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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CONTENTS

I.	INTRODUCTION	1
II.	RECOMMENDED RULING	7
III.	ISSUES	7
IV.	STATUTORY REQUIREMENTS FOR SCHEDULING	8
V.	ACCEPTED MEDICAL USE IN TREATEMENT - CHEMOTHERAPY	10
	Findings of Fact	10
	Discussion	26
VI.	ACCEPTED MEDICAL USE IN TREATMENT - GLAUCOMA	35
	Findings of Fact	35
	Discussion	38
VII.	ACCEPTED MEDICAL USE IN TREATMENT - MULTIPLE SCLEROSIS, SPASTICITY & HYPERPARATHYROIDISM	40
	Findings of Fact	40
	Discussion	54
VIII.	ACCEPTED SAFETY FOR USE UNDER MEDICAL SUPERVISION	56
	Findings of Fact	56
	Discussion	65
IX.	CONCLUSIONS AND RECOMMENDED DECISION	67
	CERTIFICATION OF SERVICE	69

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I.

INTRODUCTION

This is a rulemaking pursuant to the Administrative Procedure Act, 5 U.S.C. § 551, et seq., to determine whether the marijuana plant (Cannabis sativa L) considered as a whole may lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act (the Act), 21 U.S.C. § 801, et seq. None of the parties is seeking to "legalize" marijuana generally or for recreational purposes. Placement in Schedule II would mean, essentially, that physicians in the United States would not violate Federal law by prescribing marijuana for their patients for legitimate therapeutic purposes. It is contrary to Federal law for physicians to do this as long as marijuana remains in Schedule I.

This proceeding had its origins on May 18, 1972 when the National Organization for the Reform of Marijuana Laws (NORML) and two other groups submitted a petition to the Bureau of Narcotics and Dangerous Drugs (BNDD)[1], predecessor

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[1] The powers and authority granted by the Act to the Attorney General were delegated to the Director of BNDD and subsequently to the Administrator of DEA. 28 C.F.R. § 0.100, et seq.

agency to the Drug Enforcement Administration (DEA or the Agency), asking that marijuana be removed from Schedule I and freed of all controls entirely, or be transferred from Schedule I to Schedule V where it would be subject to only minimal controls. The Act by its terms had placed marijuana in Schedule I thereby declaring, as a matter of law, that it had no legitimate use in therapy in the United States and subjecting the substance to the strictest level of controls. The Act had been in effect for just over one year when NORML submitted its 1972 petition.

On September 1, 1972 the Director of BNDD announced his refusal to accept the petition for filing, stating that he was not authorized to institute proceedings for the action requested because of the provisions of the Single Convention on Narcotic Drugs, 1961. NORML appealed this action to the United States Court of Appeals for the District of Columbia Circuit. The court held that the Director had erred in rejecting the petition without "a reflective consideration and analysis," observing that the Director's refusal "was not the kind of agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process." NORML v. Ingersoll, 162 U.S. App. D.C. 67, 497 F.2d 654, 659 (1974). The court remanded the matter in January 1974 for further proceedings not inconsistent with its opinion, "to be denominated a consideration on the merits." Id.

A three-day hearing was held at DEA[2] by Administrative Law Judge Lewis Parker in January 1975. The judge found in NORML's favor on several issues but the Acting Administrator of DEA entered a final order denying NORML's petition "in all respects." NORML again petitioned the court for review. Finding fault

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2 DEA became the successor agency to BNDD in a reorganization carried out pursuant to Reorganization Plan No. 2 of 1973, eff. July 1, 1973. 38 Fed. Reg. 15932 (1973).

with DEA's final order the court again remanded for further proceedings not inconsistent with its opinion. NORML v. DEA, 182 U.S. App. D.C. 114, 559 F.2d 735 (1977). The Court directed the then-Acting Administrator of DEA to refer NORML's petition to the Secretary of the Department of Health, Education and Welfare (HEW) for findings and, thereafter, to comply with the rulemaking procedures outlined in the Act at 21 U.S.C. § 811 (a) and (b).

On remand the Administrator of DEA referred NORML's petition to HEW for scientific and medical evaluation. On June 4, 1979 the Secretary of HEW advised the Administrator of the results of the HEW evaluation and recommended that marijuana remain in Schedule I. Without holding any further hearing the Administrator of DEA proceeded to issue a final order ten days later denying NORML's petition and declining to initiate proceedings to transfer marijuana from Schedule I. 44 Fed. Reg. 36123 (1979). NORML went back to the Court of Appeals.

When the case was called for oral argument there was discussion of the then-present status of the matter. DEA had moved for a partial remand. The court found that "reconsideration of all the issues in this case would be appropriate" and again remanded it to DEA, observing: "We regrettably find it necessary to remind respondents [DEA and HEW] of an agency's obligation on remand not to 'do anything which is contrary to either the letter or spirit of the mandate construed in the light of the opinion of [the] court deciding the case.'" (Citations omitted.) NORML v. DEA, et al., No. 79-1660, United States Court of Appeals for the District of Columbia Circuit, unpublished order filed October 16, 1980. DEA was directed to refer all the substances at issue to the Department of Health and Human Services (HHS), successor agency to HEW,for scien-

tific and medical findings and recommendations on scheduling. DEA did so and HHS has responded. In a letter dated April 1, 1986 the then-Acting Deputy Administrator of DEA requested this administrative law judge to commence hearing procedures as to the proposed rescheduling of marijuana and its components.

After the judge conferred with counsel for NORML and DEA, a notice was published in the Federal Register on June 24, 1986 announcing that hearings would be held on NORML's petition for the rescheduling of marijuana and its components commencing on August 21, 1986 and giving any interested person who desired to participate the opportunity to do so. 51 Fed. Reg. 22946 (1986).

Of the three original petitioning organizations in 1972 only NORML is a party to the present proceeding. In addition the following entities responded to the Federal Register notice and have become parties, participating to varying degrees: the Alliance for Cannabis Therapeutics (ACT), Cannabis Corporation of America (CCA) and Carl Eric Olsen, all seeking transfer of marijuana to Schedule II; the Agency, National Federation of Parents for Drug-Free Youth (NFP) and the International Association of Chiefs of Police (IACP), all contending that marijuana should remain in Schedule I.

Preliminary prehearing sessions were held on August 21 and December 5, 1986 and on February 20, 1987.[3] During the preliminary stages, on January 20, 1987, NORML filed an amended petition for rescheduling. This new petition abandoned NORML's previous requests for the complete de-scheduling of marijuana or rescheduling to Schedule V. It asks only that marijuana be placed in Schedule II.

At a prehearing conference on February 20, 1987 this amended petition was

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[3] Transcripts of these three preliminary prehearing sessions are included in the record.

discussed.[4] All parties present stipulated, for the purpose of this proceeding, that marijuana has a high potential for abuse and that abuse of the marijuana plant may lead to severe psychological or physical dependence. They then agreed that the principal issue in this proceeding would be stated thus:

> Whether the marijuana plant, considered as a whole,[5] may

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4 The transcript of this prehearing conference and of the subsequent hearing sessions comprise 15 volumes numbered as follows:

Vol. I - Prehearing Conference, October 16, 1987

Vol. II - Cross Examination, November 19, 1987

Vol. III - Cross Examination, December 8, 1987

Vol. IV - Cross Examination, December 9, 1987

Vol. V - Cross Examination, January 5, 1988

Vol. VI - Cross Examination, January 6, 1988

Vol. VII - Cross Examination, January 7, 1988

Vol. VIII - Cross Examination, January 26, 1988

Vol. IX - Cross Examination, January 27, 1988

Vol. X - Cross Examination, January 28, 1988

Vol. XI - Cross Examination, January 29, 1988

Vol. XII - Cross Examination, February 2, 1988

Vol. XIII - Cross Examination, February 4, 1988

Vol. XIV - Cross Examination, February 5, 1988

Vol. XV - Oral Argument, June 10, 1988

Pages of the transcript are cited herein by volume and page, e.g. "Tr. V-96"; "G-" identifies an Agency exhibit.

5 Throughout this opinion the term "marijuana" refers to "the marijuana plant, considered as a whole".

lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act.

Two subsidiary issues were agreed on, as follows:

1. Whether the marijuana plant has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.

2. Whether there is a lack of accepted safety for use of the marijuana plant under medical supervision.

As stated above, the parties favoring transfer from Schedule I to Schedule II are NORML, ACT, CCA and Carl Eric Olsen. Those favoring retaining marijuana in Schedule I are the Agency, NFP and IACP.

During the Spring and Summer of 1987 the parties identified their witnesses and put the direct examination testimony of each witness in writing in affidavit form. Copies of these affidavits were exchanged. Similarly, the parties assembled their proposed exhibits and exchanged copies. Opportunity was provided for each party to submit objections to the direct examination testimony and exhibits proffered by the others. The objections submitted were considered by the administrative law judge and ruled on. The testimony and exhibits not excluded were admitted into the record. Thereafter hearing sessions were held at which witnesses were subjected to cross-examination. These sessions were held in New Orleans, Louisiana on November 18 and 19, 1987; in San Francisco, California on December 8 and 9, 1987; and in Washington, D.C. on January 5 through 8 and 26 through 29, and on February 2, 4 and 5, 1988. The parties have submitted proposed findings and conclusions and briefs. Oral arguments were heard by the judge on June 10, 1988 in Washington.

II.

RECOMMENDED RULING

It is recommended that the proposed findings and conclusions submitted by the parties to the administrative law judge be rejected by the Administrator except to the extent they are included in those hereinafter set forth, for the reason that they are irrelevant or unduly repetitious or not supported by a preponderance of the evidence. 21 C.F.R. § 1316.65(a)(1).

