In the Iowa District Court
in and for
Polk County Iowa

George McMahon, Bryan Scott, and Barbara Douglass, Petitioners and Carl E. Olsen, Intervenor *vs.* The Iowa Board of Pharmacy, Respondent	Docket No. CV 7415

Petitioners' Brief

Submitted on behalf of Peitioners by

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I. STATEMENT OF ISSUES PRESENTED FOR REVIEW

A. Whether the decision of the Board of Pharmacy was erroneous and an abuse of discretion under the standards set forth in Iowa Code Section 17A.19, Subsection 10, because the Board of Pharmacy ignored its duty to engage in a statutorily prescribed analysis, and instead, considered other factors that were not relevant to its assigned mission.

Authorities:

B. Whether, as a matter of law, this Court can and should determine that Marijuana has "accepted medical use in treatment in the United States" for purposes of regulation under Iowa's Controlled Substances Act, Iowa Code Chapter 124.

Authorities:

II. PRELIMINARY STATEMENT

This case does not require, or even permit, this Court to "legalize" marijuana, nor can the Board of Pharmacy do so. Only the Iowa General Assembly can make the decision to move marijuana from Schedule I of Iowa's Controlled Substances Act to another schedule or decide de-list it altogether. In adjusting its policy on control and usage of marijuana (or any other substance) the Iowa legislature only commands the Board of Pharmacy to do one thing: properly advise the legislature when a drug or substance no longer belongs in its current classification based on scheduling criteria that the legislature has statutorily provided.

The Iowa General Assembly is quite capable of taking the wisdom imparted by the Board of Pharmacy and combining it with other considerations in making a final determination; but, when the legislature has placed responsibility and its trust in an agency to keep it informed of the facts on the ground and that agency decides instead to insert its own judgment about whether the legislature should receive that information, the legislative process is short circuited and issues that deserve the light of legislative debate are instead buried without a fair hearing.

This is an issue, moreover, having serious consequences for public health and the quality of life of many, many, individuals who are afflicted with severely debilitating symptoms that are far better controlled with marijuana than with other drugs or substances. Petitioner's realize that even if their case is successful, the most that they will achieve is the kindling of a regulatory and legislative debate over moving marijuana to a schedule where it would almost certainly still be subject to rigorous control. However, the stigma in Iowa assigned to marijuana as a substance

officially classified as having “no accepted medical use in treatment in the United States” could ultimately be removed, and those who truly need to use marijuana for severe medical conditions would stand a far better chance of obtaining therapeutic access under medical supervision. The proper foundation for future action is sound advice from the Iowa Board of Pharmacy to the Iowa General Assembly concerning the true status of medically supervised marijuana use for treatment purposes in the United States.

III. STATEMENT OF THE CASE

A. Parties

The Petitioners are Iowa citizens who need to use marijuana for purposes of controlling or alleviating debilitating and life threatening symptoms that can not be controlled effectively through other therapies. Barbara Douglass and George McMahon have served as case specific examples of the need to authorize medicinal use of marijuana in both the courts[1] and in public.[2]

George McMahon has used marijuana to control pain, spasm and nausea under medical supervision for over 18 years through a program initiated by the federal government for which he

[1] Conant v. Walters, 309 F.3d 629, 648 (9th Cir. 2002). cert. den. 540 U.S. 946 (Appendix)

> Barbara M. Douglass was diagnosed with Multiple Sclerosis in 1988 at the age of 22. In 1991, Ms. Douglass began receiving herbal cannabis from the United States government upon the advice and assistance of her physician. Prior to this date, Ms. Douglass had never tried cannabis. Each month, the government provides her physician with one can containing three hundred cannabis cigarettes, each weighing 7/10 oz. Ms. Douglass and her physician report that herbal cannabis provides relief from pain and spasms and stimulates her appetite to counteract the effects of wasting syndrome from which she suffered prior to using cannabis. Ms. Douglass has never experienced any adverse side effects from marijuana. Without cannabis, Ms. Douglass believes she would not be alive today.
>
> George Lee McMahon was born July 22, 1950, with Nail Patella Syndrome, a rare genetic disorder that causes severe pain, nausea and muscle spasms. Mr. McMahon tried conventional medications to treat his symptoms, but found the side effects of these medications to be intolerable. In the early 1980s, Mr. McMahon discovered that herbal cannabis alleviated his pain, nausea and spasms, stimulated his appetite and allowed him to sleep through the night. In 1988, Mr. McMahon informed his physician that he was successfully self-medicating with cannabis. His physician ordered him to cease his cannabis use and return to prescription medications. Over the following six months, Mr. McMahon's health progressively degenerated. Mr. McMahon's physician then helped Mr. McMahon apply to the federal government's Compassionate Care IND Program. In March 1990, Mr. McMahon was accepted into the program and for the past decade has received 300 cannabis cigarettes each month from the United States government. Mr. McMahon and his physician believe that without cannabis Mr. McMahon would not be alive today.

[2] http://en.wikipedia.org/wiki/Compassionate_Investigational_New_Drug_program

qualified.[3] No new patients have been accepted into that program since 1992 and he may be one of only three participants left. Mr. McMahon cannot take alternative therapies because they have proven ineffective and at times life threatening. If his current doctor dies or retires, he is at great risk of losing his access to medically supervised marijuana therapy through the program and would be forced to consider illegal use of marijuana or discontinuing treatment for his debilitating symptoms. [*Record*, Tab D, p. 6, l. 1—15[4]; *Statement McMahon* (to be filed)]

Barbara Douglass suffers from multiple sclerosis. She has also been in the federal treatment program since 1991 and has used marijuana to control her symptoms including spasms, nausea and shaking of the hands. Her therapy was interrupted when her doctor retired and she is having difficulty getting her therapy restarted due to the fact that the schedule I status of marijuana in Iowa drastically limits her choice of physicians to those who are willing to deal with professional issues that might arise from involving themselves in her treatment [*Record,* Tab D, p.6, l.16-17; *Statement Douglass* (to be filed)].

[3] Eddy, CSR Report for Congress,Medical Marijuana: Review and Analysis of Federal and State Policies, May 15, 2007, Order Code RL33211, page 8:

> "In 1978, FDA created the Investigational New Drug (IND) Compassionate Access Program, allowing patients whose serious medical conditions could be relieved only by marijuana to apply for and receive marijuana from the federal government. Over the next 14 years, other patients, less than 100 in total, were admitted to the program for conditions including chemotherapy induced nausea and vomiting (emesis), glaucoma, spasticity, and weight loss. Then, in 1992, in response to a large number of applications from AIDS patients who sought to use medical cannabis to increase appetite and reverse wasting disease, the George H.W. Bush Administration closed the program to all new applicants. Several previously approved patients remain in the program today and continue to receive their monthly supply of government-grown medical marijuana."

