



Waiting to Exhale: Medical Marijuana and Its Uncertain Future

Citation

Waiting to Exhale: Medical Marijuana and Its Uncertain Future (1995 Third Year Paper)

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8846737>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

WAITING TO EXHALE: MEDICAL MARIJUANA AND ITS UNCERTAIN FUTURE

I. Introduction

Therapeutic use of marijuana is a political, medical and moral issue that has provoked controversy throughout this century. On one side of the debate is the governments desire to prevent drug abuse and to make certain that medical therapies are scientifically sound and do not raise false hopes. On the other side are the interests of desperately ill patients who long for relief and desire autonomous decision-making over their own well-being. Caught in the middle are loved ones of the seriously ill, physicians, and the general public, who wish to be law abiding, yet who remain convinced and confused about the medical uses of marijuana.

Both sides have their extremes. Proponents of a drug-free America argue that *any* legalization of marijuana, including loosening restrictions for medical testing and use, should be prohibited. Groups such as the National Federation of Parents for a Drug-Free Youth believe that marijuana is dangerous and can be a gateway to more serious drug use.¹ However, medical studies show that marijuana has few side effects, is not addictive, and is generally safer than cigarettes, alcohol, and even aspirin.² In addition, there is no evidence that recreational use of marijuana leads to the use of more dangerous drugs.³

On the other hand, advocates of complete legalization of marijuana claim that marijuana is not harmful and thus should be accessible to *anyone* who wants it, not just seriously ill patients. However, nonprofit institutions such as the National Organization for the Reform of Marijuana Laws have ultimately lost every attempt to even begin to loosen the restrictions on marijuana.⁴ Although government-sanctioned studies have repeatedly recommended decriminalizing possession of marijuana, the government's response

12 ROBERT C. RANDALL, MARIJUANA, MEDICINE, AND THE LAW 395 (1989).

²Judy Foremen, *Medical Marijuana –A Cure ora Curse?*, BOSTON GLOBE, Oct. 7, 1991, at 25.

³LESTER GRINSPOON & JAMES B. BAKALAR, MARIHUANA, THE FORBIDDEN MEDICINE 147 (1993).

⁴See National Org. for the Reform of Marijuana Laws v. Ingersoll, 497 F.2d 654 (D.C. Cir. 1974); National

Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin., 559 F.2d 735 (D.C. Cir. 1977);

National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin. & Dept of Heath Education

& Welfare, No. 79-1660 (D.C. Cir. Oct. 16, 1980); Alliance for Cannabis Therapeutics v. Drug

Enforcement Admin, 930 F.2d 936 (D.C. Cir. 1991); and Alliance for Cannabis
Therapeutics v. Drug
Enforcement Admin., 15 F.3d 1131 (D.C. Cir. 1994).

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

to these studies in the past has sent a clear message: any legalization of marijuana is political suicide when our country's drug problems and crime rate have escalated.

This paper will analyze the political and legal history of medical marijuana and its current legal status in the United States. I will argue throughout that the present lack of access to marijuana for medicinal purposes is unwarranted. I will conclude with a discussion of such possible future solutions as:

(1) approval of a marijuana New Drug Application (NDA) by the Food and Drug Administration ('FDA'); (2) a Congressional statute allowing marijuana to be prescribed; and, most importantly, (3) education of the public about the medical uses of marijuana.

II. History of Medical Marijuana

A. Pre-1937

Marijuana (*Cannabis sativa*) has been used as a medicine in India, China, the Middle East, Southeast Asia, South Africa, and South America for thousands of years.⁵ In the United States, the medicinal properties of marijuana were first recognized in the mid-nineteenth century.⁶ From 1840-1900 Western medical literature proliferated with findings of the therapeutic value of marijuana.⁷ Medical reports indicate that during this time American physicians recommended marijuana for tetanus, migraines, neuralgia, convulsions, as a sleep aid, as an appetite stimulant, and as a general pain killer.⁸ Marijuana was even listed as a recognized medicine in the *United States Pharmacopoeia* from 1850 through 1942.⁹

B. The Marijuana Tax Act of 1937

Although Marijuana was included in the Food and Drug Act in 1915,¹⁰ it was not until Congress passed the Marijuana Tax Act (MTA) of 1937 that the medicinal use of marijuana met its legal demise.¹¹ Under the MTA, anyone using marijuana for industrial or medical purposes was required to register and pay a tax of a dollar an ounce.¹² Even though the MTA was aimed at stopping recreational marijuana use

⁵GRINSPOON, *supra* note 3, at 3.

⁶*Id.* at 4.

⁷*Id.* at 5.

⁸*Id.* at 5-7.

⁹JEROME HIMMELSTEIN, *THE STRANGE CAREER OF MARIJUANA* 22(1983).

¹⁰*Id.* at 23.

¹¹Marijuana Tax Act, 26 U.S.C. § 4741 *et seq.* (1964) (repealed).

¹²GPJNSPCJ)N *supra* note 3, at 8.

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

(the MTA charged recreational users \$100 per ounce),¹³ the enormous record-keeping requirements for medicinal use discouraged doctors from using marijuana.¹⁴

The history of the passage of the MTA illustrates the beginning of the government's crusade against marijuana and helps explain the current stigma attached to its use for any purpose. Before the Act was passed, Harry J. Anslinger, then the Commissioner of the Treasury Department's Bureau of Narcotics, (the forerunner of the Drug Enforcement Administration) ran a successful media campaign depicting marijuana use as addictive and the cause of violence and psychosis.¹⁵ The most memorable aspect of Anslinger's campaign is the film *Reefer Madness*, which graphically portrayed the potential evils of marijuana, including allegations that marijuana caused one man to murder his entire family.¹⁶ Thus, by using powerful imagery and symbols, Anslinger provoked mass hysteria about the dangers of marijuana with little to no evidence that the drug was harmful, yet with the support of most of the medical community.¹⁷

Some scholars believe that Anslinger's war against marijuana was borne out of racism and xenophobia. At the time the MTA was passed, recreational users of marijuana included mostly Mexican immigrants and black jazz musicians.¹⁸ Some social scientists argue that the federal government preyed upon existing anti-Mexican sentiment by implying that since Mexican-Americans and other marginalized groups used marijuana, marijuana must produce violence and other anti-social behavior stereotypically associated with these groups.¹⁹ Thus, marijuana was classified as a narcotic, and not regulated as permissively as alcohol and tobacco, which were vices native to white European-Americans.²⁰

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ See *United States v. Clary*, 846 F. Supp. 768, 775 (E.D. Miss. 1994).

