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Breaking the Federal/State Impasse Over Medical Marijuana: A Proposal

Marsha N. Cohen*

INTRODUCTION

The potential use of marijuana as a pharmaceutical raises many difficult policy issues requiring resolution in political as well as scientific spheres. The passage of Proposition 215, the Compassionate Use Act, by

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1. Proposition 215, effective November 6, 1996, added section 11362.5 to the California Health and Safety Code, as follows:
   (a) This section shall be known and may be cited as the Compassionate Use Act of 1996.
   (b)(1) The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:
   (A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person’s health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.
   (B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.
   (C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana.
   (2) Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for non-medical purposes.
   (e) Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes.
   (d) Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient’s primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral
California voters in November 1996 began a legal skirmish between state and federal governments that contributes nothing toward resolving the questions upon which sound public policy should be based. Those questions include: is marijuana safe and effective for medical use? If so, for what purposes is it safe and effective? At what dose should it be prescribed, and in what dosage form should it be available? What are the contraindications to its use?

Sufficient studies designed to answer such questions about marijuana have been delayed or prevented. The federal government, which controls the legal supply of marijuana, has resisted most researchers' attempts to obtain marijuana for clinical testing. As a consequence, proponents of "medical marijuana" have not felt constrained to limit their claims for marijuana's efficacy to those for which there is good evidence. Respected medical authorities believe that marijuana is effective for certain uses, for which it ought to be thoroughly tested and made available. Yet under federal law marijuana is a Schedule I controlled substance, which cannot be prescribed or used, and is deemed to have "no currently accepted medical use in treatment in the United States," even though its primary active

recommendation or approval of a physician.

(e) For the purposes of this section, "primary caregiver" means the individual designated by the person exempted under this section who has consistently assumed responsibility for the housing, health, or safety of that person.

CAL. HEALTH & SAFETY CODE § 11362.5 (West 2000).

2. See Marlene Cimons, Marijuana Studies to be Aided by Likely Policy Reversal; Health: Move by Clinton Will Make the Drug Available to Scientists to Examine Its Medical Effects. A Flood of Research Proposals is Anticipated, L.A. TIMES, May 21, 1999, at A15. See also infra notes 56-57 and accompanying text.


4. See Mary Curtius and Bettina Boxall, Pot Has Uses as Medicine, U.S. Panel Says, L.A. TIMES, Mar. 18, 1999, at A1; see also MARIJUANA AND MEDICINE, supra note 3, at 179-80.

5. 21 U.S.C. § 812(b)(1)(B) (1994). Under the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (Controlled Substances Act) [hereinafter CSA], administered by the Drug Enforcement Administration, drugs subject to abuse are listed in one of five Schedules, based upon criteria listed in the Act. See id. § 812(a); see generally id. §§ 801-971. If a drug has a high potential for abuse but no currently accepted medical use in treatment, and a lack of accepted safety for use under medical supervision, it is a Schedule I drug. See id. § 812(b)(1). Generally Schedule I drugs are illegal and cannot be manufactured, prescribed, dispensed or used, except for investigatory purposes and subject to strict government approvals. See id. § 823(f); see also CAL. HEALTH & SAFETY CODE § 11212 (West 1991). Marijuana is a Schedule I controlled substance under federal law; its manufacture, distribution, possession with the intent to manufacture or distribute, and simple possession are all illegal. See 21 U.S.C. §§ 841(a)(1), 844 (1994); see also United States v. Cannabis Cultivators Club, 5 F. Supp. 2d 1086, 1092 (N.D. Cal. 1998).

In contrast, Schedule II drugs, while they have a high potential for abuse which might lead to severe psychological or physical dependence, have a currently accepted medical use.
ingredient has been available by prescription in oral dosage form since 1986. In fact, that prescription drug, Marinol®, has just been downgraded from Schedule II to the less-restrictive federal Schedule III.

Federal concerns about drug abuse and politicians' concerns about appearing 'soft on drugs' have adversely affected the testing and availability of what might be an important addition to the pharmaceutical armamentarium.

Nevertheless, the medical marijuana policy passed by the voters of California (and, in various forms, by voters of several other states) is

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See 21 U.S.C. § 812(b)(2) (1994). They are available for sale by prescription only under the most stringent regulatory controls. See id. § 829(a). Schedule III drugs have a currently accepted medical use and less potential for abuse than Schedule I or II substances. See id. § 812(b)(3). Abuse may lead to moderate or low physical dependence or high psychological dependence. See id. Regulation of the sale of Schedule III drugs is less stringent than that of Schedule II drugs. See, e.g., WILLIAM MARCUS & MARSHA COHEN, PHARMACY LAW FOR CALIFORNIA PHARMACISTS 122-26 (3d ed. 1999).

6. In 1985, the Food and Drug Administration (FDA) approved the marketing of dronabinol (trade name Marinol®), the isomer of delta 9-trans-tetrahydrocannabinol (THC) believed to be the major psychoactive component of marijuana, after its sponsor demonstrated its safety and efficacy for relief of nausea and vomiting in cancer chemotherapy patients. See Schedules of Controlled Substances: Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol, 64 Fed. Reg. 35928, 35928 (1999) (to be codified at 21 C.F.R. §§ 1308, 1312) [hereinafter Rescheduling Dronabinol].