[4] Petitioners acknowledge that the "Unidentifed Guest" whose remarks appear in the transcript at the Pharmacy Board meeting is George McMahon.

B. Proceedings Below

On May 12, 2008, the Intervenor in this action, Carl Olsen, filed a "Petition for Rule Making or Action." The Petition sought rescheduling of Marijuana to remove that substance from Schedule I of Iowa's Controlled Substances Act ["*ICSA*"] on grounds that *Gonzales v. Oregon*, 546 U.S. 243 (2006) clarified that under federal law, the individual states and not the federal government have sole power to determine the bounds of acceptable medical practice—including the proper medical use of controlled substances that does not constitute drug dealing or illegal trafficking as those activities are traditionally understood. Olsen's petition went on to state that at least twelve states now "accept the safety of Marijuana for medical use" by law [*Record*, Tab A].

On June 24, 2008, Petitioners McMahon and Scott filed their petition and intervention with the Iowa Board of Pharmacy, requesting that the Board recommend to the Iowa General Assembly that marijuana be removed from Schedule I and appropriately rescheduled. The petition of intervention argued that "Section 124.203 of the Iowa Code… **requires**…[*the*] Board" to recommend that marijuana be rescheduled, because it "no longer meets the mandatory legislative criteria established for listing a substance in Schedule I of the Iowa Controlled Substances Act. Iowa Code Section 124.204. Again the primary reason advanced was the fact that 12 other states had legalized the use of marijuana for medical purposes. [*Record*, Tab B]

The Petition filed by McMahon and Scott pointed out that over 20% of the U.S. population is now covered by state laws authorizing the use of marijuana for purposes of medical

treatment. On November 4th, 2008 Michigan became the 13th state to approve the use of marijuana for use in medical treatment bringing the percentage of population living in states that have approved medical use of marijuana to nearly 1/4 of the country.[5] Additionally, "Arizona's law, approved by 65% of the voters permits marijuana prescriptions, but there is no active program in the state because federal law prohibits doctors from "prescribing" marijuana."[6] Still, the Arizona law can be deemed an official recognition of the medical use of marijuana. Arizona's population comprises another 2.06% of the U.S. estimated total in 2006.

Although the examples Arizona and Michigan were not cited to the Pharmacy Board prior to its Decision on July 29, 2008 it was acknowledged by the Board's counsel at the hearing [*Record*, Tab D, p.5, l.4] and also in the Board's final decision and Order that "numerous states have legalized medicinal use of marijuana." [*Record*, Tab E, p.2]. The Iowa Board of Pharmacy expressed in its final Order that it was "neither accepting or rejecting Olsen's assertion that the medicinal value of marijuana is established by legislation adopted in other states." [*Id.*] The Board concluded that it could avoid addressing the impact of medical legalization of marijuana in other states, because:

> "before recommending to the Iowa legislature that marijuana be moved from schedule I to schedule II, the Board would also need to make a finding that marijuana lacks a high potential for abuse. *See* Iowa Code 124.203 (2007).

[5] Michigan had an estimated population in 2006 of 10,095,643 people or approximately 3.37% of the U.S. population, bringing the portion of U.S. population with medical access to mariuana up to 23.97%.

[6] Congressional Research Service: "A Report for Congress—Medical Marijuana: Review and Analysis of Federal and State Policies (updated May 15, 2007), page 21.

[*Id.*] {To be clear, the Petitioners and Intervenors in the proceeding below were not asking , that marijuana specifically be moved to Schedule II [*e.g.*, *Record*., Tab D, p. 6], nor were they contesting that marijuana "lacks a high potential for abuse." [*Record*, Tabs A and B]}

At the meeting at which the Board actually voted to deny the petitions for agency action, there was no discussion of the need to establish whether marijuana lacks a "high potential for abuse." Rather, the sole reason given at that time for denying relief was the consideration that rescheduling on the state level seemed to the Board to be premature in view of the fact that marijuana has not been rescheduled at the federal level[7] [*Record*, Tab D]. The Board was concerned that any recommendation to the legislature might result in the future entrapment of Iowans who might be in need of marijuana for medical reasons [*Id.,* p. 7]. The Board's brief deliberations simply reiterated that assumption. Despite its expressed concern for Iowans who might seek permission to use marijuana in treatment, the Board did not engage in any weighing

[7] LEMAN OLSON: Great. I think Scott is telling us that while this might be the a time to step in the effort that Mr. Olson is pursuing, we may be giving false hope to the patients that would be hopeful. Is this Board ready to make a decision on this request, on this petition?

VERNON BENJAMIN: In my opinion, we don't have to put the cart before the horse: we need to find out what they [*the federal authorities*] are going to do. If they reclassified on their level, I think we would do on our end as well.

SUSAN FREY: I would agree with that. I would hate to put out information that someone would assume that because we did reclassify it, that it was within their purview to use it for their own use and put them in jeopardy for federal prosecution. I don't think that is what the Board we are there to protect our patients and our citizens, so I would not be able to vote for this petition.

LEMAN OLSON: Somebody care to make a motion in regard to this petition?

SUSAN FREY: I would move we deny the petition.

EDWARD MAIER: Second.

LEMAN OLSON: There is a motion and a second. All in favor please say Aye. (Ayes.) Opposed: (None.) Okay, thank you.

of potential harm due to feared future entrapment under federal law compared to the present harm in continuing to prosecute terminally and chronically ill medical marijuana users under state law [*Record*, Tab D]. Nor did the Board evaluate the likelihood of unfair entrapment.

In its Order issued some time after its meeting, the Board of Pharmacy re-iterated its concern that rescheduling marijuana on the state level should not precede rescheduling on the federal level because it would "create an unfortunate situation" where "a person in compliance with Iowa law could be prosecuted under the [*federal*] Controlled Substances Act" [*Record*, Tab E, p.2]. In support of that conclusion, the Board cited *Gonzales v. Raich*, 545 U.S. 1 (2005)[8]. Again, there was no weighing of alternatives or comparisons made with the harm to those in need of medical marijuana under the present prosecutorial regime.[9]

In the end, it is not clear to what extent fear of misleading medical marijuana users into legal difficulties formed any part of the basis for the final decision below, inasmuch as the final

[8] In *Raich,* the U.S. Supreme Court determined that the federal Government's interest in preventing unlawful interstate trafficking in marijuana was sufficient to permit it to maintain prosecutions against marijuana suppliers despite the fact that their activities might be legally permitted under California's medical marijuana law.

