

RL30274

CRS Report for Congress

Medical Use of Marijuana: Policy and Regulatory Issues

Updated March 1, 2002

Blanchard Randall IV
Analyst in Social Sciences
Domestic Social Policy Division

Distributed by Penny Hill Press

<http://pennyhill.com>



Prepared for Members and
Committees of Congress

Medical Use of Marijuana: Policy and Regulatory Issues

Summary

In recent years, there has been much debate over whether marijuana, an illegal drug, can provide patients with a level of therapeutic relief comparable to existing pharmaceutical treatments. While this idea is hardly new, it is advanced by some proponents as deserving more scientific inquiry. Advocates for the medical use of marijuana contend that there is already sufficient scientific evidence to justify rescheduling marijuana under the Controlled Substances Act, a change that would give it the necessary legal recognition to be used for medicinal purposes. This has already occurred in the case of dronabinol, the synthetic form of the main psychoactive ingredient in marijuana, which has been available as an oral prescription drug since 1986 under its brand name Marinol.

To address these viewpoints, several comprehensive studies were done in the late 1990s to evaluate medicinal claims made for smoked marijuana and determine whether they are supported by convincing scientific evidence. In 1997, the NIH convened an Ad Hoc Group of Experts, which concluded that scientific evidence was insufficient to definitively assess marijuana's therapeutic potential and advised that the traditional scientific process should be allowed to evaluate the drug's use for certain disorders. In its 1999 report *Marijuana and Medicine: Assessing the Science Base*, the Institute of Medicine (IOM) concluded that the therapeutic effects of smoking marijuana were modest. IOM noted, however, that while marijuana's active components are potentially effective in treating certain medical conditions, they should be tested rigorously in controlled clinical trials.

The medical marijuana debate gained attention at the state level in 1996, when voters in California and Arizona approved ballot initiatives allowing doctors to prescribe the drug for therapeutic uses. In 1998, similar propositions were adopted in Alaska, Nevada, Oregon, and Washington, and reaffirmed in Arizona. Voters in Maine adopted a medical marijuana initiative in 1999. In 2000, medical marijuana was approved by voters in Colorado, reconfirmed in Nevada, and passed by the legislature in Hawaii. Federal health officials assert that these initiatives are part of a strategy to soften the nation's drug laws, and that public policy would be better served if science, rather than the ballot box, were used to judge the drug's utility.

Congress has responded to the state initiatives by passing various measures reconfirming marijuana's status as a Schedule I controlled substance with no currently accepted medical use in the United States. Congress has also said that it supports the existing federal legal process for determining the safety and effectiveness of drugs, and opposes efforts to circumvent this process by legalizing marijuana, or any other Schedule I controlled drug, for medical use without valid clinical evidence and the approval of the Food and Drug Administration. Although bills have been introduced in the 107th Congress to let doctors prescribe marijuana in states with laws that allow it, thus far Congress has opposed this idea until the drug's alleged therapeutic benefits have been confirmed scientifically. Until such studies are done, and more convincing data emerge, reports of marijuana's medicinal prowess will hinge as much on anecdotal evidence as the controlled clinical investigation.

Contents

Historical Background	1
Federal Regulation of Marijuana	3
Drug Enforcement Administration: The Controlled Substances Act ..	3
Food and Drug Administration: Federal Food, Drug, and Cosmetic Act	6
Citizen's Petitions Seeking Marijuana's Rescheduling Under the Controlled Substances Act	7
Previous Government Actions Relating to Marijuana	9
NCI's Past THC Distribution Program	9
FDA Approves Synthetic Marijuana: Marinol	9
PHS Ends Marijuana Treatment Use Program	10
Synthetic Versus Smoked Marijuana	11
Medical Uses of Marijuana	12
Chemotherapy and Nausea Treatment	12
Appetite Stimulation	16
Movement Disorders	17
Glaucoma	18
Analgesia	18
Summary of Findings of the Medical Literature	19
Current Research on Medical Marijuana	21
Medical Marijuana: State Ballot Initiatives	22
Medical Marijuana: Canada	26
Medical Marijuana: The U.S. Supreme Court	27
Medical Marijuana and Congress: Recent Legislation	29
Conclusion	32

Medical Use of Marijuana: Policy and Regulatory Issues

Historical Background

Marijuana, or by its botanical name *Cannabis sativa*, has been cultivated worldwide for centuries. The *Cannabis* plant, also raised for the production of hemp fiber, is more generally grown and consumed (smoked) for its medicinal and psychoactive effects. In the United States, historical accounts of the drug's use, both for recreational and medicinal purposes, date back to the nineteenth century and earlier. In those earlier years, marijuana use was legal under state and federal law, but it was smoked more to achieve intoxication than to relieve medical symptoms. By the 1840s, however, marijuana's therapeutic potential gained a modicum of recognition among some U.S. physicians, and from 1850 to the early 1940s the drug was included in the *United States Pharmacopoeia* as a recognized medicinal.¹ Societal opinion about marijuana began to shift in the early 1900s as more and more of the general public and politicians came to believe that use of the drug was connected to the rising crime rate.

By 1935, most states had laws prohibiting either the use, sale, or possession of marijuana. Shortly thereafter, Congress enacted the 1937 Marijuana Tax Act² which, rather than outlawing the substance, imposed a tax on its growers, sellers, and buyers. The Act's passage resulted in all medicinal products containing marijuana being withdrawn from the market, and in 1941, the drug was dropped from recognition by *The National Formulary* and *The U.S. Pharmacopoeia*.³ Possession and sale of the drug remained illegal under state law.

Congressional enactment of the Comprehensive Drug Abuse Prevention and Control Act⁴ of 1970 led to an overhaul of existing state and federal statutes governing marijuana. Commonly referred to as the Controlled Substances Act (CSA), it replaced and updated most previous laws concerned with illicit drugs and

¹ Bliz, Gregg A. The Medical Use of Marijuana: the Politics of Medicine. *Hamline Journal of Public Law and Policy*, v. 13, spring 1992. p. 118.

² In *Leary v. United States*, 395 U.S. 6 (1968), the U.S. Supreme Court later declared that portions of the Act were unconstitutional because by requiring citizens to pay a federal tax, particularly for a drug that was illegal under state law, the statute compelled self-incrimination, a violation of the Fifth Amendment.

³ Ray, Oakley, and Charles Ksir. *Drugs, Society, and Human Behavior*. 8th ed. WCB/McGraw-Hill, 1999. p. 415. (Hereafter cited as Ray, *Drugs, Society, and Human Behavior*.)

⁴ 21 U.S.C., Section 801, et seq.

consolidated them under the jurisdiction of federal control. Existing state laws regulating illicit drugs, though they remained in effect, were overridden by the new federal statute. The CSA established a new system for scheduling all drugs based on their potential for abuse. Under the law, drugs with the highest potential for abuse and no generally accepted medical use, even under the supervision of a licensed physician, were defined as Schedule I drugs. Accordingly, Congress placed marijuana in Schedule I of the Act where it remains to this day.

Despite law enforcement's efforts to control its distribution and use, marijuana has over the years acquired a reputation as the most widely used illicit substance in the nation. At the same time there has evolved a growing body of evidence scientifically documenting the health risks associated with its use. Chronic marijuana smoking can adversely affect the lungs, the cardiovascular system, and possibly the immune and reproductive systems as well. It is also well established that marijuana intoxication can adversely affect a person's coordination, and impair their motor and decision-making skills. Certain psychological health problems and various forms of nefarious behavior have also been associated with use of the drug. In addition, there is the belief, still adhered to by some, that marijuana serves as a "gateway"⁵ substance leading to the use of more dangerous drugs, such as cocaine and heroin.

Despite these health ramifications, by the early 1970s, debate over the health consequences of marijuana turned as a growing number of people began smoking the drug as a means of coping with medical problems that were not responsive to conventional medications. In particular, marijuana was being smoked for its alleged therapeutic benefits by patients suffering from acute pain from various causes, cancer, human immunodeficiency virus (HIV), and a host of other medical complications. To supporters of this trend, this is all the clinical and empirical evidence needed to support their view that, for some patients, smoking the drug should be permitted for medical purposes. Moreover, people who have long criticized what they consider to be overly punitive federal anti-drug laws, now argue that these same statutes are sometimes used to make felons out of law-abiding citizens who occasionally smoke marijuana for therapeutic relief.

Opponents of allowing marijuana to be used for medicinal purposes view the debate from an entirely different perspective. They claim that marijuana – whether it is smoked for medicinal or recreational purposes – presents serious behavioral and physiological risks that are neither trivial nor acceptable from a health standpoint. Moreover, they argue that smoked marijuana has not been shown to be safe and effective for treating any medical condition, primarily because its alleged therapeutic utility has yet to be sufficiently demonstrated in well-controlled clinical trials. They challenge the notion that marijuana offers patients medicinal benefits superior to

⁵ With respect to the rationale behind the argument that marijuana serves as a "gateway" drug, the Institute of Medicine, in its 1999 report *Marijuana and Medicine: Assessing the Science Base* [cited herein], offered the following: "In the sense that marijuana use typically precedes rather than follows initiation of other illicit drug use, it is indeed a 'gateway' drug. But because underage smoking and alcohol use typically precede marijuana use, marijuana is not the most common, and is rarely the first, 'gateway' to illicit drug use. There is no conclusive evidence that the drug effects of marijuana are causally linked to the subsequent abuse of other illicit drugs."

those from conventional pharmaceuticals, and maintain that the drug should not be encouraged for general medical use.

Somewhere between these divergent views lies the opinion of some physicians and scientists that marijuana should at least undergo further scientific evaluation to determine whether it has a legitimate place in medical treatment. To date, only a handful of elected officials have been willing to supported this scientific approach.

Much of the controversy surrounding the medical marijuana issue stems in part from a long-standing disagreement between supporters and government health and law enforcement officials over whether smoking marijuana provides patients a safer and more effective form of treatment than taking oral-dose dronabinol, its synthetic pharmaceutical equivalent. In this report, marijuana refers to the leaves and flowering tops of the *Cannabis* plant, thought to contain more than 400 different chemicals.⁶ At least 60 of these, referred to as cannabinoids, are unique to the cannabis plant. One such cannabinoid, delta-9-tetrahydrocannabinol – or THC, is believed to be the primary chemical component responsible for the drug's psychopharmacological effects. Dronabinol refers to delta-9-tetrahydrocannabinol's synthetic pharmaceutical equivalent.

Dronabinol was first synthesized in the mid-1960s. However, there was little commercial interest in marketing it as a pharmaceutical product until 1981 when its production patents were purchased by the Unimed company.⁷ Following clinical trials to affirm its safety and effectiveness, oral-dose dronabinol was approved by the Food and Drug Administration (FDA) in 1985 under its brand-name Marinol for treating nausea experienced by cancer patients undergoing chemotherapy.⁸ For enforcement purposes, dronabinol – a controlled substance with some abuse potential of its own – was transferred administratively from Scheduled I to Schedule II of the CSA.⁹ The regulatory implications of this change are discussed in the next section of this report.

Federal Regulation of Marijuana

Drug Enforcement Administration: The Controlled Substances Act.

The Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, is the statute on which the federal government bases most of its authority to regulate what it considers to be harmful and abusable chemical (i.e., drug) substances. The Act is enforced by the Drug Enforcement

⁶ Ray, *Drugs, Society, and Human Behavior*, p. 410.

⁷ Chakravarty, Subrata N. Pot of Gold. *Forbes*, September 12, 1983. p. 44. (Hereafter cited as Chakravarty, *Pot of Gold*)

⁸ Russell, Christine. Marijuana-based Drug for Nausea Approved. *The Washington Post*, Friday, June 7, 1985. p. A16.

⁹ U.S. Dept. of Justice. Drug Enforcement Administration. Schedules of Controlled Substances: Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules from Schedule I to Schedule II; Statement of Policy. *Federal Register*, v. 51, no. 92, May 13, 1986. p. 17476.

Administration (DEA), a branch of the Department of Justice. Under the CSA, drugs, referred to statutorily as “controlled substances,” are placed into one of five schedules. A substance’s scheduling is determined by its potential for abuse, safety concerns, and whether it has a accepted use in medicine.

Drugs, or their chemical precursors, placed in Schedule I are the most restrictively controlled substances covered by the Act. Included in this schedule are such drugs as heroin, other opiate derivatives, hallucinogenic substances (LSD, marijuana, psilocybin, mescaline), and more recently, a host of so-called “designer” drugs such as methylenedioxymethamphetamine, better known as MDMA or Ecstasy. Although Schedule I drugs can be used for experimental and analytical purposes, their unauthorized manufacture, distribution, and/or possession is strictly illegal. To be relegated to Schedule I, a drug or chemical must: have a high potential for abuse; have no currently accepted medical use in treatment in the United States; and lack accepted safety even for [human] use under medical supervision.

Drugs with less potential for abuse, and a recognized medical use, are assigned to Schedules II through V. Most of these are pharmaceutical products, available by prescription only. Drugs [or their primary psychoactive ingredient] placed in Schedule II are distinguished further by unique restrictions such as annual production quotas and more restrictive limitations on their prescribing. Congress or the Justice Department, through their respective law and rule making authority, can add to, transfer, or remove potentially abusable and dangerous drugs from the five schedules. Under the CSA, before a drug or other substance is assigned to a particular schedule, its potential for abuse, dependence liability, and overall risk to public health, must be determined by the Attorney General. In making this determination, the Attorney General must obtain from the Secretary of Health and Human Services (HHS) a recommendation as to whether the drug should be added [or rescheduled] as a controlled substance. The factors that distinguish the abuse potential characteristics of one schedule from another are shown in the box below, along with examples of drugs typical to each.

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. [Examples: heroin, LSD, marijuana, mescaline, methaqualone, phencyclidine, and 3, 4-methylenedioxymethamphetamine, better known as MDMA or Ecstasy.]

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 substance may lead to severe psychological or physical dependence. [Examples: codeine, dronabinol (synthetic tetrahydrocannabinol), methadone, opium extracts (morphine), certain sedative/hypnotics, stimulants (cocaine, methamphetamine, methylphenidate).]

Schedule III – (A) The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II; (B) The drug or other substance has a currently accepted medical use in treatment in the United States; (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence. [Examples: anabolic steroids, certain appetite suppressants, pain medications (aspirin or acetaminophen with codeine), and some barbiturates.]

Schedule IV – (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III; (B) The drug or other substance has a currently accepted medical use in treatment in the United States; (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III. [Examples: appetite suppressants, Darvon, anti-anxiety agents (Xanax and Valium).]

Schedule V – (A) The drug or other substance has a low potential for abuse relative to drugs or other substances in Schedule IV; (B) The drug or other substance has a currently accepted medical use in treatment in the United States; (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV. [Examples: cough or cold medications containing lower doses of codeine.]

Source: 21 U.S.C., Section 801. Drug examples are from various sources including: 21 CFR 1308.11 and the *Physicians' Desk Reference*, 55th ed., 2001.

When Congress passed the CSA, it placed marijuana along with other well known illegal drugs (e.g., heroin, LSD, etc.) into Schedule I, where most of them remain today. By taking this action, Congress stated de facto that drugs relegated to this schedule were not only highly abusable, but moreover, had no recognized medical use, even for patients being treated by a licensed physician.

Changing current law to allow patients to use marijuana for medicinal purposes raises a host of contentious scientific, regulatory, and political issues. For the drug to be available for general medical use, each of its alleged therapeutic uses would have to be scientifically documented through well designed clinical investigations. In addition to being proven safe and effective, marijuana would have to be rescheduled from Schedule I to Schedule II of the CSA. To justify such a major change in scheduling, both the Justice Department and the Department of Health and Human Services (DHHS) would have to be persuaded that marijuana smoking poses less risk than previously thought, and that the drug has achieved wider therapeutic recognition by the medical profession. Until these policy and regulatory changes coincide, there is little to suggest that the government will modify its longstanding opposition to the drug's use — medical or otherwise.

Food and Drug Administration: Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration (FDA), an agency of the Public Health Service (PHS) within the DHHS, is responsible for enforcing the nation's food and drug laws governed by the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under this authority, FDA requires that all pharmaceutical products undergo clinical evaluation to determine their safety and effectiveness before they are approved for general medical use. Comprehensive testing is required, regardless of whether the drug is chemically produced in the laboratory or originates from a natural plant or animal source.

Section 201(g)(1) of the FD&C Act defines the term “drug” to mean articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. Under Section 201(p) the term “new drug” is defined as “any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof” As such, when smoked or otherwise consumed for *therapeutic* purposes, marijuana would also be considered a “new” drug in the sense that, under the law, it has yet to become “recognized” as safe and effective by “experts qualified by scientific training and experience.” Once a drug has been subjected to sufficient clinical evaluation, and physicians gain more practical experience with its use, its previous status as a new drug can change.

To gain FDA approval, a new drug's safety and effectiveness must be confirmed by “substantial evidence” which is defined as evidence:

... consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.¹⁰

Conducting such clinical investigations generally requires designing testing protocols that are randomized, blinded, and usually placebo-controlled. Such studies minimize testing bias and greatly enhance the likelihood that the data will be statistically significant, and not the result of random chance. Confirming a drug's safety and effectiveness is a major undertaking, involving multiple corroborative studies, usually requiring significant financial resources.

Unlike pre-approval studies of drugs intended for oral use, clinical trials using a substance like natural marijuana — which has to be smoked, often have added complications. To conduct such studies, investigators must have a supply of the drug that is virtually “pharmaceutical” like in quality; capable of delivering its primary psychoactive ingredient — tetrahydrocannabinol — in calibrated milligram doses. Also, since marijuana smoke has an easily discernible taste and smell, researchers and study subjects may find comparing the drug's effects to that of a placebo somewhat problematic. Further, conducting experimental work with controlled

¹⁰ 21 U.S.C. 505.

substances like marijuana requires compliance with DEA regulatory procedures. By law, Schedule I controlled substances may be used for experimental purposes, but investigators must register with the agency, and abide by its stringent record-keeping and security requirements.

Citizen's Petitions Seeking Marijuana's Rescheduling Under the Controlled Substances Act. Since the early 1970s, advocacy groups have employed a variety of strategies to challenge marijuana's scheduling under the CSA. What started initially as a routine citizen's petition challenging the drug's original scheduling, has evolved into a medico/legal debate that has gone on for the better part of three decades. Although the original citizen's petition was rejected by DEA's predecessor, the Bureau of Narcotics and Dangerous Drugs,¹¹ the petitioners instigated a succession of appeals, hearing requests, and a variety of other court proceedings.

By the early 1980s, much of the debate and legal maneuvering between government officials and medical marijuana supporters centered on the issue of whether there was sufficient scientific evidence to support the many therapeutic claims being made for smoked marijuana, and whether that evidence met the statutory requirements for a scheduling change. During years of administrative proceedings, advocates have submitted published scientific studies and other data to show that marijuana had pharmacotherapeutic benefits capable of treating a variety of medical conditions. For the most part, the validity of these studies has been challenged by DEA on the grounds that they violated one or more traditional scientific experimental methods – either that too few patients were involved, the studies were not double-blind (i.e., research subjects were aware that they were receiving the drug), or they were not conducted in a randomized fashion.

Pro-medical marijuana supporters were largely unsuccessful in their efforts to persuade the Justice Department that the drug has a currently accepted medical use in treatment – or at least a medical use with severe restrictions, until 1988 when a DEA administrative law judge ruled favorably on a petition pending at the time and declared that marijuana's medical use was clear beyond any question. Moreover, he recommended that the drug be made legally available for some medical purposes.¹²

After reconsideration of the judge's recommendation, DEA published a denial of the marijuana rescheduling petition,¹³ and announced that it would not accept the opinion that marijuana has an accepted medical use in treatment of some medical conditions. Instead, the agency declared that marijuana must remain in Schedule I of the CSA because it has no accepted medical use in treatment of any condition in

¹¹ U.S. Dept. of Justice. Bureau of Narcotics and Dangerous Drugs. Schedule of Controlled Substances: Petition to Remove Marijuana or in the Alternative to Control Marijuana in Schedule V of the Controlled Substances Act. *Federal Register*, v. 37, no. 174, September 7, 1972. p. 18097.

¹² Isikoff, Michael. Administrative Judge Urges Medicinal Use of Marijuana. *The Washington Post*, September 7, 1988. p. A2.

¹³ U.S. Dept. of Justice. Drug Enforcement Administration. Marijuana Scheduling Petition; Denial of Petition. *Federal Register*, v. 54, no. 249, December 29, 1989. p. 53767.

the United States, and because it cannot be safely used – even under a doctor’s supervision.

The petition denial was appealed and in 1991 the United States Court of Appeals for the District of Columbia Circuit ordered the DEA to reconsider its 1989 decision that marijuana has no currently accepted use in medical treatment in the United States.¹⁴ The judicial panel said the agency acted unreasonably in evaluating the drug’s effectiveness for cancer and other seriously ill patients. Nevertheless, after additional review of the entire record, the DEA Administrator issued a final order on March 18, 1992 denying the rescheduling petition once more and reiterating the agency’s opinion that natural marijuana has no currently accepted medical use.¹⁵

The legal confrontation between DEA and proponents of changing U.S. marijuana laws has continued through the 1990s. After DEA issued its final order, the Drug Policy Foundation, the National Organization for the Reform of Marijuana Laws (NORML), and the Alliance for Cannabis Therapeutics (ACT) petitioned the U.S. District Court of Appeals for the District of Columbia seeking a review of DEA’s final order declining to reschedule marijuana from Schedule I to Schedule II of the CSA. In 1994, the D.C. Circuit Court of Appeals held that it would not reconsider ACT’s petition for review of DEA’s final order.¹⁶ The court cited its previous disposition of the matter in *ACT v. DEA*, 930 F. 2d 936 (D.C. Cir. 1991), upheld the agency’s action, and held that on remand, the Administrator had provided a satisfactory explanation of the initial final order.