7. In 1992, the FDA approved the marketing of Marinol® for the treatment of anorexia associated with weight loss in AIDS patients. See id. Marijuana and its components were all Schedule I controlled substances in 1985; therefore Marinol® could not have been marketed until the Drug Enforcement Administration (DEA) moved the product into Schedule II, which it did in 1986. See id. This rescheduling did not affect the classification of pure dronabinol which, "as a tetrahydrocannabinol with no currently accepted medical use in treatment in the United States," remains a Schedule I controlled substance. Id. The DEA recently moved Marinol® from Schedule II to Schedule III at the request of its sponsor, Unimed Pharmaceuticals, thereby easing the restrictions on prescription refills and lessening record-keeping requirements and distribution restrictions. See id.

8. Those states are Alaska, Arizona, Maine, Oregon and Washington; Nevada voters will make a final decision on this issue in November 2000. See Claire Cooper & Denny Walsh, Medical Pot Wins in Court: Need for Treatment Ruled Valid Defense, SACRAMENTO BEE, Sept. 14, 1999, at A1. Maine’s initiative is the most recently adopted. See Medical Marijuana: Maine Approves Initiative, AM. HEALTH LINE, Nov. 4, 1999. These state ballot measures are described in Marcia Twersky, Medical Marijuana: Putting the Power Where It Belongs, 93 NW. U. L. REV. 547, 580-84 (1999). In 1998, Congress passed legislation preventing the counting of ballots cast on a District of Columbia medical marijuana initiative. When the votes were finally counted one year later, the voters favored legalizing the medical use of marijuana by a two-to-one margin. See Medical Marijuana: D.C. Voters Have Spoken, USA TODAY, Sept. 14, 1999, at 17A. Some additional states (Connecticut, Louisiana, New Hampshire, Ohio, Vermont, Virginia and Wisconsin) have laws that allow physicians to prescribe marijuana for medical purposes or permit a medical necessity defense to a state criminal prosecution. See MARIJUANA AND MEDICINE, supra note 3, at 17; see also Allison L. Bergstrom, Medical Use of Marijuana: A Look at Federal & State Responses to California’s Compassionate Use Act, 2 DEPAUL J. HEALTH CARE L. 155, 162-63 (medical necessity defense cases).

Twenty years ago, a number of states established programs to engage in clinical research using marijuana or to allow physicians to distribute marijuana to patients. See Nicole Dogwill, The Burning Question: How Will the United States Deal with the Medical-
deeply flawed. If marijuana is a safe and effective drug, it ought to be available through the same channels as all other drugs, prescribed by a licensed professional and dispensed by a registered pharmacist. Our system of prescription drug distribution is intended to assure that patients receive appropriate medications in correct dosages, avoid dangerous interactions with other drugs and foods and receive sufficient information about their drugs to assure their safe use. Ordinarily, highly-trained professional pharmacists dispense drugs upon prescription by a licensed prescriber, usually a physician. The complex regulatory system for prescription drug distribution reflects the importance society places on the protection of individual and public health. Proposition 215 does not even require a prescription to possess or cultivate marijuana; because of federal legal restrictions on prescribers, a physician need only “recommend” its use. Furthermore, the initiative makes no provision for either buying or selling marijuana, only for possessing or cultivating it, thus failing to provide any logical distribution scheme even for those it allows to use marijuana.

A more basic flaw is that Proposition 215 is extremely vague about the universe of patients entitled to use marijuana, covering those who suffer from “cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.” Thus, a large percentage of Californians would seem to qualify. The failure to tailor the relief offered by the initiative to those with serious illnesses for which there was some evidence of marijuana’s efficacy fueled the opposition to the medical marijuana concept.

This policy commentary summarizes the current legal and scientific status of medical marijuana and serves as an appeal to California Governor

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*Marijuana Debate*? 1988 DET. C.L. REV. 247, 255-76. These programs largely floundered because of their cost, the bureaucracy involved, and the development of Marinol®. See id.

9. *See generally MARCUS & COHEN, supra note 5.*

10. The authors of the initiative could not require a prescription because prescribers would risk their licenses to prescribe controlled substances if they issued prescriptions for marijuana. *See 21 U.S.C. §§ 824(a)(2) (1994).*


13. *See, e.g., James P. Fox et al., Argument Against Proposition 215, in VOTER INFORMATION PAMPHLET 61 (Nov. 1996).*

The proponents of this deceptive and poorly written initiative want to exploit public compassion for the sick in order to legalize and legitimize the widespread use of marijuana in California. Proposition 215 DOES NOT restrict the use of marijuana to AIDS, cancer, glaucoma and other serious illnesses.

READ THE FINE PRINT. Proposition 215 legalizes marijuana use for “any other illness for which marijuana provides relief.” This could include stress, headaches, upset stomach, insomnia, a stiff neck . . . or just about anything.

*Id.*
Gray Davis to mobilize the power, position, and resources of his office to break the impasse between the federal and state governments on the issue of marijuana as medicine.

A PROPOSAL

A committed and courageous leader\textsuperscript{14} could rescue us from the legal and practical morass in which medical marijuana is now mired. In partnership with his fellow governors of states in which medical marijuana initiatives have recently become law, Governor Davis should:

(1) Issue a strong statement that supporting the appropriate use of marijuana in medical practice, like the long-accepted use of heroin and cocaine derivatives, is not an endorsement of non-medical use of marijuana or any other illegal drug, and should be considered a scientific and not a political question.\textsuperscript{15}

(2) Support, as he has done with his recent approval of a marijuana research law,\textsuperscript{16} the scientific determination of whether marijuana is safe and effective and, if so, at what dose and in what form. He should commit the State of California to seeking all necessary financial support, through charitable donors and/or commercial partners,\textsuperscript{17} to conduct clinical studies at the University of California or elsewhere. If the results demonstrate marijuana’s safety and efficacy, the state would file a New Drug Application to obtain marketing approval from the Food and Drug

\begin{footnotes}
\item[14] Time Magazine recently acclaimed Governor Davis as “fearless” for other policy initiatives, particularly HMO reform. Steve Lopez, \textit{The Most Fearless Governor in America; California thought it was electing a timid, inoffensive Governor. Instead, Gray Davis is knocking heads, even passing HMO reform,} TIME, Oct. 11, 1999, at 32.

