nations 1976), p. 138.

9/ NORML's alleged goals include increasing the availability of marijuana derivatives for therapeutic purposes. It is hard to reconcile this with NORML's present attempt to delay the availability of THC until the more difficult marijuana issue is also resolved.

DHHS recommendation is found to be inconsistent with current treaty obligations, the United States could petition for international rescheduling. See NORML v. Ingersoll, supra, 497 F.2d at 658. Indeed, DHHS is now considering whether to request the Secretary of State to petition for international rescheduling of THC, pursuant to 21 U.S.C. § 811(d)(5).10/

For these reasons, the respondents are in full compliance with all prior orders of this Court regarding the consideration of international treaty issues.

d. The Time Schedule Used By DHHS Is Not Unreasonable

Finally, NORML alleges that respondents have failed to review the marijuana plant materials quickly enough and, thus, have violated provisions of the Administrative Procedure Act, 5 U.S.C. §§ 555(b) and 706(1), and of the CSA, 21 U.S.C. § 811(b). NORML's Motion at 22.

NORML's petition was referred to DHHS by DEA in April of 1981. Since that time, DHHS convened an advisory committee meeting on one of the substances, THC. In March 1982,

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10/ The procedures now being followed by federal respondents are the exact opposite of the procedure, overturned by this Court in NORML v. Ingersoll, supra, of holding out treaty restrictions as mooting the need for a full scientific and medical evaluation.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule I to Schedule II; Statement of Policy

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final Rule and Statement of Policy.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) 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. As a result of this rule, the regulatory controls and criminal sanctions of Schedule II of the CSA will apply to the manufacture, distribution, importation and exportation of dronabinol pharmaceutical products. 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. The Administrator herein also issues a statement of policy regarding review, under the public interest criteria of 21 U.S.C. 823(f) and 824(a)(4), of the DEA registrations of practitioners who distribute or dispense dronabinol for purposes at variance with the FDA approved indications for use of the approved product. A notice is published elsewhere in this isue of the **Federal Register** that withdraws the proposed rule entitled Changes in Protocol Requirements for Researchers and Prescription Requirements for Practitioners (50 FR 42184–42186, October 18, 1985).

EFFECTIVE DATE: May 13, 1986.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone: (202) 633–1366.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

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

A proposed rule was published in the **Federal Register** on October 18, 1985 (50 FR 42186–42187), proposing that dronabinol in sesame oil and encapsulated in soft gelatin capsules in a drug product approved by the U.S. Food and Drug Administration be transferred from Schedule I to Schedule II of the Controlled Substances Act (21 U.S.C. 801 et seq.). Concurrently, a proposal was published which proposed changes in protocol requirements for researchers and prescription requirements for practitioners (50 FR 42184–42186). Interested persons were given until November 18, 1985, to submit comments or objections regarding each of the proposals.

Thirteen individuals or organizations availed themselves of the opportunity to comment, object or request an administrative hearing. Two organizations, Cannabis Corporation of America and National Organization for the Reform of Marijuana Laws (NORML), requested hearings. Both requests for hearings were subsequently withdrawn. Comments or objections were submitted by or on behalf of the following: Alliance for Cannabis Therapeutics, American College of Neuropsychopharmacology, American Medical Association, American Pharmaceutical Association, Arkansas Department of Health, Committee on Problems of Drug Dependence, Inc., Mr. Ansis M. Helmanis, the law offices of Kleinfeld, Kaplan and Becker, Marcos A. S. Lima, M.D., H. G. Pars Pharmaceutical Laboratories and the Pharmaceutical Manufacturers Association.