In 1995, Jon Gettman, a former National Director of NORML, submitted a personal petition to DEA calling for the rescheduling of marijuana. The petition requested that marijuana and all cannabinoids be removed from Schedules I and II of the Controlled Substances Act, based on the claim that the drug does not have the potential for abuse the statute requires for inclusion in those schedules.¹⁷ When a petition calls for the rescheduling of a controlled substance, by law it is referred to the Department of Health and Human Services (HHS) for further scientific and medical evaluation. Based on the HHS evaluation of other relevant data, DEA concluded that there was no substantial evidence that marijuana should be removed from Schedule I. In a letter dated March 20, 2001, DEA Administrator Donnie R. Marshall denied Gettman’s petition to initiate rulemaking proceedings to reschedule marijuana.¹⁸

¹⁴ *Alliance for Cannabis Therapeutics v. DEA*, 930 F. 2d 936 (D.C. Cir. 1991).

¹⁵ U.S. Dept. of Justice. Drug Enforcement Administration. Marijuana Scheduling Petition; Denial of Petition; Remand. *Federal Register*, v. 57, no. 59, March 26, 1992. p. 10499.

¹⁶ *Alliance for Cannabis Therapeutics v. DEA*, 15 F. 3d 1131 (D.C. Cir. 1994).

¹⁷ National Drug Strategy Network. Petition to Repeal Marijuana Prohibition Filed by Jon Gettman. November 6, 1998. [<http://www.ndsn.org/NOV95/PETITION.html>]

¹⁸ U.S. Dept. of Justice. Drug Enforcement Administration. Denial of Petition; Notice. *Federal Register*, v. 66, no. 75, April 18, 2001. p. 20037.

Previous Government Actions Relating to Marijuana

NCI's Past THC Distribution Program. In 1980, the National Cancer Institute (NCI) received approval from FDA and DEA to begin distributing oral doses of THC as an investigational anti-nausea drug for patients receiving chemotherapy.¹⁹ The THC capsules were made available under the Institute's group C guidelines, which were developed originally to allow cancer patients access to promising anti-cancer drugs – with potential therapeutic value – before they gained official FDA approval for medical use.

The novel program served to make oral THC available nationally to treat nausea in patients undergoing cancer chemotherapy. While the program was operational, encapsulated synthetic THC was distributed through qualified hospitals and clinics. The drug was never made available at retail pharmacies. At the time, the federal government was hoping a pharmaceutical company would come forward and show interest in marketing THC. Reportedly, NCI planned to continue the THC distribution until a drug manufacturer received final FDA approval to sell the drug (see section on FDA's approval of Marinol).²⁰

NCI's distribution program was set up to make THC available for treatment purposes, and was not designed to test the drug's safety and efficacy in a controlled clinical trial. In one instance, however, an effort was made to evaluate the overall success of the program in Wisconsin by its Controlled Substances Board.²¹ The Board concluded that the state's distribution mechanism was adequate, and confirmed that oral THC was effective in relieving nausea and vomiting. It also noted, however, that adverse central nervous system side effects were prevalent, especially in older patients.

FDA Approves Synthetic Marijuana: Marinol. In 1985, the pharmaceutical firm Unimed received FDA approval to market dronabinol, a synthetically derived form of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. Sold under the trade name Marinol, this orally consumed drug was originally approved for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. As such, Unimed showed substantial evidence that this oral form of THC was safe and effective for its intended use. To accommodate scheduling for the new synthetic form of marijuana, DEA issued a ruling and policy statement transferring dronabinol from Schedule I into Schedule II of the Controlled Substances Act.²² This regulatory action did not affect

¹⁹ Okie, Susan. Cancer Victims to Get Marijuana Ingredient. *The Washington Post*, November 11, 1980. p. A1.

²⁰ Chakravarty, *Pot of Gold*, p. 44.

²¹ Treffert, Darold A., and David E. Joranson. Delta-9-Tetrahydrocannabinol and Therapeutic Research Legislation for Cancer Patients. *Journal of the American Medical Association*, March 18, 1983. p. 1469-1472.

²² U.S. Dept. of Justice. Drug Enforcement Administration. Schedules of Controlled (continued...)

the status of natural marijuana or other tetrahydrocannabinols – which remain in Schedule I. Available only by prescription, Marinol's official labeling explains the criteria for determining which chemotherapy patients will be the best candidates for its use, the adverse effects they may experience, and a warning that use of the drug should be limited to the amount necessary for a single cycle of chemotherapy of a few days duration.

Subsequent clinical investigations confirmed an earlier hypothesis that synthetic marijuana might also be a valuable appetite stimulant for treating acquired immunodeficiency syndrome (AIDS) patients suffering from HIV-wasting syndrome, a condition of undesired weight loss and concomitant malnutrition. In late 1992, Unimed received FDA approval to market dronabinol as a treatment for patients suffering from this form of anorexia.²³ Currently, Unimed is developing new formulations and delivery mechanisms for dronabinol (e.g., metered inhalant aerosol doses) that some patients might find more accommodating than smoked marijuana.

Supporters of allowing marijuana to be smoked for medicinal purposes were less than enthusiastic over the government's original approval and rescheduling of synthetic THC, even for treating such conditions as nausea and HIV-wasting syndrome. From their viewpoint, smoked marijuana offers superior pharmacological benefits over the drug's pill form, and the approval of oral THC had less to do with sanctioning a new cancer chemotherapy treatment than it did with maintaining the government's longstanding position that marijuana smoking, even for therapeutic purposes, is both harmful and illegal, and has no acceptable place in medical practice.

In July 1999, DEA issued a final rule transferring Marinol from Schedule II to Schedule III of the Controlled Substances Act.²⁴ The agency was responding to a 1995 petition from Unimed asking for a reconsideration of Marinol's scheduling. The petition sought only the rescheduling of the drug's prescription form and not tetrahydrocannabinol or natural marijuana, both of which will remain in Schedule I under the Act. The reclassification was granted after a review by DEA and the DHHS found that there was little evidence of illicit abuse of the drug. With the rescheduling, Marinol will be subject to the lesser regulatory controls and criminal sanctions of Schedule III. The action will also lift annual production quotas for the drug previously imposed under Schedule II.

PHS Ends Marijuana Treatment Use Program. For several years, under aegis of its investigational or "treatment use" policy, FDA allowed a limited number

²² (...continued)

Substances: Rescheduling of Synthetic Dronabinol in Sesame Oil and Encapsulation in Soft Gelatin Capsules From Schedule I to Schedule II; Statement of Policy. *Federal Register*, v. 51, no. 92, May 13, 1986. p. 17476.

²³ Two Drugs Approved for AIDS. *The Washington Post*, December 24, 1992. p. A5.

²⁴ U.S. Dept. of Justice. Drug Enforcement Administration. Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol [(-)-delta nine-(trans)-Tetrahydrocannabinol] in Sesame Oil and Encapsulated in Soft Gelatin Capsules From Schedule II to Schedule III. *Federal Register*, v. 64, no. 127, July 2, 1999. p. 35928.

of seriously ill patients to use smoked marijuana for “compassionate” purposes.²⁵ The drug was grown by the federal government on its “marijuana farm” in Oxford, Mississippi.

On June 21, 1991, Public Health Service (PHS) officials announced that the marijuana treatment program would be phased out.²⁶ Among the reasons offered for the policy shift was that more patients than originally anticipated were seeking admission and that expansion of the treatment program might send a “bad signal” to the rest of the country. PHS officials explained that a continuation of the program could have been perceived as the government endorsing marijuana smoking as a form of medical therapy, a position that might weaken the administration’s policy against the use of illegal drugs.

The program was officially terminated on March 9, 1992, when PHS officials announced that the government would continue to support participants currently in the program, but would no longer accept new applicants. Instead, they said the government would encourage patients wishing to apply for the treatment program to seek alternative means of medical therapy. In defending its position, PHS stated there was no scientific evidence that the drug was assisting patients, and issued a warning that using smoked marijuana as a form of medical therapy might be harmful to people with compromised immune systems (i.e., AIDS patients).²⁷

Synthetic Versus Smoked Marijuana

Among the contentious issues in the medical marijuana debate, none is more central than the argument over whether smoked marijuana is therapeutically and pharmacologically superior to drugs made from synthetic THC like dronabinol (Marinol). Proponents, particularly those who back the use of natural marijuana, argue that the drug’s primary active ingredient THC, can be more rapidly and efficiently absorbed via the lungs through smoking. They also maintain that by employing this route of administration, patients have better control over their dosage and can experience more rapid symptomatic relief.

However, some health experts and government officials argue to the contrary. They insist that people who smoke marijuana frequently are exposing themselves to a rather crude and potentially harmful drug delivery system. Moreover, they argue that the smoke from a burning marijuana cigarette contains a variety of toxic chemicals that could be harmful, especially to users whose medical condition might

²⁵ Ray, *Drugs, Society, and Human Behavior*, p. 415. According to the authors, FDA’s involvement in the use of marijuana as a medication began in 1975 following the outcome of a legal dispute over a patient’s desire to smoke marijuana for treating glaucoma. As part of the resolution in the case, a limited program was started whereby the National Institute on Drug Abuse would provide medical-grade marijuana cigarettes to certain patients under an FDA-approved “compassionate use” protocol.

²⁶ Isikoff, Michael. HHS to Phase Out Marijuana Program. *The Washington Post*, June 22, 1991. p. A14.

²⁷ U.S. Rescinds Approval of Marijuana as Therapy. *The New York Times*, March 11, 1992. p. A21.

be compromised further by choosing to smoke the drug for self-treatment. Also, they maintain that there is little evidence, based on controlled clinical trial, that smoking marijuana offers patients any therapeutic advantages over a synthetic THC product like Marinol. As such, health officials advise that before patients insist on trying natural marijuana, they should first seek a doctor's prescription and start with the synthetic version of the drug.

Medical Uses of Marijuana

The issue of smoking marijuana as a means of treating the symptoms associated with certain medical conditions has been debated for nearly 30 years. Starting with claims made in the early 1970s by some cancer and glaucoma patients that smoking marijuana could counter complications associated with their diseases, the number of therapeutic claims made for the drug has increased substantially. Today, the list of conditions that are allegedly treatable by smoking the drug has expanded to include pain, symptoms related to AIDS, and spasticity associated with various movement disorders.

Although historical accounts of marijuana's medicinal applications date back centuries, most reports are based on anecdotal rather than science-based clinical evaluations. However, beginning in the early 1970s, when marijuana was deemed by Congress to have "no currently accepted medical use" as a result of being placed in Schedule I of the Controlled Substance Act, both medical marijuana supporters and investigators began looking at whether the drug's ever-expanding list of claimed health benefits was supportable by scientific evidence. Trying to reach such determinative evidence has been problematic.

The information contained in this section of the report is excerpted from several sources that focus primarily on the medicinal uses for marijuana, and its oral-dose forms, most frequently cited by patients and covered in the medical literature. These uses typically include chemotherapy-related nausea treatment, appetite stimulation for HIV patients, movement disorders such as multiple sclerosis, glaucoma, and analgesia. The sources referenced include past and current scientific review articles, the National Institutes of Health's (NIH) 1997 *Workshop on the Medical Utility of Marijuana*,²⁸ and the Institutes of Medicine's (IOM) 1999 report *Marijuana and Medicine: Assessing the Science Base*.²⁹ In addition to being frequently cited, they provide a comprehensive evaluation of the scientific, social, and political issues involved.