III.

ISSUES

As noted above, the agreed issues are as follows:

Principle issue:

Whether the marijuana plant, considered as a whole, may lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act.

Subsidiary issues:

1. Whether the marijuana plant has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.

2. Whether there is a lack of accepted safety for use of the marijuana plant under medical supervision.

IV.

STATUTORY REQUIREMENTS FOR SCHEDULING

The Act provides (21 U.S.C. § 812(b)) that a drug or other substance may not be placed in any schedule unless certain specified findings are made with respect to it. The findings required for Schedule I and Schedule II are as follows:

> Schedule I. -
>
> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.
>
> Schedule II. -
>
> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
>
> (C) Abuse of the drug or other substances [sic] may lead to severe psychological or physical dependence.

As noted above the parties have stipulated, for the purpose of this proceeding, that marijuana has a high potential for abuse and that abuse of it may lead to severe psychological or physical dependence. Thus the dispute between the two sides in this proceeding is narrowed to whether or not marijuana has a currently accepted medical use in treatment in the United States, and whether or not there is a lack of accepted safety for use of marijuana under medical supervision.

The issues as framed here contemplate marijuana's being placed only in

Schedule I or Schedule II. The criteria for placement in any of the other three schedules established by the Act are irrelevant to this proceeding.

V.

ACCEPTED MEDICAL USE IN TREATMENT

- CHEMOTHERAPY

With respect to whether or not marijuana has a "currently accepted medical use in treatment in the United States" for chemotherapy patients, the record shows the following facts to be uncontroverted.

Findings Of Fact

1. One of the most serious problems experienced by cancer patients undergoing chemotherapy for their cancer is severe nausea and vomiting caused by their reaction to the toxic (poisonous) chemicals administered to them in the course of this treatment. This nausea and vomiting at times becomes life threatening. The therapy itself creates a tremendous strain on the body. Some patients cannot tolerate the severe nausea and vomiting and discontinue treatment. Beginning in the 1970's there was considerable doctor-to-doctor communication in the United States concerning patients known by their doctors to be surreptitiously using marijuana with notable success to overcome or lessen their nausea and vomiting.

2. Young patients generally achieve better control over nausea and vomiting from smoking marijuana than do older patients, particularly when the older patient has not been provided with detailed information on how to smoke marijuana.

3. Marijuana cigarettes in many cases are superior to synthetic THC capsules in reducing chemotherapy-induced nausea and vomiting. Marijuana

cigarettes have an important, clear advantage over synthetic THC capsules in that the natural marijuana is inhaled and generally takes effect more quickly than the synthetic capsule which is ingested and must be processed through the digestive system before it takes effect.

4. Attempting to orally administer the synthetic THC capsule to a vomiting patient presents obvious problems - it is vomited right back up before it can have any effect.

5. Many physicians, some engaged in medical practice and some teaching in medical schools, have accepted smoking marijuana as effective in controlling or reducing the severe nausea and vomiting (emesis) experienced by some cancer patients undergoing chemotherapy for cancer.

6. Such physicians include board-certified internists, oncologists and psychiatrists. (Oncology is the treatment of cancer through the use of highly toxic chemicals, or chemotherapy.)

7. Doctors who have come to accept the usefulness of marijuana in controlling or reducing emesis resulting from chemotherapy have done so as the result of reading reports of studies and anecdotal reports in their professional literature, and as the result of observing patients and listening to reports directly from patients.

8. Some cancer patients who have acknowledged to doctors that they smoke marijuana for emesis control have indicated in their discussions that, although they may have first smoked marijuana recreationally, they accidentally found that doing so helped reduce the emesis resulting from their chemotherapy. They consistently indicated that they felt better and got symptomatic relief from the intense nausea and vomiting caused by the chemotherapy. These patients

were no longer simply getting high, but were engaged in medically treating their illness, albeit with an illegal substance. Other chemotherapy patients began smoking marijuana to control their emesis only after hearing reports that the practice had proven helpful to others. Such patients had not smoked marijuana recreationally.

9. This successful use of marijuana has given many cancer chemotherapy patients a much more positive outlook on their overall treatment, once they were relieved of the debilitating, exhausting and extremely unpleasant nausea and vomiting previously resulting from their chemotherapy treatment.

10. In about December 1977 the previously underground patient practice of using marijuana to control emesis burst into the public media in New Mexico when a young cancer patient, Lynn Pearson, began publicly to discuss his use of marijuana. Mr. Pearson besought the New Mexico legislature to pass legislation making marijuana available legally to seriously ill patients whom it might help. As a result, professionals in the public health sector in New Mexico more closely examined how marijuana might be made legally available to assist in meeting what now openly appeared to be a widely recognized patient need.

11. In many cases doctors have found that, in addition to suppressing nausea and vomiting, smoking marijuana is a highly successful appetite stimulant. The importance of appetite stimulation in cancer therapy cannot be overstated. Patients receiving chemotherapy often lose tremendous amounts of weight. They endanger their lives because they lose interest in food and in eating. The resulting sharp reduction in weight may well affect their prognosis. Marijuana smoking induces some patients to eat. The benefits are obvious, doctors have found. There is no significant loss of weight. Some patients will gain weight.

This allows them to retain strength and makes them better able to fight the cancer. Pyschologically, patients who can continue to eat even while receiving chemotherapy maintain a balanced outlook and are better able to cope with their disease and its treatment, doctors have found.

12. Synthetic anti-emetic agents have been in existence and utilized for a number of years. Since about 1980 some new synthetic agents have been developed which appear to be more effective in controlling and reducing chemotherapy-induced nausea and vomiting than were some of those available in the 1970's. But marijuana still is found more effective for this purpose in some people than any of the synthetic agents, even the newer ones.

13. By the late 1970's in the Washington, D.C. area there was a growing recognition among health care professionals and the public that marijuana had therapeutic value in reducing the adverse effects of some chemotherapy treatments. With this increasing public awareness came increasing pressure from patients on doctors for information about marijuana and its therapeutic uses. Many patients moved into forms of unsupervised self-treatment. While such self-treatment often proved very effective, it has certain hazards, ranging from arrest for purchase or use of an illegal drug to possibly serious medical complications from contaminated sources or adulterated materials. Yet, some patients are willing to run these risks to obtain relief from the debilitating nausea and vomiting caused by their chemotherapy treatments.

14. Every oncologist known to one Washington, D.C. practicing internist and board-certified oncologist has had patients who used marijuana with great success to prevent or diminish chemotherapy-induced nausea and vomiting. Chemotherapy patients reporting directly to that Washington doctor that they

have smoked marijuana medicinally vomit less and eat better than patients who do not smoke it. By gaining control over their severe nausea and vomiting these patients undergo a change of mood and have a better mental outlook than patients who, using the standard anti-emetic drugs, are unable to gain such control.

15. The vomiting induced by chemotherapeutic drugs may last up to four days following the chemotherapy treatment. The vomiting can be intense, protracted and, in some instances, is unendurable. The nausea which follows such vomiting is also deep and prolonged. Nausea may prevent a patient from taking regular food or even much water for periods of weeks at a time.

16. Nausea and vomiting of this severity degrades the quality of life for these patients, weakening them physically, and destroying the will to fight the cancer. A desire to end the chemotherapy treatment in order to escape the emesis can supersede the will to live. Thus the emesis, itself, can truly be considered a life-threatening consequence of many cancer treatments. Doctors have known such cases to occur. Doctors have known other cases where marijuana smoking has enabled the patient to endure, and thus continue, chemotherapy treatments with the result that the cancer has gone into remission and the patient has returned to a full, active satisfying life.

17. In San Francisco chemotherapy patients were surreptitiously using marijuana to control emesis by the early 1970's. By 1976 virtually every young cancer patient receiving chemotherapy at the University of California in San Francisco was using marijuana to control emesis with great success. The use of marijuana for this purpose had become generally accepted by the patients and increasingly by their physicians as a valid and effective form of treatment. This was particularly true for younger cancer patients, somewhat less common for

older ones. By 1979 about 25% to 30% of the patients seen by one San Francisco oncologist were using marijuana to control emesis, about 45 to 50 patients per year. Such percentages and numbers vary from city to city. A doctor in Kansas City who sees about 150 to 200 new cancer patients per year found that over the 15 years 1972 to 1987 about 5% of the patients he saw, or a total of about 75, used marijuana medicinally.

18. By 1987 marijuana no longer generated the intense interest in the world of oncology that it had previously, but it remains a viable tool, commonly employed, in the medical treatment of chemotherapy patients. There has evolved an unwritten but accepted standard of treatment within the community of oncologists in the San Francisco, California area which readily accepts the use of marijuana.

19. As of the Spring of 1987 in the San Francisco area, patients receiving chemotherapy commonly smoked marijuana in hospitals during their treatments. This in-hospital use, which takes place in rooms behind closed doors, does not bother staff, is expected by physicians and welcomed by nurses who, instead of having to run back and forth with containers of vomit, can treat patients whose emesis is better controlled than it would be without marijuana. Medical institutions in the Bay area where use of marijuana obtained on the streets is quite common, although discrete, include the University of California at San Francisco Hospital, the Mount Zion Hospital and the Franklin Hospital. In effect, marijuana is readily accepted throughout the oncologic community in the Bay area for its benefits in connection with chemotherapy. The same situation exists in other large metropolitan areas of the United States.

20. About 50% of the patients seen by one San Francisco oncologist

during the year 1987 were smoking marijuana medicinally. This is about 90 to 95 individuals. This number is higher than during the previous ten years due to the nature of this physician's practice which includes patients from the "tenderloin" area of San Francisco, many of whom are suffering from AIDS-related lymphosarcoma. These patients smoke marijuana to control their nausea and vomiting, not to "get high." They self-titrate, i.e., smoke the marijuana only as long as needed to overcome the nausea, to prevent vomiting.