[9] Consider the recent case of State v. Bonjour:

> Bonjour [*was*] a man in his sixties living with AIDS. Bonjour's doctor told the district court he must take a cocktail of toxic drugs to prolong his life. His doctor also told the district court this cocktail of toxic drugs has serious side effects, which include nausea, vomiting, poor appetite, diarrhea, and neuropathy. These side effects have not allowed Bonjour to stay on the strict regimen of his AIDS' drugs, which is critical for these drugs to work. Bonjour's doctor attempted to relieve the side effects of the drugs by other medication, including Marinol, a synthetic form of marijuana, used to control nausea and vomiting. These medications were ineffective in controlling these side effects, so Bonjour started to use marijuana in his cooking to alleviate the side effects. The marijuana controlled the side effects more effectively than the Marinol and allowed Bonjour to maintain his strict regimen of drugs. Bonjour's health has improved with his use of marijuana.

Id. 694 N.W.2d 511, 515 (2005) *dissenting op., Wiggins.*

Bonjour was convicted of manufacturing (growing) marijuana adding to his troubles.

written Order ultimately disposed of the petitions on lack of proof concerning marijuana's "potential for abuse" [*Id.*]. However, Petitioners will assume, for purpose of briefing, that the danger of misleading Iowa citizens remained as a significant and independent ground for the Board's decision to not even consider whether marijuana should be rescheduled. [*Record*, Tab E, p.2]

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IV. ARGUMENT

A. Burdens of Persuasion

In the proceedings below it is clear that the Board and the Petitioners had differing ideas as to who had the burden to establish what, and why. After the Petitions were filed the Board did not schedule a hearing. {*Compare,* IAC Ch.657-10.37(124,126) Revision of controlled substances schedules,[10] which permits a hearing in the case of a substance which is alleged to no longer be under federal control.} But, the Board did place the petitions on its agenda for a regularly scheduled board meeting and did decide at the hearing to allow the petitioners an opportunity to speak. Following the Board's decision it was clear that the Board desired proofs of two propositions:

a. That marijuana does not have a high potential for abuse, and

b. That the federal DEA has authorized medicinal use of marijuana.

Under the Iowa Administrative Procedures Act, the burden of demonstrating "the required … invalidity of agency action is on the party asserting invalidity." Iowa Code, §17A.19(7). However, that does not compel the assumption that the agency based its decision below on proper grounds.

[10] 0.37(1) Application for exception. Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in any of the schedules in Iowa Code chapter 124 excepted from the application of all or any part of that chapter may apply to the board for such exception.

a. An application for an exception under this rule shall provide evidence that an exception has been granted under the federal Controlled Substances Act.

b. The board shall permit any interested person to file written comments on or objections to the proposal for exception and shall designate the time during which such filings may be made. After consideration of the application and any comments on or objections to the proposal for exception, the board shall issue its findings on the application.

B. Standards of Review

To summarize the Iowa Administrative Procedures Act, this court has broad authority to either affirm the decision below or to remand the case to the agency for further proceedings. However, the court "**shall** reverse, modify, or grant other appropriate relief from agency action… if it determines that substantial rights of the person seeking judicial relief have been prejudiced because the agency action is…[*inter alia*] *c*. based upon an erroneous interpretation of a provision of law,… *f*. Based on a determination of fact… that is not supported by substantial evidence…, *i*. …wholly irrational, [*or*] *k*. …not required by law and its negative impact on the private rights affected is …grossly disproportionate to the benefits accruing to the public…" Iowa Code, §17A.19(10).

The action of the agency below falls into the areas of mandatory relief identified above. The Pharmacy Board ignored the commandments of statute regarding its duty and the standards to be employed in its decision making and thus based its determination upon an erroneous interpretation of law. The Board concluded without "substantial evidence" that potential medical marijuana users in Iowa would suffer increased legal harm at the hands of prosecutors if its actions led to legalization of medical marijuana in Iowa, and the Board decided to ignore its duty to report to the legislature, thus engaging in an action (forbearance) that was not required and which portends great harm to the petitioners in proportion to any net harm that might be suffered by the public.

In evaluating the actions of the agency below, the court:

a. Shall not give any deference to the view of the agency with respect to whether particular matters have been vested by a provision of law in the discretion of the agency.

b. Should not give any deference to the view of the agency with respect to particular matters that have not been vested by a provision of law in the discretion of the agency.

c. Shall give appropriate deference to the view of the agency with respect to particular matters that have been vested by a provision of law in the discretion of the agency.

Iowa Code, §17A.19(11).

C. Statutory Interpretation

The statute foremost in issue in this case is Iowa Code §124.203 which ends in this final instruction:

> If the board finds that any substance included in schedule I does not meet these criteria, **it shall recommend** that the general assembly place the substance in a different schedule or remove it from the list of controlled substances, as appropriate.

{*emphasis added*}

Iowa Code, §4.1(30) controls interpretation here:

> 30. Shall, must, and may. Unless otherwise specifically provided by the general assembly, whenever the following words are used in a statute enacted after July 1, 1971,[11] their meaning and application shall be:
>
> a. **The word "shall" imposes a duty**. {*emphasis supplied*}

[11] "In 1971 the legislature repealed the Uniform Narcotic Drug Act and enacted the Uniform Controlled Substances Act." State v. Bonjour, 694 N.W.2d 511 (Iowa 2005) *dissenting op. J. Wiggins*

There is no doubt that Section 203 of the ICSA imposes an inescapable duty on the Board of Pharmacy to recommend changes to the Iowa Legislature "if it finds" that marijuana does not meet the criteria for listing in that schedule. The only question about the Board's responsibility in this case is whether it has any discretion not to make timely findings under that section. Petitioners submit that the Board enjoys no such discretion.

