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3

DOC NO	Doc Type	Document Description	No of Pages	Doc Date	Restrictions
1	LIST	ACTIVE IND'S FOR THC AND CANNABIS THERAPEUTIC RESEARCH PARTICIPANTS LIST	3	3/1/1984	B6

Freedom of Information Act - [5 U.S.C. 552(b)]

B-1 National security classified information [(b)(1) of the FOIA]

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TELEX
Telex # 684465

THE WHITE HOUSE

WASHINGTON

February 14, 1984

Mr. Wallace Riley
President, American Bar Association
c/o Las Vegas Hilton
3000 Paradise Road
Las Vegas, NV 89109

Dear Mr. Riley:

The legal profession has an opportunity to do a major public service and, by so doing, enhance its image with the American public by voting against any motion to make marijuana available as a therapeutic item.

I think you will find that the States which have approved the "therapeutic use of marijuana," have in fact approved the use of a synthetic compound called Delta 9-THC (or Delta 9 - Tetrahydrocannabinol). Confusing Delta 9-THC and marijuana is a serious mistake and sends the wrong message to the American public, that there is nothing wrong with marijuana use.

Marijuana use causes serious health problems as clearly indicated by the 60,000 young people who are admitted for treatment each year because of its use.

For the benefit, credibility and reputation of the ABA and for all Americans, I strongly urge you to reconsider.

Sincerely,



Carlton E. Turner, Ph.D.
Special Assistant to the President
for Drug Abuse Policy

DAILY JOURNAL

AMERICAN BAR ASSOCIATION
HOUSE OF DELEGATES

REPORT OF ACTION TAKEN AT
1984 MIDYEAR MEETING
LAS VEGAS, NEVADA

See #109

February 13-14, 1984

<u>REPORT NO.</u>	<u>PROPOSED BY</u>	<u>SHORT TITLE</u>	<u>ACTION TAKEN*</u>
8	Illinois State Bar Assn	clinical legal work	Not approved
100A	S Ad Law	FOIA amendments	Amended, then approved*
100B	S Ad Law	Access to records under Privacy Act and FOIA	Approved
101	StC Lawyers' Title Gty Funds	Model Title Insurance Act	Approved
102A	S Tax	Accumulated taxable income	Approved
102B	S Tax	Aggregate stock ownership rules	Approved
102C	S Tax	Appeals from interlocutory orders of the U.S. Tax Court	Approved
102D	S Tax	Tax refund actions	Approved
102E	S Tax	Discharge of indebtedness	Approved
102F	S Tax	Amendments to tax returns	Approved
102G	S Tax	Boot in a reorganization exchange	Approved
102H	S Tax	Subchapter K amendments	Approved

*See attachment.

<u>REPORT NO.</u>	<u>PROPOSED BY</u>	<u>SHORT TITLE</u>	<u>ACTION TAKEN*</u>
103A	S Family Law	Issues affecting children	Approved
103B	S Family Law	Standards of Practice for Divorce Mediators	Deferred
104	S Intl Law	United Nations	Approved
105	StC Lgl Assts	Approval of paralegal programs	Approved
106	StC Assn Stds for Crim Just	Bail on appeal	Approved
107A	NCCUSL	Uniform Transfers to Minors Act	Approved
107B	NCCUSL	Uniform Premarital Agreement Act	Approved
107C	NCCUSL	Uniform Marital Property Act	Deferred
108A	S Crim Just	Armed Career Criminal Act	Approved
108B	S Crim Just	Grand jury principle	Approved
109	S Individ Rts	Medical use of marijuana	Amended, then approved*
110	S Pub Contr	U.S. Claims Court	Withdrawn
111	S Patent, Trademark & Copyright Law	Appointment of lawyers to Court of Appeals for Federal Circuit	Withdrawn
112A	Law Student Division	Amend Standards for the Approval of Law Schools	Deferred
112B	Law Student Division	Amend Standards for the Approval of Law Schools	Deferred
112C	Law Student Division	Income-Dependent Education Assistance Act	Deferred
113	StC Lawyer Referral & Info Serv	Standards of Practice for a Lawyer Referral and Information Service	Approved

*See attachment.

ATTACHMENT

100A

The resolution was amended to delete the word "and" in line 4, and insert the words "in order."

109

The resolution was amended to read: Be It Resolved, That the American Bar Association supports federal legislation to remove federal prohibition against the treatment of patients with marijuana under the supervision of a physician and under controls adequate to prevent any diversion or other improper use of medicinal marijuana.

115

The resolution was amended to insert in line 9 immediately following the words "three years" the language ", with a cumulative tracking of and reporting on ABA and section membership acquisition, retention and attrition data."

400

The House accepted the report of the House Membership Committee and authorized the Committee to draft appropriate amendments to the Constitution and Bylaws for consideration at the 1984 Annual Meeting.

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IND

-NDA



AMERICAN BAR ASSOCIATION
REPORT TO THE HOUSE OF DELEGATES
SECTION OF INDIVIDUAL RIGHTS AND RESPONSIBILITIES

RECOMMENDATION

BE IT RESOLVED, that the American Bar Association recognizes that persons who suffer from serious illnesses for which marijuana has a medically recognized therapeutic value have a right to be treated with marijuana under the supervision of a physician, and that the American Bar Association supports federal legislation to establish a program under which such patients can be treated with marijuana under the supervision of a physician and under controls adequate to prevent any diversion or other improper use of medicinal marijuana.

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REPORT

Numerous recent clinical studies have demonstrated that marijuana has significant therapeutic value in the treatment of two catastrophic illnesses — cancer and glaucoma. Marijuana alleviates the severe nausea and vomiting caused by cancer chemotherapy; it also reduces the blinding elevation of pressure within the eye that is caused by glaucoma.

In response to these studies, since 1978 thirty-three states have enacted legislation permitting the medical prescription and use of marijuana without criminal penalty. The federal government, however, has retained criminal penalties against all uses of marijuana, including medical uses. As a result, those seriously ill citizens with cancer or glaucoma who could be helped through the use of marijuana are placed in an untenable position: either they must forgo medical treatment that could save their eyesight or even their lives or they must risk criminal sanctions by illegally obtaining and using "street" marijuana. The prospects of criminal prosecution for medical use of marijuana are not hypothetical — individuals using marijuana for medical purposes have been brought to trial and even convicted.