21. The State of New Mexico set up a program in 1978 to make marijuana available to cancer patients pursuant to an act of the State legislature. The legislature had accepted marijuana as having medical use in treatment. It overwhelmingly passed this legislation so as to make marijuana available for use in therapy, not just for research. Marijuana and synthetic THC were given to patients, administered under medical supervision, to control or reduce emesis. The marijuana was in the form of cigarettes obtained from the Federal government. The program operated from 1979 until 1986, when funding for it was terminated by the State. During those seven years about 250 cancer patients in New Mexico received either marijuana cigarettes or THC. Twenty or 25 physicians in New Mexico sought and obtained marijuana cigarettes or THC for their cancer patients during that period. All of the oncologists in New Mexico accepted marijuana as effective for some of their patients. At least ten hospitals were involved in this program in New Mexico, in which cancer patients smoked their marijuana cigarettes. The hospitals accepted this medicinal marijuana smoking by patients. Voluminous reports filed by the participating physicians make it clear that marijuana is a highly effective anti-emetic substance. It was found in the New Mexico program to be far superior to the best available conventional

anti-emetic drug, Compazine, and clearly superior to synthetic THC pills. More than 90% of the patients who received marijuana within the New Mexico program reported significant or total relief from nausea and vomiting. Before the program began cancer patients were surreptitiously smoking marijuana in New Mexico to lessen or control their emesis resulting from chemotherapy treatments. They reported to physicians that it was successful for this purpose. Physicians were aware that this was going on.

22. In 1978 the Louisiana legislature became one of the first-State legislatures in the nation to recognize the efficacy of marijuana in controlling emesis by enacting legislation intended to make marijuana available by prescription for therapeutic use by chemotherapy patients. This enactment shows that there was widespread acceptance in Louisiana of the therapeutic value of marijuana. After a State Marijuana Prescription Review Board was established, pursuant to that legislation, it became apparent that, because of Federal restrictions, marijuana could be obtained legally only for use in cumbersome, formal research programs. Eventually a research program was entered into by the State, utilizing synthetic THC, but without much enthusiasm, since most professionals who had wanted to use marijuana clinically, to treat patients, had neither the time, resources nor inclination to get involved in this limited, formal study. The original purpose of the Louisiana legislation was frustrated by the Federal authorities. Some patients, who had hoped to obtain marijuana for medical use legally after enactment of the State legislation, went outside the law and obtained it illicitly. Some physicians in Louisiana accept marijuana as having a distinct medical value in the treatment of the nausea and vomiting associated with certain types of chemotherapy treatments.

23. In 1980 the State of Georgia enacted legislation authorizing a therapeutic research program for the evaluation of marijuana as a medically recognized therapeutic substance. Its enactment was supported by letters from a number of Georgia oncologists and other Georgia physicians, including the Chief of Oncology at Grady Hospital and staff oncologists at Emory University Medical Clinic. Sponsors of the legislation orginally intended the enactment of a law making marijuana available for clinical, therapeutic use by patients. The bill was referred to as the "Marijuana-as-Medicine" bill. The final legislation was crafted, however, of necessity, merely to set up a research program in order to obtain marijuana from the one legitimate source available - the Federal Government, which would not make the substance available for any purpose other than conducting a research program. The act was passed by an overwhelming majority in the lower house of the legislature and unanimously in the Senate. In January 1983 an evaluation of the program, which by then had had 44 evaluable marijuana smoking patient-participants, accepted marijuana smoking as being an effective anti-emetic agent.

24. In Boston, Massachusetts in 1977 a nurse in a hospital suggested to a chemotherapy patient, suffering greatly from the therapy and at the point of refusing further treatment, that smoking marijuana might help relieve his nausea and vomiting. The patient's doctor, when asked about it later, stated that many of his younger patients were smoking marijuana. Those who did so seemed to have less trouble with nausea and vomiting. The patient in question obtained some marijuana and smoked it, in the hospital, immediately before his next chemotherapy treatment. Doctors, nurses and orderlies coming into the room as he finished smoking realized what the patient had been doing. None of them

made any comment. The marijuana was completely successful with this patient, who accepted it as effective in controlling his nausea and vomiting. Instead of being sick for weeks following chemotherapy, and having trouble going to work, as had been the case, the patient was ready to return to work 48 hours after that chemotherapy treatment. The patient thereafter always smoked marijuana, in the hospital, before chemotherapy. The doctors were aware of it, openly approved of it and encouraged him to continue. The patient resumed eating regular meals and regained lost weight, his mood improved markedly, he became more active and outgoing and began doing things together with his wife that he had not done since beginning chemotherapy.

25. During the remaining two years of this patient's life, before his cancer ended it, he came to know other cancer patients who were smoking marijuana to relieve the adverse effects of their chemotherapy. Most of these patients had learned about using marijuana medically from their doctors who, having accepted its effectiveness, subtly encouraged them to use it.

26. A Boston psychiatrist and professor, who travels about the country, has found a minor conspiracy to break the law among oncologists and nurses in every oncology center he has visited to let patients smoke marijuana before and during cancer chemotherapy. He has talked with dozens of these health care oncologists who encourage their patients to do this and who regard this as an accepted medical usage of marijuana. He has known nurses who have obtained marijuana for patients unable to obtain it for themselves.

27. A cancer patient residing in Beaverton, Michigan smoked marijuana medicinally in the nearby hospital where he was undergoing chemotherapy from early 1979 until he died of his cancer in October of that year. He smoked it in

his hospital room after his parents made arrangements with the hospital for him to do so. Smoking marijuana controlled his post-chemotherapy nausea and vomiting, enabled him to eat regular meals again with his family, and he became outgoing and talkative. His parents accepted his marijuana smoking as effective and helpful. Two clergymen, among others, brought marijuana to this patient's home. Many people at the hospital supported the patient's marijuana therapy, none doubted its helpfulness or discouraged it. This patient was asked for help by other patients. He taught some who lived nearby how to form the marijuana cigarettes and properly inhale the smoke to obtain relief from nausea and vomiting. When an article about this patient's smoking marijuana appeared in a local newspaper, he and his family heard from many other cancer patients who were doing the same. Most of them made an effort to inform their doctors. Most physicians who knew their patients smoked marijuana medicinally approved, accepting marijuana's therapeutic helpfulness in reducing nausea and vomiting.

28. In October 1979 the Michigan legislature enacted legislation whose underlying purpose was to make marijuana available therapeutically for cancer patients and others. The State Senate passed the bill 29-5, the House of Representatives 100-0. In March 1982 the Michigan legislature passed a resolution asking the Federal Congress to try to alter Federal policies which prevent physicians from prescribing marijuana for legitimate medical applications and prohibit its use in medical treatments.

29. In Denver, Colorado a teenage cancer patient has been smoking marijuana to control nausea and vomiting since 1986. He has done this in his hospital room both before and after chemotherapy. His doctor and hospital staff know he does this. The doctor has stated that he would prescribe marijuana for

this patient if it were legal to do so. Other patients in the Denver area smoke marijuana for the same purpose. This patient's doctor, and nurses with whom he comes in contact, understand that cancer patients smoke marijuana to reduce or control emesis. They accept it.

30. In late 1980 a three year old boy was brought by his parents to a hospital in Spokane, Washington. The child was diagnosed as having cancer. Surgery was performed. Chemotherapy was begun. The child became extremely nauseated and vomited for days after each chemotherapy treatment. He could not eat regularly. He lost strength. He lost weight. His body's ability to ward off common infections, other life-threatening infections, significantly decreased. Chemotherapy's after-effects caused the child great suffering. They caused his watching parents great suffering. Several standard, available anti-emetic agents were tried by the child's doctors. None of them succeeded in controlling his nausea or vomiting. Learning of the existence of research studies with THC or marijuana the parents asked the child's doctor to arrange for their son to be the subject of such a study so that he might have access to marijuana. The doctor refused, citing the volume of paperwork and record-keeping detail required in such programs and his lack of administrative personnel to handle it.

31. The child's mother read an article about marijuana smoking helping chemotherapy patients. She obtained some marijuana from friends. She baked cookies for her child with marijuana in them. She made tea for him with marijuana in it. When the child ate these cookies or drank this tea in connection with his chemotherapy, he did not vomit. His strength returned. He regained lost weight. His spirits revived. The parents told the doctors and nurses at the hospital of their giving marijuana to their child. None objected.

They all accepted smoking marijuana as effective in controlling chemotherapy-induced nausea and vomiting. They were interested to see the results of the cookies.

32. Soon this child was riding a tricycle in the hallways of the Spokane hospital shortly after his chemotherapy treatments while other children there were still vomiting into pans, tied to intervenous bottles in an attempt to re-hydrate them, to replace the liquids they were vomiting up. Parents of some of the other patients asked the parents of this "lively" child how he seemed to tolerate his chemotherapy so well. They told of the marijuana use. Of those parents who began giving marijuana to their children, none ever reported back encountering any adverse side effects. In the vast majority of these cases, the other parents reported significant reduction in their children's vomiting and appetite stimulation as the result of marijuana. The staff, doctors and nurses at the hospital knew of this passing on of information about marijuana to other parents. They approved. They never told the first parents to hide their son's medicinal use of marijuana. They accepted the effectiveness of the cookies and the tea containing marijuana.