Chemotherapy and Nausea Treatment. Research data published in the late 1970s suggested that oral marijuana – referring to the synthetic form of its psychoactive ingredient tetrahydrocannabinol (THC) – was effective in controlling nausea experienced by some cancer patients who were undergoing radiation and

²⁸ National Institutes of Health. *Workshop on the Medical Utility of Marijuana; a Report to the Director*, August 1997. [<http://www.health.org/medmarj.htm>], April 8, 1999.

²⁹ Institute of Medicine. *Marijuana and Medicine: Assessing the Science Base*. Washington, D.C., National Academy Press, 1999. [<http://www.nap.edu/books/0309071550/html/>] (Hereafter cited as IOM, *Marijuana and Medicine: Assessing the Science Base*)

chemotherapy. Researchers Frytak and Moertel who reviewed major studies that had been conducted to characterize THC's role in cancer therapy concluded that:

At the present time, it would appear that THC may have some clinical role as an antiemetic [anti-nausea] agent in teenagers or very young adults who have proved resistant to phenothiazines – [phenothiazines are powerful neuropsychiatric drugs that can also be used to treat nausea] particularly those young patients who have previously found marijuana to be tolerable. In cancer patients in the usual older age groups, THC cannot be recommended because a safe and effective dose has not yet been established. Regardless of age group, particular caution must be observed for possible serious adverse drug interactions that have not yet been clearly elucidated.³⁰

Early clinical evaluations of marijuana were conducted primarily using oral dose synthetic THC rather than the smoked natural form of the drug. However, in an early placebo controlled study, published in the *Annals of Internal Medicine*, Chang and associates examined the efficacy of oral and smoked THC as an antiemetic and found that the smoked form of the drug was more reliable than the oral form in achieving blood concentration of THC necessary for therapeutic purposes. Chang also noted, however, that for some patients, especially nonsmokers, the inhalation of marijuana smoke was quite harsh and objectionable.³¹ In a separate study published in the same journal issue, Frytak and colleagues, in referring to Chang's data, said one might conclude that the inhalation route for THC would be the most effective. They concluded, however, that although clinical studies showed oral THC to be effective in treating nausea associated with chemotherapy:

the preparation of standardized THC [marijuana] cigarettes is quite tedious, and many patients would find this route unacceptable. Smoking the substance we know as marijuana (a combination of over 300 chemical agents, some inherently carcinogenic) would not be an acceptable substitute for THC either.³²

In 1982, the Institute of Medicine of the National Academy of Sciences issued a report entitled *Marijuana and Health*. The report's executive summary made the following observations about marijuana's therapeutic potential:

Preliminary studies suggest that marijuana and its derivatives or analogues might be useful in the treatment of the raised intraocular pressure of glaucoma, in the

³⁰ Frytak, Stephen, and Charles G. Moertel. Management of Nausea and Vomiting in the Cancer Patient. *Journal of the American Medical Association*, v. 245, January 23-30, 1981. p. 395.

³¹ Chang, A. E., et al. Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate: A Prospective Randomized Evaluation. *Annals of Internal Medicine*, v. 91, 1979. p. 823.

³² Frytak, Stephen, et al. Delta-9-Tetrahydrocannabinol as an Antiemetic for Patients Receiving Cancer Chemotherapy: A Comparison with Prochlorperazine and a Placebo. *Annals of Internal Medicine*, v. 91, 1979. p. 830.

control of the severe nausea and vomiting caused by cancer chemotherapy, and in the treatment of asthma.³³

However, the report added the following caution:

... in these and all other conditions, much more work is needed. Because marijuana and [oral] delta-9-THC often produce troublesome psychotropic or cardiovascular effects that limit their therapeutic usefulness, particularly in older patients, the greatest therapeutic potential probably lies in the use of synthetic analogues of marijuana derivatives with higher ratios of therapeutic to undesirable effects.³⁴

A 1997 critique of marijuana's medicinal applications challenged the caliber of many of these earlier studies. In this often cited review article, Voth and Schwartz noted that most of the studies conducted to compare marijuana (THC) to either another drug or a placebo in treating nausea experienced by patients undergoing chemotherapy, used oral THC rather than smoked marijuana.³⁵ They "found no pattern of THC efficacy for any type of tumor or chemotherapy," but concluded that oral THC doses "have been effective in treating nausea associated with cancer chemotherapy if patients are pretreated and doses are repeated every 3 to 6 hours for approximately 24 hours."³⁶ Additionally, the authors pointed out that "numerous safe and effective non-cannabinoids are available for the control of chemotherapy-associated nausea," and noted the importance of these alternatives "given the side effects found in studies of THC."³⁷

In a similar type of review article, published in 1998 in the *Journal of the American Pharmaceutical Association*, Taylor noted that several studies have demonstrated that smoking marijuana is at least as effective as prochlorperazine – an anti-nausea drug.³⁸ He went on to say, however, that due to the availability of newer anti-nausea medications, the number of cancer physicians recommending illicit marijuana is now quite small. In commenting on a recent study measuring the effectiveness of intravenous ondansetron (Zofran) and dexamethasone, Taylor noted that the two drug combination produced a complete anti-emetic response in a vast majority of the patients. He cautioned, however, that these results also demonstrate that approximately 20% of cancer chemotherapy patients will not receive a full anti-

³³ Institute of Medicine. Division of Health Sciences Policy. *Marijuana and Health*. Washington, D.C., National Academy Press, 1982. p. 4.

³⁴ Ibid.

³⁵ Voth, Eric A., and Richard H. Schwartz. Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana. *Annals of Internal Medicine*, v. 126, May 1997. (Hereafter cited as Voth, Medicinal Applications of Delta-9-Tetrahydrocannabinol)

³⁶ Ibid., p. 792.

³⁷ Ibid., p. 792.

³⁸ Taylor, H. Gordon. Analysis of the Medical Use of Marijuana and its Societal Implications. *Journal of the American Pharmaceutical Association*, v. 38, March/April 1998. p. 220-227. (Hereafter cited as Taylor, Analysis of the Medical Use of Marijuana)

emetic response to ondansetron, and for this group, especially those with extreme retching, there are anecdotal reports that smoking marijuana may be a benefit.³⁹

In 1997, the Ad Hoc Group of Experts⁴⁰ released its report entitled *Workshop on the Medical Utility of Marijuana*.⁴¹ The report's executive summary recognized that "there is a large body of literature on the effects of cannabinoids on chemotherapy-induced nausea and vomiting," and reiterated the fact that "most of the clinical studies used oral dronabinol [synthetic THC] rather than smoked marijuana."⁴² The Expert Group also reconfirmed the point that "since the approval of dronabinol in the mid-1980s for the relief of nausea and vomiting associated with cancer chemotherapy, more effective antiemetics have been developed, such as ondansetron, granisetron, and dolasetron, each combined with dexamethasone."⁴³ According to the Expert Group, "the relative efficacy of cannabinoids versus these newer antiemetics has not been evaluated."⁴⁴ Their summary concluded by noting that it is still unknown whether smoked marijuana would benefit patients who do not respond to these newer antinausea drugs.

In its 1999 report, *Marijuana and Medicine: Assessing the Science Base*, the Institute of Medicine (IOM) pointed out that the mechanism by which chemotherapy induces vomiting is not completely understood. The report gives a description of the qualities anti-emetic drugs should have that would be most advantageous to patients, and speculates that most chemotherapy patients would probably not want to use marijuana or THC for nausea control. It noted that the psychoactive chemicals in marijuana are "mildly effective in preventing emesis in some patients receiving cancer chemotherapy," but that there are pharmaceutical preparations available today that are more effective.⁴⁵ IOM also observed, however, that "until the development of rapid-onset antiemetic drug delivery systems, there will likely remain a subpopulation of patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis."⁴⁶ It stated further that for some of these patients, the harmful effects of smoking marijuana for a short period of time might be outweighed by the drug's antinausea benefits, especially in those who suffer from severe nausea which cannot be controlled by traditional medication. The IOM

³⁹ Ibid., p. 224.

⁴⁰ The Ad Hoc Group of Experts was an NIH appointed team of doctors and scientists who conducted a 2-day scientific workshop on the medical use of marijuana. The public meeting was held February 19-20, 1997.

⁴¹ National Institutes of Health. The Ad Hoc Group of Experts. *Workshop on the Medical Utility of Marijuana, Report to the Director*, August 1997. (Hereafter cited as National Institutes of Health, *Workshop on the Medical Utility of Marijuana*)

⁴² Ibid., p. 3.

⁴³ Ibid., p. 3.

⁴⁴ Ibid., p. 3.

⁴⁵ IOM, *Marijuana and Medicine: Assessing the Science Base*, p. 148.

⁴⁶ Ibid., p. 154.

recommends that these patients should be evaluated, on a case-by-case basis, and treated under close medical supervision.⁴⁷

Appetite Stimulation. According to Voth and Schwartz, “the literature contains few studies with objective data on the use of either pure THC or crude marijuana for appetite stimulation.”⁴⁸ Without speculating on whether smoking marijuana can act as an effective appetite stimulant, the authors allowed that, “the appetite-stimulating effect of THC [orally administered] may be beneficial for patients with wasting related to the acquired immunodeficiency syndrome (AIDS) and those with severe cancer related anorexia.”⁴⁹ However, after noting the beneficial relationship between the use of oral dronabinol and wasting syndrome, they pointed out that “this issue is complex because appetite stimulation is a surrogate measure for useful weight maintenance or gain and for effective calorie intake, which are far more important measures than appetite alone.”⁵⁰

In his review article, Taylor acknowledged that AIDS patients “commonly smoke marijuana to relieve the nausea caused by antiretroviral drugs and for weight gain.”⁵¹ He also agreed that there are numerous anecdotal reports of marijuana’s superiority over oral dronabinol in treating weight loss, and that AIDS patients report that smoking it makes them feel better in general. Taylor warned, however, that because of their compromised immune systems, AIDS patients are more susceptible to possible bacteriological contaminants that may be in marijuana. He also noted that because “smoking drugs does increase the risk of *Pneumocystis carinii* and bacterial pneumonias in HIV-positive patients,” they are more at risk for the consequences of marijuana-induced injury to their immune systems.⁵² Commenting on the issue of whether smoking marijuana can increase the viral load on AIDS patients, Taylor reported that there is no confirmatory evidence to support this hypothesis, and emphasized that “one study found no indication that psychoactive drugs, including marijuana, accelerate the progression of AIDS.”⁵³

The report from the Expert Group reached essentially the same conclusions, agreeing that studies and survey data in health populations “have shown a strong relationship between marijuana use and increased food intake.”⁵⁴ However, it also acknowledged that there have been no controlled studies of marijuana in the AIDS-wasting syndrome, nor any systematic studies of the drug’s effects on immunological

⁴⁷ Ibid., p. 154.