¹⁷ One of the only opponents of the MTA was Dr. W.C. Woodward, the legislative counsel for the American Medical Association. GRINSPOON, *supra* note 3, at 9. Woodward argued for less restrictive regulation to study the medicinal uses of marijuana. *Id.*

¹⁸ HIMMELSTEIN *supra* note 9.

¹⁹ HIMMELSTEIN, *supra* note 9, at 29.

²⁰ Gregg A. Bilz, *The Medical Use of Marijuana: The Politics of Medicine*, 13 HAMLIN J. PUBL. L. & POL'Y 117(1992).

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

C. Subsequent Reports and Studies

Despite the federal government's efforts to portray marijuana as an addictive and dangerous drug, not everyone was convinced. In 1938, New York Mayor Fiorello LaGuardia commissioned a medical team to study the medical, sociological, and psychological aspects of marijuana use in New York City.²¹ This committee published a report in 1944, entitled *The Marijuana Problem in the City of New York (The LaGuardia Report)*. The LaGuardia Report contradicted much of the propaganda surrounding the passage of the MTA by concluding that marijuana use was not addictive, did not cause aggressive or anti-social behavior, and did not promote criminal activity.²²

At first, the Journal of the American Medical Association (AMA) applauded the findings of the LaGuardia Report, by describing it as a careful study and by acknowledging marijuana's potential therapeutic use for treating depression, appetite loss, and opiate addiction.²³ However, one month later the AMA succumbed to pressure by Anslinger and the Bureau of Narcotics and published an editorial denouncing the LaGuardia Report as unscientific, uncritical and scientifically dubious.²⁴ Taking a fervent political position, the AMA went on to state that [public officials will do well to disregard this study, and continue to regard marihuana as a menace wherever it is purveyed.²⁵ Due to the bitter attacks against it, the LaGuardia Report was discredited and subsequently largely ignored by doctors, politicians and patients.

For a few decades, the government lost interest in investigating the effects of marijuana. However, in 1971 President Nixon established the National Commission on Marihuana and Drug Abuse. This commission, known as the Shafer Commission, named after Chairman Raymond P. Shafer, released its report entitled *Marihuana: A Signal of Misunderstanding* on March 22, 1972.²⁶ As is apparent by the

²¹GRINSPOON *supra* note 3, at 11.

²² *Id.* Incidentally, today, virtually everyone who is knowledgeable about the effects of marijuana agrees that marijuana does not lead to violence. See STEVEN B. DUKE & ALBERT C. GROSS, *AMERICA'S LONGEST WAR: RETHINKING OUR TRAGIC CRUSADE AGAINST DRUGS* 44(1993).

²³GRINSPOCJN *supra* note 3, at 12.

²⁴ *Id.*

²⁶Bilz, *supra* note 20; NATIONAL COMMISSION ON MARIJUANA AND DRUG ABUSE, *MARIHUANA: A SIGNAL OF MISUNDERSTANDING* 16(1972).

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

report's title, the results of the study were unwelcome by President Nixon, particularly at a time when marijuana use was associated with the anti-establishment, hippie-culture of the 1960's and early 1970's.

The Shafer Commission's Report boldly attempted to demythologize the misconceptions of marijuana brought about by previous administrations. Among other things, the Commission found that there was no rational basis for passing the Marijuana Tax Act of 1937,²⁷ that marijuana is not addictive or significantly harmful, and that it should not be classified as a narcotic.²⁸ More importantly, the Shafer Commission's controversial stance that personal possession of marijuana be decriminalized, overshadowed their recommendation that marijuana be thoroughly researched for potential medical uses.²⁹ Instead of considering the conclusions in the report, President Nixon vowed to ignore them and to declare a war on drugs.³⁰

The next significant study done regarding the health effects of marijuana was a study commissioned by the National Institutes of Health and completed by a panel of the National Academy of Sciences (NAS) in February in 1982. Although the NAS panel stated that marijuana justifies serious national concern,³¹ it also made promising findings regarding the use of marijuana and marijuana derivatives in treating glaucoma, asthma, and nausea resulting from chemotherapy treatment.³² In addition, the NAS panel made an urgent plea for further research regarding therapeutic uses of marijuana as well as for further research investigating the long-term effects of the drug.³³

However, the findings of this NAS panel were soon eclipsed by the findings of another NAS panel a few months later. In July of 1982, the Committee on Substance Abuse and Habitual Behavior released their study, commissioned in 1978 by the federal National Institute on Drug Abuse (NIDA), regarding the fiscal and social costs of enforcing marijuana laws.³⁴ This NAS panel recommended that possession of small amounts of marijuana be decriminalized because the costs of enforcing the law outweighed the

²⁷Bilz, *supra* note 20.

²⁸NY TIMES, Feb. 13, 1972, at 1.

²⁹Id.; Bilz, *supra* note 20.

³⁰N.Y. TIMES, May 20, 1971, at 50; Bilz, *supra* note 20.