33. The first child's cancer went into remission. Then it returned and spread. Emotionally drained, the parents moved the family back to San Diego, California to be near their own parents. Their son was admitted to a hospital in San Diego. The parents informed the doctors, nurses and social workers there of their son's therapeutic use of marijuana. No one objected. The child's doctor in San Diego strongly supported the parent's giving marijuana to him. Here in California, as in Spokane, other parents noticed the striking difference between their children after chemotherarpy and the first child.

Other parents asked the parents of the first child about it, were told of the use of marijuana, tried it with their children, and saw dramatic improvement. They accepted its effectiveness. In the words of the mother of the first child: ". . . When your kid is riding a tricycle while his other hospital buddies are hooked up to IV needles, their heads hung over vomiting buckets, you don't need a federal agency to tell you marijuana is effective. The evidence is in front of you, so stark it cannot be ignored."[6]

34. There is at least one hospital in Tucson, Arizona where medicinal use of marijuana by chemotherapy patients is encouraged by the nursing staff and some physicians.

35. In addition to the physicians mentioned in the Findings above, mostly oncologists and other practicioners, the following doctors and health care professionals, representing several different areas of expertise, accept marijuana as medically useful in controlling or reducing emesis and testified to that effect in these proceedings:

a. George Goldstein, Ph.D., psychologist, Secretary of Health for the State of New Mexico from 1978 to 1983 and chief administrator in the implementation of the New Mexico program utilizing marijuana;

b Dr. Daniel Danzak, psychiatrist and former head of the New Mexico program utilizing marijuana;

c. Dr. Tod Mikuriya, psychiatrist and editor of Marijuana: Medical Papers, a book presenting an historical perspective of marijuana's medical use;

d. Dr. Norman Zinberg, general psychiatrist and Professor of Psychiatry at Harvard Medical School since 1951;

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6 Affidavit of Janet Andrews, ACT rebuttal witness, par. 98.

e. Dr. John Morgan, psychopharmacologist, Board-certified in Internal Medicine, full Professor and Director of Pharmacology at the City University of New York;

f. Dr. Phillip Jobe, neuropsychopharmacologist with a practice in Illinois and former Professor of Pharmacology and Psychiatry at the Louisiana State University School of Medicine in Shreveport, Louisiana, from 1974 to 1984;

g. Dr. Arthur Kaufman, formerly a general practitioner in Maryland, currently Vice-President of a private medical consulting group involved in the evaluation of the quality of care of all the U.S. military hospitals throughout the world, who has had extensive experience in drug abuse treatment and rehabilitation programs;

h. Dr. J. Thomas Ungerleider, a full Professor of Psychiatry at the University of California in Los Angeles with extensive experience in research on the medical use of drugs;

i. Dr. Andrew Weil, ethnopharmacologist, Associate Director of Social Perspectives in Medicine at the College of Medicine at the University of Arizona, with extensive research on medicinal plants; and

j. Dr. Lester Grinspoon, a practicing psychiatrist and Associate Professor at Harvard Medical School.

36. Certain law enforcement authorities have been outspoken in their acceptance of marijuana as an antiemetic agent. Robert T. Stephan, Attorney General of the State of Kansas, and himself a former cancer patient, said of chemotherapy in his affidavit in this record: "The treatment becomes a terror." His cancer is now in remission. He came to know a number of health care professionals whose medical judgment he respected. They had accepted marijuana

as having medical use in treatment. He was elected Vice President of the National Association of Attorneys General (NAAG) in 1983. He was instrumental in the adoption by that body in June 1983 of a resolution acknowledging the efficacy of marijuana for cancer and glaucoma patients. The resolution expressed the support of NAAG for legislation then pending in the Congress to make marijuana available on prescription to cancer and glaucoma patients. The resolution was adopted by an overwhelming margin. NAAG's President, the Attorney General of Montana, issued a statement that marijuana does have accepted medical uses and is improperly classified at present. The Chairman of NAAG's Criminal Law and Law Enforcement Committee, the Attorney General of Pennsylvania, issued a statement emphasizing that the proposed rescheduling of marijuana would in no way affect or impede existing efforts by law enforcement authorities to crack down on illegal drug trafficking.

37. At least one court has accepted marijuana as having medical use in treatment for chemotherapy patients. On January 23, 1978 the Superior Court of Imperial County, California issued orders authorizing a cancer patient to possess and use marijuana for therapeutic purposes under the direction of a physician. Another order authorized and directed the Sheriff of the county to release marijuana from supplies on hand and deliver it to that patient in such form as to be usable in the form of cigarettes.

38. During the period 1978-1980 polls were taken to ascertain the degree of public acceptance of marijuana as effective in treating cancer and glaucoma patients. A poll in Nebraska brought slightly over 1,000 responses - 83% favored making marijuana available by prescription, 12% were opposed, 5% were undecided. A poll in Pennsylvania elicited 1,008 responses - 83.1% favored availability by prescription, 12.2% were opposed, 4.7% were undecided. These

two surveys were conducted by professional polling companies. The Detroit Free Press conducted a telephone poll in which 85.4% of those responding favored access to marijuana by prescription. In the State of Washington the State Medical Association conducted a poll in which 80% of the doctors belonging to the Association favored controlled availability of marijuana for medical purposes.

Discussion

From the foregoing uncontroverted facts it is clear beyond any question that many people find marijuana to have, in the words of the Act, an "accepted medical use in treatment in the United States" in effecting relief for cancer patients. Oncologists, physicians treating cancer patients, accept this. Other medical practitioners and researchers accept this. Medical faculty professors accept it. Nurses performing hands-on patient care accept it.

Patients accept it. As counsel for CCA perceptively pointed out at oral argument, acceptance by the patient is of vital importance. Doctors accept a therapeutic agent or process only if it "works" for the patient. If the patient does not accept, the doctor cannot administer the treatment. The patient's informed consent is vital. The doctor ascertains the patient's acceptance by observing and listening to the patient. Acceptance by the doctor depends on what he sees in the patient and hears from the patient. Unquestionably, patients in large numbers have accepted marijuana as useful in treating their emesis. The have found that it "works". Doctors, evaluating their patients, can have no basis more sound than that for their own acceptance.

Of relevance, also, is the acceptance of marijuana by state attorneys-

general, officials whose primary concern is law enforcement. A large number of them have no fear that placing marijuana in Schedule II, thus making it available for legitimate therapy, will in any way impede existing efforts of law enforcement authorities to crack down on illegal drug trafficking.

The Act does not specify by whom a drug or substance must be "accepted [for] medical use in treatment" in order to meet the Act's "accepted" requirement for placement in Schedule II. Department of Justice witnesses told the Congress during hearings in 1970 preceeding passage of the Act that "the medical profession" would make this determination, that the matter would be "determined by the medical community." The Deputy Chief Counsel of BNDD, whose office had written the bill with this language in it, told the House subcommittee that "this basic determination . . . is not made by any part of the federal government. It is made by the medical community as to whether or not the drug has medical use or doesn't".[7]

No one would seriously contend that these Justice Department witnesses meant that the entire medical community would have to be in agreement on the usefulness of a drug or substance. Seldom, if ever, do all lawyers agree on a point of law. Seldom, if ever, do all doctors agree on a medical question. How many are required here? A majority of 51%? It would be unrealistic to attempt a plebescite of all doctors in the country on such a question every time it arises, to obtain a majority vote.

In determining whether a medical procedure utilized by a doctor is actionable as malpractice the courts have adopted the rule that it is acceptable

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7 Drug Abuse Control Amendments - 1970: Hearings on H.R. 11701 and H.R. 13743 Before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 91st Congress, 2d Sess. 678, 696, 718 (1970) (Statement of John E. Ingersoll, Director, BNDD).

for a doctor to employ a method of treatment supported by a respectable minority of physicians.

In Hood v. Phillips, 537 S.W. 2d 291 (1976) the Texas Court of Civil Appeals was dealing with a claim of medical malpractice resulting from a surgical procedure claimed to have been unnecessary. The court quoted from an Arizona court decision holding that

> a method of treatment, as espoused and used by . . . a respectable minority of physicians in the United States, cannot be said to be an inappropriate method of treatment or to be malpractice as a matter of law even though it has not been accepted as a proper method of treatment by the medical profession generally.

Ibid. at 294. Noting that the Federal District court in the Arizona case found a "respectable minority" composed of sixty-five physicians throughout the United States, the Texas court adopted as "the better rule" to apply in its case, that

> a physician is not guilty of malpractice where the method of treatment used is supported by a respectable minority of physicians.

Ibid.

In Chumbler v. McClure, 505 F.2d 489 (6th Cir. 1974) the Federal courts were dealing with a medical malpractice case under their diversity jurisdiction, applying Tennessee law. The Court of Appeals said:

> . . . The most favorable interpretation that may be placed on the testimony adduced at trial below is that there is a division of opinion in the medical profession regarding the use of Premarin in the Treatment of cerebral vascular insufficiency, and that Dr. McClure was alone among neurosurgeons in Nashville in using such therapy. The test for malpractice and for community standards is not to be determined solely by a plebiscite. Where two or more schools of thought exist among competent members of the medical profession concerning proper medical treatment for a given ailment, each of which is supported by responsible

> medical authority, it is not malpractice to be among the minority in a given city who follow one of the accepted schools.

505 F.2d at 492 (Emphasis added). See, also, Leech v. Bralliar, 275 F.Supp. 897 (D.Ariz., 1967).

How do we ascertain whether there exists a school of thought supported by responsible medical authority, and thus "accepted"? We listen to the physicians.

> The court and jury must have a standard measure which they are to use in measuring the acts of a doctor to determine whether he exercised a reasonable degree of care and skill; they are not permitted to set up and use any arbitrary or artificial standard of measurement that the jury may wish to apply. The proper standard of measurement is to be established by testimony of physicians, for it is a medical question.