\item[15] Editorial writers supporting medical marijuana make this distinction. For example, the San Francisco Chronicle wrote, “Just for the record, we deplore illegal drug use by anyone and urge kids to stay clean. Marijuana should not be used for recreation, and adults who use it as medicine should not drive or operate heavy equipment.” Editorial, \textit{Marijuana as Medicine: Let’s Make the Law Work,} S.F. CHRON., Apr. 25, 1999, at 8.

\item[16] The Marijuana Research Act of 1999 authorizes the Regents of the University of California to implement a three-year California Marijuana Research Program to study the safety and efficacy of marijuana and, if appropriate, to develop guidelines for its administration and use. \textit{See S.B. 847, 1999-2000 Sess. (Cal. 1999).} The bill did not include an appropriation for these purposes. \textit{See id.}

\item[17] Drug development is both expensive and risky; only a small percentage of drugs that enter the testing process are proven to be safe and effective. \textit{See MARIJUANA AND MEDICINE, supra note 3, at 194-98.} Companies seek intellectual property protection for products early in the testing process to protect their investments. These companies will be wary about investing in clinical testing of marijuana (even if one discounts the sociopolitical aspects of marketing it) because neither marijuana nor cannabinoid extract from marijuana is likely to meet the criteria for patent protection. \textit{See id.} at 218. If an alternative method of drug administration were developed (such as a marijuana inhaler or a skin patch), the product would more likely qualify for patent protection, justifying the costs of development. \textit{See id.} at 205-06. There also may be a limited period of marketing exclusivity available to the first applicant for a marijuana NDA, even if no patent protection is available. \textit{See 21 U.S.C. § 355(j)(4)(D)(iii) (1994).}
\end{footnotes}
Administration (FDA).

(3) Seek a firm commitment by the federal government, in return for California’s role in clarifying its medical benefits or lack thereof, to provide marijuana for the necessary testing and, if results demonstrate medical uses, to reclassify marijuana from Schedule I to Schedule II of the federal Controlled Substances Act to the extent and for the purposes for which the FDA has approved its marketing.\(^8\)

(4) Commit the full resources of the Office of the Governor, at such time as marijuana in any form is available through pharmaceutical channels or has been determined to have no medical benefits, to obtain the repeal as unnecessary of the provisions of California law added by Proposition 215.\(^9\)

Federal officials' concern about abuse of marijuana should be ameliorated, not exacerbated, by cooperating with its study and pharmaceutical approval. The recently-adopted medical marijuana provisions of various state laws surely are at least complicating\(^2\) (and

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\(^8\) The United States has treaty obligations that require it to maintain certain levels of control on drugs of abuse. However, rescheduling of marijuana to Schedule II appears to be consistent with those obligations. See MARIJUANA AND MEDICINE, supra note 3, at 217; see also Rescheduling Dronabinol, supra note 6.

\(^9\) See CAL. CONST. art. II, §10(c) (an initiative may be amended by a statute, adopted by the Legislature and approved by the voters).

\(^2\) Law enforcement officials in the field cannot easily distinguish between legitimate ‘patients’ entitled to medical marijuana and all others; it is a waste of resources to arrest those who are entitled under state laws such as Proposition 215 to possess marijuana. See Michael Simmons, Pot Reform Stalls in Sacramento, L.A. WKLY., Sept. 3, 1999, at 19.

After Proposition 215 passed, then-Attorney General Dan Lungren refused to enforce it and left to local law enforcement officials and district attorneys the decision whether to apply the state law. See id. Current Attorney General Bill Lockyer convened a task force of law enforcement officials and medical marijuana advocates in January 1999 to address the concerns regarding the means to distinguish legitimate from illegitimate medical users of marijuana. See Maura Dolan & Mary Curtius, Medical Need a Factor in Pot Cases, Court Says; Health: Federal Appeals Panel Rules That Marijuana Centers May Distribute Drug if Patient Faces Serious Harm, L.A. TIMES, Sept. 14, 1999, at A1. The Medical Marijuana Task Force recommended that a state registry of patients entitled to Proposition 215’s benefits be created, and identification cards provided, to simplify law enforcement at the local level. See id. The proposal was introduced in the California Legislature as S.B. 848, 1999-2000 Sess. (Cal. 1999), but tabled on the final day of the 1999 legislative session after controversy over whether the patient registry should be mandatory or optional. See id. Some opponents of the mandatory registry fear it would make patients targets for federal prosecution. See id. Proponents intend to reintroduce the idea in the 2000 legislative session. See id.; see also Simmons, supra.