³¹*The Potshot That Backfired; Science agency rejects its own study on easing marijuana laws*, TIME, Jul.

19, 1982, at 79.

³²*Another Sort of Smoke; Marijuana: Justifies Serious National Concern*, TIME, Mar. 8, 1992, at 73.

³³Matt Clark & Mary Hagar, *The Hazards of Marijuana*, NEWSWEEK, Mar. 8, 1982, at 89.

³⁴*The Potshot That Backfired*, *supra* note 31.

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Huh

benefits.³⁵ The attention given to this panel's *legal* conclusions overshadowed the previous panel's positive *medical* conclusions concerning therapeutic use of marijuana. The panel's recommendation of partial legalization was vehemently criticized by the president of the NAS and the director of NIDA and was completely at odds with the Reagan administration's hard-line stance against all drugs, including marijuana.³⁶

III. The Legal Status of Medical Marijuana Today

A. *The Controlled Substances Act*

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act (CSA).³⁷ The CSA was enacted in the face of the nation's growing drug problem and was the federal government's first effort at a comprehensive regulatory scheme for hazardous drugs. The CSA classifies a drug or substance into one of five different Schedules, depending on criteria such as safety and potential for abuse.³⁸

Congress placed the marijuana plant in Schedule I, the category of drugs with the most severe controls, restrictions, and penalties for use.³⁹ In order to be a Schedule I drug, the CSA mandates findings by the Drug Enforcement Administration (DEA, a division of the Department of Justice under the Attorney General) that: (1) the drug or other substance has a high potential for abuse; (2) the drug or other substance has *no currently accepted medical use* in treatment in the United States; and (3) there is a lack of accepted safety for use of the drug or other substance under medical supervision.⁴⁰ Other Schedule I drugs include heroin and LSD.⁴¹

Schedule II drugs are less stringently regulated but are still considered dangerous. The criteria for Schedule II drugs are somewhat different: (1) the drug or substance still has a high potential for abuse; (2) however, 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*; and (3) abuse of the drug or other substance

³⁵ *Id.*

³⁶ 21 U.S.C. §§ 801-971 (1988).

³⁷ *Id.* at § 812.

³⁸ *Id.*; 930 F.2d at 937.

³⁹ 21 U.S.C. at § 812(b)(1).

⁴⁰ *Id.* at § 812.

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

may lead to severe psychological or physical dependence.⁴² Schedule II drugs include drugs such as cocaine, morphine, amphetamines and barbiturates.⁴³ Tetrahydrocannabinol (THC), the principal active ingredient in marijuana, and its synthetic equivalents are Schedule II drugs.⁴⁴

The CSA allows a drug to be transferred between schedules either by a motion by the Attorney General (i.e. the DEA) or by a challenge to the Attorney General's classification by the Secretary of Health, Education & Welfare (Now known as the Department of Health & Human services, which includes the Food & Drug administration (FDA)), or by any interested party.⁴⁵ Re-classification is important because Schedule I and Schedule II drugs are regulated differently. On the one hand, the DEA has discretion whether or not to accept or deny registration by potential manufacturers and distributors of both Schedule I and Schedule II drugs and may limit the manufacturer to a particular assigned quota.⁴⁶ However, Schedule I drugs are subject to much stricter research application requirements than Schedule II drugs and Schedule I drugs are not permitted to be prescribed by doctors.⁴⁷ Thus, re-classification from Schedule I to Schedule II is particularly significant for medical marijuana research and use and has been the subject of litigation for over twenty years.

B. Efforts to Reschedule Marijuana to Schedule II

The National Organization for the Reform of Marijuana Laws (NORML) filed a rule-making petition on May 18, 1972, requesting that the Bureau of Narcotics and Dangerous Drugs (now the DEA) reschedule marijuana from Schedule I to Schedule II.⁴⁸ This lawsuit initiated a lengthy and complex legal battle that eventually ended only last year. Much of the litigation centered around the statutory interpretation and administrative discretion of the DEA. Specifically, the litigation focused on whether or not marijuana has the Schedule II requirement of a *currently accepted medical use in treatment* or whether there is a *currently accepted medical use with severe restrictions*. The arguments made in these

⁴² *Id.* at § 812(b)(2).

⁴³ *Id.* at § 812.; Bilz, *supra* note 20.

⁴⁴ Bilz, *supra* note 20.

⁴⁵ 21 U.S.C. at § 811(a).

⁴⁶ *Id.* at § 823(a)-(c).

⁴⁷ *Id.* at § 823(0).

48497 F.2d at 655.

,qM, 4.

Student [D# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

court proceedings are illustrative of the numerous differing interests surrounding the issue of medical marijuana.

After initial complications involving the effect of international obligations on re-scheduling and the need for an FDA evaluation regarding medical and scientific findings, the DEA finally held public hearings in front of Administrative Law Judge Francis L. Young concerning whether or not the marijuana plant should be rescheduled in 1986.⁵⁰ Advocates in favor of rescheduling included NORML, The Alliance For Cannabis Therapeutics (ACT, the name plaintiff in the proceedings), The Cannabis Corporation of America (CCA), and the Zion Coptic Church (a religious organization which believes marijuana is sacred). The parties opposing marijuana's rescheduling included the DEA, the International Chiefs of Police (ICOP) and the National Federation of Parents for Drug Free Youth (NFP).⁵⁰