Hayes v. Brown, 133 S.E. 2d. 102(Ga., 1963) at 105.

As noted above, there is no question but that this record shows a great many physicians, and others, to have "accepted" marijuana as having a medical use in the treatment of cancer patients' emesis. True, all physicians have not "accepted" it. But to require universal, 100% acceptance would be unreasonable. Acceptance by "a respectable minority" of physicians is all that can reasonably be required. The record here establishes conclusively that at least "a respectable minority" of physicians has "accepted" marijuana as having a "medical use in treatment in the United States." That others may not makes no difference.

The administrative law judge recommended this same approach for determining whether a drug has an "accepted medical use in treatment" in The Matter Of MDMA Scheduling, Docket No. 84-48. The Adminstrator, in his first final rule in that proceeding, issued on October 8, 1986[8], declined to adopt this approach. He

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8 51 Fed. Reg. 36552 (1986).

ruled, instead, that DEA's decision on whether or not a drug or other substance had an accepted medical use in treatment in the United States would be determined simply by ascertaining whether or not "the drug or other substance is lawfully marketed in the United States pursuant to the Federal Food, Drug and Cosmetic Act of 1938 . . . ."[9]

The United States Court of Appeals for the First Circuit held that the Administrator erred in so ruling.[10] That court vacated the final order of October 8, 1986 and remanded the matter of MDMA's scheduling for further consideration. The court directed that, on remand, the Administrator would not be permitted to treat the absence of interstate marketing approval by FDA as conclusive evidence on the question of accepted medical use under the Act.

In his third final rule[11] on the matter of the scheduling of MDMA the Administrator made a series of findings of fact as to MDMA, the drug there under consideration, with respect to the evidence in that record. On those findings he based his last final rule in the case.[12]

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9 Ibid., at 36558.

10 Grinspoon v. Drug Enforcement Administration, 828 F.2d 881 (1st. Cir., 1987).

11 53 Fed. Reg. 5156 (1988). A second final rule had been issued on January 20, 1988. It merely removed MDMA from Schedule I pursuant to the mandate of the Court of Appeals which had voided the first final rule placing it there. Subsequently the third final rule was issued, without any further hearings, again placing MDMA in Schedule I. There was no further appeal.

12 In neither the first nor the third final rule in the MDMA case does the Administrator take any cognizance of the statements to the Congressional committee by predecessor Agency officials that the determination as to "accepted medical use in treatment" is to be made by the medical community and not by any part of the federal government. See page 27, above. It is curious that the Administrator makes no effort whatever to show how the BNDD representatives were mistaken or to explain why he now has abandoned their interpretation. They wrote that language into the original bill.

That third final rule dealing with MDMA is dealing with a synthetic, "simple", "single-action" drug. What might be appropriate criteria for a "simple" drug like MDMA may not be appropriate for a "complex" substance with a number of active components. The criteria applied to MDMA, a synthetic drug, are not appropriate for application to marijuana, which is a natural plant substance.

The First Circuit Court of Appeals in the MDMA case told the Administrator that he should not treat the absence of FDA interstate marketing approval as conclusive evidence of lack of currently accepted medical use. The court did not forbid the Administrator from considering the absence of FDA approval as a factor when determining the existence of accepted medical use. Yet on remand, in his third final order, the Administrator adopted by reference 18 of the numbered findings he had made in the first final order. Each of these findings had to do with requirements imposed by FDA for approval of a new drug application (NDA) or of an investigational new drug exemption (IND). These requirements deal with data resulting from controlled studies and scientifically conducted investigations and tests.

Among those findings incorporated into the third final MDMA order from the first, and relied on by the Administrator, was the determination and recommendation of the FDA that the drug there in question was not "accepted". In relying on the FDA's action the Administrator apparently overlooked the fact that the FDA clearly stated that it was interpreting "accepted medical use" in the Act as being equivalent to receiving FDA approval for lawful marketing under the FDCA. Thus the Administrator accepted as a basis for his MDMA third final rule the FDA recommendation which was based upon a statutory interpretation which the Court.

of Appeals had condemned.

The Administrator in that third final rule made a series of further findings. Again, the central concern in these findings was the content of test results and the sufficiency or adequacy of studies and scientific reports. A careful reading of the criteria considered in the MDMA third final order reveals that the Administrator was really considering the question: Should the drug be accepted for medical use?; rather than the question: Has the drug been accepted for medical use? By considering little else but scientific test results and reports the Administrator was making a determination as to whether or not, in his opinion, MDMA ought to be accepted for medical use in treatment.

The Agency's arguments in the present case are to the same effect. In a word, they address the wrong question. It is not for this Agency to tell doctors whether they should or should not accept a drug or substance for medical use. The statute directs the Administrator merely to ascertain whether, in fact, doctors have done so.

The MDMA third final order mistakenly looks to FDA criteria for guidance in choosing criteria for DEA to apply. Under the Food, Drug and Cosmetic Act the FDA is deciding - properly, under that statute - whether a new drug should be introduced into interstate commerce. Thus it is appropriate for the FDA to rely heavily on test results and scientific inquiry to ascertain whether a drug is effective and whether it is safe. The FDA must look at a drug and pass judgement on its intrinsic qualities. The DEA, on the other hand, is charged by 21 U.S.C. § 812(b)(1)(B) and (2)(B) with ascertaining what it is that other people have done with respect to a drug or substance: "Have they accepted it?;" not "Should they accept it?"

In the MDMA third final order DEA is actually making the decision that doctors have to make, rather than trying to ascertain the decision which doctors have made. Consciously or not, the Agency is undertaking to tell doctors what they should or should not accept. In so doing the Agency is acting beyond the authority granted in the Act.

It is entirely proper for the Administrator to consider the pharmacology of a drug and scientific test results in connection with determining abuse potential. But abuse potential is not in issue in this marijuana proceeding.

There is another reason why DEA should not be guided by FDA criteria in ascertaining whether or not marijuana has an accepted medical use in treatment. These criteria are applied by FDA pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act (FDCA), as amended.[13] When the FDA is making an inquiry pursuant to that legislation it is looking at a synthetically formed new drug. The marijuana plant is anything but a new drug. Uncontroverted evidence in this record indicates that marijuana was being used therapeutically by mankind 2000 years before the Birth of Christ.[14]

Uncontroverted evidence further establishes that in this country today "new drugs" are developed by pharmaceutical companies possessing resources sufficient to bear the enormous expense of testing a new drug, obtaining FDA approval of its efficacy and safety, and marketing it successfully. No company undertakes the investment required unless it has a patent on the drug, so it can recoup its development costs and make a profit. At oral argument Government counsel conceded that "the FDA system is constructed for pharmaceutical companies. I won't

13 21 U.S.C. § 355.

14 Alice M. O'Leary, direct, par. 9.

deny that."[15]

Since the substance being considered in this case is a natural plant rather than a synthetic new drug, it is unreasonable to make FDA-type criteria determinative of the issue in this case, particularly so when such criteria are irrelevant to the question posed by the Act: Does the substance have an accepted medical use in treatment?

Finally, the Agency in this proceeding relies in part on the FDA's recommendation that the Administrator retain marijuana in Schedule I. But, as in the MDMA case, that recommendation is based upon FDA's equating "accepted medical use" under the Act with being approved for marketing by FDA under the Food, Drug and Cosmetic Act, the interpretation condemned by the First Circuit in the MDMA case. See Attachment A, p.24, to exhibit G-1 and exhibit G-2.

The overwhelming preponderance of the evidence in this record establishes that marijuana has a currently accepted medical use in treatment in the United States for nausea and vomiting resulting from chemotheraphy treatments in some cancer patients. To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious.

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15 Tr. XV-37.

VI.

ACCEPTED MEDICAL USE IN TREATMENT

- GLAUCOMA

Findings of Fact

The preponderance of the evidence establishes the following facts with respect to the accepted medical use of marijuana in the treatment of glaucoma.

1. Glaucoma is a disease of the eye characterized by the excessive accumulation of fluid causing increased intraocular pressure, distorted vision and, ultimately, blindness. In its early stages this pressure can sometimes be relieved by the administration of drugs. When such medical treatment fails adequately to reduce the intraocular pressure (IOP), surgery is generally resorted to. Although useful in many cases, there is a high incidence of failure with some types of surgery. Further, serious complications can occur as a result of invasive surgery. Newer, non-invasive procedures such as laser trabeculoplasty are thought by some to offer much greater efficacy with fewer complications. Unless the IOP is relieved and brought to a satisfactory level by one means or another, the patient will go blind.

2. Two highly qualified and experienced ophthalmologists in the United States have accepted marijuana as having a medical use in treatment for glaucoma. They are John C. Merritt, M.D. and Richard D. North, M.D. Each of them is both a clinician, treating patients, and a researcher. Dr. Merritt is also a professor of ophthalmology. Dr. North has served as a medical officer in ophthalmology for the Department of Health, Education and Welfare and has worked with the Public Health Service and FDA.

3. Dr. Merritt's experience with glaucoma patients using marijuana medicinally includes one Robert Randall and, insofar as the evidence here establishes per petitioners' briefs, an unspecified number of other patients, something in excess of 40.

4. Dr. North has treated only one glaucoma patient using marijuana medicinally - the same Robert Randall mentioned immediately above. Dr. North had monitored Mr. Randall's medicinal use of marijuana for nine years as of May 1987.

5. Dr. Merritt has accepted marijuana as having an important place in the treatment of "End Stage" glaucoma. "End Stage" glaucoma, essentially, defines a patient who has already lost substantial amounts of vision; available glaucoma control drugs are no longer able adequately to reduce the intraocular pressure (IOP) to prevent further, progressive sight loss; the patient, lacking additional IOP reductions, will go blind.