⁴⁸ Voth, *Medicinal Applications of Delta-9-Tetrahydrocannabinol*, p. 793.

⁴⁹ Ibid., p. 793.

⁵⁰ Ibid., p. 793.

⁵¹ Taylor, *Analysis of the Medical Use of Marijuana*, p. 224.

⁵² Ibid., p. 224.

⁵³ Ibid., p. 224.

⁵⁴ National Institutes of Health, *Workshop on the Medical Utility of Marijuana*, p. 4.

status in HIV-infected patients.⁵⁵ The Expert Group also cautioned that smoking [tobacco, marijuana, or crack cocaine] drugs in general has been shown to increase the risk of developing bacterial pneumonia in HIV-positive immune-compromised patients.

IOM's recent characterization of marijuana's use in the treatment of malnutrition and wasting syndrome differed little from the previous reports. It noted that the use of cannabinoids to stimulate appetite and increase weight gain has only been clinically evaluated in trials that used oral synthetic THC rather than smoked marijuana. IOM called attention to the fact that malnutrition and weight loss can be treated with the prescription drug megestrol acetate. Sold under the brand name Megace, this appetite stimulant was approved in 1993, and is considered to be more effective than dronabinol in inducing weight gain.⁵⁶ IOM stated that although controlled laboratory studies on normal, healthy adults have shown that smoked marijuana can increase appetite, food intake, and body weight, to date, there have been no controlled investigations to determine whether the drug has the same positive effect in HIV patients.⁵⁷ According to IOM, a clinical trial of this type is currently underway.

Movement Disorders. The reviews referred to in this report reached similar conclusions regarding the use of marijuana in treating a variety of neurological and movement disorders. They stipulated, for the most part, that several anecdotal and a few case studies have been reported attesting to the drug's role in relieving spasticity associated with multiple sclerosis (MS). Voth reported, however, that in one well-controlled study of the effects of smoking marijuana in MS patients, their "posture and balance were negatively affected by the treatment and were actually worse than at baseline."⁵⁸

In addressing marijuana's place in the treatment of other neurological disorders, the Expert Group said that there was evidence from animal studies to suggest a possible role for cannabinoids in the treatment of certain types of epileptic seizures. They qualified this hypothesis, however, by noting that there is little information on the use of the drug for the actual treatment of epilepsy. In addition, the Expert Group reported that neither smoked marijuana nor oral THC has proven effective in treating Parkinson's disease or Huntington's chorea.⁵⁹

IOM uses the expression "movement disorders" to describe a broad group of neurological complications that affect the brain, spinal cord, or peripheral nerves and muscles. In the case of multiple sclerosis, IOM acknowledged that marijuana is frequently reported to reduce the muscle spasticity associated with the disease, but then it noted that these abundant anecdotal reports are not well-supported by clinical

⁵⁵ Ibid., p. 4.

⁵⁶ IOM, *Marijuana and Medicine: Assessing the Science Base*, p. 156.

⁵⁷ Ibid., p. 156.

⁵⁸ Voth, *Medicinal Applications of Delta-9-Tetrahydrocannabinol*, p. 794.

⁵⁹ National Institutes of Health, *Workshop on the Medical Utility of Marijuana*, p. 3.

data.⁶⁰ In addition, IOM said that, due to a lack of good animal models to study spasticity in MS, there is virtually “no supporting animal data to encourage clinical research.”⁶¹ Regardless, the report encouraged the investigation of the drug for potential use in MS therapy.

According to the IOM report, the use of smoked marijuana to treat other movement disorders appears to be even less encouraging. After surveying the literature for evidence of marijuana’s effectiveness in treating such movement disorders as dystonia (abnormal tension in bodily tissue), Huntington’s Disease, Parkinson’s Disease, and Tourettes Syndrome, the IOM concluded that although there are a few isolated reports of individuals with such disorders benefitting from marijuana, there are, as yet, no published surveys indicating that most patients gain any significant relief from using the drug.⁶² IOM also noted that “with the exception of multiple sclerosis, the evidence to recommend clinical trials of cannabinoids in movement disorders is relatively weak.”⁶³

Glaucoma. All sources agreed that cannabinoids can lower the intraocular pressure (IOP) associated with glaucoma in humans. Voth pointed out, however, that even though THC is beneficial for the treatment of glaucoma, “no evidence indicates that either pure THC or crude marijuana affects or arrests the underlying disease.”⁶⁴ Taylor also acknowledged that marijuana has therapeutic potential, but emphasized that because THC cannot penetrate into the cornea, glaucoma is best treated with ophthalmic drops.⁶⁵ In contrast, the Expert Group, contended that a topical dose of THC had been developed, but that it turned out to be ineffective in lowering intraocular pressure.⁶⁶

IOM confirmed that cannabinoids or marijuana can reduce IOP when administered orally, intravenously, or by inhalation, but not when administered topically. Furthermore, it stated that even though evidence shows that a reduction in IOP by medications or surgery can slow the rate of glaucoma progression, “there is no direct evidence to support the benefits of cannabinoids or marijuana on the natural progression of glaucoma, visual acuity, or optic atrophy.”⁶⁷

Analgesia. Voth discussed the use of marijuana for analgesia or pain relief only in the context of a handful of illnesses [e.g., headache, dysentery, menstrual cramps, and depression] that are often cited by marijuana advocates as medical

⁶⁰ IOM, *Marijuana and Medicine: Assessing the Science Base*, p. 161.

⁶¹ *Ibid.*, p. 161.

⁶² *Ibid.*, p. 169.

⁶³ *Ibid.*, p. 170.

⁶⁴ Voth, *Medicinal Applications of Delta-9-Tetrahydrocannabinol*, p. 794.

⁶⁵ Taylor, *Analysis of the Medical Use of Marijuana*, p. 224.

⁶⁶ National Institutes of Health, *Workshop on the Medical Utility of Marijuana*, p. 4.

⁶⁷ IOM, *Marijuana and Medicine: Assessing the Science Base*, p. 175.

reasons to justify the drug being available as a prescription medication.⁶⁸ As such, he does not address specifically whether oral or smoked marijuana possesses any pain relieving qualities.

The Expert Group reported that no clinical trials have been conducted to examine the impact of smoked marijuana in patients with naturally occurring pain. However, they did identify two controlled clinical studies of cancer pain comparing graded doses of oral delta-9-THC to placebo, one of which included graded doses of codeine as a control. The Group reported that studies indeed showed an analgesic effect, but that the therapeutic margin between doses that produced useful analgesia, and those that produced unacceptable central nervous system effects, was quite narrow.⁶⁹ Taylor's findings were in virtual agreement with the Expert Group. He acknowledged that marijuana has been used for centuries to relieve pain, but that scientifically controlled studies confirming this use are almost nonexistent.⁷⁰

IOM reviewed studies conducted to assess marijuana's pain-relieving capacity and found that although clinical trials have been few, "data from animal studies indicate that cannabinoids could be useful analgesics."⁷¹ Where clinical evaluations were conducted, notably in studies where pain was experimentally-induced, consistent analgesia was not demonstrated. Several methodological flaws were noted in these studies. However, in studies it considered methodologically sound, IOM concluded that the most encouraging clinical data came from cancer studies where the analgesic effects of cannabinoids compared favorably with a weak analgesic such as codeine.

In pain associated with minor surgical procedures, IOM found no analgesic effect of THC, and where marijuana smoking was used for treating migraine headaches, they found no conclusive clinical data to support the drug's use. Despite the inherent limitations in some studies reviewed, IOM concluded that evidence from animal and human studies suggest that cannabinoids "can produce a significant analgesic effect," but that the effect's magnitude and whether it can be maintained over time, needed to be addressed in future studies.⁷²

Summary of Findings of the Medical Literature. These summaries of the literature on medical marijuana made an effort to assess the scientific validity behind the many therapeutic claims made for the drug. Although the evaluations review essentially the same published scientific literature, and agreed on several scientific points, there was a lack of consensus on the interpretation of the data. Voth, for instance, acknowledged that oral [synthetic] THC is useful in treating patients with chemotherapy-induced nausea or AIDS-associated wasting syndrome. Furthermore, he predicted that if newer and more refined delivery mechanisms are

⁶⁸ Voth, *Medicinal Applications of Delta-9-Tetrahydrocannabinol*, p. 795.

⁶⁹ National Institutes of Health, *Workshop on the Medical Utility of Marijuana*, p. 2.

⁷⁰ Taylor, *Analysis of the Medical Use of Marijuana*, p. 224.

⁷¹ IOM, *Marijuana and Medicine: Assessing the Science Base*, p. 140.

⁷² *Ibid.*, p. 145.

ever developed for THC, the drug may achieve even wider acceptance in medical practice. However, on the issue of whether smoked marijuana has medicinal value, Voth was adamant that “crude marijuana does not qualify as a medicine,” and should remain a Schedule I drug.⁷³

Taylor, on the other hand, offers a somewhat different point of view. He agrees with Voth in noting the risks associated with chronic marijuana smoking: toxicity to the lungs, potential exposure to certain disease-producing contaminants, and possible impairment of the immune system. Unlike Voth, however, he makes less of an issue over whether the evidence for or against marijuana’s medical use is based on controlled studies using the oral or the smoked form of the drug, and states that from his perspective, “marijuana clearly benefits patients with intractable pain, neurological disorders, nausea and vomiting, and glaucoma.”⁷⁴ Taylor speculates further that marijuana’s mechanism of action is probably different from those of drugs typically used to treat these conditions, and may, therefore have adjunctive value.⁷⁵

Based on their reviews of contemporary studies conducted to address marijuana’s therapeutic potential, both the Expert Group and IOM concluded that further scientific research is needed. They stressed that many of the answers in the ongoing scientific and medical debate over the safe and effective use of marijuana, or its synthetic analogues, will be forthcoming only through additional well-controlled clinical investigations. The Expert Group advised that researchers give consideration to the full range of potential questions that could be addressed, propose ways to address the most important of these, and design their study protocols accordingly.⁷⁶ Adopting this strategy, they felt, might enhance the possibility of gaining funding support from federal agencies.

The IOM also offered several recommendations relating to future studies of marijuana and cannabinoid drugs. It acknowledged that completed scientific studies support the therapeutic potential of cannabinoids in the treatment of certain medical conditions, but also pointed out that the drug’s therapeutic value is probably influenced significantly by its psychological effects. According to the Institute, these effects can be subjective and either influence symptoms in a way that might create false impressions, or be interpreted as a beneficial form of adjunctive therapy.⁷⁷ IOM further cautioned that because marijuana is a crude THC delivery system capable of delivering other harmful substances, smoked marijuana should generally not be recommended for medical use.

With this thought in mind, the Institute predicted that if there is any future for the drug as a medicine, it will come from its isolated cannabinoids and their synthetic

⁷³ Voth, *Medicinal Applications of Delta-9-Tetrahydrocannabinol*, p. 796.

⁷⁴ Taylor, *Analysis of the Medical Use of Marijuana*, p. 226.

⁷⁵ *Ibid.*, p. 226.

⁷⁶ National Institutes of Health, *Workshop on the Medical Utility of Marijuana*, p. 38.