First, such discretion would be at odds with the purpose of the final instruction in Section 203. The legislature's desire to accurately schedule substances for regulation with advice from the Board of Pharmacy, could be completely undermined if the Board of Pharmacy were given unrestrained authority to ignore its advisory duties under Section 203. Second, the ICSA itself calls for the Board to make at least one annual review of all the schedules. Iowa Code Section 124.201.[12] Third, it appears that the Iowa General Assembly has been waiting on the Board of Pharmacy to make investigations into and decisions about medicinal use of marijuana for quite some time.

The history of this particular issue in Iowa is set forth in Justice Wiggin's dissenting in *Bonjour, supra.,* :

[12] 1. Section 201 states: The board shall administer the regulatory provisions of this chapter. Annually, within thirty days after the convening of each regular session of the general assembly, the board shall recommend to the general assembly any deletions from, or revisions in the schedules of substances, enumerated in section 124.204, 124.206, 124.208, 124.210, or 124.212, which it deems **necessary or** advisable. * * *" {*emphasis supplied*}

While this section, unlike Section 203, appears to give the Pharmacy Board discretion to advise or not to advise in its annual report, it must be read in *pari materia* with section 203. The language of section 203 may very well create a mandatory situation in which it is "necessary" for the Board to make a report to the General Assembly. Moreover, Section 203 is not specifically tied to the Board's annual report. Its provisions kick in whenever the Board finds that Schedule I's criteria are not met.

In 1971, the legislature repealed the Uniform Narcotic Drug Act and enacted the Uniform Controlled Substances Act. … While Iowa's enactment of the Uniform Controlled Substances Act is a substantial adoption of the major provisions of the uniform act, Iowa's act contains some provisions not contained in the uniform act. *Id.* …

Iowa's act, as originally enacted, classified marijuana as a Schedule I controlled substance without exception. Iowa Code § 204.204(4)(*j*) (1973). … In 1979, the legislature amended Iowa's act classifying marijuana as a Schedule I substance "except as otherwise provided by the rules of the board of pharmacy examiners for medical purposes."*Id.* § 204.204(4)(*j*) (1981). In the same amendment, the legislature added a new provision to the list of Schedule I substances providing, "[t]his section does not apply to marijuana... when utilized for medical purposes pursuant to rules of the state board of pharmacy examiners." *Id.* § 204.204(6).

In the session laws adopting the 1979 amendments, the legislature also provided funding for the board of pharmacy examiners to establish "a research program for the medicinal use of marijuana." … the board of pharmacy examiners adopted rules establishing a research program investigating the medical use of marijuana. Iowa Admin. …. The rules clearly recognized the legislature did not preclude the medical use of marijuana in Iowa's Controlled Substances Act by stating: "Nothing in these rules will preclude the use of any available dosage forms of marijuana or tetrahydrocannabinols." *Id.* …

In 1987, the board of pharmacy examiners rescinded its rules establishing a research program into the medical use of marijuana because the legislature amended Iowa's Controlled Substances Act classifying marijuana as a Schedule II substance.[FN2]

> FN2. By statute, the board of pharmacy examiners has the duty to recommend revisions to the schedules of controlled substances. Iowa Code §§ 204.201(1); 204.205 (1987).

…The provision amending the Code classifying marijuana as a Schedule II substance provided in relevant part: "[m]arijuana is deemed to be a Schedule II substance when used for medicinal purposes pursuant to rules of the board of pharmacy examiners." Iowa Code § 204.206(7) (1987). A Schedule II substance "has currently accepted medical use in treatment in

> the United States, or currently accepted medical use with severe restrictions." *Id.* § 204.205(2).…
>
> In 1990, the legislature amended this section of the Code one more time. The legislature continued to classify marijuana as a Schedule II substance, when used for medical purposes pursuant to rules of the board of pharmacy examiners. *Id.* § 204.206(7) (1991). It provided:
>
> > Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances [is a Schedule II substance]:
> >
> > *a.* Marijuana when used for medicinal purposes pursuant to rules of the board of pharmacy examiners.…
>
> The 1990 amendment continues to be the law today. *See* Iowa Code § 124.206(7) (2003).

State v. Bonjour, 694 N.W.2d 511, 515-16 (2005) *dissenting op., J. Wiggins.*

The *Bonjour* majority noted: "…our legislature has foreseen the potential medical uses for marijuana but has deferred on the issue until the Board of Pharmacy Examiners has acted." *Id.,* 513.

Thus, the legislature has been inviting the Board of Pharmacy to authorize medicinal use of marijuana for nearly 3 decades. The fact that the Board has been steadfast in its unwillingness to even consider authorizing medical marijuana under schedule II means that there is only one kind of marijuana in Iowa—marijuana that is controlled under schedule I of the ICSA. But events have overtaken the Board's reluctance to respond. The fact that marijuana is now used medicinally in the U.S. can no longer be denied, and, as a consequence, marijuana no longer meets the criteria for listing in Schedule I of the ICSA.

Nor can the past intransigence of the Board stand as some defense for the status quo:

> With respect to the weight given long-standing administrative interpretations of a statute we said in Consolidated Freightways Corp. v. Nicholas, 258 Iowa 115, 121, 122, 137 N.W.2d 900, 905:
>
> '* * * (I)t must be remembered that the plain provisions of the statute cannot be altered by an administrative rule or regulation, no matter how long it has existed or been exercised by administrative authority. Clarion Ready Mixed Concrete Co. v. Iowa State Tax Commission, 252 Iowa 500, 507, 107 N.W.2d 553, 558, and citations. To permit a commission or board to change the law by giving to the statute or Act an interpretation or construction of which its words are not susceptible would be a departure from the meaning expressed by the words of the statute. Hindman v. Reaser, 246 Iowa 1375, 72 N.W.2d 559. * * *.'
>
> See also Nishnabotna Valley Rural Elec. Coop. v. Iowa P. & L. Co., Iowa, 161 N.W.2d 348, 352.

State v. Jennie Coulter Day Nursery, 218 N.W.2d 579, 582, (Iowa 1974)

D. ISSUE A:

> WHETHER THE …BOARD OF PHARMACY …IGNORED ITS DUTY TO ENGAGE IN A STATUTORILY PRESCRIBED ANALYSIS, AND INSTEAD, CONSIDERED OTHER FACTORS THAT WERE NOT RELEVANT TO ITS ASSIGNED MISSION.