6. Robert S. Hepler, M.D., is a highly qualified and experienced ophthalmologist. He has done research with respect to the effect of smoking marijuana on glaucoma. In December 1975 he prescribed marijuana for the same Robert Randall mentioned above as a research subject. Dr. Hepler found that large dosages of smoked marijuana effectively reduced Robert Randall's IOP into the safe range over an entire test day. He concluded that the only known alternative to preserve Randall's sight which would avoid the significant risks of surgery is to include marijuana as part of Randall's prescribed medical regimen. He further concluded in 1977 that, if marijuana could have been legally prescribed, he would have prescribed it for Randall as part of Randall's regular glaucoma maintenance program had he been Randall's personal physician.

Nonetheless, in 1987 Dr. Hepler was of the opinion that marijuana did not have a currently accepted medical use in the United States for the treatment of glaucoma.

7. Four glaucoma patients testified in these proceedings. Each has found marijuana to be of help in controlling IOP.

8. In 1984 the treatment of glaucoma with Cannabis was the subject of an Ophthalmology Grand Rounds at the University of California, San Francisco. A questionnaire was distributed which queried the ophthalmologists on cannabis therapy for glaucoma patients refractory to standard treatment. Many of them have glaucoma patients who have asked about marijuana. Most of the responding ophthalmologists believed that THC capsules or smoked marijuana need to be available for patients who have not benefitted significantly from standard treatment.

9. In about 1978 an unspecified number of persons in the public health service sector in New Mexico, including some physicians, accepted marijuana as having medical use in treating glaucoma.

10. A majority of an unspecified number of ophthalmologists known to Arthur Kaufman, M.D., who was formerly in general practice but now is employed as a medical program administrator, accept marijuana as having medical use in treatment of glaucoma.

11. In addition to the physicians identified and referred to in the findings above, the testimony of patients in this record establishes that no more than three or four other physicians consider marijuana to be medically useful in the treatment of glaucoma in the United States. One of those physicians actually wrote a prescription for marijuana for a patient, which, of course, she was unable to have filled.

12. There are test results showing that smoking marijuana has reduced the IOP in some glaucoma patients. There is continuing research underway in the United States as to the therapeutic effect of marijuana on glaucoma.

Discussion

Petitioners' briefs fail to show that the preponderance of the evidence in the record with respect to marijuana and glaucoma establishes that a respectable minority of physicians accepts marijuana as being useful in the treatment of glaucoma in the United States.

This conclusion is not to be taken in any way as criticism of the opinions of the ophthalmologists who testified that they accept marijuana for this purpose. The failure lies with petitioners. In their briefs they do not point out hard, specific evidence in this record sufficient to establish that a respectable minority of physicians has accepted their position.

There is a great volume of evidence here, and much discussion in the briefs, about the protracted case of Robert Randall. But when all is said and done, his experience presents but one case. The record contains sworn testimony of three ophthalmologists who have treated Mr. Randall. One of them tells us of a relatively small number of other glaucoma patients whom he has treated with marijuana and whom he knows to have responded favorably. Another of these three doctors has successfully treated only Randall with marijuana. The third testifies, despite his successful experience in treating Randall, that marijuana does not have an accepted use in such treatment.

In addition to Robert Randall, Petitioners point to the testimony of three other glaucoma patients. Their case histories are impressive, but they contribute

little to the carrying of Petitioner's burden of showing that marijuana is accepted for medical treatment of glaucoma by a respectable minority of physicians. See pages 26-29, above.

Petitioners have placed in evidence copies of a number of newspaper clippings reporting statements by persons claiming that marijuana has helped their glaucoma. The administrative law judge is unable to give significant weight to this evidence. Had these persons tesified so as to have been subject to cross-examination, a different situation would be presented. But these newspaper reports of extra-judicial statements, neither tested by informed inquiry nor supported by a doctor's opinion, are not entitled to much weight. They are of little, if any, materiality.

Beyond the evidence referred to above there is little other "hard" evidence, pointed out by petitioners, of physicans accepting marijuana for treatment of glaucoma. Such evidence as that concerning a survey of a group of San Francisco ophthalmologists is ambiguous, at best. The relevant document establishes merely that most of the doctors on the grand rounds, who responded to an inquiry, believed that the THC capsules or marijuana ought to be available.

In sum, the evidence here tending to show that marijuana is accepted for treatment of glaucoma falls far, far short of the quantum of evidence tending to show that marijuana is accepted for treatment of emesis in cancer patients. The preponderance of the evidence here, identified by petitioners in their briefs, does not establish that a respectable minority of physicians has accepted marijuana for glaucoma treatment.

VII.

ACCEPTED MEDICAL USE IN TREATMENT - MULTIPLE SCLEROSIS, SPASTICITY AND HYPERPARATHYROIDISM

Findings Of Fact

The preponderance of the evidence clearly establishes the following facts with respect to marijuana's use in connection with multiple sclerosis, spasticity and hyperparathyroidism.

1. Multiple sclerosis is the major cause of neurological disability among young and middle-aged adults in the United States today. It is a life-long disease. It can be extremely debilitating to some of its victims but it does not shorten the life span of most of them. Its cause is yet to be determined. It attacks the myelin sheath, the coating or insulation surrounding the message-carrying nerve fibers in the brain and spinal cord. Once the myelin sheath is destroyed, it is replaced by plaques of hardened tissue known as sclerosis. During the initial stages of the disease nerve impulses are transmitted with only minor interruptions. As the disease progresses, the plaques may completely obstruct the impulses along certain nerve systems. These obstructions produce malfunctions. The effects are sporadic in most individuals and the effects often occur episodically, triggered either by malfunction of the nerve impulses or by external factors.

2. Over time many patients develop spasticity, the involuntary and abnormal contraction of muscle or muscle fibers. (Spasticity can also result from serious injuries to the spinal cord, not related to multiple sclerosis.)

3. The symptoms of multiple sclerosis vary according to the area of

the nervous system which is affected and according to the severity of the disease. The symptoms can include one or more of the following: weakness, tingling, numbness, impaired sensation, lack of coordination, disturbances in equilibrium, double vision, loss of vision, involuntary rapid movement of the eyes (nystagmus), slurred speech, tremors, stiffness, spasticity, weakness of limbs, sexual dysfunction, paralysis, and impaired bladder and bowel functions.

4. Each person afflicted by multiple sclerosis is affected differently. In some persons, the symptoms of the disease are barely detectable, even over long periods of time. In these cases, the persons can live their lives as if they did not suffer from the disease. In others, more of the symptoms are present and acute, thereby limiting their physical capabilities. Moreover, others may experience sporadic, but acute, symptoms.

5. At this time, there is no known prevention or cure for multiple sclerosis. Instead, there are only treatments for the symptoms of the disease. There are very few drugs specifically designed to treat spasticity. These drugs often cause very serious side effects. At the present time two drugs are approved by FDA as "safe" and "effective" for the specific indication of spasticity. These drugs are Dantrium and Lioresal baclofen.

6. Unfortunately, neither Dantrium nor Lioresal is a very effective spasm control drug. Their marginal medical utility, high toxicity and potential for serious adverse effects make these drugs difficult to use in spasticity therapy.

7. As a result, many physicians routinely prescribe tranquilizers, muscle relaxants, mood elevators and sedatives such as Valium to patients experiencing spasticity. While these drugs do not directly reduce spasticity

they may weaken the patient's muscle tone, thus making the spasms less noticeable. Alternatively, they may induce sleep or so tranquilize the patient that normal mental and physical functions are impossible.

8. A healthy, athletic young woman named Valerie Cover was stricken with multiple sclerosis while in her early twenties. She consulted several medical specialists and followed all the customary regimens and prescribed methods for coping with this debilitating disease over a period of several years. None of these proved availing. Two years after first experiencing the symptoms of multiple sclerosis her active, productive life - as an athlete, Navy officer's wife and mother - was effectively over. The Social Security Administration declared her totally disabled. To move about her home she had to sit on a skateboard and push herself around. She spent most of her time in bed or sitting in a wheelchair.

9. An occasional marijuana smoker in her teens, before her marriage, she had not smoked it for five years as of February 1986. Then a neighbor suggested that marijuana just might help Mrs. Cover's multiple sclerosis, having read that it had helped cancer patient's control their emesis. Mrs. Cover acceded to the suggestion.

10. Just before smoking the marijuana cigarette produced by her neighbor, Mrs. Cover had been throwing up and suffering from spasms. Within five minutes of smoking part of the marijuana cigarette she stopped vomiting, no longer felt nauseous and noticed that the intensity of her spasms was significantly reduced. She stood up unaided.

11. Mrs. Cover began smoking marijuana whenever she felt nauseated. When she did so it controlled her vomiting, stopped the nausea and increased her

appetite. It helped ease and control her spasticity. Her limbs were much easier to control. After three months of smoking marijuana she could walk unassisted, had regained all of her lost weight, her seizures became almost nonexistent. She could again care for her children. She could drive an automobile again. She regained the ability to lead a normal life.

12. Concerned that her use of this illegal substance might jeopardize the career of her Navy officer husband, Mrs. Cover stopped smoking marijuana several times. Each time she did so, after about a month, she had retrogressed to the point that her multiple sclerosis again had her confined to bed and wheelchair or skateboard. As of the Spring of 1987 Mrs. Cover had resumed smoking marijuana regularly on an "as needed" basis. Her multiple sclerosis symptoms are under excellent control. She has obtained a full-time job. She still needs a wheelchair on rare occasions, but generally has full use of her limbs and can walk around with relative ease.