The members of the legal profession have a special obligation to protest when the legal system itself forces American citizens to choose between their respect for the law and the health or well-being of themselves or others. As embodied in the

criminal defense of necessity (a defense that courts have accepted in at least two criminal prosecutions for medical use of marijuana), the common law has long recognized that an individual has a fundamental right not to be placed in the position of having to choose between criminal punishment and the threat of death or serious bodily harm. By continuing its criminal prohibition against medical use of marijuana, the federal government is placing critically ill American citizens in precisely this position.

Legislation is now pending in the United States House of Representatives that would permit physicians to use marijuana in the treatment of glaucoma and the vomiting caused by cancer chemotherapy. H.R. 2282, which has bipartisan support from more than sixty co-sponsors, would not change existing federal criminal penalties for non-medical use of marijuana or for use of marijuana without the supervision of a physician.

The American Bar Association should adopt the proposed recommendation. By so doing, it would add its voice to those of other respected institutions — including the National Association of Attorneys General and the state legislatures of Michigan, New Hampshire, and New Mexico ^{1/} — that have called for federal legislation that would allow seriously ill individuals to use marijuana under a physician's direction.

I. CLINICAL EVIDENCE OF THE THERAPEUTIC VALUE OF MARIJUANA

Recent clinical studies, many of which were funded and administered by state governments, show that marijuana has proven medical value in treating two life- and sight-threatening conditions: First, in the treatment of the nausea and vomiting that accompany cancer chemotherapy and, second, in the reduction of the blinding elevation of intraocular pressure (pressure within the eye) suffered by patients with glaucoma.

A. Treatment of Nausea and Vomiting Caused by Cancer Chemotherapy

In the last fifteen years, many anticancer chemotherapy drugs have been developed. These drugs have dramatically increased cure rates for many types of

^{1/} See National Association of Attorneys General, "Resolution on Therapeutic Use of Marijuana" (policy position adopted at June 22-25, 1983 meeting); State of New Hampshire, Senate Concurrent Resolution No. 4 (concurred in by New Hampshire House of Representatives March 8, 1983); State of Michigan, Senate Concurrent Resolution No. 473 (concurred in by Michigan House of Representatives March 17, 1982); New Mexico Senate Memorial No. 42 (35th Legislature, State of New Mexico, Second Session, 1982).

cancer, including choriocarcinoma, Hodgkin's disease, and testicular cancer. 2/ Many anticancer chemotherapeutic agents are, however, highly toxic and cause a wide variety of undesirable side effects. One of the most common side effects of chemotherapy is severe nausea and vomiting. The vomiting is extremely violent and long-lasting (as long as 48-72 hours), and may cause bone fractures, ruptures, dehydration, weight loss, and general malaise. 3/ The late Senator Hubert Humphrey described this vomiting and nausea as a "living hell." 4/ A substantial number of cancer victims choose to discontinue chemotherapy, even when they are responding, because of this nausea and vomiting. 5/ Thus, as Dr. John MacDonald of the National Cancer Institute has stated, nausea and vomiting can "become a lethal side effect of chemotherapy." 6/

According to Dr. MacDonald of the National Cancer Institute, "The need for effective antiemetic agents to alleviate this side effect is imperative." 7/ However, many persons undergoing chemotherapy do not receive relief from nausea and vomiting from any of the currently available antiemetics. Compazine, for years the standard antiemetic (anti-nausea agent), does not reduce nausea and vomiting in as many as 60 to 75 percent of patients. 8/ A more recently developed antiemetic, delta-9-tetrahydrocannabinol ("delta-9-THC") is more effective than Compazine, but still does not succeed in alleviating nausea and vomiting in as many as 20 to 50 percent of chemotherapy patients (results vary depending on the particular clinical

2/ Laszlo, Emesis as Limiting Toxicity in Cancer Chemotherapy, in Antiemetics and Cancer Chemotherapy (J. Laszlo ed. 1983); Hearing Before the Select Committee on Narcotics Abuse and Control, The Therapeutic Uses of Marihuana and Schedule I Drugs, 96th Congress, Second Session, at 2 (May 20, 1980) (hereinafter "Select Committee Marihuana Hearing").

3/ Penta, Poster, Bruno & MacDonald, Clinical Trials with Antiemetic Agents in Cancer Patients Receiving Chemotherapy, 21 J. Clinical Pharmacology 11s, 11s (1981).

4/ Select Committee Marihuana Hearing, supra note 2, at 2.

5/ See Penta, Poster, and Bruno, The Pharmacologic Treatment of Nausea and Vomiting Caused by Cancer Chemotherapy: A Review, in Antiemetics and Cancer Chemotherapy 53, 82 (J. Laszlo ed. 1983); Institute of Medicine, Marijuana and Health 142 (1982). The report Marijuana and Health, which is frequently cited herein, was prepared by the Institute of Medicine of the National Academy of Sciences. The Food and Drug Administration has characterized this volume as a "comprehensive" report written by "an impartial and disinterested group of scientists whose goal was an accurate statement of our current knowledge about the relationship of cannabis use to the public health." 47 Fed. Reg. 28141, 28146 (June 29, 1982).

6/ See Select Committee Marihuana Hearing, supra note 2, at 62.

7/ Id.

8/ Annual Report to the New York Governor and Legislature, The Antonio G. Olivieri Controlled Substances Therapeutic Research Program, at 4 (September 1, 1982).

study. 9/ In addition, clinical research suggests that many patients develop a tolerance to THC after repeated chemotherapy sessions. 10/ And, although studies are continuing with new, experimental antiemetics, many of these experimental drugs cause severe side effects 11/ and none has to date proved effective for all patients. 12/

Because no single satisfactory antiemetic has yet been developed, there is an urgent need for additional antiemetic drugs, so that oncologists (cancer specialists) will have an "arsenal" of drugs available for use in battling the potentially lethal nausea and vomiting of chemotherapy. Five recent clinical studies that have been conducted under the auspices of state governments demonstrate unequivocally that inhaled natural marijuana is highly effective in preventing or reducing nausea and vomiting caused by chemotherapy. The reported effectiveness rates ranged from 90% (New Mexico and Tennessee studies) to 73% (Georgia). (The results of these studies are set forth in more detail in the margin.) 13/ Moreover, a sixth study, conducted by

9/ See id., Appendix D; Penta, Poster, Bruno & McDonald, supra note 3, at 16s-17s.