I. *Arguments for Rescheduling Marijuana: The Patients, the Parents and the Doctors*

The parties who argued that marijuana be rescheduled, submitted poignant testimony from many patients who used marijuana to alleviate the pain they suffered from such debilitating diseases as glaucoma, cancer, multiple sclerosis, quadriplegia and severe neuro-dermatitis.⁵¹ For example, Valerie Leigh Cover, a twenty-eight year old woman afflicted with multiple sclerosis, had become addicted to Valium and was suffering from spasms and severe nausea and vomiting. After she stopped taking Valium and began to smoke marijuana, she testified that she no longer felt nauseous. .. noticed [hen intense spasms were significantly reduced and her appetite began to increase.⁵² Moreover, because most of these patients obtained marijuana illegally, they suffered constant anxiety about the possibility of arrest and were enraged at potentially being branded a criminal for using the only substance that provided relief from the pain of their otherwise incurable diseases.⁵³ In addition to this anecdotal evidence from patients, ACT also submitted affidavits from relatives, and particularly from parents of the seriously ill, who also testified to

49~j Fed. Reg. 22946-01 (1986); 559 F.2d at 735. The issue of whether synthetic reproductions of THC could be classified under Schedule I or II was settled in the meantime. On May 31, 1985, the FDA approved a NDA for Marmnol Capsules, containing a synthetic form of THC. Subsequently, the DEA placed Marinol on Schedule II. 51 Fed. Reg. 17476(1986); 51 Fed. Reg. 22,946(1986).

⁵⁰ROBERT C. RANDALL, M ARIJUANA, MEDICINE, AND THE LAW ix, x (1988).

at 1-5.

⁵² 1d at 231.

⁵³ 1d at 105.

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

the apparent therapeutic effects of marijuana on their loved ones and who made desperate pleas to make marijuana accessible. ~

ACT and their co-parties' most important evidence was the testimony by doctors and pharmacologists regarding the accepted medical use of marijuana. The doctors who testified on behalf of rescheduling marijuana argued that although synthetic THC is available for prescription under Schedule II constraints, smoking marijuana is actually preferable to taking a pill. These experts stated that their patients could more easily control their dosage with a joint, that pills are difficult to keep down for patients suffering from nausea and vomiting, and that by inhaling smoke, the effects of the drug are felt more quickly.⁵⁵

From this testimony, it is apparent that the ban on medical marijuana places constraints on the doctor-patient relationship and forces many doctors to violate their ethical duty to practice medicine for the good of their patients. The physicians who testified before the AU in favor of rescheduling cited not only the safety and effectiveness of medical marijuana, but also noted their frustration in being unable to prescribe marijuana freely.⁵⁶ Feeling that their hands were tied, these physicians were often put in an untenable position: they could either not even mention marijuana and its possible therapeutic effects, in which case their patients would suffer, or they could suggest illegal acquisition of the drug, in which case they would be advocating breaking the law. In either case they did not (and still do not) even have the option of prescribing marijuana.

2. *Arguments Against Rescheduling Marijuana: The Government, the Parents and the Doctors*

The DEA testimony consisted overwhelmingly of arguments from physicians and pharmacologists who felt that there simply were not enough properly controlled scientific and medical studies to show that the marijuana plant has an accepted medical use in the United States for treating such diseases as glaucoma, multiple sclerosis and nausea and resulting from chemotherapy.⁵⁷ Chemists noted that there are over 400 different chemicals and 60 cannabinoids identified in the marijuana plant, many of

⁵⁴ *Id.* at 1-5.

⁵⁵ *Id.* at 83, 140.

at 147, 163.

⁵⁷ *Id.* at 359, 365, 385.

Student ID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

which have not been tested for safety and all of which appear in varying degrees in each plant.⁵⁸ In addition, the DEA argued that smoking marijuana may have unwanted side-effects such as increased heart rate and adverse effects on the lungs, and maintained that synthetic oral THC is equally, if not more effective.⁵⁹

It is important to note that the DEA did not argue that the use of marijuana for medical purposes is necessarily *ineffective*, but only that there is insufficient data for an accepted medical use.⁶⁰ However, it is difficult to ascertain how much of the testimony by the scientific community against rescheduling marijuana was prompted by an unconscious reaction to the substances' stigma as a Schedule I illegal drug. Many well-established doctors were not willing to face the *political* repercussions associated with calling marijuana safe for use as a medicine.

The DEAs position during the hearings effectively prohibited marijuana from ever being rescheduled in the near future: the marijuana plant has not been subjected to rigorous enough testing to be a Schedule II drug, yet its status as a Schedule I drug makes it very difficult to research both because of the logistical constraints and because of the reproach doctors might face for investigating the drug. If the DEA had implicit political or social policy reasons for keeping a lock on marijuana as a Schedule I substance (such as the fact that marijuana is associated throughout history with dissident groups or that any legalization is politically impossible when engaged in a war on drugs) they were careful to never articulate them on the record in the hearings.

The arguments made by the National Federation of Parents for a Drug Free Youth were probably more honest than those made by the DEA. Instead of focusing exclusively on the scientific uncertainty of medical marijuana, the NEP argued that rescheduling marijuana sends the wrong message to a nation that is engaged in a battle for its very survival because of epidemic drug abuse.⁶¹ In addition, the NEP believed that young people would interpret rescheduling as a sign that marijuana is OK and that [wie then

⁵⁸ *Id.* at 314: In addition, testimony of one of DEA's scientists reveals that some natural occurring plants such as Digitalis, have been used for centuries as drugs within our cultural milieu. *Id.* at 327-28.

Arguably, marijuana was also part of our cultural milieu before it was effectively banned by the Marijuana Tax Act in 1937.

⁵⁹ *Id.* at 314; 2 RANDALL, *supra* note I, at 267, 286. 602 RANDALL, *supra* note 1, at 281.

⁶¹ *Id.* at 395.

Student ID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

have another youngster trying marijuana, the gateway drug and probably starting down the road that leads to nowhere but destruction. 62 Although this stepping stone argument has been popular rhetoric for denouncing marijuana, no study has ever substantiated this theory.⁶³

In any case, both of NFP's arguments, that rescheduling sends the wrong message and that marijuana is a gateway drug, are erroneous in the discussion about making marijuana available for desperately ill patients. Allowing medical marijuana only sends the wrong message if the public remains uneducated about the therapeutic effects of the drug on patients with severe disabilities. Until the debate about *medical* marijuana is sufficiently distinguished between the debate about total *legalization* of marijuana, the arguments of the NEP will continue to be persuasive to politicians and the public.