13. Mrs. Cover's doctor has accepted the effectiveness of marijuana in her case. He questioned her closely about her use of it, telling her that it is the most effective drug known in reducing vomiting. Mrs. Cover and her doctor are now in the process of filing an Investigational New Drug (IND) application with FDA so that she can legally obtain the marijuana she needs to lead a reasonably normal life.

14. Martha Hirsch is a young woman in her mid-thirties. She first exhibited symptoms of multiple sclerosis at age 19 and it was diagnosed at that time. Her condition has grown progressively worse. She has been under the care of physicians and hospitalized for treatment. Many drugs have been prescribed for her by her doctors. At one point in 1983 she listed the drugs that had been

prescribed for her. There were 17 on the list. None of them has given her the relief from her multiple sclerosis symptoms that marijuana has.

15. During the early stages in the development of her illness Ms. Hirsch found that smoking marijuana improved the quality of her life, keeping her spasms under control. Her balance improved. She seldom needed to use her cane for support. Her condition lately has deteriorated. As of May 1987 she was experiencing severe, painful spasms. She had an indwelling catheter in her bladder. She had lost her locomotive abilities and was wheelchair bound. She could seldom find marijuana on the illegal market and, when she did, she often could not afford to purchase it. When she did obtain some, however, and smoked it, her entire body seemed to relax, her spasms decreased or disappeared, she slept better and her dizzy spells vanished. The relaxation of her leg muscles after smoking marijuana has been confirmed by her personal care attendant's examination of them.

16. The personal care attendant has told Ms. Hirsch that she, the attendant, treats a number of patients who smoke marijuana for relief of multiple sclerosis symptoms. In about 1980 another patient told Ms. Hirsch that he knew many patients who smoke marijuana to relieve their spasms. Through him she met other patients and found that marijuana was commonly used by many multiple sclerosis patients. Most of these persons had told their doctors about their doing so. None of those doctors advised against the practice and some encouraged it.

17. Among the drugs prescribed by doctors for Ms. Hirsch was ACTH. This failed to give her any therapeutic benefit or to control her spasticity. It did produce a number of adverse effects, including severe nausea and vomiting which, in turn, were partly controlled by rectally administered anti-emetic

drugs.

18. Another drug prescribed for her was Lioresal, intended to reduce her spasms. It was not very effective in so doing. But it did cause Ms. Hirsch to have hallucinations. On two occasions, while using this drug, Ms. Hirsch "saw" a large fire in her bedroom and called for help. There was no fire. She stopped using that drug. Ms. Hirsch has experienced no adverse reactions with marijuana.

19. Ms. Hirsch's doctor has accepted marijuana as beneficial for her. He agreed to write her a prescription for it, if that would help her obtain it. She has asked him if he would file an IND application with FDA for her. He replied that the paperwork was "overwhelming". He indicated willingness to help in this undertaking after Ms. Hirsch found someone else willing to put the paperwork together.

20. When Greg Paufler was in his early twenties, employed by Prudential Insurance Company, he began to experience the first symptoms of multiple sclerosis. His condition worsened as the disease intensified. He had to be hospitalized. He lost the ability to walk, to stand. Diagnosed as having multiple sclerosis, a doctor prescribed ACTH for him, an intensive form of steroid therapy. He lost all control over his limbs and experienced severe, painful spasms. His arms and legs became numb.

21. ACTH had no beneficial effects. The doctor continued to prescribe it over many months. ACTH made Paufler ravenously hungry and he began gaining a great deal of weight. ACTH caused fluid retention and Paufler became bloated, rapidly gaining weight. His doctor thought Paufler should continue this steroid therapy, even though it caused the adverse effects mentioned plus the possiblity of sudden heart attack or death due to respiratory failure. Increased dosages

of this FDA-approved drug caused fluid to press against Paufler's lungs making it difficult for him to breathe and causing his legs and feet to become swollen. The steroid therapy caused severe, intense depression marked by abrupt mood shifts. Throughout, the spasms continued and Paufler's limbs remained out of control. The doctor insisted that ACTH was the only therapy likely to be of any help with the multiple sclerosis, despite its adverse effects. Another, oral, steroid was eventually substituted.

22. One day Paufler became semi-catatonic while sitting in his living room at home. He was rushed to the hospital emergency room. He nearly died. Lab reports indicated, among other things, a nearly total lack of potassium in his body. He was given massive injections of potassium in the emergency room and placed on an oral supplement. Paufler resolved to take no more steroids.

23. From time to time, prior to this point, Paufler had smoked marijuana socially with visiting friends, seek some relief from his misery in a temporary "high". He now began smoking marijuana more often. After some weeks he found that he could stand and then walk a bit. His doctor dismissed the idea that marijuana could be helpful with multiple sclerosis, and Paufler, himself, was skeptical at first. He began discontinuing it for a while, then resuming.

24. Paufler found that when he did not smoke marijuana his condition worsened, he suffered more intense spasms more frequently. When he smoked marijuana, his condition would stabilize and then improve; spasms were more controlled and less severe; he felt better; he regained control over his limbs and could walk totally unaided. His vision, often blurred and unfocused, improved. Eventually he began smoking marijuana on a daily basis. He ventured outdoors. He was soon walking half a block. His eyesight returned to normal.

His central field blindness cleared up. He could focus well enough to read again. One evening he went out with his children and found he could kick a soccer ball again.

25. Paufler has smoked marijuana regularly since 1980. Since that time his multiple sclerosis has been well controlled. His doctor has been astonished at Paufler's recovery. Paufler can now run. He can stand on one foot with his eyes closed. The contrast with his condition, several years ago, seems miraculous. Smoking marijuana when Paufler feels an attack coming on shortens the attack. Paufler's doctor has looked Paufler in the eye and told him to keep doing whatever it is he's doing because it works. Paufler and his doctor are exploring the possbility of obtaining a compassionate IND to provide legal access to marijuana for Paufler.

26. Paufler learned in about 1980 of the success of one Sam Diana, a multiple sclerosis patient, in asserting the defense of "medical necessity" in court when charged with using or possessing marijuana. He learned that doctors, researchers and other multiple sclerosis patients had supported Diana's position in the court proceeding.

27. Irwin Rosenfeld has been diagnosed as having Pseudo Pseudo Hypoparathyroidism. This uncommon disease causes bone spurs to appear and grow all over the body. Over the patient's lifetime hundreds of these spurs can grow, any one of which can become malignant at any time. The resulting cancer would spread quickly and the patient would die.

28. Even without development of a malignancy, the disease causes enormous pain. The spurs press upon adjacent body tissue, nerves and organs. In Rosenfeld's case, he could neither sit still nor lie down, nor could he walk,

without experiencing pain. Working in his furniture store in Portsmouth, Virginia, Mr. Rosenfeld was on his feet moving furniture all day long. The lifting and walking caused serious problems as muscles and tissues rubbed over the spurs of bone. He tore muscles and hemorrhaged almost daily.

29. Rosenfeld's symptoms first appeared about the age of ten. Various drugs were prescribed for him for pain relief. He was taking extremely powerful narcotics. By the age of 19 his therapy included 300 mg. of Sopor (a powerful sleeping agent) and very high doses of Dilaudid. He was found to be allergic to barbiturates. Taking massive doses of pain control drugs, as prescribed, made it very difficult for Rosenfeld to function normally. If he took enough of them to control the pain, he could barely concentrate on his schoolwork. By the time he reached his early twenties Rosenfeld's monthly drug intake was between 120 to 140 Dilaudid tablets, 30 or more Sopor sleeping pills and dozens of muscle relaxants.

30. At college in Florida Rosenfeld was introduced to marijuana by classmates. He experimented with it recreationally. He never experienced a "high" or "buzz" or "floating sensation" from it. One day he smoked marijuana while playing chess with a friend. It had been very difficult for him to sit for more than five or ten minutes at a time because of tumors in the backs of his legs. Suddenly he realized that, absorbed in his chess game, and smoking marijuana, he had remained sitting for over an hour - with no pain. He experimented further and found that his pain was reduced whenever he smoked marijuana.

31. Rosenfeld told his doctor of his discovery. The doctor opined that it was possible that the marijuana was relieving the pain. Something

certainly was - there was a drastic decrease in Rosenfeld's need for such drugs as Dilaudid and Demerol and for sleeping pills. The quality of pain relief which followed his smoking of marijuana was superior to any he had experienced before. As his dosages of powerful conventional drugs decreased, Rosenfeld became less withdrawn from the world, more able to interact and function. So he has continued to the present time.

32. After some time Rosenfeld's doctor accepted the fact that the marijuana was therapeutically helpful to Rosenfeld and submitted an IND application to FDA to obtain supplies of it legally for Rosenfeld. The doctor has insisted, however, that he not be publicly identified. After some effort the IND application was granted. Rosenfeld is receiving supplies of marijuana from NIDA. Rosenfeld testified before a committee of the Virginia legislature in about 1979 in support of legislation to make marijuana available for therapeutic purposes in that State.

33. In 1969, at age 19, David Branstetter dove into the shallow end of a swimming pool and broke his neck. He became a quadraplegic, losing control over the movement of his arms and legs. After being hospitalized for 18 months he returned home. Valium was prescribed for him to reduce the severe spasms associated with his condition. He became mildly addicted to Valium. Although it helped mask his spasms, it made Branstetter more withdrawn and less able to take care of himself. He stopped taking Valium for fear of the consequences of long-term addiction. His spasms then became uncontrollable, often becoming so bad they would throw him from his wheelchair.

34. In about 1973 Branstetter began smoking marijuana recreationally. He discovered that his severe spasms stopped whenever he smoked marijuana.

Unlike Valium, which only masked his symptoms and caused him to feel drunk and out of control, marijuana brought his spasmodic condition under control without impairing his faculties. When he was smoking marijuana regularly he was more active, alert and outgoing.