10/ See Sweet, et al., Delta-9-Tetrahydrocannabinol as an Antiemetic for Patients Receiving Cancer Chemotherapy, 21 J. Clinical Pharmacology 70s, 74s (1981); Chang, et al., Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate: A Prospective, Randomized Evaluation, 91 Ann. Internal Medicine 819, 823 (1979); see also New York Research Report, supra note 8, at D22-D24.

11/ For example, human clinical testing of Nabilone, an initially promising experimental antiemetic, was discontinued when it was determined that it caused central nervous system toxicity in dogs. See Penta, Poster, Bruno & MacDonald, supra note 3, at 185. Other experimental drugs have caused such side effects as hallucinations, psychotic episodes, jaundice, dizziness, spasms, dysphoria, and blurred vision. See, e.g., id. at 155; Lucas, Phenothiazines as Antiemetics, in Antiemetics and Cancer Chemotherapy 93, 100-104 (J. Laszlo ed. 1983); Neidhart, et al., Comparative Trial of the Antiemetic Effects of THC and Haloperidol, 21 J. Clinical Pharmacology 38s, 41s (1981); Cronin, et al., Antiemetic Effect of Intramuscular Levonantradol in Patients Receiving Anticancer Therapy, 21 J. Clinical Pharmacology 43s, 47s (1981); Einhorn, et al., Nabilone: An Effective Antiemetic in Patients Receiving Cancer Chemotherapy, 21 J. Clinical Pharmacology 64s, 68s-69s (1981).

12/ See Penta, Poster, Bruno & MacDonald, supra note 3; see generally Antiemetics and Cancer Research (J. Laszlo ed. 1983).

13/ a. New Mexico: The Lynn Pierson Therapeutic Research Program: A Report on Progress to Date (March 1983 report to the New Mexico State Legislature). This study was described by Dr. Richard Crout, Director of the Bureau of Drugs of the U.S. Food and Drug Administration, as a "careful comparison between [marijuana] cigarettes and THC capsules." Select Committee Marijuana Hearings, supra note 2, at 77. The researchers conducting the New Mexico study concluded that smoked marijuana has been "determined to be effective in combatting and overcoming nausea

(Continued)

Dr. Alfred Chang and funded by the National Cancer Institute, indicated that marijuana used in combination with THC has a 93% effectiveness rate in alleviating nausea and vomiting. 14/

(Footnote 13 continued)

and vomiting that are produced by chemotherapy." This study showed that of 64 chemotherapy patients using marijuana to combat nausea and vomiting, 90.39% showed a positive response. By comparison, delta-9-THC capsules were found to produce a positive response in only 59.65% of the patients. The researchers concluded that "the marijuana cigarettes, when smoked, produce much greater overall positive effectiveness than does the delta-9-THC when orally ingested."

b. New York: Annual Report to the New York Governor and Legislature, The Antonio G. Olivieri Controlled Substances Therapeutic Research Program (September 1, 1982). The initial results of this research program indicated "substantial patient benefit from inhalation marijuana." Of the 18 patients included in the initial results, 83.3% (15) benefited.

c. Georgia: Georgia Patient Qualification Review Board, Evaluation of the Use of Both Marijuana and THC in Cancer Patients for the Relief of Nausea and Vomiting Associated with Cancer Chemotherapy After Failure of Conventional Anti-Emetic Therapy: Efficacy and Toxicity (January 20, 1983). This research program used both smoked marijuana and oral delta-9-THC. The report of the program's results concluded, "We found both marijuana smoking and THC capsules to be effective antiemetics." This study showed a 73.1% success rate for patient-controlled smoking of marijuana (13 of 18 patients) as compared to a 76.0% success rate for patients taking oral delta-9-THC. The difference in success rates between smoking and delta-9-THC capsules was not considered significant.

d. Tennessee: State of Tennessee Annual Report, Evaluation of Marijuana and Tetrahydrocannabinol in Treatment of Nausea and/or Vomiting Associated with Cancer Therapy Unresponsive to Conventional Anti-Emetic Therapy: Efficacy and Toxicity (July 1983). The initial progress report from Tennessee's research program concluded, "We found both marijuana smoking and THC capsules to be effective antiemetics. We found an approximate 23% higher success rate among those patients smoking than among those patients administered THC capsules." The study reported a 90.4% success rate for smoked marijuana (19 of 21 patients), as compared to a 66.7% success rate for delta-9-THC.

e. Michigan: Michigan Department of Public Health Marijuana Therapeutic Research Project, Data Compiled by Michigan Cancer Foundation Department of Social Oncology, Evaluation Unit (March 18, 1982). This study shows that for 86 reported instances of patients using marijuana, in 77.9% of the cases the patient experienced only moderate nausea or no nausea.

14/ Chang, et al., Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate, 91 Annals of Internal Medicine 819

(Continued)

The state research studies, Dr. Chang's study, and clinical observations by practicing oncologists leave no doubt that marijuana is medically useful in treating the nausea and vomiting caused by chemotherapy. ^{15/} The Institute of Medicine of the National Academy of Sciences concluded in its 1982 report Marihuana and Health that marijuana is antiemetic. ^{16/} Many prominent cancer researchers and practicing oncologists, including Dr. Stephen Sallan of the Harvard University Medical School, Dr. Solomon Garb of the University of Colorado Medical Center, ^{17/} Dr. LaSalle D. Leffall of the Howard University Medical School and a past president of the American Cancer Society, ^{18/} and Dr. John Laszlo of the Duke University Medical Center ^{19/} have concluded that marijuana is valuable in treating chemotherapy-induced nausea and vomiting and should be made available for medical use.

(Footnote 14 continued)

(1979). In this randomized, double-blind study, chemotherapy patients were first given delta-9-THC. When vomiting and nausea developed, they were then switched to smoked marijuana. This combination of delta-9-THC and marijuana produced a reduction of nausea and vomiting in 93% of patients. Dr. Chang also observed that smoked marijuana more reliably achieved an antiemetic effect than delta-9-THC.