Having considered the comments and objections presented by the above listed parties, the requirements of the Controlled Substances Act and the Convention on Psychotropic Substances (T.I.A.S. 9725, July 15, 1980), the Administrator has decided (a) to proceed with the rescheduling of dronabinol as proposed at 50 FR 42186–42187 and (b) to issue a statement of policy regarding review of the distribution or dispensing of dronabinol by practitioner registrants which deviates from approved medical use to insure compliance with the obligations of the United States as a signatory to the Convention on Psychotropic Substances. The previously proposed regulations relating to dronabinol are withdrawn elsewhere in this issue of the **Federal Register.**

(a) Transfer of FDA Approved Dronabinol Drug Products From Schedule I to Schedule II

Having considered the comments and objections presented by the above listed parties and based on the investigations and review of the Drug Enforcement Administration, with attention to the obligations of the United States under the Convention on Psychotropic Substances, and relying on the scientific and medical evaluation and recommendation of the Assistant Secretary for Health of the Department of Health and Human Services, acting on behalf of the Secretary of the Department of Health and Human Services, in accordance with 21 U.S.C. 811(b), and the Food and Drug Administration approval of a new drug application for Marinol capsules, the Administrator of the Drug Enforcement Administration, pursuant to the provisions of 21 U.S.C. 811(a), finds that:

1. Dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration approved drug product has a high potential for abuse;

2. Dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration approved drug product has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and

3. Dronabinol (synthetic) in sesame oil and encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration approved drug product may lead to severe psychological or physical dependence.

The above findings are consistent with placement of dronabinol approved drug products into Schedule II of the CSA. The transfer of the product from Schedule I to Schedule II is effective on May 13, 1986 with selected implementation dates as indicated. In the event that this imposes special hardships on any registrant, the Drug Enforcement Administration will entertain any justified request for an extention of time to comply with the Schedule II regulations. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports a FDA approved dronabinol drug product, or who engages in research or conducts instructional activities with such a substance must be registered to conduct such activities in accordance with Parts

1301 and 1311 of Title 21 of the Code of Federal Regulations. Any person currently registered to handle dronabinol in Schedule I may continue activities under that registration until approved or denied registration in Schedule II, provided such registrant has filed an application for registration in Schedule II with DEA on or before June 12, 1986. Any persons not currently registered and proposing to engage in such activities may not conduct activities with the drug product until properly registered in Schedule II.

2. *Security.* FDA approved dronabinol drug products must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), (c) and (d), 1301.73, 1301.74, 1301.75(b) and (c) and § 1301.76 of Title 21 of the Code of Federal Regulations. Dronabinol and all mixtures, compounds and preparations thereof, except for dronabinol in sesame oil and encapsulated in soft gelatin capsules in a FDA approved drug product, remain in Schedule I and must be stored in accordance with § 1301.75(a).

3. *Labeling and Packaging.* All labels and labeling for commercial containers of FDA approved dronabinol drug products must comply with the requirements of §§ 1302.03–1302.05 and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations. Current products distributed or dispensed for approved research and labeled as Schedule I products may continue to be distributed and dispensed until May 13, 1987.

4. *Quotas.* All persons required to obtain quotas for dronabinol drug products shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of FDA approved dronabinol drug product shall take an inventory, pursuant to § 1304.04 and §§ 1304.11–1304.19 of Title 21 of the Code of Federal Regulations, of all stocks on hand as of June 12, 1986.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21–1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding FDA approved dronabinol drug products.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.34–1304.37 of Title 21 of the Code of Federal Regulations shall do so regarding FDA approved dronabinol drug products.

8. *Order Forms.* All registrants involved in the distribution of dronabinol drug products shall comply with the order form requirements of Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Prescriptions.* FDA approved dronabinol drug products have been approved for use in medical treatment and the drug may be dispensed by prescription. All prescriptions for FDA approved dronabinol drug products shall comply with §§ 1306.01–1306.06 and §§ 1306.11–1306.15 of Title 21 of the Code of Federal Regulations.

10. *Importation and Exportation.* All importation and exportation of dronabinol drug products shall be in compliance with Parts 1311 and 1312 of Title 21 of the Code of Federal Regulations.