3. *The Outcome of the Litigation*

Judge Young issued his decision on September 6, 1988. Creating somewhat of a public fervor,

Judge Young concluded that the provisions of the CSA required the transfer of marijuana from Schedule I

to Schedule H.⁶⁴ Judge Young dismissed the notion that rescheduling will 'send a signal' that marijuana is

'OK' for recreational use,⁶⁵ holding that this fear is specious and should not be allowed to override the

legitimate need of countless sufferers who can be provided with relief when marijuana is prescribed by a

physician in a legitimate case. 66

However, John Law, then the Administrator of the DEA, vehemently overruled the AU decision, rejecting the medical and testimonial evidence that marijuana has an accepted medical use.⁶⁷ The Administrator chastised the irresponsible and irrational statements propounded by the pro-marijuana parties and called Judge Young's finding appalling.⁶⁸ In addition, the Administrator argued that the testimony advocating rescheduling may be rejected as quackery and that ACT and NORML have falsely

⁶² *Id.*; This argument is also known as the stepping stone hypothesis, and was probably first introduced

by the Anslinger campaign for the passage of the Marijuana Tax Act in the 1930's. HIMMELSTEIN, *supra*

note 9, at 86.

⁶³GRINSPOON, *supra* note 3, at 445.

M₂ RANDALL, *supra* note 1, at 445.

65J4

~Id

6754 Fed. Reg. 53767, 53770 (1989).

⁶⁸ *Id* at 53783.

⁶⁹ *Id.* at 53784.

⁷⁰ *Id.*

1993 F.2d at 937. ⁷² *Id.* at 939.

Student LD# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

raised the expectations of many seriously ill persons by claiming that marijuana has medical usefulness in treating emesis, glaucoma, spasticity and other illnesses.⁶⁹

Two elements of the Administrator's decision are particularly striking. First, throughout the Administrator's opinion, he continuously referred to ACT, NORML and the CCA as the *pro-marijuana parties*, an effective rhetorical technique misbranding these parties as having advocated complete and utter legalization of marijuana throughout the hearings. In addition, this was the first time the government raised the false hopes argument, whereby the Administrator argued that ACT and NORML had perpetrated a dangerous and cruel hoax on the American public by advocating medical use of marijuana.⁷⁰ This allegation is misplaced in a legal proceeding for the rescheduling of a substance. ACT and NORML were exercising their legal right under the CSA to petition for the rescheduling of a drug. These parties were not *marketing* marijuana to the American public. This kind of false hopes argument is best left for use by the FDA in situations where manufacturers mislead the public as to the therapeutic effects of a drug under the Food, Drug, and Cosmetic Act and is irrelevant in a proceeding under the CSA.

ACT and NORML petitioned for review of the Administrator's decision. In *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration*, the D.C. Circuit agreed with petitioners that the DEA Administrator may have relied on several factors in the determination of whether or not marijuana has an accepted medical use which were impossible to satisfy because of the drug's restrictive Schedule I status.⁷¹ In his opinion, the Administrator used an eight-factor test for determining the currently accepted medical use of marijuana. The D.C. Circuit remanded the case to the Administrator for an explanation of how a Schedule I illegal drug could ever satisfy the factors requiring general availability of the substance and its use, recognition of its use in generally accepted pharmacopoeia, medical references, etc. and recognition and use... by a substantial segment of the medical practitioners in the U.S.⁷²

In March of 1992, Robert C. Bonner, then the Administrator of the DEA, issued another order condensing the initial eight-factor test into a five-factor test for determining when a drug has a currently

4.

r Student ID# 304 0376 20 57 Food & Drug Law Final Prof. Hutt

accepted medical use and holding that marijuana did not satisfy the five-factor test.⁷³ In February of

1994, the D.C. Circuit reviewed this subsequent order and held that the new test was not impossible for a

Schedule I drug to meet and that the Administrator's decision not to reschedule marijuana was reasonable

and supported by substantial evidence on the record. ~

C. FDA Compassionate Use INDs

In the midst of the rescheduling petition and the ensuing litigation, the FDA began receiving applications from patients who wished to use medical marijuana under a Compassionate Use Investigational New Drug (IND) program. The program was cumbersome and time consuming:

physicians had to file special forms with the DEA and the application then had to be approved by the DEA and the FDA.⁷⁵ If the form was approved, the doctor then had to fill out special order forms and send them to National Institute on Drug Abuse.⁷⁶ In addition, doctors were reluctant to have themselves stigmatized as marijuana advocates and some felt that their government research grants would be jeopardized if they filed for Compassionate Use INDs for their patients. 77

For about fifteen years, the marijuana was grown at a NIDA research farm in Oxford, Mississippi, but even at its peak only fifteen people received marijuana under the program.⁷⁸ The FDA received hundreds of applications from the inception of the program and they were deluged with thousands of applications from people with AIDS beginning in 1989. ~ AIDS sufferers cited marijuana as welcome relief from the nausea brought on by AZT and claimed that marijuana was an effective drug in helping AIDS-related anorexia.⁸⁰

Although the onslaught of applications from AIDS patients desiring medical marijuana added a new vocal advocate for the therapeutic uses of marijuana, the Department of Health and Human Services

7357 Fed. Reg. 10499, 10507 (1992).

⁷⁴15F.3dat 1136.

⁷⁵GRINSPOON, *supra* note 3, at 20-21.

⁷⁷DUKE & GROSS, *supra* note 22, at 183.