^{15/} Additional work and research are clearly needed to separate the compounds in marijuana that are therapeutically useful from those that cause unwanted side effects, such as euphoria. But in the interim, any adverse side effects of marijuana are far outweighed by the benefits to be gained by a patient facing the horrors of chemotherapy, including possible death. Chemotherapy patients almost invariably choose to accept any risk of adverse effects from marijuana rather than endure the vomiting. See, e.g., Select Committee Marihuana Hearings, supra note 2, at 20-21. Moreover, other antiemetics, especially THC, have equally if not more severe side effects. See, e.g., sources cited in note 11 supra; Kluin-Neleman, et al., Delta-9-Tetrahydrocannabinol as an Antiemetic in Patients Treated with Cancer Chemotherapy, 21 Vet. Human Toxicology 338 (1979). Indeed, the chemotherapy itself has far more serious potential consequences than the antiemetics, including marijuana. See Laszlo, Tetrahydrocannabinol: From Pot to Prescription?, 91 Annals of Internal Medicine 916 (1979).

^{16/} Marijuana and Health, supra note 5, at 144.

^{17/} Select Committee Marihuana Hearing, supra note 2, at 17-26 (statements of Drs. Sallan and Garb).

^{18/} "Cancer Society Chief Urges Marijuana Use to Ease Pain," New York Times, April 6, 1979.

^{19/} Laszlo, Tetrahydrocannabinol: From Pot to Prescription?, 91 Annals of Internal Medicine 916 (1979).

B. Treatment of Glaucoma

Glaucoma is one of the leading causes of blindness in the world. Approximately 300,000 new cases are diagnosed each year in the United States. The primary symptom of glaucoma is an increase in pressure within the eye sufficient to damage the optic nerve. If not controlled, this elevated pressure causes progressive loss of vision and eventual blindness. Most glaucoma patients can control their intraocular pressure through currently available anti-glaucoma medications, but these medications are not effective for all patients. ^{20/} For these persons, as the Institute of Medicine of the National Academy of Sciences concluded in its 1982 report Marijuana and Health, "there is a particularly urgent need to find effective drugs." ^{21/} The pharmacologic control of glaucoma is preferred to surgery, because surgical treatment of glaucoma entails a high incidence of failure and the possibility of serious complications. ^{22/}

Marijuana has a limited, but essential, medical use in the treatment of glaucoma — as a drug of last resort when other drugs have failed. Many studies in the 1970s and 1980s have clearly demonstrated that smoking marijuana substantially reduces the blinding intraocular pressure in glaucoma victims. ^{23/} As glaucoma researcher Keith Green concluded after a review of these studies, "There is no question that smoking of marijuana . . . lead[s] to a fall in intraocular pressure." ^{24/} Dr. John Merritt, Associate Professor of Ophthalmology at the University of North Carolina, another leading investigator of the use of marijuana in treating glaucoma, testified before a committee of the U.S. House of Representatives as follows:

"Question: Is marihuana good for glaucoma?"

"Answer: Since we know that lowering the intraocular pressure is beneficial to any subject with glaucoma — then YES — it is good." ^{25/}

^{20/} Marijuana and Health, *supra* note 5, at 140; Green, Marijuana and the Eye — A Review, 1 *Journal of Toxicology - Cutaneous and Ocular Toxicology* 3, 11-12 (1982).

^{21/} Marijuana and Health, *supra* note 5, at 140.

^{22/} See id.; Green, *supra* note 20, at 11.

^{23/} See, e.g., Hepler & Frank, Marijuana Smoking and Intraocular Pressure, 217 *J. Am. Med. Ass'n* 1392 (1971); Hepler, Frank & Ungerleider, Pupillary Constriction After Marijuana Smoking, 74 *Am. J. Ophthalmology* 1185 (1972); Merritt, et al., Effect of Marihuana on Intraocular and Blood Pressure in Glaucoma, 87 *Ophthalmology* 222 (1980); Hepler & Petrus, Experiences with Administration of Marihuana to Glaucoma in the Therapeutic Potential of Marihuana 63 (S. Cohen & R. Stillman eds. 1976).

^{24/} Green, *supra* note 20, at 17; see Marijuana and Health, *supra* note 5, at 140.

^{25/} Select Committee Marihuana Hearing, *supra* note 2, at 41, 146.

Dr. Merritt and Professor Green both are careful to point out that smoked marijuana is not the drug of first choice in treatment of glaucoma. 26/ Four or more marijuana cigarettes a day may be necessary to sustain a reduction in intraocular pressure, 27/ and this level of marijuana smoking may have undesirable side effects, including increased heart rate, decreased blood pressure, and pulmonary difficulties from the inhalation of marijuana smoke. 28/ Because of these side effects, Dr. Merritt does not recommend the use of marijuana by elderly glaucoma patients or by glaucoma patients with cardiopulmonary problems. 29/

Unfortunately, no glaucoma treatment is risk-free. All current conventional therapies for glaucoma have well-documented and potentially serious adverse side effects. 30/ When marijuana's relatively mild potential side effects are weighed against either (a) the blindness that will result from uncontrolled elevation of intraocular pressure or (b) the serious adverse side effects of conventional anti-glaucoma drugs, it is clear that marijuana serves a valuable therapeutic function as a drug of last resort for glaucoma patients.

When conventional glaucoma drugs fail to reduce intraocular pressure, patients and physicians should be allowed to decide whether the potential side effects of marijuana are outweighed by the alternatives of surgical intervention or blindness. This choice is permitted for patients who wish to use conventional glaucoma drugs, which have side effects that are in many respects far more serious than those of marijuana.

26/ Id. at 41, 146-47; Green, supra note 20, at 17-19.

27/ Marijuana and Health, supra note 5, at 140.

28/ Id. at 140; see also id. at 57-79. The side effects of chronic marijuana use at this level do not include intoxication or a "high," as a tolerance to this effect develops over time. See Green, supra note 20, at 11-12; Affidavit of John C. Merritt, M.D. (April 5, 1978) (filed in Randall v. United States, Civ. Action No. 78-817 (D.D.C. 1978)) (based on physician observations of glaucoma patient controlling intraocular pressure through use of marijuana).