11. *Criminal Liability.* Any activity with respect to FDA approved dronabinol drug products not authorized by or in violation of the Controlled Substances Act or the Controlled Substances Import and Export Act continues to be unlawful. The applicable penalties after May 13, 1986 shall be those of a Schedule II substance.

12. *Other.* In all other respects, this order is effective on May 13, 1986.

(b) Statement of Policy

The Administrator takes special note of the fact that synthetic tetrahydrocannabinol in all forms, including dronabinol, remains internationally controlled in Schedule I of the Convention on Psychotropic Substances. Under the special obligations of the Convention, to which the United States is a party, relative to Schedule I substances, Article 7 requires in part that parties shall "prohibit all use except for scientific and *very limited medical purposes* . . ." (emphasis added). The Administrator also notes that the official "Commentary on the Convention on Psychotropic Substances" provides guidance to parties in meeting this obligation consistent with national laws and policies.

The Administrator finds that the existing requirements of Schedule II of the Controlled Substances Act can provide adequate controls and restrictions to comply with the obligations of the Convention on Psychotropic Substances when coupled with effective oversight and enforcement, such as provided for in the Dangerous Drug Diversion Control Act of 1984 (part B of chapter V of Title II of Pub. L. 98–473). The Administrator notes that experience has demonstrated that there are medical practitioners registered to dispense Schedule II substance who abuse that registration and prescribe or dispense Schedule II substances outside the scope of the legitimate medical practice.

On May 31, 1985, the Food and Drug Administration (FDA) approved the drug product, Marinol capsules, containing dronabinol for nausea associated with cancer treatment. Considering the nature of this drug, it is reasonable to assume that drug abusers will attempt to seek out practitioner registrants willing to prescribe the drug for abuse purposes, under the guise of legitimate medical practice, as frequently occurs with other Schedule II substances. DEA has encountered practitioners who attempt to justify illegal or improper distribution or dispensing by claiming unique knowledge of a drug's effectiveness for a broad range of medical indications. While it is expected that legitimate structured research programs may document additional medical indications for dronabinol, prescribing which deviates from the recognized approved medical use must be questioned in keeping with the United States obligations to prohibit all use except for scientific and very limited medical purposes.

Therefore, in keeping with sound domestic drug control policy and the United States obligations under the Convention on Psychotropic Substances, the Administrator hereby issues this statement of policy:

Any person registered by DEA to distribute, prescribe, administer or dispense controlled substances in Schedule II who engages in the distribution or dispensing of dronabinol for medical indications outside the approved use associated with cancer treatment, except within the confines of a structured and recognized research program, may subject his or her controlled substances registration to review under the provisions of 21 U.S.C. 823(f) and 824(a)(4) as being inconsistent with the public interest. DEA will take action to revoke that registration if it is found that such distribution or dispensing constitutes a threat to the public health and safety, and in addition will pursue any criminal sanctions which may be warranted under 21 U.S.C. 841(a)(1). See *United States* v. *Moore*, 423 U.S. 122 (1975).

The proposed rule which was published at 50 FR 42184–42186, October 18, 1985, entitled Changes in Protocol Requirements for Researchers and Prescription Requirements for Practitioners, is withdrawn elsewhere in this issue of the **Federal Register.**

Pursuant to sections 3(c)(3) and 3(e)(2)(C) of Executive Order 12291 (46

FR 13193), this statement of policy has been submitted for review by the Office of Management and Budget. In accordance with the provisions of 21 U.S.C. 811(a), this order to reschedule certain drug products which contain synthetic dronabinol from Schedule I to Schedule II is a formal rulemaking "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 have been exempted from the consultation requirements of Executive Order 12291.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the rescheduling of formulations which contain dronabinol, as ordered herein, will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354, September 19, 1980). This action will allow the marketing of a drug product which has been approved by the FDA.