Some local jurisdictions have adopted identification systems for legitimate users of medical marijuana. See Rachel Gordon, S.F. Approves ID Cards for Medical Pot, S.F. EXAMINER, Jan. 25, 2000, at A-3; see also California Dateline/Snapshots of Life in the Golden State, L.A. TIMES, June 29, 1999, at A3; Andrew LaMar, Mendocino Offers Marijuana ID Cards Protect Medical Users from Arrest, THE PRESS DEMOCRAT (Santa Rosa, Cal.), June 25, 1999, at B1; Patrick O’Neill, Medical Marijuana Card Will Cost $150 Per Year, PORTLAND OREGONIAN, May 1, 1999, at A1. At least one claim has been filed against a county by a patient with a doctor’s recommendation, charging improper arrest for growing marijuana. See Pamela Martineau, $10 Million Claim Filed in Pot Arrest, Cancer Patient Had Presciption, SACRAMENTO BEE, Apr. 21, 1999, at B1.
probably also diminishing) state efforts to enforce remaining prohibitions on marijuana use. Placing medical use of marijuana entirely within the framework of the existing health care system, subject to the controls imposed on all other drugs, would be both better law and better medicine.

THE LEGAL STATUS OF MEDICAL MARIJUANA

In California, mere possession of a limited quantity of marijuana has been only a misdemeanor since 1973, subjecting those convicted to a $100 fine.\textsuperscript{21} By contrast, sale or possession for sale of marijuana is a felony.\textsuperscript{22} Under federal law, marijuana is a Schedule I controlled substance and therefore is illegal to manufacture, distribute or possess.\textsuperscript{23} Federal law enforcement officials have focused their attention on wholesale possession and distribution of illegal drugs, while the states and localities have largely dealt with retail-level distribution.\textsuperscript{24} Federal and state controlled substance laws work together; the federal law does not supersede state law. The states may and often do apply different and more complex controls on controlled substances, particularly with respect to record keeping at the pharmacy distribution level, but the states cannot allow what federal law prohibits.\textsuperscript{25}

Prior to the passage of Proposition 215, California law prohibited entirely the possession, sale, transportation and cultivation of marijuana.\textsuperscript{26} Although there is some public sentiment for decriminalization of marijuana, it is unlikely that Californians would have passed an initiative in 1996 decriminalizing its use for all purposes.\textsuperscript{27} However, Californians were sympathetic\textsuperscript{28} to the argument that marijuana should be available to relieve the suffering of the seriously ill, which was the stated limited purpose behind the initiative.\textsuperscript{29} The initiative was placed on the ballot only

\textsuperscript{21} See \textsc{Cal. Health \\& Safety Code} § 11357(b) (West 1991).
\textsuperscript{22} See \textit{id.} §§ 11359, 11360.
\textsuperscript{23} See \textsc{21 U.S.C.} §§ 841(a)(1), 844 (1994).
\textsuperscript{24} A federal government spokesman said, after passage of Proposition 215, that the DEA has “never gone after individual pot smokers,” and would continue to concentrate on imports and growers. Glen Martin, \textit{Both Sides Say 215 Decriminalizes Pot Use/Prosecution Will Be Difficult}, S.F. CHRON., Nov. 7, 1996, at A17. Further, the State of California has insufficient resources to investigate and prosecute local street-level sales and purchases of marijuana, and relies on local police to prosecute retail marijuana users. Telephone Interview with Robert Elsberg, Senior Special Agent in Charge, Bureau of Narcotic Enforcement, California Department of Justice (Nov. 10, 1999).
\textsuperscript{25} See \textsc{21 U.S.C.} § 903 (1994); see also \textsc{Marcus \\& Cohen, supra} note 5 at 18. For example, California has long imposed considerably more detailed requirements on prescriptions for Schedule II drugs than are required by federal law. \textit{See id.} at 122-123.
\textsuperscript{26} See \textsc{Cal. Health \\& Safety Code} §§ 11357-11361 (West 1999).
\textsuperscript{28} See United States v. Cannabis Cultivators Club, 5 F. Supp. 2d 1086, 1091 (N.D. Cal. 1998) (noting that Proposition 215 passed with 56% of the vote).
\textsuperscript{29} “Proposition 215 will allow seriously and terminally ill patients to legally use
after similar legislation had twice been passed by the California Legislature, but vetoed by then-Governor Pete Wilson.\footnote{See Dr. Richard Cohen et al., \textit{Argument in Favor of Proposition 215}, in \textit{Voter Information Pamphlet} 60, 60 (Nov. 1996).}

A number of cannabis ‘clubs’ had sprouted around California even before Proposition 215 passed.\footnote{See id.} At the clubs, people claiming medical need were able to purchase marijuana if they could produce their physician’s recommendation.\footnote{See id.} The cannabis club distribution model, although clearly illegal under both state and federal law, was tacitly accepted by some local law enforcement officials.\footnote{See id.} The public seemed to expect this model would prevail if Proposition 215 passed.

It was only after the initiative passed that many voters became aware that it might change little in the legal landscape concerning marijuana. First, the initiative merely created a defense to California prosecutions for possession and cultivation of marijuana; state as well as federal prohibitions on buying or selling marijuana remained in place.\footnote{See \textit{People v. Trippet}, 56 Cal. App. 4th 1532, 1550 (1997), modified \textit{57 Cal. App. 4th} 754A (1997), \textit{reh’g denied}, 1997 Cal. LEXIS 8225 (1997). For a discussion of \textit{Trippet}, see Bergstrom, \textit{supra} note 8, at 169-82.} The cannabis clubs, California courts held, could not continue to sell marijuana to patients, even if they did not profit from the sales. Neither were the clubs “primary caregivers” authorized to acquire or grow marijuana on the patients’ behalf.\footnote{See \textit{People ex rel. Lungren v. Peron}, 59 Cal. App. 4th at 1389-99.}