29/ Select Committee Marihuana Hearing, supra note 2, at 41, 146-47.

30/ The potential side effects of conventional medications for glaucoma include blurring and additional loss of vision, headaches, brow-aches, spasms of the eyelid muscles, cysts in the pupillary margin of the iris, an increase in the incidence of cataracts, tachycardia (rapid beating of the heart), hypertension, palpitations, sweating, tremors, anorexia (substantially diminished appetite), gastric distress, vomiting, nausea, diarrhea, alterations of potassium metabolism, dysphoria, renal stones, impotence, severe depression, rapid mood shifts, corneal anesthesia, decreased lacrimation, and systemic effects (decreased pulse rate, bradycardia). See Green, supra note 20, at 11-12; Marijuana and Health, supra note 5, at 140; Affidavit of Robert S. Hepler, M.D. (February 17, 1978) (filed in Randall v. United States, Civ. Action No. 78-817 (D.D.C. 1978)).

II. FEDERAL CONSTRAINTS ON THE MEDICAL USE OF MARIJUANA

Under the present federal regulatory framework, patients or physicians who either use or prescribe marijuana for medical purposes are subject to the criminal sanctions of fines and imprisonment. Criminal penalties for the medical use of marijuana are prescribed both by the Controlled Substances Act 31/ and by the Food, Drug, and Cosmetic Act. 32/

Marijuana is classified as a Schedule I drug under the Controlled Substances Act. 33/ Schedule I, the most restrictive classification, is reserved for drugs with "a high potential for abuse" and "no currently accepted medical use in the United States." 34/ There is no provision in the Controlled Substances Act for the prescription of Schedule I drugs; dispensation of Schedule I drugs is restricted to those conducting "bona fide research." 35/ Accordingly, the Controlled Substances Act bars any medical prescription or use of marijuana. A physician who provides marijuana to a patient for medical use is subject to up to four years' imprisonment and a fine of up to \$30,000 on the first offense; 36/ a non-physician who provides a patient with marijuana for medical use is subject to up to five years' imprisonment and a fine of up to \$15,000 on the first offense. 37/ A patient who uses marijuana for medical purposes is subject to up to one year of imprisonment and a \$5,000 fine on the first offense. 38/

The Food, Drug and Cosmetic Act also provides criminal penalties for anyone, including a physician, who introduces marijuana into interstate commerce by providing it to another person for medical use. Marijuana, when used for therapeutic purposes, is a "new drug" within the meaning of the the Food, Drug and Cosmetic Act. 39/ Therefore, before marijuana can be introduced into interstate commerce, the Food and Drug Administration must approve a New Drug Application for the therapeutic use of marijuana. 40/ No New Drug Application for marijuana has even been filed. Accordingly, any person who introduces marijuana into interstate

31/ 21 U.S.C. §§ 801-966.

32/ 21 U.S.C. §§ 301-392.

33/ 21 U.S.C. § 812.

34/ Id.

35/ See 21 U.S.C. §§ 823(f), 829.

36/ See 21 U.S.C. § 843.

37/ See 21 U.S.C. § 841.

38/ See 21 U.S.C. § 844.

39/ See 21 U.S.C. § 321 (p).

40/ See 21 U.S.C. § 355(a)-(b).

commerce by providing another person with marijuana for medical use is subject to criminal sanctions of imprisonment for up to one year and a fine of up to \$1,000, for the first offense. 41/

In reaction to the numerous clinical studies showing medical value of marijuana, thirty-three state legislatures have recognized the inappropriateness of continuing to provide criminal penalties for the medical use of marijuana and of continuing to classify marijuana as a drug without current medical uses in the United States. These states have enacted statutes permitting therapeutic use of marijuana without criminal penalty. 42/ However, these state statutes standing alone have been insufficient to permit medical use of marijuana. Under the Supremacy Clause, the federal criminal prohibitions against medical use of marijuana remain in full effect. 43/ Moreover, the federal Drug Enforcement Administration has taken the official position that it will not rule out a test case criminal prosecution of physicians or their patients for medical use of marijuana pursuant to a state law because "we need to keep open the issue of Federal prominence [sic] in deciding what substances are safe and efficacious for use in medical treatment in the United States." 44/ In at least one instance, the Drug Enforcement Administration intervened in a state court proceeding to prevent a state court from ordering confiscated marijuana released to a cancer victim who wished to use it in conjunction with chemotherapy. 45/

The result of the federal government's position has, unsurprisingly, been that the state governments wishing to make marijuana medically available have been forced to submit "Investigational New Drug" protocols to the federal Food and Drug Administration pursuant to 21 U.S.C. § 823(f) for permission to conduct "research" with marijuana. In addition, states have had to apply to the Drug Enforcement Administration for a registration for use of Schedule I drugs under the Controlled

41/ See 21 U.S.C. §§ 331(d), 333.

42/ These states are Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Iowa, Louisiana, Maine, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin. For illustrative statutes, see 19 Connecticut Gen. Stat. Ann. § 19-453 (1982 Supp.); 26 Gen. Stat. North Carolina § 90-101(h) (1982 Supp.); Oregon Rev. Stat. § 475.515 (1982 Supp.); 3 New Hampshire Rev. Stat. Ann. § 318-B: 9VII, B:10 VI.

43/ See Cooper, Therapeutic Use of Marijuana and Heroin: The Legal Framework, 35 Food Drug Cosmetic L.J. 68, 71-72 (1980).

44/ See Letter from Peter B. Bensinger, DEA Administrator to Sidney I. Lezak, U.S. Attorney (June 28, 1979).

45/ See "U.S. Derails 'Pot' Treatment Plan", Riverside (Calif.) Enterprise (March 20, 1979).