⁷⁸Michael Isikoff, *Compassionate Marijuana Use Supplies for Medical Needs are in Jeopardy*, WASH.

POST, Nov. 12, 1991, at z19.

⁷⁹GRINSPOON, *supra* note 3, at 21.

⁸⁰BiIz, *supra* note 20; Mike McKee, *Caught in the Drug War Cross Fire*, THE RECORDER, Apr. 30, 1992, at 1.

W

Student ID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

decided to phase out the Compassionate Use IND program in 1991.⁸¹ The revocation of the program just at a point when thousands of AIDS patients had applied did not strike some as a coincidence, but more as a continuation of the Reagan-Bush anti-AIDS stance. Comments from James O. Mason, director of the Public Health Service seem to support this view, for Mason said he thought allowing AIDS patients to smoke marijuana may interfere with their ability to use a condom and generally practice safe sex.⁸²

However, HHS officials cited political reasons for ending the IND program, stating that it gives a bad signal and arguing that it undercut official Bush administration policy against the use of illegal drugs.⁸³ In addition, government officials claimed that marijuana posed the same health risks as those cited by the DEA in the rescheduling litigation. The policy change to halt the Compassionate Use INDs was actually an inter-agency decision made by the DEA, the Public Health Service and the National Institute of Health.⁸⁵ The FDA had approved at least twenty seven seriously ill patients for the program when it was canceled.⁸⁶ None of these individuals were ever provided marijuana under the program despite having their applications accepted; thus, if anyone raised the false hopes of the desperately ill it was the government.

D. Federal Legislation

An attempt at passing legislation mandating that medical marijuana be available failed. In 1985, Representative Stewart McKinney (Conn.) introduced a bill entitled Legislation to End Prohibition of Medical Use of Marijuana for Seriously ill Americans.⁸⁷ It is not surprising that the bill was unsuccessful, for before it was even introduced the Reagan administration had already rejected the findings of two NAS panels regarding the potential therapeutic uses and legalization of marijuana.⁸⁸ Efforts to pass a bill legalizing the therapeutic use of heroin have also been futile.⁸⁹

⁸¹Michael Isikoff, *HHS to Phase Out Marijuana Program*, WASH. POST., June 22, 1991, at A14.

⁸²Isikoff, *supra* note 78.

⁸³*Id*

⁸⁴Dianne Klein, *The Empty Pot: U.S. Draws Criticism for Decision to Halt Little-Known Program to Distribute Free Marijuana to the Seriously Ill*, LOS ANG. TIMES, Apr. 1, 1992, at A3.

87131 CONG. REC. H2678-05 (1985).

⁸⁸*See supra* notes 3 1-36 and accompanying text.

89135 CONG. REC. S289-01 (1989).

W

r Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

E. State Legislation

State governments responded more favorably to the need for therapeutic marijuana, yet they faced serious implementation problems caused by preemption by federal laws. At one point, at least thirty-five states passed legislation approving the medical use of marijuana for certain patients. These statutes provided medical marijuana in the guise of creating state therapeutic research programs, which typically required doctors to certify to the state that their patients were seriously ill and unresponsive to conventional medical treatment.⁹¹

However, because of marijuana's status as a Schedule I drug under the CSA, these states were dependent on dispensing marijuana through the federal government and had to get FDA approval for their IND programs.⁹² As a result, the bureaucratic procedure and lengthy delays forced most states to abandon their efforts at providing medical marijuana. Some states have even repealed their legislation and some statutes have expired.⁹³ Recent action by California Governor Pete Wilson suggests that the states are taking a more conservative approach. Despite the passage of a San Francisco referendum in 1991 urging California to permit doctors to prescribe marijuana for seriously ill patients,⁹⁴ Wilson recently vetoed legislation that would have allowed physicians to prescribe marijuana, citing conflicts with federal law and policy.⁹⁵

F. The Medical Necessity Defense

Some state and federal courts have allowed an individual charged with possession of marijuana to claim a medical necessity defense.⁹⁶ Robert Randall, the founder of ACT and a glaucoma sufferer, was

GRINSPOON, *supra* note 3, at 17. The states which enacted such legislation include: Alabama, Alaska,

Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Iowa, Louisiana, Maine,

Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New York, North

Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia,

Washington, West Virginia, and Wisconsin. *Id.*

⁹¹ See MICH. STAT. ANN. §§ 333.7335-36(1984) (expired 1982).

⁹² GRINSPOON, *supra* note 3, at 17.

⁹³ MICH. REV. STAT. ANN. §§ 333.7335-36(1984) (expired 1982); CAL. HEALTH & SAFETY CODE §§

11260-11270(1985), *repealed by* Stats. 1984, ch. 417, § 5, eff. July 11, 1984, operative June 30, 1989;

ALASKA STAT. § 17, ch. 35(1984), *repealed by* ALASKA STAT. § 22, ch. 146(1986); LA. REV. STAT.

ANN. § 40:1021-: 1026 (1985), *repealed by* Acts 1989, No. 662, § 8, eff. July 7, 1989; ME. REV. STAT.

ANN. tit. 22, §§ 2401-2420 (1984), *repealed by* § 2410, eff. Sept. 14, 1981.

⁹⁴Isikoff, *supra* note 78.

⁹⁵*Wilson vetoes marijuana, AIDS bills*, CANCER RESEARCHER WEEKLY, Oct. 17, 1994, at 12.

⁹⁶United States v. Burgon, 894 F.2d 188 (6th Cir.), *cert. denied*, 111 S.Ct. 157 (1990); Jenks v. State, 582

So.2d 676(1991); State v. Bachman, 595 P.2d 287 (1979); State v. Diana, 604 P.2d 1312 (1979).