Second, the conflict with federal law, while referenced in the arguments presented in the \textit{Voter Information Pamphlet},\footnote{See, e.g., Sheriff Brad Gates et al., \textit{Rebuttal to Argument in Favor of Proposition 215}, \textit{Voter Information Pamphlet} 60, 60 (Nov. 1996).} had often been overlooked or under-emphasized in discussions of the initiative.\footnote{See, e.g., Jonathan Marshall, \textit{Prop. 215 May Allow Pot Use at Work}, S.F. CHRON., Nov. 16, 1996, at A1; see also Martin, \textit{supra} note 24. While the public and media may not have focused on this conflict, attorneys and marijuana proponents recognized the legal problem. As an assistant district attorney who helped set up a county’s medical marijuana club put it, “We knew 215 wasn’t legal under federal statutes . . . this is law school 101 stuff.” John Roemer, \textit{Feds’ Crackdown Stirs the Pot Club Bar}, S.F. DAILY J., Jan. 12, 1998, at 1, 2.} Marijuana’s continued illegality under federal law could be an insurmountable obstacle to its distribution even for limited purposes.

One aspect of the federal government’s initial response to the initiative
was to threaten sanctions against physicians "who recommend or prescribe Schedule I controlled substances." Physicians must maintain licensure by DEA to prescribe any controlled substance; most participate in the federal Medicare and Medicaid programs to receive fees for services to patients covered by those programs. The threats were challenged by physicians as impermissibly vague, an infringement on their First Amendment rights and adversely affecting the treatment of patients suffering from life-threatening diseases. Federal District Judge Fern Smith issued a preliminary injunction in April 1997 against the federal government threatening or prosecuting physicians, revoking their DEA licenses or excluding them from participation in the Medicare or Medicaid programs because of their conduct with respect to patient use of marijuana that is not itself a criminal offense. As of March 2000, the underlying case is still in the pretrial stage.

The cannabis clubs were an obvious target of prosecution, and the federal government has been more successful in challenging marijuana distribution than physician recommendations for its use. In United States v. Cannabis Cultivators Club, Federal District Judge Charles Breyer issued a preliminary injunction in May 1998 against six medical cannabis clubs and their principals, holding that the federal prohibition against the distribution of marijuana except for use in an approved research project is in direct conflict with Proposition 215's limited legalization of marijuana.

On appeal, however, the Ninth Circuit, without vacating the injunction, remanded to Judge Breyer to reconsider his refusal to modify the injunction to permit distribution of marijuana to those patients for whom it is a medical necessity. Judge Breyer had dismissed consideration of a necessity defense on the grounds that no individualized evidence of necessity had been adduced. The Ninth Circuit stated that the plaintiffs had offered evidence:

[T]hat there is a class of people with serious medical conditions for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; who will suffer serious harm if

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39. See id. at 701. Note that the decision only prohibits prosecuting California physicians "unless the government in good faith believes that it has probable cause to charge under the federal aiding and abetting and/or conspiracy statutes. This requires that the government believe that it can prove that a physician had the specific intent to aid and abet or conspire." Id. The line between exercising one's First Amendment rights and aiding and abetting violation of the Controlled Substances Act remains hazy.
40. Cannabis Cultivators Club, 5 F. Supp. 2d at 1100. Other smaller groups have quietly continued to distribute marijuana, with the support of local and state law enforcement officials. See Edward Epstein, Lockyer Gives Quiet O.K. to S.F. Pot Clubs/But Distribution Should be Discreet and Low-Profile, S.F. CHRON., Mar. 29, 1999, at A15.
41. See United States v. Oakland Cannabis Buyers' Cooperative, 190 F.3d 1109, 1115 (9th Cir. 1999).
42. See Cannabis Cultivators Club, 5 F. Supp. 2d at 1102.
they are denied cannabis; and for whom there is no legal alternative
to cannabis for the effective treatment of their medical conditions
because they have tried other alternatives and have found that they
are ineffective, or that they result in intolerable side effects.\(^{43}\)

In contrast, the government had not identified any interest in
preventing distribution of marijuana to those with medical needs, nor had it
rebutted plaintiffs' evidence that marijuana is the only effective treatment
for a large group of seriously ill individuals. Thus, the Ninth Circuit held,
the district court's summary denial of the modification of the injunction
was error.\(^{44}\)

Proponents of medical marijuana and the media celebrated the Ninth
Circuit decision as a triumph. Medical Pot Wins in Court: Need for
Treatment Ruled Valid Defense, read the headline in the Sacramento Bee.\(^{45}\)
That celebration is premature for two reasons.

First, the government is likely to pursue this case as far as possible. It
petitioned for rehearing, suggesting rehearing en banc, arguing cogently
that the necessity defense is far more limited in scope than the panel's
decision would apply it, and inapplicable where the legislature has weighed
the policy issues and failed to exempt the conduct at issue. Smugglers of
laetrile, an unapproved drug thought by some to be effective cancer
treatment, failed in their medical necessity defense in the Ninth Circuit.\(^{46}\)
The government also challenged an exemption from a prospective
injunction based on necessity as "peculiarly paradoxical," because the
defendants here could seek relief via the political or administrative
process.\(^{47}\) The petition was denied on March 1, 2000; the government can
now seek Supreme Court review.