⁷⁷ IOM, *Marijuana and Medicine: Assessing the Science Base*, p. 10.

derivatives. It further stated that because isolated cannabinoids can provide more reliable effects than crude plant mixtures, the purpose of clinical trial using smoked marijuana should not be the development of marijuana as a licensed drug.⁷⁸ In order to gain a better understanding of the health risks associated with smoking marijuana, including further insight into its medical legitimacy, IOM recommended the following:

- Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because cannabinoids have different effects in the body, research should include, but not be restricted to, effects attributable to THC alone.
- Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.
- Psychological effects of cannabinoids such as anxiety reduction and sedation – which can influence perceived medical benefits – should be evaluated in clinical trials.
- Studies to define the individual health risks of smoking marijuana should be conducted, especially in populations where use is prevalent.
- Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (6 months or less); be conducted in patients with conditions for which there is a reasonable expectation of effectiveness; be approved by an Institutional Review Board (IRB); collect data about efficacy.
- Short-term use of smoked marijuana (6 months or less) for patients with debilitating symptoms must meet the following conditions: failure of all approved drugs to provide relief has been documented; the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs; treatment is administered under medical supervision in a manner that allows assessment of treatment effectiveness; and research involves an IRB-like process that can provide guidance within 24 hours of a physician's request to provide marijuana for a specified use.

Current Research on Medical Marijuana

In response to IOM's recommendations, the Department of Health and Human Services (DHHS), on May 21, 1999, announced new policies and procedures for obtaining research-grade marijuana for purposes of conducting scientifically valid clinical investigations using the drug.⁷⁹ The marijuana provided is available not only for NIH-supported studies, but for research funded by other sources as well. According to DHHS, an ad-hoc Public Health Service committee reviews non-NIH-funded clinical studies to determine if they are designed in a way that will produce the kind of safety and efficacy data needed to meet FDA's drug approval standards. Researchers who want to investigate the potential therapeutic effects of smoking

⁷⁸ Ibid., p. 11.

⁷⁹ U.S. Dept. of Health and Human Services. Fact Sheet. Investigating Possible Medical Uses of Marijuana. May 21, 1999. [<http://www.hhs.gov/news/press/1999pres/990521.html>]

marijuana have to file an Investigational New Drug application with the FDA and be properly registered with the DEA for using a Schedule I substance.

While it has become a bit easier in recent years to obtain research-grade marijuana to conduct clinical studies, the number of clinical investigators involved in federally supported studies of the drug's therapeutic potential is quite small. According to the National Institute on Drug Abuse (NIDA), the National Institutes of Health is currently supporting only one research project looking at the medical benefits of smoked marijuana. Under the direction of Dr. Margaret Haney at the New York State Psychiatric Institute, the study is measuring the effects of THC and marijuana in individuals with HIV/AIDS. The purpose of the study, which is co-funded by NIDA and the National Center for Complementary and Alternative Medicine, is to compare the effects of smoked marijuana and oral THC in HIV patients with unintended weight loss. In addition to analyzing food intake and body composition, the researchers are measuring mood, physical symptoms (e.g., nausea, stomach pain), psychomotor task performance, and sleep in order to assess the specificity of drug effects on food intake in relation to other behaviors. Funded for \$1,341,926 over 3 years, with an estimated funding level of \$496,454 for FY2002, the study is expected to be completed in June 2003.

In another study, supported by several NIH Institutes and recently completed, Dr. Donald Abrams at the University of California, San Francisco, conducted a randomized prospective study to assess the short-term effects of smoked marijuana and oral THC on the metabolism of protease inhibitors (the latest-generation AIDS drug), the immune system, and the level of HIV-1 viral load in persons with HIV-1 infection. The study also measured changes in weight gain or in appetite. Study participants received either NIDA supplied marijuana cigarettes, an oral tablet of THC, or placebo capsules. A preliminary report on the study at the World AIDS Conference reported that patients with HIV infection taking protease inhibitors did not experience short-term adverse virologic effects for using cannabinoids, either oral or smoked. The results of the Abrams study have yet to be published.

Medical Marijuana: State Ballot Initiatives

During the past 5 years, voters at the state level have agreed to a variety of initiatives that allow patients to smoke marijuana for medical purposes. In 1996, after lengthy and contentious petition drives waged chiefly by active supporters of the drug's medical use, citizens in California and Arizona passed referendums making marijuana legally available for therapeutic purposes.⁸⁰ The Arizona initiative was considered to be the more controversial of the two. Where the proposition adopted in California allowed only marijuana to be "prescribed" for seriously ill patients, the one passed in Arizona would have allowed the use of virtually any Schedule I controlled substance so long as it was prescribed by two physicians. Although Arizona's first medical marijuana initiative was later overturned by the state legislature, the initiative was back on the ballot for reconsideration during the 1998 election.

⁸⁰ During the 1996 election, the marijuana ballot initiatives under consideration were Proposition 215 in California; Proposition 200 in Arizona.

With the 1998 election the list grew as medical marijuana referendums were considered by voters in several other states.⁸¹ Initiatives were passed in Alaska, Arizona (for the second time), the District of Columbia, Nevada, Oregon, and Washington. In addition, voters in Colorado adopted Amendment 19, allowing for the medical use of marijuana. The amendment was later invalidated, however, when Colorado's Secretary of State ruled that its backers had not collected the required number of signatures. When legal challenges and subsequent recounts determined that the number of signatures had been sufficient, the Colorado Supreme Court ordered that the amendment be placed on the ballot for 2000, where it passed handily.

In the District of Columbia, residents voted on Initiative 59, a referendum that would have permitted the possession, use, cultivation and distribution of marijuana if recommended by a physician for serious illness. However, the results were not tabulated and released right away due to an amendment attached to the District's FY1999 appropriation bill⁸² that barred spending any money to tally the initiative's final vote count. The amendment, sponsored by Representative Robert Barr, was eventually challenged in U.S. District Court, and on September 17, 1999, U.S. District Judge Richard Roberts held that the so-called "Barr Amendment" did not preclude the D.C. Board of Elections and Ethics from counting, announcing or certifying the results of the referendum.⁸³ When the results were finally released, Initiative 59 had passed with 69% of the vote.⁸⁴

Despite the Judge's ruling, it is unlikely that patients in the District of Columbia will be able to smoke marijuana for medicinal purposes anytime soon. The reason is that during consideration of the District's FY2000 budget, the 106th Congress agreed to an amendment blocking any effort to reduce penalties associated with the possession, use, or distribution of any Schedule I controlled drug or any tetrahydrocannabinol (marijuana) derivative. Going even further, the amendment said that "the Legalization of Marijuana for Medical Treatment Initiative of 1998, also known as Initiative 59, approved by the electors of the District of Columbia on November 3, 1998, shall not take effect."⁸⁵ This same restrictive language has been included in the District of Columbia's FY2001 and FY2002 appropriations bills (see discussion of the medical marijuana legislation introduced in the 106th Congress).

In 1999, voters in Maine agreed to a referendum allowing doctors to prescribe marijuana for patients with specified debilitating conditions. In the 2000 election, marijuana initiatives were back on the ballot once again. Voters in Colorado adopted

⁸¹ The information on state medical marijuana referendums was excerpted from the following websites: [<http://www.lindesmith.org/news/election2.html>], [<http://norml.org/medical/pets98.html>], and [<http://www.levelers.org/election98.html>].

⁸² P.L. 105-277, Section 171: Omnibus Consolidated and Emergency Supplemental Appropriation Act, 1999.

⁸³ *Wayne Turner, et al. v. District of Columbia Bd. Of Elections and Ethics*, Civ. Action No. 98-2634(RWR), (D.C.D.C. Sept. 17, 1999), 1999 U.S. Dist. LEXIS 16595.

⁸⁴ Miller, Bill, and Spencer S. Hsu. Results Are Out: Marijuana Initiative Passes. *The Washington Post*. September 21, 1999. p. A1.

⁸⁵ P.L. 106-113, Section 167: Consolidated Appropriation Act, FY2000.

their medical marijuana amendment for the second time, while citizens in Nevada passed the same marijuana question they had considered back in 1998.⁸⁶ Besides the election referendums, the state legislature in Hawaii became the first to approve the use of marijuana for certain medical conditions.⁸⁷ To date, with the exception of the District of Columbia, whose medical marijuana initiative has been stymied by Congress, the following states have adopted referendums or legislation (Hawaii) allowing patients to smoke marijuana for therapeutic purposes:

Alaska: Measure 8 – Passed in 1998, the measure lets patients suffering from debilitating medical conditions possess up to 1 ounce of marijuana or three mature plants for medicinal use. It directs the state to create a confidential registry of patients entitled to use marijuana for medicinal purposes under the Act. The measure exempts physicians from prosecution under state law for advising patients about marijuana’s medical benefits.

Arizona: Proposition 200 – The 1996 referendum would have allowed Arizona physicians to prescribe any Schedule I controlled substance (i.e., marijuana, heroin, LSD, etc.) to treat disease or relieve the pain and suffering of seriously or terminally ill patients. However, when the referendum was adopted, the state legislature stepped in and passed a law that said that Schedule I drugs (like marijuana) could be prescribed by doctors only if they were approved by FDA and authorized by the U.S. Congress first. In the 1998 election, voters considered Proposition 300, which, if passed, would have allowed the state legislature’s medical marijuana bill to become law. In the end, Proposition 300 was defeated, allowing Arizona doctors to prescribe Schedule I controlled drugs under the terms of the original Proposition 200.

California: Proposition 215 – Called the Compassionate Use Act of 1996, the proposition ensures that seriously ill Californians have the right to obtain and use marijuana for medical purposes. The medical use of the drug must be deemed appropriate and recommended by a physician who has determined that the patient’s health would benefit from the use of marijuana. Patients and primary caregivers who use marijuana for medical purposes are not subject to criminal prosecution. Also, the proposition encouraged federal and state governments to implement a plan to provide for the drug’s safe and affordable distribution for patients in need.

Colorado: Amendment 20 – Adopted in 2000, the amendment allows patients diagnosed with a serious or chronic illness and their caregivers to legally possess up to two ounces of marijuana for medical purposes. It also lets doctors provide seriously or chronically ill patients a written statement that they might benefit from the medical use of marijuana. Lastly, it establishes a confidential registry of patients and their caregivers who are allowed to possess marijuana for medicinal purposes.

Hawaii: Act 228 – Hawaii is the only state where the medical use of marijuana has been sanctioned through the legislative process rather than the ballot box. Signed into law in 2000, the legislation’s stated purpose is “to ensure that seriously ill people

⁸⁶ Under Nevada law, an initiative must be approved in two consecutive general elections before it becomes law.

⁸⁷ Act 228, Session Laws 2000.

are not penalized by the State for the use of marijuana for strictly medical purposes when the patient's treating physician provides a professional opinion that the benefits of medical marijuana would likely outweigh the health risks for qualifying patient." The statute also allows qualifying patients and primary caregivers to assert the medical use of marijuana as an affirmative defense against any prosecution involving use of the drug for medical purposes.