Student ID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

the first person to successfully assert the defense in the D.C. Superior Court in 1976. In 1992, the Maine legislature passed a law establishing an affirmative defense for marijuana users who were diagnosed with glaucoma and who suffered side effects from radiation treatment.⁹⁸ However, Maine Governor John McKernan vetoed the legislation under pressure from the federal government.

The medical necessity defense, while potentially useful in some situations, is not accessible to everyone who uses marijuana for medicinal purposes and is unattractive because of its availability only after a seriously ill patient has been arrested. The courts which have allowed a medical necessity defense typically require expert medical testimony that the harm from the defendant's disease is serious and imminent and that conventional medical alternatives are ineffective or unavailable. This puts a difficult burden of proof on a defendant and is costly. In addition, some states, like Minnesota and New Jersey, have rejected the medical necessity defense altogether.

W. The Future Of The Therapeutic Use Of Marijuana

Medical marijuana will never be available for prescription on a national level until it is transferred to Schedule II of the CSA. The courts in the *ACT* rescheduling litigation effectively foreclosed any opportunity by citizen groups to petition for rescheduling in the near future by affirming the DEA's position that more rigorous and scientifically accepted research must be done on marijuana before it can be considered to have a currently accepted medical use. Anecdotal evidence from sufferers of glaucoma, multiple sclerosis, cancer, and AIDS, and affidavits from their physicians are insufficient. Even a 1991 study done by Richard Doblin and Mark Kleinman of Harvard's Kennedy School revealing that forty-eight percent of the oncologists surveyed said they would prescribe marijuana for some of their patients if it were legal is not enough to prove that marijuana is accepted by the medical community.¹⁰²

⁹⁷United States v. Randall, 104 Daily Wash.L.Rep. 2249 (D.C. Super. 1976).

⁹⁸McKee, *supra* note 80.

Id.

¹⁰⁰*Id.*; 595 P.2d at 287.

¹⁰¹State v. Tate, 505 A.2d 941 (1986); State v. Hanson, 468 N.W.2d 77(1991).

¹⁰²Brian Hecht, *Out of Joint: The Case for Medicinal Marijuana*, NEW REPUBLIC, Jul. 15, 1991, at 7.

Student ID# 304 0376 20 57
Food & Drug Law Final
Prof. Hutt

A. *Proving Accepted Medical Use of Marijuana and the Role of the FDA in Rescheduling*

Since it is unlikely that the DEA will change its tough war on drugs stance and recommend rescheduling itself, one possible way to demonstrate marijuana's accepted therapeutic use is through endorsement by the FDA. The CSA provides that the FDA may recommend that a substance not be controlled.¹⁰³ The FDA's scientific and medical findings are binding on the DEA and the DEA may not control a substance if the FDA recommends against it.¹⁰⁴

However, while it is not legally necessary for a drug to go through the NDA process in order for it to be rescheduled,¹⁰⁵ typically the FDA only recommends to the DEA that a drug be rescheduled after it has approved a NDA for the drug. For example, the FDA did not recommend rescheduling THC and its synthetic equivalent *dronabinol* (Marmnol capsules) to Schedule II until a NDA was approved for both substances.¹⁰⁶ Other drugs, such as *levo-alphaacetylmethadol* (LAAM) have also been transferred to Schedule H upon approval of a NDA.¹⁰⁷ Thus, the rescheduling of marijuana by the FDA hinges on whether or not the drug could pass the rigorous requirements imposed by the IND/NDA process.

Marijuana will most likely never be approved by the FDA under a NDA. First, the bureaucratic difficulties in researching a Schedule I drug are burdensome.¹⁰⁸ In addition, researching marijuana presents special problems because it is a plant. Pharmaceutical companies are uninterested in investing in marijuana because it can not be patented and because it contains many chemicals, instead of one chemical that can be isolated and reproduced synthetically.¹⁰⁹ In addition, because the IND/NDA process is incredibly costly, the drug companies will only sponsor a NDA if there is reasonably certainty that the application will be approved – a guarantee that can not be made in light of the political implications surrounding marijuana.

Even if a sponsor could be found, the appropriate controlled studies may be difficult to administer. The FDA usually requires placebo-controlled studies, which some doctors are unwilling to do on patients 10321 U.S.C. at §811(a).

¹⁰⁵Grinspoon v. Drug Enforcement Administration, 828 F.2d 881 (1st Cir. 1987).

10647 Fed. Reg. 10080(1982); 51 Fed. Reg. 17476 (1986).
10758 Fed. Reg. 25790 (1993).

supra notes 46-47 and accompanying text.

¹⁰⁹GPJNSPOON, *supra* note 3, at 157.

Student ID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

who are seriously ill. Donald Abrams, chairman of San Francisco's Community Consortium, has attempted to devise a trial comparing the efficacy of inhaled marijuana to synthetic THC on AIDS patients.⁰ Frustrated by FDA requirements regarding controlled studies, Abrams stated [patients with HIV wasting syndrome should not be given an inert substance for 12 weeks.]¹¹ Thus, the near impossibility of performing the appropriate scientific studies on marijuana collapses into larger criticisms of the lengthy and costly IND/NDA process and its discriminatory affect on the desperately ill.