Second, even if the Ninth Circuit's recent decision stands, one must
wonder how Judge Breyer, on remand, can comply with its instructions to

\(^{43}\) \textit{Oakland Cannabis Buyers' Cooperative}, 190 F.3d at 1115. The court also found that
the district court had erroneously believed that it had no discretion to modify the injunction
and that the plaintiffs' proposed amendment related to a matter affecting the public interest.
\textit{See id.} at 1114.

\(^{44}\) \textit{See id.} at 1115. The Ninth Circuit cites as the basis for the necessity defense the case of
United States v. Aguilar, 883 F.2d 662, 693 (9th Cir. 1989), in which the court found that
the proponents of the defense (in an immigration case involving the sanctuary movement)
were not entitled to its benefit because they failed to demonstrate that they lacked any other
alternative. To be entitled to the defense, the defendant must demonstrate: "(1) that he was
faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent
harm; (3) that he reasonably anticipated a causal relation between his conduct and the harm
to be avoided; and (4) that there were no other legal alternatives to violating the law." \textit{See id.}

\(^{45}\) Cooper & Walsh, supra note 8; \textit{see also} Federal Appeals Court Opens Door to Legal
Use of Medical Marijuana, PR NEWSWIRE, Sept. 15, 1999.

\(^{46}\) \textit{See} Brief for Appellee at 10, United States v. Oakland Cannabis Buyers' Cooperative
and Jeffrey Jones, 190 F.3d 1109 (9th Cir. 1999) (Nos. 98-16950, 98-17044, 98-17137)
(citing United States v. Richardson, 588 F.2d 1235, 1239 (9th Cir. 1978)).

\(^{47}\) \textit{Id.} at 13-14.
reconsider modifying his injunction to exempt "seriously ill individuals
who need cannabis for medical purposes . . . [and] to consider [and set
forth] . . . the criteria for a medical necessity exemption . . . ." 48 These
instructions presuppose the existence of scientific and medical information
about marijuana that is not yet available.

MARIJUANA AS MEDICINE: BY WHAT CRITERIA?

The necessity of cannabis for medical purposes logically depends upon
its efficacy for those purposes. However, marijuana, other than in the form
of the prescription pharmaceutical Marinol®, is not an approved drug. 49
Thus, there has been no authoritative review of its safety and efficacy for
various types of ailments. 50 In seeking to make marijuana available to the
ill, however, the California electorate's views were in line with the best of
contemporary medicine. For a long time, physicians have failed to use
adequate amounts of controlled substances, particularly for pain
management, because of inappropriate fears of causing addiction or
habituation and concerns about disciplinary risks. 51 In response, more than
thirty-five states have passed laws, statements or guidelines on pain
management in recent years. California's Intractable Pain Treatment Act
promotes the appropriate use of controlled substances in the treatment of
pain that has not been relieved after other reasonable efforts. 52

For a significant period of time, physicians have believed that
marijuana is effective for certain medical purposes, in particular to relieve
pain, to control nausea and vomiting caused by cancer chemotherapy, to
alleviate AIDS wasting syndrome, to reduce interocular pressure in
glaucoma and to relieve neurological symptoms such as muscle spasticity,

48. Oakland Canabis Buyers' Cooperative, 190 F.3d at 1115 (emphasis added).
49. Independent of its illegality as a Schedule I controlled substance under federal law,
marijuana is also an illegal drug, at least for interstate shipment, under provisions of federal
drug law. No drug may be shipped interstate unless a New Drug Application has been
approved, based upon a finding by the FDA that it is safe and effective for the uses
prescribed, recommended or suggested in the drug's labeling. See United States v.
Rutherford, 442 U.S. 544, 546 (1979). The only exemptions are investigative drugs (with
appropriate FDA approval) and "grandfathered" drugs, those commercially used or sold for
the same conditions prior to the advent of federal regulation. Id. at 548. In a case involving
the drug Laetrile, alleged to be an effective treatment for cancer, the United States Supreme
Court held that there was no implied exemption for drugs for terminally ill patients. See id.
at 552. It is instructive to note that by the time of the Supreme Court decision, seventeen
states had legalized the prescription and use of Laetrile for cancer within their state
boundaries; similar statutes had been defeated in fourteen other states. Id. at 554 n.10.
Laetrile, made from apricot pits, was not a controlled substance under federal law.
50. The most authoritative review of marijuana's safety and efficacy is that of the
Institute of Medicine of the National Academy of Sciences, published in 1999, and it called
for further clinical study. See generally MARIJUANA AND MEDICINE, supra note 3.
51. See, e.g., Erin Hoover Barnett, A Revolution in Relief, The Oregonian, Sept. 12,
52. See Cal. Bus. & Prof. Code § 2241.5 (1991); see also Marcus & Cohen, supra
note 5, at 173-74.
among many others. However, because of the potency of the placebo effect, clinical observations alone are insufficient to demonstrate efficacy in seeking approval to sell a new drug.

To market marijuana as a pharmaceutical requires both adequate clinical studies of its safety and efficacy and its rescheduling, at least in some forms and for some purposes, from schedule I to schedule II. Attempts to accomplish both have been frustrated.

Access to marijuana is essential for clinical studies of the safety and efficacy of marijuana to proceed. The federal government, through the National Institute on Drug Abuse, controls the legal domestic supply of marijuana, which it grows on a farm at the University of Mississippi. For two decades it has been virtually impossible for all but a few federally-funded researchers to obtain a legal supply. In May 1999, the federal Department of Health and Human Services (HHS) adopted new rules to allow privately-funded researchers access to that legal supply on a cost-reimbursable basis. Before this change, the government was providing marijuana only to four medical studies. Dr. Donald Abrams, assistant director of the AIDS program at San Francisco General Hospital and a professor of clinical medicine at the University of California, San Francisco, tried for five years before he received approval to obtain marijuana for a study of the short-term effects of cannabinoids in patients with HIV infection. In that study, Dr. Abrams is comparing the effects of smoked marijuana with orally-ingested dronabinol.