1. Significance of "potential for abuse."

Iowa's Controlled Substances Act ["*ICSA*"] logically divides substances into several schedules based on their dangerousness and utility for society. In theory the schedules appear to be mutually exclusive. Thus, substances listed on schedule I are those that are supposed to have "a high potential for abuse" **and** either "no accepted medical use in treatment in the United States" or lack accepted safety for use in treatment under medical supervision. Iowa Code Section 124.203

Subsequent to the adoption of Iowa's Controlled Substances Act, the federal DEA analytically merged the issue of a substance having "lack of accepted safety" with the issue of whether it has "accepted medical use," upon the consideration that a substance cannot have the one quality without the other. 57 FR 10499, 10504 ("Marijuana Scheduling Petition; Denial of Petition; Remand" March, 26, 1992). In other words, substances that have achieved approval for medical use only include those that are considered at the same time to have accepted safety under medical supervision. In the proceedings below, no hairs were split on this point. Iowa Code Section 203, itself, lists the two concepts, "accepted safety" and "accepted use" as alternative formulations within the same numbered criterion. In essence, there are but two distinct requisites under schedule I for inclusion of substances: lack of medical acceptance within the United States combined with a "high potential for abuse."

Schedule II, likewise includes drugs that "have a high potential for abuse." What distinguishes Schedule II substances from Schedule I is that substances in Schedule II have "currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions" Iowa Code Section 124.205. Schedule III controls substances that have a "potential for abuse less than the substances in schedules I and II" The **sole factor** that distinguishes substances that are to be listed in Schedule I from the other schedules is lack of "accepted medical use in treatment in the United States." *Accord*, *Raich* 545 U.S. at 14, 125 S. Ct. at 2204.

Therefore, the Board of Pharmacy indulged in clear legal error when it determined it could not recommend removal of marijuana from Schedule I without first finding that "marijuana lacks a high potential for abuse" [*Record*, Tab E, p.2] Stated in terms of the Iowa Administrative Procedures Act ["*APA*"], the Board based its decision "upon an erroneous interpretation of a provision of law."

2. Concern for federal supremacy

As noted above it is not apparent to what extent, **if any**, the Board based its decision on issues of federalism, and particularly on its espoused concern for the legal welfare of those who might be tempted to use marijuana for reasons of medical necessity. To the extent that the Board felt its decision was mandated or even excused by federal law or the threat of federal prosecutions, it, once more engaged in clear legal error. To the extent that the Board determined that wholesale federal prosecutions of desperately ill Iowans would result from any recommendation it might make to the Iowa legislature, it was guilty of assuming an outcome that, in the words of the APA, is "not supported by substantial evidence" and of ignoring its duties in a way that was "not required by law," *viz:*

a. Supremacy clause.

To those uninitiated in the concepts of federalism as they play out in the regulation of medical marijuana, it might seem that federal regulation must always reign absolute and supreme. However, the U.S. Supreme Court has determined that the role of the Attorney General

to regulate substances that can be abused is really quite limited. *See*, Gonzales v. Oregon, 546 U.S. 243, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006). The Attorney General can schedule substances only at the federal level and only in consultation with the Secretary of Health and Human Services, employing criteria set forth by Congress.[13] The Attorney General's scheduling power only goes to regulating trafficking in illicit drugs and does not extend to determining what drugs or substances may be employed in the legitimate practice of medicine. Decisions about "acceptable medical use" of drugs and other substances have been deliberately left by Congress under principles of federalism to the individual states.[14] *Id*. {Holding Atty. Gen. lacks power to proscribe use of controlled drugs for physician assisted suicide.}

The Board of Pharmacy was aware prior to its decision below that it was under no obligation to mimic federal scheduling practices when fulfilling its duty to advise the legislature

[13] Excerpts from *Gonzales:*

> The Attorney General does not have the sole delegated authority under the CSA. He must instead share it with, and in some respects defer to, the Secretary, whose functions are likewise delineated and confined by the statute. The CSA allocates decisionmaking powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary. In the scheduling context, for example, the Secretary's recommendations on scientific and medical matters bind the Attorney General. The Attorney General cannot control a substance if the Secretary disagrees. [p. 265]

[14] Excerpts from *Gonzales:*

> The structure of the CSA, then, conveys unwillingness to cede medical judgments to an Executive official who lacks medical expertise.[p. 266]* * *Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally.* * *The structure and operation of the CSA presume and rely upon a functioning medical profession regulated **under the States' police powers**. [p. 270] * * *The Government, in the end, maintains that the prescription requirement delegates to a single Executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality. The text and structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance and the congressional role in maintaining it. [p. 275] {*emphasis added*}

under Iowa Code Section 124.203. The Board's counsel stated: "…Mr. Olsen is correct, that the State of Iowa, in theory at least, set its own schedules for controlled substances and so forth." [*Record*, Tab D, p. 4]

In Gonzales v. Raich, 545 U.S. 1, 125 S.Ct. 2195, 162 L.Ed.2d 1(2005), which apparently drove much of the decision making below [*Record*, Tab D, p. 4; Tab E, p. 2] it is interesting to note that the U.S. Supreme Court did not dispose of the case on the grounds that federal drug scheduling policy invalidated California's medical marijuana law. Rather the Court simply held that federal law could still be applied to a purely *intra*state situation so long as it appeared that *inter*state commerce would be substantially affected.

While the states have no power to prevent the DEA from enforcing federal drug laws within their respective jurisdictions when the interstate commerce clause can be invoked, they are by no means enslaved: The federal government lacks power to require states to enforce federal law simply under the supremacy clause alone.

> We held in *New York* that Congress cannot compel the States to enact or enforce a federal regulatory program. Today we hold that Congress cannot circumvent that prohibition by conscripting the State's officers directly. The Federal Government may neither issue directives requiring the States to address particular problems, nor command the States' officers, or those of their political subdivisions, to administer or enforce a federal regulatory program. It matters not whether policymaking is involved, and no case-by-case weighing of the burdens or benefits is necessary; such commands are fundamentally incompatible with our constitutional system of dual sovereignty.

Printz v. U.S., 521 U.S. 898,*935 117 S.Ct. 2365,*2384 138 L.Ed.2d 914 (1997) {Striking Brady Law provisions that imposed gun regulation duties on local sheriffs.}

In Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) the 9th Circuit upheld an injunction against a DEA policy that would have federally punished California doctors for recommending medical use of marijuana to their patients. While the panel was able to dispose of the government's arguments on free speech grounds alone, Judge Kozinski noted in his concurrence (p. 646) that:

> If the federal government could make it illegal under federal law to remove a state-law penalty, it could then accomplish exactly what the commandeering doctrine prohibits: The federal government could force the state to criminalize behavior it has chosen to make legal. That patients may be more likely to violate federal law if the additional deterrent of state liability is removed may worry the federal government, but the proper response-according to *New York* and *Printz*-is to ratchet up the federal regulatory regime, not to commandeer that of the state.