35. Marijuana controlled his spasms so well that Branstetter could go out with friends and he began to play billiards again. The longer he smoked marijuana the more he was able to use his arms and hands. Marijuana also improved his bladder control and bowel movements.

36. At times the illegal marijuana Branstetter was smoking became very expensive and sometimes was unavailable. During periods when he did not have marijuana his spasms would return, preventing Branstetter from living a "normal" life. He would begin to shake uncontrollably, his body would feel tense, and his muscles would spasm.

37. In 1979 Branstetter was arrested and convicted of possession of marijuana. He was placed on probation for two years. During that period he continued smoking marijuana and truthfully reportd this, and the reason for it, to his probation officer whenever asked about it. No action was taken against Branstetter by the court or probation authorities because of his continuing use of marijuana, except once in the wake of his publicly testifying about it before the Missouri legislature. Then, although adverse action was threatened by the judge, nothing was actually done.

38. In 1981 Branstetter and a friend, a paraplegic, participated in a research study testing the therapeutic effects of synthetic THC on spasticity. Placed on the THC Branstetter found that it did help control his spasms but appeared to became less effective with repeated use. Also, unlike marijuana,

synthetic THC had a powerful mind-altering effect he found annoying. When the study ended the researcher strongly suggested that Branstetter continue smoking marijuana to control his spasms.

39. None of Branstetter's doctors have told him to stop smoking marijuana while several, directly and indirectly, have encouraged him to continue. Branstetter knows of almost 20 other patients, paraplegics, quadraplegics and multiple sclerosis sufferers, who smoke marijuana to control their spasticity.

40. In 1981 a State of Washington Superior Court judge, sitting without a jury, found Samuel D. Diana not guilty of the charge of unlawful possession of marijuana. In so doing the judge upheld Diana's defense of medical necessity. Diana had been a multiple sclerosis patient since at least 1973. He testified that smoking marijuana relieved his symptoms of double vision, tremors, unsteady walk, impaired hearing, tendency to vomit in the mornings and stiffness in the joints of his hands and legs.

41. Among the witnesses was a physician who had examined defendant Diana before and after he had used marijuana. This doctor tesified that marijuana had been effective therapeutically for Diana, that other medication had proven ineffective for Diana and that, while marijuana may have some detrimental effects, Diana would receive more benefit than harm from smoking it. The doctor was not aware of any other drug that would be as effective as marijuana for Mr. Diana. Other witnesses included three persons afflicted with multiple sclerosis who tesified in detail as to marijuana's beneficial effect on their illness.

42. In acquitting defendant Diana of unlawful possession of marijuana the trial judge found that the three requirements for the defense of medical necessity had been established, namely: defendant's reasonable belief that his

use of marijuana was necessary to minimize the effects of multiple sclerosis; the benefits derived from its use are greater than the harm sought to be prevented by the controlled substances law; and no drug is as effective as marijuana in minimizing the effects of the disease in the defendant.

43. Denis Petro, M.D., is a neurologist of broad experience, ranging from active practice in neurology to teaching the subject in medical school and employment by FDA as a medical officer reviewing IND's and NDA's. He has also been employed by pharmaceutical companies and has served as a consultant to the State of New York. He is well acquainted with the case histories of three patients who have successfully utilized marijuana to control severe spasticity when other, FDA-approved drugs failed to do so. Dr. Petro knows of other cases of patients who, he has determined, have effectively used marijuana to control their spasticity. He has heard reports of additional patients with multiple sclerosis, paraplegia and quadriplagia doing the same. There are reports published in the literature known to Dr. Petro, over the period at least 1970 - 1986, of clinical tests demonstrating that marijuana and THC are effective in controlling or reducing spasticity in patients.

44. Large numbers of paraplegic and quadriplegic patients, particularly in Veterans Hospitals, routinely smoke marijuana to reduce spasticity. While this mode of treatment is illegal, it is generally tolerated, if not openly encouraged, by physicians in charge of such wards who accept this practice as being of benefit to their patients. There are many spinal cord injury patients in Veterans Hospitals.

45. Dr. Petro sought FDA approval to conduct research with spasticity patients using marijuana. FDA refused but, for reasons unknown to him, allowed

him to make a study using synthetic THC. He and colleagues made such a study. They concluded that synthetic THC effected a significant reduction in spasticity among multiple sclerosis patients, but study participants who had also smoked marijuana reported consistently that marijuana was more effective.

46. Dr. Petro accepts marijuana as having a medical use in the treatment of spasticity in the United States. If it were legally available and he was engaged in an active medical practice again, he would not hesitate to prescribe marijuana, when appropriate, to patients afflicted with uncontrollable spasticity.

47. Dr. Petro presented a paper to a meeting of the American Academy of Neurology. The paper was accepted for presentation. After he presented it Dr. Petro found that many of the neurologists present at this most prestigious meeting were in agreement with his acceptance of marijuana as having a medical use in the treatment of spasticity.

48. Dr. Andrew Weil, a general medicine practitioner in Tucson, Arizona, who also teaches at the University of Arizona College of Medicine, accepts marijuana as having a medical use in the treatment of spasticity. In multiple sclerosis patients the muscles become tense and rigid because their nerve supply is interrupted. Marijuana relieves this spasticity in many patients, he has found. He would prescribe it to selected patients if it were legally available.

49. Dr. Lester B. Collins, III, a neurologist, then treating about 20 multiple sclerosis patients a year, seeing two or three new ones each year, stated in 1983 that he had no doubt that marijuana worked symptomatically for some multiple sclerosis patients. He said that it does not alter the course of

the disease but it does relieve the symptoms of spasticity.

50. Dr. John P. Morgan, board certified in internal medicine, Professor of Medicine and Director of Pharmacology at CCNY Medical School in New York and Associate Professor of Medicine and Pharmacology at Mt. Sinai School of Medicine, accepts marijuana as having medical use in treatment in the United States. If he were practicing medicine and marijuana were legally available he would prescribe it when indicated to patients with legitimate medical needs.

Discussion

Based upon the rationale set out in pages 26 to 34, above, the administrative law judge concludes that, within the meaning of the Act, 21 U.S.C. § 812(b)(2)(B), marijuana "has a currently accepted medical use in treatment in the United States" for spasticity resulting from multiple sclerosis and other causes. It would be unreasonable, arbitrary and capricious to find otherwise. The facts set out above, uncontroverted by the Agency, establish beyond question that some doctors in the United States accept marijuana as helpful in such treatment for some patients. The record here shows that they constitute a significant minority of physicians. Nothing more can reasonably be required. That some doctors would have more studies and test results in hand before accepting marijuana's usefulness here is irrelevant.

The same is true with respect to the hyperparathyroidism from which Irvin Rosenfeld suffers. His disease is so rare, and so few physicians appear to be familiar with it, that acceptance by one doctor of marijuana as being useful in treating it ought to satisfy the requirement for a significant minority. The Agency points to no evidence of record tending to establish that marijuana is

not accepted by doctors in connection with this most unusual ailment. Refusal to acknowledge acceptance by a significant minority, in light of the case history detailed in this record, would be unreasonable, arbitrary and capricious.

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.

IX.

CONCLUSION AND RECOMMENDED DECISION

Based upon the foregoing facts and reasoning, the administrative law judge concludes that the provisions of the Act permit and require the transfer of marijuana from Schedule I to Schedule II. The judge realizes that strong emotions are aroused on both sides of any discussion concerning the use of marijuana. Nonetheless it is essential for this Agency, and its Administrator, calmly and dispassionately to review the evidence of record, correctly apply the law, and act accordingly.

Marijuana can be harmful. Marijuana is abused. But the same is true of dozens of drugs or substances which are listed in Schedule II so that they can be employed in treatment by physicians in proper cases, despite their abuse potenial.

Transferring marijuana from Schedule I to Schedule II will not, of course, make it immediately available in pharmacies throughout the country for legitimate use in treatment. Other government authorities, Federal and State, will doubtless have to act before that might occur. But this Agency is not charged with responsibility, or given authority, over the myriad other regulatory decisions that may be required before marijuana can actually be legally available. This Agency is charged merely with determining the placement of marijuana pursuant to the provisions of the Act. Under our system of laws the responsibilities of other regulatory bodies are the concerns of those bodies, not of this Agency.

There are those who, in all sincerety, argue that the transfer of marijuana

to Schedule II will "send a signal" that marijuana is "OK" generally for recreational use. This argument is specious. It presents no valid reason for refraining from taking an action required by law in light of the evidence. If marijuana should be placed in Schedule II, in obedience to the law, then that is where marijuana should be placed, regardless of misinterpretation of the placement by some. The reasons for the placement can, and should, be clearly explained at the time the action is taken. The fear of sending such a signal cannot be permitted to override the legitimate need, amply demonstrated in this record, of countless suffers for the relief marijuana can provide when prescribed by a physician in a legitimate case.

The evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.

The administrative law judge recommends that the Administrator conclude that the marijuana plant considered as a whole has a currently accepted medical use in treatment in the United States, that there is no lack of accepted safety for use of it under medical supervision and that it may lawfully be transferred from Schedule I to Schedule II. The judge recommends that the Administrator transfer marijuana from Schedule I to Schedule II.

Dated: SEP 6 1988

Francis L. Young
Administrative Law Judge

CERTIFICATION OF SERVICE

This is to certify that the undersigned on SEP 6 1988 , caused a copy of the foregoing to be delivered to

Madeleine R. Shirley, Esq.
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and caused a copy to be mailed, postage paid, to each of the following:

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(Signed)

Dianne L. Martin
Hearing Clerk