A 1972 petition to reschedule marijuana resulted in five trips to the

53. See MARIJUANA AND MEDICINE, supra note 3, at 137-38.
54. 21 C.F.R. § 314.126(e) (1999); see also Herbal Roulette, CONSUMER REP., Nov. 1995, at 698, 700. Both the patients' and the clinical investigators' expectations can influence their reports of a treatment's efficacy. See MARIJUANA AND MEDICINE, supra note 3, at 138-39.
55. See sources cited supra note 5.
56. There is some dispute about the validity of this widely-repeated contention. See MARIJUANA AND MEDICINE, supra note 3, at 214 (marijuana researchers who have been successful in the highly competitive NIH research grants process have had marijuana supplied for their projects; only a quarter to a third of all NIH grant applications are funded). Dr. Donald Abrams' long struggle to proceed with marijuana research (see infra note 58 and accompanying text) is dismissed in this report as the case "of a single individual." Id. Researchers could seek federally-supplied marijuana through a protocol review program outside the NIH grants process. See id. at 213. Whether researchers have been stymied by perception or reality of failure or by bureaucratic hurdles concerning marijuana supply, or by the many other economic and regulatory barriers to profiting from marijuana as a pharmaceutical, the result is the same. There is a lack of controlled clinical studies of the effect of marijuana on a number of the symptoms for which its use has been advocated. See id. at 218-19.
57. See Cimons, supra note 2; see also Richard Sisk, U.S. to Deal Reefer But It'll Only Sell for Research Use, DAILY NEWS (New York, N.Y.), May 22, 1999, at 2.
58. See Donald I. Abrams, M.D., Medical Marijuana: Tribulations and Trials, 30 J. PSYCHOACTIVE DRUGS 163, 168 (1998). Note that approval of this study, because it was being conducted in California with a controlled substance, also was required from the California Research Advisory Panel. See id. at 165.
District of Columbia Circuit, in the last of which, in 1994, the DEA’s denial was upheld.9 A new reclassification petition was referred by the DEA to the Secretary of Health and Human Services in December 1997, after DEA determined that the petition raised scientific and medical issues not previously evaluated by HHS.60 The Institute of Medicine report has subsequently concluded that marijuana may be effective for treatment of pain in a number of patient groups, for nausea in patients for whom other anti-emetic drugs are ineffective and for wasting syndrome in AIDS patients, among other potential uses.61 This report encouraged researchers to find alternatives to smoking, such as inhalers, as a means of administering marijuana as a drug, because of the dangers inherent in smoking and the variability of the drug effect from a natural plant product.62 However, until a “non-smoked, rapid-onset cannabinoid drug delivery system becomes available,” the experts indicated there is no clear alternative to smoking marijuana for certain patients, and urged its controlled availability for their short-term (under six months) use.63 Whether this report’s conclusions will satisfy DEA and HHS that there is a “currently accepted medical use in treatment” for marijuana, justifying its reclassification, has yet to be seen.64

The approval of the cannabinoid drug Marinol® has not satisfied the demand either for marijuana or marijuana-derived drugs for several reasons. First, Marinol® is only available in capsule form, a disadvantage for patients suffering from nausea and vomiting. Second, nausea and vomiting are themselves adverse reactions experienced by three to ten percent of Marinol® users.65 Third, patients find they can control more carefully the dosage and side effects of the rapid-onset smoked marijuana than the delayed-onset, standard dose Marinol®.66 Fourth (and not widely

60. See Cannabis Cultivators Club, 5 F. Supp. 2d at 1101.
62. See MARIJUANA AND MEDICINE, supra note 3, at 154.
63. See id. at 159.
64. See id. at 177-78.
65. See id.
66. Id. at 178-79.
67. The medical community supports reclassification. In January 1997, the editors of the NEW ENGLAND JOURNAL OF MEDICINE, one of the nation’s foremost scholarly medical journals, urged the reclassification of marijuana to Schedule II to make possible clinical research and controlled medical use. See Jerome P. Kassirer, Editorial: Federal Foolishness and Marijuana, 336 NEW ENG. J. MED. 336, 336 (1997).
69. See MARIJUANA AND MEDICINE, supra note 3, at 156, 248.
discussed), Marinol® is perceived to cost considerably more than equivalent doses of smokeable marijuana obtained from street sources.\(^70\) While comparative cost should not be a factor in determining medical necessity, dosage form issues would be relevant.