The main opinion in *Conant* states at page 639:

> Our decision is consistent with principles of federalism that have left states as the primary regulators of professional conduct. See Whalen v. Roe, 429 U.S. 589, 603 n. 30, 97 S.Ct. 869, 51 L.Ed.2d 64 (1977) (recognizing states' broad police powers to regulate the administration of drugs by health professionals); Linder v. United States, 268 U.S. 5, 18, 45 S.Ct. 446, 69 L.Ed. 819 (1925) ("direct control of medical practice in the states is beyond the power of the federal government").

In State v. Nelson, 346 Mont. 366, 195 P.3d 826 (Mont., 2008) the Montana Supreme Court ruled, similarly, that state controlled substances law was not trumped by federal law in imposing restrictions on probation. The probation condition requiring the defendant to obey all

federal laws could not be used to prevent the defendant from becoming a medical user of marijuana as permitted under Montana law.

Considering the statutory imperatives directed at the Iowa Board of Pharmacy in Iowa's Controlled Substances Act, there is no room for the Board to abstain from action in deference to federal authorities. The charge to the Board is to make its own investigations and recommendations to the Iowa General Assembly. It is to examine controllable substances based on criteria established by state law and no where among those criteria is there any deference to federal scheduling decisions. *See,* Iowa Code, Sections 124.201 & 124.203.[15]

Even when a new controlled substance is scheduled by the federal government, the ICSA directs the Board of Pharmacy to make its own independent examination after opportunity for a public hearing. If the new substance is accepted by the Board for scheduling under Iowa law, its listing is only temporary unless the legislature concurs in its next session. Iowa Code §124.201(4). This evinces the clear intent of the Iowa General Assembly that decisions about scheduling of controlled substances be made at the state and not the national level, and that the Iowa Board of Pharmacy should always have an active role in those assessments.

A *laissez-faire* approach to regulation granting all authority and deference to the federal government on questions of scheduling is neither contemplated, nor permitted under Iowa's

[15] Iowa Code Section 124.201 addresses the discretionary authority of the Board to recommend changes or additions to the ICSA schedules. It provides 8 substantive factors the Board should consider relating to scheduling based on potential for abuse. Section 201 is not relevant to the Board's recommendation in this case, because Schedule I and Schedule II do not vary on the issue of "potential for abuse," and because section 203 imposes an additional duty to recommend changes when a drug on that schedule becomes medically acceptable for use in treatment.

Controlled Substances Act. When our legislature said in Section 203 that the Board "shall recommend" it meant nothing less.

b. Concern over Entrapment.

The Board was concerned that any recommendation it might make with respect to moving marijuana out of schedule I would be futile and an invitation for entrapment of medical marijuana users who assume they could not be prosecuted under federal law. Again, these are not factors that the statute permits the Board to consider nor grounds for avoiding its duties.

Rescheduling of marijuana on the state level is not necessarily futile as thousands of medical marijuana users across the country could, no doubt, attest. But rescheduling, even if it does not result in legalizing the medical use of marijuana, can have subtler effects as well. Individuals like Petitioners McMahon and Douglass will find it easier to find a physician to supervise their treatment. Physicians may find more courage to talk to their patients frankly about the pros and cons of marijuana as a treatment option. (The Schedule I status of marijuana as a substance with no acknowledged medical value in Iowa, certainly must chill the advice of physicians who have their licenses to protect.)

Though irrelevant to begin with, the Board's concern that medical marijuana users in Iowa would be unwittingly subjected to federal prosecution appears to be a supposition without substantial support. The truth is, that the federal government has never been very interested in enforcement of marijuana activities on a purely local scale. In Gonzales v. Raich, *supra.,* the

very case cited by the Board to exemplify its concern that any move toward legalization of medical marijuana would lead to unfair criminal prosecutions of Iowan's under federal law, there was no reported federal prosecution. That case was prompted by a high profile DEA raid on the home of a medical marijuana user in California. After a three hour standoff, DEA officials merely destroyed Monson's 6 marijuana plants. *Id.,* 545 U.S. at 7.

This should come as no surprise. In his concurring opinion in *Connet,* J. Kozinski noted that local enforcement of the federal marijuana prohibition is rare:

> Following the passage of California's medical marijuana initiative, federal officials expressed concern that the measure would seriously affect the federal government's drug enforcement effort. They explained that federal drug policies rely heavily on the states' enforcement of their own drug laws to achieve federal objectives. In hearings before the Senate Judiciary Committee, DEA Administrator Thomas A. Constantine stated:
>
> > I have always felt ... that the federalization of crime is very difficult to carry out; that crime, just in essence, is for the most part a local problem and addressed very well locally, in my experience. We now have a situation where local law enforcement is unsure.... The numbers of investigations that you would talk about that might be presently being conducted by the [Arizona state police] at the gram level or the milligram level would be beyond our capacity to conduct those types of individual investigations without abandoning the major organized crime investigations.
>
> Prescription for Addiction? The Arizona and California Medical Drug Use Initiatives: Hearing Before the S. Comm. on the Judiciary, 104th Cong. 42-43, 45 (1996) …; see also Tim Golden, Doctors Are Focus of Plan To Fight New Drug Laws: Officials Deal with Narcotics' Medical Use, N.Y. Times, Dec. 23, 1996, at A10 ("Federal agents and prosecutors in fact pursue only a small fraction of the country's drug cases. In most districts, officials said, United States Attorneys bring Federal charges only if a marijuana case involves the cultivation of at least 500 plants grown indoors, 1,000 plants grown outdoors, or the possession of more than 1,000 pounds.").

In view of the federal government's historic aversion to prosecuting individual users of patients who are allowed to use marijuana for medicinal purposes under state law, the concerns of the Iowa Pharmacy Board on this point seem conjectural at best. Missing is any serious weighing of harms and benefits to the public and patients who may be in serious need of medical access to marijuana. Because the Board's cost/benefit analysis on this point was so absent it can not stand as a rational basis for departing from its statutorily mandated duties under Section 124.203. The Board's intransigence has stalled an important legislative debate on medicinal marijuana.