Substances Act. 46/ Only ten states have been able to comply with the cumbersome DEA and FDA application procedures and have received supplies of marijuana. 47/ Their use of marijuana has been strictly restricted to research involving the therapeutic potential of marijuana. 48/

As a result of the federal government's constraints on the medical use of marijuana, the State legislatures of Michigan, New Hampshire, and New Mexico have passed resolutions condemning the federal government and its regulatory agencies for depriving patients of medical access to marijuana. The Michigan resolution, for example, alleges that the "federal agencies" have "through regulatory ploys and obscure bureaucratic devices, resisted and obstructed the intent of the Michigan Legislature" to "obtain marijuana for medical applications." All three of these State resolutions call for federal legislation to remove these bureaucratic barriers. 49/

III. CRIMINAL PROSECUTIONS FOR MEDICAL USE OF MARIJUANA

It is only within the context of these few, relatively small state research programs that therapeutic use of marijuana is permitted today. The lack of greater availability of marijuana to those with glaucoma and cancer has caused great hardship. In addition to those individuals who have suffered unnecessarily from nausea and vomiting during cancer chemotherapy, those who have discontinued chemotherapy for potentially curable cancers because of unbearably severe vomiting, and those who have unnecessarily lost their vision to glaucoma, many persons have had to risk criminal penalties in order to obtain supplies of illicit marijuana for themselves or loved ones in desperate need of it. There are numerous press reports of situations in which persons wholly unfamiliar with the drug culture are forced to go onto the streets to purchase marijuana for medical use. 50/

46/ See Cooper, supra note 43, at 80-81.

47/ These are California, Florida, Georgia, Illinois, Michigan, New Mexico, New York, Oregon, Washington, and Tennessee. Letter from Edward C. Tocus, Chief, FDA Drug Abuse Staff to James R. Young (Oct. 15, 1982). Tennessee began to receive marijuana after October 15, 1982.

48/ See 47 Fed. Reg. 28141, 28151 (June 29, 1982).

49/ See note 1 supra.

50/ See, e.g., "Prescription Pot: Cancer Patients' Use of Marijuana Grows Despite Many Barriers," The Wall Street Journal, March 1, 1982 (mother of five-year-old child with cancer buys marijuana); "Man Bought Pot for Sick Wife," The Milwaukee Journal, March 9, 1982 (73 year-old man bought \$150 worth of marijuana from "pusher" for dying wife undergoing chemotherapy); Select Committee Marijuana Hearing, supra note 2, at 4-6 (testimony of cancer patient Anna Guttentag).

Moreover, there have been several criminal prosecutions of patients for medical use of marijuana, 51/ and at least one conviction. 52/ In two cases, courts have dismissed criminal prosecutions of patients who were using marijuana for medical purposes on the ground that such use was justified by the doctrine of "necessity." In United States v. Randall, 53/ the trial court ruled that the defendant, who had been arrested for use of marijuana to control his glaucoma, could not be criminally punished for violation of the drug laws because he satisfied the requirements of the common law defense of necessity. Under that doctrine, an act in violation of the criminal law may be excused if the act was performed in order to avoid an evil greater than the evil the law was intended to prevent. 54/ The defense is thus available where an individual acts in order to avoid the threat of death, serious bodily harm, or impairment of health. 55/ The Randall court ruled that the evil avoided by the defendant's use of marijuana — the prevention of his blindness from glaucoma — outweighed the evil of the putative crime — growing and consuming marijuana in his residence. The court reasoned that little injury to the general public could result from such private, medical use of marijuana. 56/ Accordingly, the court recognized the defendant's "right" to "protect his body" through the use of marijuana. 57/ A defense of medical necessity for use of marijuana was also accepted by the court in Washington v. Diana. 58/

IV. NEED FOR FEDERAL LEGISLATION

Structural change in the present regulatory system is necessary to make marijuana legally available to all glaucoma and cancer patients with a medical need

51/ See, e.g., United States v. Randall, 104 Daily Wash. L. Rep. 2249 (D.C. Super. Ct. Nov. 24, 1976); Washington v. Diana, No. 25230 (Super. Ct., Spokane County, Washington March 4, 1981). Many such cases are not officially reported and their final disposition is unknown. See, e.g., "Woman, 70, Pleads Innocent to Pot Charge," Cape Cod (Mass.) Times, February 1, 1983 (defendant claims use of marijuana was for treatment of glaucoma).

52/ See "Teen with Cancer Sentenced in Pot Case," Houston Post, January 14, 1983.

53/ 104 Daily Wash. L. Rep. 2249 (D.C. Super. Ct. Nov. 24, 1976).

54/ See id. at 2251-52; Model Penal Code § 3.02(1)(a) (Proposed Official Draft, 1962).

55/ See, Note, Medical Necessity as a Defense to Criminal Liability: United States v. Randall, 46 Geo. Wash. L. Rev. 273, 281-84 (1978).

56/ See 104 Daily Wash. L. Rep. at 2252-53.

57/ Id. at 2252; cf. Roe v. Wade, 410 U.S. 113, 164 (1973) (state may not prohibit third trimester abortions that are "necessary to preserve the life or health of the mother").

58/ No. 25230 (Super. Ct., Spokane County, Washington, March 4, 1981) (verdict of the court acting in lieu of a jury).

for it. Given the urgent need of these persons for immediate access to marijuana, prompt action is needed.

The federal regulatory agencies are not capable of taking expeditious action that will make marijuana medically available; congressional action is necessary. There are several reasons for this.

First, under the Food, Drug and Cosmetic Act, the FDA cannot permit the introduction of a "new drug," such as marijuana, into interstate commerce unless a New Drug Application (NDA) for the drug has been filed with the agency, and reviewed and approved by the agency. ^{59/} No sponsor of an NDA for marijuana has come forward. Thus, even though the FDA now has in its files the results of at least five state-sponsored research studies unequivocally demonstrating the safety and efficacy of marijuana as an antiemetic, ^{60/} the FDA cannot, by statute, view these studies as demonstrating the medical value of marijuana — simply because there is no sponsor for an NDA for marijuana.

Second, it is highly unlikely that a private pharmaceutical sponsor for an NDA for marijuana will ever come forward. No drug company could obtain a patent for marijuana, since it is naturally occurring ^{61/} and no drug company can claim to have discovered its therapeutic properties. ^{62/} There is thus no profit potential and no economic incentive for a private drug company to sponsor an NDA for marijuana. Therefore, no sponsor is likely to be willing to bear the substantial research costs of pursuing an NDA for marijuana. ^{63/} The result is that the FDA may never have occasion to act on the substantial evidence that is now available concerning marijuana's medical value.