Maine: Initiative Question 2 – Agreed to in 1999, the question amends Maine law and lets patients diagnosed with certain debilitating conditions use marijuana for medical purposes when a doctor determines that the use might be beneficial. It limits the amount of marijuana a patient can possess, and allows a legally designated person to assist in using the drug. Medical marijuana use is permitted by persons under age 18 if written consent is obtained from a parent or guardian. The drug may not be used for medicinal purposes in a public place or in a workplace.

Nevada: Ballot Question No. 9 – Passed in 1998, the question amended the state's constitution allowing patients, upon the advice of a doctor, to use marijuana for the treatment or alleviation of cancer, glaucoma, AIDS, nausea, epilepsy, and various disorders characterized by muscular spasticity. The amount of marijuana patients may possess or cultivate is not specified. In Nevada, before a ballot question can become law it must be voted on and passed in consecutive elections. Question 9 passed again in year 2000.

Oregon: Measure 67 – Adopted in 1998, the measure allows patients with debilitating medical conditions to possess up to 3 ounces of marijuana, or to grow three plants for medicinal purposes, and directs the state to set up a system of registry identification cards for persons who meet the terms of the Act. The measure exempts persons engaged in the medical use of marijuana from the state's criminal laws for possession, delivery, or production of the drug. Also, the measure prohibits the possession, production, or delivery of marijuana for purposes not authorized by the provision.

Washington: Initiative 692 – Passed in 1998, the initiative allows patients with terminal or debilitating illnesses to possess up to a 60-day supply of marijuana for medical use. It says that physicians shall not be penalized for advising patients about the benefits of medical marijuana. It also says that nothing in the initiative supersedes the state's law prohibiting the acquisition, possession, manufacture, sale, or use of marijuana for non-medical purposes.

When the medical marijuana ballot initiatives were adopted in California and Arizona in 1996, the White House's Office of National Drug Control Policy (ONDCP) published a notice in the *Federal Register* calling the propositions a threat to the National Drug Control Strategy goal of reducing drug abuse in the United States.⁸⁸ Amplifying the Department of Justice's (DOJ) position further, the response stated that physicians would face legal sanction, including possible revocations of

⁸⁸ U.S. Office of National Drug Control Policy. Administration Response to Arizona Proposition 200 and California Proposition 215. *Federal Register*, v. 62, no. 28, February 11, 1997. p. 6164.

their DEA registrations, and exclusion from participating in Medicare and Medicaid programs, if they recommended or prescribed Schedule I controlled substances like marijuana.

In response, a group of California physicians and patients on January 14, 1997 filed a class-action suit contending that the government's threat to prosecute physicians who recommend the medical use of marijuana under the Compassionate Use Act of 1996 infringed on their First Amendment rights and interfered with the doctor-patient relationship.⁸⁹ Faced with the lawsuit, the Justice Department tempered its position and advised physicians that they were free to discuss with patients the risks and benefits of using marijuana for medicinal purposes.⁹⁰

After several more states adopted medical marijuana initiatives during the 1998 elections, however, ONDCP released a policy statement regarding the outcome of the referenda. The statement said, in essence, that even though the voters had agreed to referenda that would allow for the cultivation, possession, distribution, and consumption of marijuana for medical purposes under state or local law, the results of the referenda would not in any way alter marijuana's illegal status under federal law.

The statement added that even though the medical-scientific process in the United States had not closed the door on marijuana or any other substance that might offer potential therapeutic benefits, both law and common sense dictate that the process for establishing a substance as medicine should be thorough and science-based. The drug control policy office said that clinical data should be analyzed by experts in the FDA and the NIH for safety and efficacy, and if the scientific evidence demonstrates that the benefits of a substance outweigh its associated risks, the substance could be approved for medical use. According to ONDCP, this rigorous process protects public health, and allowing marijuana, or any other drug, to bypass the process would be unwise.

Medical Marijuana: Canada

In 2001, Canada became the first government to institute regulations giving citizens the legal right to possess and use marijuana for treating serious illnesses. According to Health Canada Online – the country's Website for health care information – patients can apply for an official authorization to possess marijuana for medicinal use if they fall into one of three categories: Category One – applicants who are terminally ill with a prognosis of less than 12 months to live; Category Two – patients with certain serious medical conditions such as multiple sclerosis, spinal cord injury, cancer, AIDS/HIV infection, epilepsy; and Category Three – patients who have a serious medical condition that is unresponsive to conventional therapies.⁹¹

⁸⁹ Dr. Marcus Conant, ET AL., Plaintiffs, v. Barry R. McCaffrey, as Director, United States Office of National Drug Control Policy, ET AL., Defendants.

⁹⁰ Suro, Robert. U.S. Backs Off on Doctor-Patient Marijuana Discussions. *The Washington Post*, March 2, 1997. p. A14.

⁹¹ Health Canada Online. Marijuana for Medical Purposes,

The medical marijuana program is regulated by Health Canada's Office of Cannabis Medical Access (OCMA). Under its rules, patients who qualify to participate in the program must apply to OCMA for official authorization to possess the drug. Applicants must provide information about their medical condition, whether they plan to grow their own supply of marijuana or obtain it from a dealer licensed by Health Canada. They must also include a written statement from a medical specialist verifying that all other conventional treatments have been tried.

The marijuana provided under the Canadian medical marijuana program is being grown under a 5-year, \$5.7 million contract with Prairie Plant Systems Inc. of Saskatoon, Saskatchewan.⁹² According to the company's Website, under the terms of the contract, Prairie Plant Systems Inc. will be responsible for cultivating and drying the plants; conducting laboratory analysis; fabricating and storing the marijuana cigarettes and bulk material; and distributing the product to recipients authorized by Health Canada.⁹³ The company is scheduled to make its first delivery of medicinal-grade marijuana in January 2002. It will also be supplying the drug for a variety of research projects currently being supported by Health Canada as well. According to the OCMA, currently there are 753 persons taking part in Canada's medical marijuana program: 640 exemptees under its Section 56 regulations,⁹⁴ and another 113 persons given authorization to possess the drug under its more recent 2001 regulations.

Medical Marijuana: The U.S. Supreme Court

In April 1997, federal district court Judge Fern Smith, in a class action lawsuit, issued a preliminary injunction which prohibited government officials from threatening or prosecuting physicians, revoking their licenses, or excluding them from Medicare/Medicaid participation based upon conduct relating to medical marijuana that did not rise to the level of a criminal offense.⁹⁵ In her opinion, the district judge concluded that although the use of marijuana may be illegal, the First Amendment allows physicians to discuss and advocate its use for medical purposes. The suit was finally resolved when Judge William Alsup of the U.S. District Court for the Northern District of California ruled in September 2000 that the government exceeded its statutory authority when it threatened to revoke doctors' DEA registrations under the Controlled Substances Act (CSA). Under the judge's ruling, the government was

⁹¹ (...continued)

[<http://www.hc-sc.gc.ca/english/protection/marijuana.html>]

⁹² Canadian Government Will Regulate Medical Marijuana Use Via Central Office. *Washington Fax*, August 9, 2001.

⁹³ Prairie Plant Systems Inc. [<http://www.prairieplant.com/n.htm>]

⁹⁴ Section 56 regulations refer to Section 56 of Canada's *Controlled Drugs and Substances Act*. Under the provision, Canada's Minister of Health may exempt any person, class of persons, or any controlled substance from the Act if the exemption is necessary for a medical or scientific purpose. It was this exemption which allowed persons to possess marijuana for medicinal use before the current policy and regulations were adopted in 2001.

⁹⁵ *Conant v. McCaffrey*, No. C 97-0139 FMS, 1997 U.S. Dist. LEXIS 8749 (N.D. CAL. April 30, 1997).

permanently enjoined from revoking a DEA registration merely because the doctor recommended medical marijuana to a patient based on a sincere medical judgement, and from starting any investigation solely for that reason.⁹⁶

A separate legal conflict over medical marijuana involved the sale and distribution of the drug by several buyers clubs or cooperatives in California doing business under the aegis of the state's 1996 Compassionate Use Act, better known as Proposition 215. Some of the co-ops, including the Oakland Cannabis Buyers' Cooperative (OCBC), had been operating for years before the act was passed. The U.S. Justice Department charged that the centers, including the OCBC, were operating in violation of federal drug distribution laws, and in January 1998 filed a civil suit to have them shut down.⁹⁷

In May 1998, the U.S. District Court for the Northern District of California issued a preliminary injunction ordering the centers closed. In the injunction, the court said that the distribution of marijuana by certain clubs and their agents was a probable violation of the Controlled Substances Act. Despite the district court's ruling, the Oakland Cooperative continued to make the drug available. The court found the Cooperative in contempt, rejecting the club's argument that they should be considered exempt from the CSA's prohibition against the distribution of marijuana because the distribution was "medically necessary."⁹⁸

When the court rejected the club's argument, the OCBC filed a motion asking the district judge to modify the injunction so that marijuana could continue to be distributed to patients whose physicians would certify that use of the drug was a medical necessity. The court denied the motion, accepting the government's position that the court lacked the authority to grant the modification. The Cooperative then appealed the district court's ruling to the U.S. Court of Appeals for the Ninth Circuit.⁹⁹ In September 1999, the court of appeals reversed the district court, saying that by summarily denying the Cooperative's request for a modification, the lower court had failed to undertake the required analysis.¹⁰⁰

The appellate court remanded the matter back to the district court and instructed it to reconsider the request for a modification that would, under the injunction, allow cannabis to be distributed to seriously ill individuals who need it for medical purposes. According to the Court of Appeals, the medical necessity defense was a defense that

⁹⁶ *Conant v. McCaffrey*, No. C 97-00139 WHA, 2000 U.S. Dist. LEXIS 13024 (N.D. CAL. Sept. 8, 2000).

⁹⁷ *U.S. v. Cannabis Cultivators Club*, 5 F. Supp. 2d 1086 (N.D. Cal. 1998).

⁹⁸ *Id.*, In addition, in February 1999, the district court granted the government's motion to dismiss and rejected the Cannabis Cultivator's Club claim that the cooperative had a fundamental right to be free from the government's lawful exercise of its police powers.

⁹⁹ The Cooperative appealed both the contempt order and the denial of the Cooperative's motion to modify. The appeal of the contempt order became moot when the Cooperative promised to comply with the initial preliminary injunction.

¹⁰⁰ *U.S. v. Oakland Cannabis Buyers' Cooperative*, 109 F. 3d 1109 (9th Cir. 1999).

would likely apply in the circumstances.¹⁰¹ The appellate court further instructed the district court to consider criteria for a medical necessity exemption, and, should it modify the injunction, to set forth the criteria in the modification order. On July 17, 2000, the district court, in an amended preliminary injunction, ruled that the defendants were enjoined from manufacturing or distributing marijuana under the CSA. The court granted the Cooperative's motion to modify the injunction to incorporate a medical necessity defense. Therefore, the injunction would not apply to patients who suffer from serious medical conditions and meet the criteria set forth in the injunction.¹⁰²

When this ruling was issued, the Justice Department asked the U.S. Supreme Court to overturn the "medical necessity" defense for marijuana distribution. At the same time, it appealed the ruling from the Ninth Circuit Court that had allowed the Oakland buyers' club to provide marijuana to patients with serious medical conditions. In August 2000, the U.S. Supreme Court granted the Department's request to stop the Cooperative from distributing marijuana.¹⁰³ Because the decision raised significant questions about the ability of the federal government to enforce the nation's drug laws, the Supreme Court agreed in November to hear arguments in the medical necessity case.¹⁰⁴

On May 14, 2001, the Supreme Court ruled 8 to 0 that current federal anti-drug laws provide no "medical necessity" defense against selling or growing marijuana, and that federal authorities had the discretion to obtain court orders to close down the marijuana cooperatives.¹⁰⁵ The Court's ruling did not, however, invalidate the medical marijuana initiatives adopted by various states in the past few years.