E. ISSUE B:

> WHETHER, AS A MATTER OF LAW, THIS COURT CAN AND SHOULD DETERMINE THAT MARIJUANA HAS "ACCEPTED MEDICAL USE IN TREATMENT IN THE UNITED STATES" FOR PURPOSES OF REGULATION UNDER IOWA'S CONTROLLED SUBSTANCES ACT, IOWA CODE CHAPTER 124.

1. Whether to remand

The Petitioners' essential argument before the Pharmacy Board was that "marijuana has accepted medical use in treatment in the United States" as contemplated in Iowa Code Section 124.203, as evidenced by the fact that at least 12 jurisdictions (now 13) have laws accepting the medical use of marijuana. The Pharmacy Board refused to consider, the Petitioner's argument, but did not dispute the fact that marijuana is now legally used in medical treatment in other

states. [*Record*, Tab E, p.2]. If this Court agrees that the Board erred in refusing to consider the Petitioners' arguments, then it has two options: either remand or decide the issue.

Petitioners posit that this is really a pure question of law. There is no dispute that other states "within the U.S." have legalized marijuana for medical use, and the statutes on the books speak for themselves without further proof. "A remand is for the purpose of allowing the agency to re-evaluate the evidence. However, a remand for agency fact-finding is unnecessary **when the facts are established as a matter of law**." McSpadden v. Big Ben Coal Co., 288 N.W.2d 181 (Iowa 1980). {*emphasis supplied*}

Remand might be appropriate if the Board had been given clear authority to apply its own interpretation of the law to the issues in question, but there is no such delegation of authority in the ICSA. Instead, the Board's decision below is "based upon an erroneous interpretation of a provision of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency" (Iowa Code 17A.19(10)(c), and the specified remedy under the Administrative Procedures Act is reversal, modification, or other appropriate relief from the effects of the agency's decision. Iowa Code 17A.19(10).

In federal case law, deference to the statutory interpretation of an agency or administrator is termed "*Chevron* deference."[16] In *Gonzales v. Oregon* the United States Supreme Court

[16] An administrative rule interpreting an ambiguous statute may receive substantial deference, but only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority," Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-845, 104 S.Ct. 2778, 81 L.Ed.2d 694,

determined that the U.S. Attorney General was not entitled to any form of deference, including *Chevron* deference, with respect to his interpretation of "legitimate medical purpose"[17] under the federal Controlled Substances Act.

> If a statute is ambiguous, judicial review of administrative rulemaking often demands *Chevron* deference; and the rule is judged accordingly. All would agree, we should think, that the statutory phrase "**legitimate medical purpose**" is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense. *Chevron* deference, however, is not accorded merely because the statute is ambiguous and an administrative official is involved. To begin with, the rule must be promulgated pursuant to authority Congress has delegated to the official. *Mead*, 533 U.S., at 226-227, 121 S.Ct. 2164.
>
> The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he is not authorized to make a rule declaring illegitimate **a medical standard for care and treatment of patients** that is specifically authorized under state law. * * *
>
> The starting point for this inquiry is, of course, the language of the delegation provision itself. In many cases authority is clear because the statute gives an agency broad power to enforce all provisions of the statute. * * *
>
> Congress did not delegate to the Attorney General authority to carry out or effect all provisions of the CSA. Rather, he can promulgate rules relating only to "registration" and "control," and "for the efficient execution of his functions" under the statute.

Gonzales v. Oregon, 546 U.S. 243,*258 *et seq.* The opinion in *Gonzales v. Oregon* goes on to conclude that the Attorney General's limited powers to oversee the proper scheduling of drugs

[17] The term "legitimate medical purpose" actually came from the Attorney General's own regulation, but the U.S. Supreme Court equated it with similar phrases in the statute, including "**currently accepted medical use**." *Gonzales* 546 U.S. at 257

and administering the mechanics of the federal Controlled substances act do not give him the power to prescribe how drugs can be used in medical practice.

Similarly, the Iowa Board of Pharmacy is given no authority under our own Controlled Substances Act or any other legislation to prescribe the practice of medicine. Lacking that authority, the Court is under no obligation to consult the Pharmacy Board for an interpretation of "accepted medical use." as that term is used in the ICSA. The opinion of the Board would not be entitled to any deference before the courts that ultimately decide the issue.

2. "Accepted medical use"

While the phrase "accepted medical use in treatment in the United States" may be sufficiently ambiguous to trigger an inquiry into whether deference is appropriate under *Chevron* or the Iowa Administrative Code, it is hardly indecipherable. Petitioners concede that there are many rules of interpretation and that choosing the right rules to guide interpretation is an art unto itself. While the polestar rule of statutory interpretation is to look to the legislative intent,[18] undue speculation about legislative intent is to be avoided:

> The intent of the legislature in enacting a statute is to be gathered from the statute itself. It is our duty to give it the interpretation its language calls for and not to speculate as to probable legislative intent apart from the wording used. We do not inquire what the legislature meant. We ask only what the statute means. Kruch v. Needles, 259 Iowa 470, 477, 144 N.W.2d 296, 301, and citations. See also rule 344(f)(13), Rules of Civil Procedure.

[18] *See*, Iowa Nat'l Industrial Loan Co. v. IA Dept of Revenue, 224 N.W.2d 437 (1974) listing many important rules of statutory construction in Iowa. "

Jennie Coulter Day Nursery, supra, 218 N.W.2d at 582.

In Iowa Code §124.203 the phrase "accepted medical use" is not used in isolation but in context with the phrase "**in the United States**" It is immediately clear from this language that the concept of "acceptance" has a jurisdictional focus. We now know by virtue of the decisions in *Gonzales v. Oregon* and *Conant*, that the relevant jurisdictional authority is the individual states because they are the final arbiters of what is or is not accepted medical practice in their respective territories.

Where the question of "whether marijuana has accepted medical use in treatment in the United States" can be answered by a straight forward examination of the laws of other states, it seems absurd to look for more ambiguous methods of answering the proposition. Iowa Code Section 124.203 provides no further guidance on this point. It names no official to make judgements more globally about acceptable medical practice in the United States and it provides no additional criteria for such an imaginary official to employ. For the Court to speculate here would be to speculate into legislative intent apart from the words of the statute.

The realm of controlled substance regulation is driven by precision and certainty, and it is unlikely that our legislature intended to introduce ambiguity by creating a standard that could not be definitively resolved in any other way than by reference to what is actually permitted or not permitted in other states.