Third, even if a private sponsor for an NDA for marijuana did come forward, it would take many years for the FDA's approval procedures to be complied with. The FDA has estimated that it usually takes from four to eight years to develop and obtain approval for new, commercially marketable drugs, and sometimes as long as twelve years. ^{64/} However, the approval period for marijuana would be even longer, according to the FDA. Marijuana, as a naturally occurring organic substance, is composed of more than 450 chemical compounds, more than 60 of which are unique

^{59/} 21 U.S.C. § 355(a)-(b).

^{60/} See text and note at note 13 supra.

^{61/} See 35 U.S.C. §§ 161-164.

^{62/} See 35 U.S.C. § 101.

^{63/} It has been estimated that it generally costs between \$5 and \$15 million to obtain approval of an NDA. See W. Ross, Life/Death Ratios 121 (1977).

^{64/} Letter from Robert C. Wetherell, Jr., Associate FDA Commissioner for Legislation and Information to U.S. Representative Stewart B. McKinney (June 17, 1983).

to marijuana. 65/ Under FDA procedural regulations, before an NDA sponsor could begin clinical tests of marijuana, it would be required to develop a marijuana crop that consistently maintains stable proportions of these hundreds of compounds. 66/ The FDA estimates that this step alone would add two years to the approval time for a marijuana NDA because the sponsor would have to plant and harvest several marijuana crops to achieve enough standardization to enter clinical trials with the product. Moreover, the FDA suggests that even after such a delay there still might be "great difficulty" in achieving sufficient standardization of the components of marijuana to meet its procedural standards. 67/ Thus, marijuana more than likely could not be made medically available for 6-10 years under existing FDA procedures. This result is simply unacceptable, given the body of medical data that now exists based on the highly standardized marijuana already being produced by the federal government. 68/

Fourth, marijuana is subject to international treaty obligations concerning domestic cultivation and medicinal use that the FDA cannot satisfy through administrative action. The Single Convention on Narcotic Drugs (1961), to which the United States is a party, requires that a single government agency license all domestic producers of marijuana, specify the particular plots of land on which it is to be grown, and collect the crops of all domestic producers of marijuana. 69/ The FDA does not now have statutory authority to issue licenses to marijuana producers, to regulate the production of marijuana, or to collect crops of marijuana. Moreover, at present the authority to control marijuana production is split between three government agencies — FDA, DEA, and NIDA — which would contravene the Single Convention requirement of single agency control if domestic marijuana production for medical purposes were to commence. Federal legislation is necessary to conform U.S. production of marijuana to the requirements of international law.

Marijuana is trapped in a regulatory Catch-22. FDA procedures are designed to deal with profit-generating, synthetic drugs and are incompatible with non-patentable, chemically complex marijuana. Of course, the FDA has no power to

65/ Id.; Institute of Medicine, *Marijuana and Health*, supra note 5, at 13.

66/ See Wetherell letter, supra note 64; 21 C.F.R. § 314.111(a)(5)(i)(b) (1983).

67/ See Wetherell letter, supra note 64.

68/ Since 1968, the University of Mississippi has grown marijuana for research purposes pursuant to a contract from the National Institute on Drug Abuse. According to Dr. Carlton Turner, now White House Advisor on Drug Abuse and formerly Project Director of the University of Mississippi marijuana farm, the federal government is capable of providing standardized marijuana materials of "known composition." See Grass Farm Supplies Researchers with Marijuana of Known Composition, Drug Enforcement at 12 (March 1980) (reprinted from American Medical News, April 13, 1979)).

69/ The Single Convention on Narcotic Drugs, opened for signature March 30, 1961, 18 U.S.T. 1407, 30 T.I.A.S. No. 6298, 50 U.N.T.S. 151 (ratified by U.S. in 1967), Art. 28 ¶ 1, Art. 23.

create an exception to the NDA procedures for marijuana. Moreover, the FDA and other federal agencies are powerless to take the security and licensing measures required by international law. Federal legislation is needed to break through this regulatory impasse.

V. PENDING LEGISLATION

Legislation is now pending in the House of Representatives that would make marijuana available for use in the treatment of glaucoma and the nausea and vomiting caused by anti-cancer therapies. Representative Stewart McKinney of Connecticut introduced H.R. 2282 on March 23, 1983 and it now has strong bipartisan support, with more than 60 co-sponsors. In addition, there has been broad-based public support of H.R. 2282, with endorsements by the National Association of Attorneys General, 70/ the Episcopal Church, and many newspapers, including the New York Times, the Manchester (N.H.) Union-Leader, the Chicago Sun-Times, and the Miami Herald.

H.R. 2282, which has been referred to the House Subcommittee on Health and the Environment, would amend both the Controlled Substances Act and the Food, Drug and Cosmetic Act to permit the prescription of marijuana by qualified physicians solely for use in treating the nausea and vomiting caused by anti-cancer therapies and in treating glaucoma. H.R. 2282 would have no effect on the existing federal criminal penalties for the non-medical use of marijuana. Furthermore, consistent with the international treaty obligations of the United States, control of the cultivation and distribution of therapeutic marijuana would be placed under the direct control of a single government agency, a new office within the Department of Health and Human Services. That office would also be charged with the responsibility of ensuring a supply of marijuana adequate to meet the nation's therapeutic needs. The new office is directed to set a price for medicinal marijuana that will recoup the costs of its production and distribution.

The proposed recommendation does not commit the American Bar Association to support of any specific piece of legislation, including H.R. 2282. The pendency of such legislation does highlight, however, the need for prompt action by the Association.

70/ See note 1 supra.

CONCLUSION

The American Bar Association should recognize that persons who suffer from serious illnesses for which marijuana has a medically recognized therapeutic value have a right to be treated with marijuana under the supervision of a physician. The American Bar Association should also support federal legislation to establish a program under which physicians can treat such patients with marijuana, under controls adequate to prevent any diversion or other improper use of medicinal marijuana.

Respectfully submitted,

Martha W. Barnett
Chairperson
Section of Individual
Rights and
Responsibilities

February, 1984

No. _____

Submitting Entity

Section of Individual Rights and
Responsibilities

Submitted by

Martha W. Barnett, Chairperson**1. Summary of Recommendation**

The Recommendation states that the ABA recognizes the right of individuals suffering from serious illnesses for which marijuana has therapeutic value to be treated with marijuana under the supervision of a physician. The Recommendation also states that the ABA supports federal legislation that would establish a program to permit physicians to use marijuana in the treatment of serious illnesses for which it has recognized medical value.