Pursuant to the authority vested in the Attorney General by section 201(a) of the CSA [21 U.S.C. 811(a)], as redelegated to the Administrator of the Drug Enforcement Administration by 28 CFR 0.100, and for the reasons set forth above, the Administrator hereby orders that 21 CFR 1308.12 be amended 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).

2. 21 CFR 1308.12 is amended by redesignating the existing paragraph (f) as paragraph (g) and by adding a new paragraph (f), reading as follows:

§ 1308.12 Schedule II.

* * * * *

(f) *Hallucinogenic substances.*

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

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Dated: May 1, 1986.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 86-10724 Filed 5-12-86; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Approval of Permanent Program Amendments From the State of Indiana Under the Surface Mining Control and Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Final rule.

SUMMARY: OSMRE is announcing the appproval of amendments to the Indiana Permanent Regulatory Program (hereinafter referred to as the Indiana program) received by OSMRE pursuant to the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

On January 31, 1986, Indiana submitted amendments to its program requirements regarding civil penalties, incidental boundary revisions and use of explosives.

After providing opportunity for public comment and conducting a thorough review of the program amendments, the Director, OSMRE, has determined that the amendments meet the requirements of SMCRA and the Federal regulations. Accordingly, the Director is approving these amendments. The Federal rules at 30 Part 914 which codify decisions concerning the Indiana program are being amended to implement this action.

This final rule is being made effective immediately in order to expedite the State program amendment process and encourage States to conform their programs to the Federal standards without undue delay; consistency of the State and Federal standards is required by SMCRA.

EFFECTIVE DATE: May 13, 1986

FOR FURTHER INFORMATION CONTACT: Mr. Richard D. Rieke, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Federal Building and U.S. Courthouse, Room 522, 46 East Ohio Street, Indianapolis, Indiana 46204. Telephone: (317) 269-2600.

SUPPLEMENTARY INFORMATION:

I. Background

Information regarding the general background on the Indiana State program, including the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982 **Federal Register** (47 FR 32071-32108). Subsequent actions concerning the Indiana program are identified in 30 CFR 914.15 and 30 CFR 914.16.

II. Discussion of Proposed Amendment

On January 31, 1986, the Indiana Department of Natural Resources submitted to OSMRE pursuant to 30 CFR 732.17, proposed State program amendments for approval (Administrative Record No. IND 0453). The amendments modify requirements for civil penalty assessments, incidental boundary revisions and use of explosives.

OSMRE published a notice in the **Federal Register** on February 26, 1986, announcing receipt of the proposed program amendments and procedures for the public comment period and for requesting a public hearing on the substantive adequacy of the proposed amendments (51 FR 6751). The public comment period ended March 28, 1986. There was no request for a public hearing and the hearing scheduled for March 24, 1986, was not held.

III. Director's Findings

The Director finds, in accordance with SMCRA and 30 CFR 732.15 and 732.17, that the program amendments submitted by Indiana on January 31, 1986, meet the requirements of SMCRA and 30 CFR Chapter VII. Only those areas of particular interest are discussed below in the specific findings. Discussion of only those provisions for which findings are made does not imply any deficiency in any provisions not discussed.

Civil Penalties

Indiana has amended 310 IAC 12-6-11 to provide that the regulatory authority shall assess a penalty for a violation which leads to a cessation order and for notices of violation assigned 31 points or more under the point system established in 310 IAC 12-6-12.5. The rule provides that the regulatory authority may assess a penalty for 30 points or less. Under the rule, a penalty of $5000 per day shall be assessed for mining without a permit, except under certain circumstances.

Indiana has amended 310 IAC 12-6-12 to establish the requirements for assigning points for penalties based on certain factors. The factors to be considered are: The permittee's history of violations at the particular operation (up to 30 points); the seriousness of the violation for which the penalty is being assessed (up to 15 points); the degree of the permittee's negligence or fault in the violation (up to 25 points); and degree of good faith determined from the permittee's efforts to abate the violation (up to negative 30 points).