Medical Marijuana and Congress: Recent Legislation

The adoption of the medical marijuana initiatives in California and Arizona in 1996 attracted a great deal of national attention, and all but ensured that Congress would look for ways to get involved. In fact, the first bills introduced in the 105th Congress to deal with the medical marijuana issue – the "Medical Marijuana Deterrence Act of 1997" (H.R. 1265), and the "Medical Marijuana Prevention Act" (H.R. 1310) – were offered in response to those very state referendums. The first measure would have denied federal benefits to individuals convicted of a state offense in a state that permits medicinal use of marijuana, while the second would have given the Attorney General authority to revoke a physician's right to prescribe controlled

¹⁰¹ 190 F. 3d, at 1114.

¹⁰² *U.S. v. Oakland Cannabis Buyers' Cooperative*, No. C 98-0088 CRB (N.D. Cal. July 17, 2000).

¹⁰³ Sanchez, Rene. High Court Bars Calif. Clinic's Marijuana Distribution. *The Washington Post*, August 30, 2000. p. A6.

¹⁰⁴ *U.S. v. Oakland Cannabis Buyers' Cooperative*, 121 S. Ct 563; 2000 U.S. LEXIS 7699; 69 U.S. L.W. 3363 (Nov. 27, 2000). 532 U.S. ___ (2001); No. 00-151, slip op. At 5 (May 14, 2001).

¹⁰⁵ Lane, Charles. Court Rules Against 'Medical Marijuana.' Justices Say Law Offers No Exception For Illness. *The Washington Post*, May 15, 2001. p. A1.

substances if they recommend smoking marijuana for therapeutic purposes. Congress took no action on either bill.

Proposals were also introduced to assert more control over the medical marijuana issue at the federal level. One bill (H.R. 3184), would have clarified that federal controlled substances laws still apply, even in situations where state law has authorized the use and distribution of marijuana for medical purposes. Another proposal (H.R. 1469), which was also offered as an amendment to a supplemental appropriations bill, would have prohibited federal dollars from being spent to study marijuana's potential therapeutic benefits. No action was taken on the first bill; the second was withdrawn by unanimous consent.

Legislation supporting the medical use of marijuana was also proposed during the 105th Congress. Introduced by Representative Barney Frank, the "Medical Use of Marijuana Act" (H.R. 1782), would have given marijuana de facto medical recognition by legislatively transferring the drug from Schedule I to Schedule II of the Controlled Substances Act (CSA). Moreover, the proposal would have amended both the CSA and FD&C Act so that neither statute would prohibit or restrict prescribing marijuana; prevent patients from using the drug in conjunction with a physician's orders; or prevent a licensed pharmacy from obtaining or holding marijuana for purposes of filling prescriptions. In addition, the legislation would have amended both laws so that neither could prohibit a state-established entity from producing and distributing marijuana for medical purposes. Also, the bill would have required the National Institute of Drug Abuse to make marijuana available for approved clinical investigations. No action was taken on this measure either.

Before it adjourned, however, the 105th Congress did pass a resolution expressing its support for using the traditional drug approval process for determining whether any drug, including marijuana, is safe and effective. Moreover, the legislation said that Congress opposed any effort to circumvent this process by legalizing marijuana, or any other Schedule I drug, for medical use without valid scientific evidence and the approval of the FDA. With adjournment looming, this language was incorporated into the FY1999 omnibus appropriations act.¹⁰⁶ In a separate amendment in the same bill, Congress told the District of Columbia that it could not spend appropriation money to administer its own medical marijuana ballot initiative.

During the 106th Congress, Representative Frank reintroduced the "Medical Use of Marijuana Act" (H.R. 912). Like its predecessor in the previous Congress, the legislation would have transferred marijuana from Schedule I to Schedule II of the Controlled Substances Act. It also would have amended the CSA and the FD&C Act so that neither law could prohibit or restrict the prescribing of marijuana; prevent patients from using it upon a doctor's order; or prevent pharmacies from obtaining marijuana in order to fill prescriptions in states where physicians can prescribe or recommend the drug for medicinal purposes. As in the previous bill, neither the CSA or the FD&C Act could prohibit or restrict a state entity from producing and distributing marijuana for medical use. Like the previous bill, it also directed the

¹⁰⁶ P.L. 105-277. Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999.

National Institute of Drug Abuse to make marijuana available for clinical trials. Finally, the act would not have affected any federal, state, or local law regulating or prohibiting smoking in public. Congress took no action on the proposal.

In September 1999, U.S. District Judge Richard Roberts issued his decision on the “Barr Amendment” (see section on State Ballot Initiatives), allowing the D.C. Board of Elections to proceed with tallying the votes on the marijuana ballot initiative considered the previous year. When the vote tally confirmed that the initiative had passed, some Members of Congress were already looking for legislative ways to keep the referendum from being implemented.

Using the appropriations process once again, Congress passed an amendment, also sponsored by Representative Barr, that would keep the District from legalizing marijuana for medical use. The amendment, part of the District’s FY2000 funding bill, said that none of the appropriated monies could be used to “enact or carry out any law, rule, or regulation to legalize or otherwise reduce penalties associated with the possession, use, or distribution of any Schedule I substance under the Controlled Substances Act or any tetrahydrocannabinol derivative.”¹⁰⁷ Furthermore, the amendment stated that the medical marijuana ballot initiative approved by D.C. voters on November 3, 1998, could not take effect. Congress imposed these same restrictions when it enacted appropriations bills for the District of Columbia for both FY2001¹⁰⁸ and FY2002.¹⁰⁹

Thus far, two bills have been introduced in the 107th Congress (H.R. 1344 and H.R. 2592) to address the medical marijuana issue. Both pieces of legislation are sponsored by Representative Barney Frank, and both are entitled the “States’ Rights to Medical Marijuana Act.” Similar to the proposals introduced in the previous Congress, both bills would transfer marijuana from Schedule I to Schedule II, and at the same time amend the CSA and the FD&C Act so that neither law could prevent marijuana from being prescribed or patients from using the drugs if they have a doctor’s prescription. Like before, both bills would also make it possible for pharmacies to obtain marijuana in order to fill prescriptions in those states where the drug can be prescribed. The proposals were given a title the sponsor felt would be more in concert with the various medical marijuana initiatives and laws being adopted in the states.

Although the two bills are very similar, H.R. 1344 includes a provision that would direct the National Institute on Drug Abuse (NIDA) to supply government-grown marijuana for all FDA approved clinical trials. However, when H.R. 2592 was introduced, the NIDA provision was dropped from the bill for several reasons, according to the sponsor. First of all, the sponsor thought that dropping the NIDA provision might engender broader support for the bill in Congress. It was also believed that this move would help reemphasize the main purpose of the legislation,

¹⁰⁷ P.L. 106-113, Section 167: Consolidated Appropriation Act, FY2000.

¹⁰⁸ P.L. 106-553, Appendix A, Section 143: Appropriations for the District of Columbia, FY2001.

¹⁰⁹ P.L. 107-96, Section 127.

reinforcing the right of states to determine whether doctors can prescribe marijuana. And lastly, under current federal government policy, only marijuana grown by the University of Mississippi, and supplied through NIDA, can be used in clinical trials involving smoked marijuana. Apparently, some researchers have questioned the quality of the research-grade marijuana cigarettes produced by NIDA. With this concern in mind, the sponsor felt that by introducing a second version of the bill, one without the NIDA provision, it might make it somewhat easier for researchers to do clinical studies some day without necessarily having to use marijuana supplied by the federal government.

Conclusion

Public concern over treating AIDS and other life-threatening diseases has rejuvenated debate over whether experimental or unconventional forms of medical therapy should be made more easily available for patients suffering from such severely debilitating conditions. Encouraged by recent congressional action and subsequent changes in regulatory policies, patients are demanding earlier access to experimental therapies, including those still under clinical investigation. In the minds of medical marijuana advocates, allowing patients to smoke marijuana for medicinal purposes is nothing less than a pragmatic extension of this philosophy. Depending on the symptoms being treated, anecdotal claims by patients reinforce their view that smoking marijuana can offer modest therapeutic relief for some medical conditions. Undoubtedly, they will continue to press their belief that sufficient empirical and scientific evidence of marijuana's therapeutic utility exists to persuade government officials to reassess their traditional arguments against the drug's medical use. Without such a reassessment, especially on the national level, efforts to change state laws will surely continue.

Others, especially those who strongly support the nation's current laws criminalizing the use of marijuana, will, for the foreseeable future, remain firm in their conviction that smoking marijuana, even in small amounts, carries inherent health risks that far exceed its therapeutic benefits. To them, most current claims for marijuana's medicinal qualities remain unsupported by well-controlled clinical investigations. Although they may concede that the safety and effectiveness of synthetic dronabinol (Marinol) have been scientifically established for treating nausea and HIV wasting syndrome, they will continue to argue that the same cannot be said for the therapeutic benefits often attributed to smoked marijuana.

Currently there is a lack of public consensus and scientific agreement over the safety and medical efficacy of smoking marijuana. The National Institutes of Health Expert Group, the Institute of Medicine, and other authors have stated that there is little clinical evidence at present to support many of the medicinal claims made for smoking marijuana. They point out that existing evidence is, for the most part, anecdotal, and not strongly supported by conventional methods of scientific testing. These groups also note that smoking marijuana does not appear to offer significant therapeutic advantages over currently available prescription medications, and could impose additional health risks for some patients. Both the Expert Group and IOM, however, note that uncertainties remain, and assert that further scientific research is needed to resolve the continuing debate.

Some patients appear willing to accept these risks, and are likely to continue to push for the medicinal legitimacy of smoked marijuana. At the present time, however, there is little evidence that Congress is ready to support their objective. Instead, sentiments appear to be to the contrary. In a sense of the Congress resolution, adopted as part of an appropriations bill, the 105th Congress asserted its opinion that Schedule I drugs [e.g., marijuana] lack any currently accepted medical use, and are unsafe, even under a doctor's supervision. In the same measure, Congress stated that marijuana and other Schedule I drugs have not been approved by the FDA. Furthermore, the resolution expressed continued support of the existing federal legal process for determining the safety and efficacy of drugs, and opposed efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without scientific evidence and FDA's formal approval. In light of the studies discussed, or until more convincing evidence of marijuana's medical utility emerges, this view will likely continue through the 107th Congress.