2. Approval by Submitting Entity

This recommendation was approved by the I.R.&R. Council at its Executive Council Meeting in Washington, D.C. on October 21-22, 1983.

3. Background

This resolution has not previously been brought before the House of Delegates.

4. Need for Action at This Meeting

Federal legislation to permit medical use of marijuana is now pending in the House of Representatives. An indication of concern by the ABA about the use of criminal sanctions to deter medical use of marijuana could prompt expedited consideration of a legislative solution to this individual rights problem.

5. Status of Legislation

Although the Recommendation supports federal legislative action, it does not commit the ABA to support of any particular legislative proposal. H.R. 2282, which would permit limited medical use of marijuana, was introduced on March 23, 1983 and referred to the House Subcommittee on Health and the Environment. H.R. 2282 has more than 60 co-sponsors.

6. Financial Information

H.R. 2282 provides that a price should be charged for therapeutic marijuana that will recoup, within a reasonable time, the costs of producing and distributing therapeutic marijuana. The initial start-up expenditures that the program would require are not specified in the legislation.

7. Conflict of Interest

Douglas Herbert, who drafted this report, is an attorney at Steptoe & Johnson Chartered of Washington, D.C. Steptoe & Johnson represents, on a pro bono basis, the Alliance for Cannabis Therapeutics, a non-profit corporation that is seeking the enactment of federal legislation to permit the medical use of marijuana.

8. Referrals

A copy of this report with recommendations has been sent to each of the ABA's Member Sections and Divisions. A copy has also been sent to the Directors for the ABA Division of Communications, Governmental Affairs Group, Public Services Group and Professional Services Group.

American Bar Association

2588 *

05 AUG 1985

500

TO: Sally Determan, Cliff Stromberg, Dr. Carlton Turner, and Dr. Ian MacDonald

FROM: David G. Evans, Esq., Chair, Alcoholism and Drug Law Reform Committee *DE*

DATE: August 2, 1985

RE: Meeting Regarding Therapeutic Uses of Marijuana

As agreed, we will meet on August 20, 1985 at 1 PM at the law firm of Hogan and Hartson, 815 Connecticut Avenue, Washington, D.C. to discuss the resolution regarding therapeutic uses of marijuana.

I will be on vacation until August 19th. If you have any questions, please contact Gail Healy at (202) 245-1319.

DE/nd

609/292-8947
Evans N. & #

for my desk

OH

what do I need

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Department of Health and Human Services
Public Health Service
Food and Drug Administration

Memorandum

Date : July 19, 1985

To : Sue Daoulas
Drug Abuse Policy Office
Room 218, OEOB, White House
Washington, D.C. 20500

From : Edward C. Tocus, Ph.D. *Edward C. Tocus*
Chief, Drug Abuse Staff
HFN-123/FDA
5100 Fishers Lane
Rockville, Maryland 20857

Subject: Utilization of delta-9-THC and cannabis

The two pieces of information attached gives us some idea about the use of these substances. The listing of active IND's is a confidential figure since the investigators may not want to be revealed to the public. The shipment record shows very little cannabis being sent to the states. Since each unit is 300 cigarettes, for example, New Mexico in 1984 received a total of only 1800 cigarettes for the entire state. You will notice that most of the studies involve delta-9-THC, a number concern both substances and relatively few involve only cannabis. A number of the cannabis applications are for individual patients.

Concerning the delta-9-THC, I phoned Dr. Paul Vilk at the National Cancer Institute for his data. For further information his number is 496-5725. He gave me the following information;

2 1/2 mg capsules of delta-9-THC dispensed for 1984 by quarter was 15884, 15724, 14079 and 8748 to total 54435 capsules for a total of 1419 patients. 5 mg capsules dispensed for 1984 by quarter was 61337, 57227, 49740 and 41921 to total 210235 capsules for a total of 5205 patients. In 1984 there were 2603 physician investigators and 632 dispensing pharmacies. Records from NCI to state programs indicate for 1984 there were 147 pharmacies which received 693 bottles of 2.5 mg THC containing 25 capsules each and 1606 bottles of the 5 mg capsules. The National Cancer Institute authorized shipment from NIDA of a total of 4820 cigarettes to states.

NIDA reports the largest single request for cigarettes other than to the states is from a single investigator for a single patient (known to Dr. Turner). There are two single patient investigators listed under Miscellaneous Syndromes that receive small amounts of cigarettes on a regular basis.

It appears that our records indicate the scientific and therapeutic investigators are more interested in delta-9-THC and that relatively little cannabis cigarettes are being requested.

If you have questions please phone.

Totals:
264670 (cap)
6624 (pat)

SHIPMENTS OF MARIJUANA CIGARETTES TO STATE ANTIEMETIC PROGRAMS

in Units of 300 Cigarettes

STATE	1980				1981				1982				1983				1984			
	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th	1st	2nd	3rd	4th
AZ (21.25)																				
CA				* 21	58.5	17.5	10	1	0	3	0.12		0.27	3.25	1.33	2		0.30	2.16	0.77
CO (3)																				
FL (20)		*2	0	0	1															
GA				* 12							4		0	3	1					
IL																				
LA (29)																				
MI		*3	2	6	8**	3	0	6				1								
NE (23)																				
NM (46)	*0	0	1	1	2	2	2	2	0	2			2	33				3		3
NY									*20	0	0	0	20							6
OH (24)																				
OR (21)			*0	2	12	6	4													
TN											3	3	3	3	0	3		3	3	
VT																				
WA (19)	*3	0	1	15				**												
WV (306.25) 91,860	3	5 (20,700)	4	57 69	81.5	28.5 (46,500)	16	29	0	8	7.12	24	5.27	9.25	5.83	2 21.85	3	3.3	8.16	6.77 21.23

* IND FOR CHEMOTHERAPEUTIC PROGRAM APPROVED BY FDA
 * IND PROVISION FOR GLAUCOMA RESEARCH APPROVED

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