Where should Judge Breyer turn to decide for whom marijuana is medically necessary? The federal government bears significant responsibility for the paucity of controlled clinical studies of marijuana’s efficacy. If an adequate science base existed for making the medical necessity decision, the task would not be inappropriate for a federal judge. In the absence of that science base, setting the criteria for those whose illnesses necessitate the use of marijuana is an inappropriate task for a legal tribunal.\(^71\)

Judge Breyer can look for some assistance to the Institute of Medicine report acknowledging that there is no clear alternative now to marijuana for people suffering from some debilitating conditions for whom no other therapies have offered relief.\(^72\) However, this report’s broad conclusions about “the potential therapeutic value of cannabinoid drugs,” intended to encourage further research on the efficacy of marijuana and alternative dosage forms, hardly support the creation of specific criteria to determine for which patients marijuana is necessary. The Ninth Circuit limited its

\(^{70}\) See Cohen, supra note 29 ("Marinol... can cost $30,000 a year and is often less reliable and less effective"). The editors of MARIJUANA AND MEDICINE reviewed much testimony about the higher cost of Marinol® than of smoked marijuana, but noted that the indirect costs of purchasing an illegal drug, including the legal risks and lack of product guarantees, are not included in people’s calculations. Supra note 3 at 206. They concluded that Marinol® (at $200 per month) is less expensive than marijuana (at $5-10 per bag of loose plant on the street) if you have health insurance covering prescription drugs or are eligible for the manufacturer’s patient assistance program. See id. at 206-07. A price quote for Marinol® in November 1999 from a San Francisco pharmacy was as follows:

- 60 2.5 mg capsules, $238.99 (about $4 each)
- 60 5 mg capsules, $438.99 (about $7.32 each)
- 60 10 mg capsules, $984.49 (about $16.42 each)

Information obtained from Safeway Pharmacy #25-0995, San Francisco, Cal. (Nov. 17, 1999).

The street price of marijuana at the same time can only be estimated. In California the average price per pound of sensimilla marijuana was $4,000, with a range of $3,500-$6,000 depending on quality. About 900 cigarettes can be made from a pound, assuming two or three cigarettes per gram; each would cost about $4.50. Telephone interview with Gil Van Attenhoven, Operations Commander, Campaign Against Marijuana Planting, Bureau of Narcotics Enforcement, California Department of Justice (Nov. 19, 1999). As the data indicate, if a patient needed a 5 or 10 mg. Marinol® capsule to achieve the relief available from a single marijuana cigarette, the latter would be less expensive. However, if health insurance paid some of the cost of Marinol®, that might be the cheaper choice.

\(^{71}\) Scientifically-appropriate decisions and policies are impossible when adequate data are unavailable. When a lawsuit must be decided, a court cannot wait for research to yield that data. However, when the law need not “race[] ahead of science,” it ought not do so. See David L. Faigman, LEGAL ALCHEMY: THE USE AND MISUSE OF SCIENCE IN THE LAW 51 (1999).

\(^{72}\) See MARIJUANA AND MEDICINE, supra note 3, at 178.
relief to patients who are “seriously ill.” Is the patient “seriously ill” only if the prognosis is imminent death? Is it adequate that the illness is chronic or lengthy? What if the patient suffers great pain but has no risk of death or other serious impairment? Are all cancer patients undergoing chemotherapy seriously ill? All AIDS patients? How should Judge Breyer determine need for marijuana: must all other therapies have been tried? How poor must the results have been? Does need depend on the patient’s prognosis? Is pain sufficient for need, and if so, pain of what intensity? If Breyer were to accept as adequate proof of medical necessity that a patient’s physician has certified that there is both serious illness and need, he would not be meeting the Ninth Circuit’s mandate that he “set forth th[e] criteria” for medical necessity in his order. Given the inadequate state of knowledge about marijuana’s efficacy, physicians’ certifications could be based only on clinical observations that are considered inadequate for drug approval determinations. The absence of adequate scientific studies confounds judgments of medical necessity at all levels.

There are also procedural questions to face. If Judge Breyer sets criteria for medical necessity in this lawsuit against the cannabis clubs, will the clubs be allowed to remain open to serve only those patients for whom marijuana is a medical necessity, rather than all those contemplated by Proposition 215? Who will review whether each cannabis club sale was in fact justified by medical necessity: police? prosecutors? courts? Neither setting criteria for medical necessity nor policing the propriety of each instance of dispensing under those criteria appears to present issues well-suited for judicial determination.

**BREAKING THE IMPASSE**

In the three years since the passage of Proposition 215, there have been more resources devoted in California to marijuana litigation than to marijuana research. Unfortunately, the conflict between federal and state law, and the scope and meaning of the state law, are still far from resolution. From the federal government’s perspective, distribution of marijuana is entirely illegal, and it must enforce the law. Even activists in the medical marijuana movement admit that some marijuana distributors operating under the banner of serving medical need have exceeded the bounds of the state law. State law enforcement officials need a means to

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73. *Oakland Cannabis Buyers’ Cooperative*, 190 F.3d at 1115.
74. Id.
76. Scott Imler, director of the Los Angeles Cannabis Resource Center and co-author of Proposition 215 with Dennis Peron, founder of the San Francisco Cannabis Buyers’ Club, joined in the criticism of Peron’s running of the San Francisco club, where it was alleged healthy people could purchase marijuana freely and that inventory and fiscal controls were lax. “Dennis has refused to play by the rules and it’s hurting the rest of us,” he said. “It’s unfortunate for the movement.” John Ritter, *Medical Marijuana: Legal, But How Long?*,
distinguish legitimate from illegitimate users in order to implement the will of the people as expressed in the initiative.\textsuperscript{77} Government resources would be best spent resolving the questions of marijuana's safety and efficacy, and then translating the answers into appropriate public policy, including making available through pharmaceutical distribution channels a drug that otherwise is deemed illegal. The only barrier to gaining the scientific knowledge that should inform public policy is a political one. Politicians, like California Governor Gray Davis, should marshal their political resources to enable science to proceed unfettered to find the answers upon which an end to this impasse must be based.

\textsuperscript{77} See sources cited \textit{supra} note 20.