B. Congressional Action

Another way to reschedule marijuana is to amend the CSA through Congressional action. However, the possibility of passing a medical marijuana act remains uncertain in today's changing political climate. Although the Clinton administration appeared receptive to re-instituting the FDA Compassionate Use IND program, the Public Health Service decided against lifting the ban last August.¹¹² Former Surgeon General Jocelyn Elders supported using marijuana to treat certain illness; however, her dismissal may indicate that the public and the administration is not receptive to such views. In addition, the success of the Republicans in last fall's elections is attributed, in part, to a national desire for politicians to get tough on crime and drugs. Indeed, the House Republicans' Contract With America calls for wiping out crime prevention spending in the Crime Bill and building more prisons instead. Even NORML has responded to the changing of the guard in Washington, by shedding its hippie image and installing a new board in order to cater to the button-down world of blue-ribbon science and lab research, coupled with a strong aroma of libertarianism.^{1 13}

However, there are recent indications that the public is more tolerant regarding recreational use of marijuana, perhaps alleviating political pressure to brand the drug as unsafe and paving the way for public acceptance of medical marijuana. For example, in 1987, the admission by Supreme Court nominee

110 Rebecca Voelker, *Medical Marijuana: A Trial of Science and Politics*. 271 J. AM. MED. ASS'N 1645 (1994).

111j~

¹²Cynthia Hubert McClatchy, *Membership In This Club is Criminal; Underground Meeting Place Provides Marijuana to Chronically Ill*, FRESNO BEE, Sept. 4, 1994, at B 10.

³ Edward Epstein, *The Marijuana Lobby Buttons Down After 25 Years of Grass-Roots Struggles, The National Organization for the Reform of Marijuana Laws Sheds Its Long-Hair Image to Get Some Respect in Washington*, SAN FRAN. CHRON., Jan. 22, 1995, at 6/71.

Student ID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

Douglas H. Ginsburg that he had smoked marijuana while a professor at Harvard Law School was politically devastating.¹¹⁴ However, today we not only elected a President who has smoked marijuana, but also a Vice President and a Speaker of the House who have experimented with the drug (Gingrich admitted to smoking marijuana while in graduate school).¹¹⁵

The government may also be more sympathetic to the idea of medical marijuana than one might expect. In 1982, in a letter to the Journal of the American Medical Association, Gingrich himself challenged the AMA to rethink its official stance against medical marijuana in the hopes that the AMA might well discover that its own assessment of marijuana's therapeutic value has, in the past, been more than slightly shaded by federal policies that are less than neutral. ¹¹⁶ In addition, proponents of medical marijuana may find that the new anti-regulation, libertarian Republican Congress will lend an ear to the argument that seriously ill patients should be able to medicate themselves without governmental intrusion. There are signs that even the DEA has softened its approach, for a Cannabis Buyers Club in San Francisco, which has been illegally selling marijuana to people who suffer from severe afflictions, has been ignored by the DEA for at least eight months.¹¹⁷ One DEA agent admitted that marijuana was a low priority when the agency is overwhelmed with cases involving more dangerous drugs, such as heroin and crack.¹¹⁸ While these examples do not ensure the passage of an act rescheduling marijuana, they do suggest that the political tide may be turning towards acceptance of marijuana as medicine.

C. Re-education of the Public

Before any Congressional action can take place and before marijuana can be approved through a NDA, a re-education of the public on a national level about the medical uses of marijuana must occur. This education will serve to divorce marijuana from the political symbolism and rhetoric that has surrounded the *recreational use* of marijuana for the last century and will help focus the debate on the

¹¹⁴ Michael Spector & James R. Dickenson, *Politicians Line Up to Admit or Deny Past Marijuana Use*, WASH.POST., Nov. 8, 1987, at A1.

¹¹⁵ Jim Abrams, *Gingrich Fires at Clinton - He Alleges White House Staff Used Drugs*, DETROIT FREE

PRESS, Dec. 5, 1994, at SA.

¹¹⁶ Newt Gingrich, *Letter to the Editor: Legal Status of Marijuana*, 247 J. AM. MED. ASS'N 1525, 1563

(1982). Gingrich's allegations that a quarter of the White House staff uses drugs and are part of the counterculture may prove that Gingrich has changed his mind regarding medical marijuana. Abrams,

supra note 115.

¹¹⁷ McClatchy, *supra* note 112.

¹¹⁸

W.

Student ID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

medical use of the drug. Many agencies and governmental institutions could be involved in this effort as well as some non-profit organizations, such as those that focus on AIDS and cancer. Traditional media, such as newspapers, magazines and television, could be used.

This re-education about the therapeutic uses of marijuana should seek to dispel the myth that rescheduling marijuana will lead to the demise of American society by *Reefer Madness*. One way to do this is to focus on the fact that marijuana would only be available *by prescription*, just like many other dangerous drugs, and would still be subject to strict regulation. The American public must be informed that so called harder drugs, such as cocaine, are actually Schedule II drugs which may be prescribed for medical use (some eye surgeons do prescribe cocaine).¹⁹ Likewise, morphine and its synthetic substitute methadone, both highly addictive drugs, are classified under Schedule H are used by physicians for pain management and to treat heroin addiction. 120

In addition, people must become aware of the relatively insignificant risk to seriously ill patients who wish to smoke marijuana for medical purposes. Patients suffering from AIDS, terminal cancer and other severe illnesses are in constant pain. What is the risk of smoking marijuana to someone who is already facing the certainty of death? Moreover, of the thousands of years that marijuana has been used, no one has ever been known to have died from the drug. In comparison, in 1990, aspirin was cited as at least one of the possible causes of 111 drug deaths in America. 121 Medical examiners labeled aspirin as the sole cause of death for 18 of those people. 122

V. Conclusion

In short, the success of making marijuana a Schedule H substance and thus increasing its therapeutic use as well as making research easier to perform, depends primarily on increasing education. The strange legal history of medical marijuana in this country is inextricably linked with politics. Doctors, government officials, parents, and ordinary citizens will only be persuaded that marijuana has medicinal value when the issue of medical marijuana is considered completely separately from its recreational use in

¹⁹Klein, *supra* note 84.

²⁰*D1JKE* & GROSS, *supra* note 22, at 55, 293.
at 182.

Student IID# 304 0376 20 57

Food & Drug Law Final

Prof. Hutt

an some sort of an open forum. Thus, medical marijuana will only become a reality for the gravely ill when the American public decides it is time.