Only one court has endeavored to construe what constitutes "accepted medical use in treatment in the United States," and it did so 19 years **prior** to *Gonzales v. Oregon's* clarification that under the federal Controlled Substances Act it is the states who remain the decision makers concerning legitimate medical practice, and many years before any state had actually legalized the use of marijuana in medical treatment. Grinspoon v. DEA, 828 F.2d 881 (1st Cir.,1987).

At issue in *Grinspoon* was whether a drug that had not been approved for interstate marketing by the FDA could be placed in schedule I because lacking such approval it had "no accepted medical use" in the United States. The First Circuit panel confessed it did not know how the "medical use" criteria was to be treated for purposes of regulation under federal Schedule I, and ultimately remanded the case, but not before rejecting many of the DEA's assertions. The Court chastised the DEA Administrator's "clever" omission of "any reference to the fact that the pertinent phrase in section 812(b)(1)(B) reads "**in the United States**," and held that "Congress did not intend "accepted medical use in treatment in the United States" to require a finding of recognized medical use **in every state** or, as the Administrator contends, approval for interstate marketing of the substance." {*last emphasis added*} *Id*. 828 F.2d at 886. The decision in *Grinspoon* affirms that the criteria for listing in schedule I are to be evaluated by reference to what individual states are doing, rather than by making a single judgment about the United States in general.

According to the Congressional Research Service in a recent report to Congress:

> Twelve states, covering about 22% of the U.S. population, have enacted laws to allow the use of cannabis for medical purposes.[19] These states have removed state-level criminal penalties for the cultivation, possession, and use of medical marijuana, if such use has been recommended by a medical doctor.

CRS Report to Congress: "Medical Marijuana: Review and Analysis of Federal and State Policies, updated May 15, 2007. [*A copy of this report is appended to the electronic version of this brief*] Since that report, Michigan has been added to the list.

This Court can and should find that marijuana no longer meet the criteria for listing in Schedule I of the Iowa Controlled Substances Act because no less than 13 states have accepted marijuana for medical use in treatment under supervision of a physician.

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[19] Alaska (Stat. §11.71.090); California (Cal.Health & Safety Code Ann. §11362.5) and(2003 CA S.B. 420 (SN)); Colorado (Colo.Const. Art. XVIII §14); Hawaii (Rev.Stat.§§329-121 to 329-128); Maine (Me.Rev.Stat.Ann. tit.22 §1102 or 2382-B(5)); Montana(Mont.Code Ann. §§50-46-101 to 50-46-210); Nevada (Nev.Rev.Stat.Ann. §§453A.010 to453A.400); New Mexico (S.B. 523); Oregon (Ore.Rev.Stat. §§475.300 to 475.346); RhodeIsland (RI ST §§21-28.6-1); Vermont (Vt.Stat.Ann. tit. 18, §§4472-4474d); Washington(Wash.Rev.Code Ann. §§69.51A.005 to 69.51A.902). [*Source, CRS Report to Congress,*footnote 59]

CONCLUSION

The inaction of the Iowa Board of Pharmacy falls into the areas of mandatory relief under the Iowa Administrative Procedures Act. The Board has ignored the commandments of statute regarding its duty to review the scheduling of drugs as imposed by Iowa Code Section 124.203. The Board's action was based on erroneous interpretations of law, irrelevant criteria, and suppositions made without substantial evidence. From the petitioner's viewpoint, a decision not to review whether marijuana should be moved from schedule I amounts to a decision to keep marijuana in Schedule I. The Board's inaction is not required or even permitted by statute and ultimately harms the petitioners by placing them at risk of losing or not gaining medical access to marijuana, as well as members of the public who would likely benefit should marijuana be recognized as an alternative therapy in the legitimate practice of medicine.

The Court should enter a declaratory ruling that marijuana no longer meets the criteria for inclusion in Schedule I of Iowa's Controlled Substances Act, and the Court should direct the Iowa Board of Pharmacy to prepare and present to the Iowa legislature a recommendation for removal of marijuana from schedule I and rescheduling as appropriate.

Brief for Petitioners
McMahon *et al.* v. Bd. of Pharmacy
Polk County District Court, CV 7415

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Certificate of Service

I certify that on or before January 16th, 2009 I served the other parties to this action with notice of this motion by mailing true copies to all parties of record or their attorneys as the case may be at the addresses shown below:

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CRS Report for Congress

Medical Marijuana: Review and Analysis of Federal and State Policies

Updated May 15, 2007

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Prepared for Members and Committees of Congress

Medical Marijuana:
Review and Analysis of Federal and State Policies

Summary

The issue before Congress is whether to continue the federal prosecution of medical marijuana patients and their providers, in accordance with the federal Controlled Substances Act, or whether to relax federal marijuana prohibition enough to permit the medicinal use of botanical cannabis products when recommended by a physician, especially where permitted under state law.

The first action on medical marijuana in the current Congress occurred on April 18, 2007, at markup of the Prescription Drug User Fee Act (S. 1082). The Senate Committee on Health, Education, Labor, and Pensions adopted an amendment requiring "that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration."

Two bills that have been introduced in recent Congresses are expected to be reintroduced in the 110th Congress: The States' Rights to Medical Marijuana Act would move marijuana from Schedule I to Schedule II of the Controlled Substances Act and make it available under federal law for medical use in the states with medical marijuana programs, and the Steve McWilliams Truth in Trials Act would make it possible for defendants in federal court to reveal to juries that their marijuana activity was medically related and legal under state law.

Twelve states, mostly in the West, have enacted laws allowing the use of marijuana for medical purposes, and many thousands of patients are seeking relief from a variety of serious illnesses by smoking marijuana or using other herbal cannabis preparations. Meanwhile, the federal Drug Enforcement Administration refuses to recognize these state laws and continues to investigate and arrest, under federal statute, medical marijuana providers and users in those states and elsewhere.

Claims and counterclaims about medical marijuana — much debated by journalists and academics, policymakers at all levels of government, and interested citizens — include the following: Marijuana is harmful and has no medical value; marijuana effectively treats the symptoms of certain diseases; smoking is an improper route of drug administration; marijuana should be rescheduled to permit medical use; state medical marijuana laws send the wrong message and lead to increased illicit drug use; the medical marijuana movement undermines the war on drugs; patients should not be arrested for using medical marijuana; the federal government should allow the states to experiment and should not interfere with state medical marijuana programs; medical marijuana laws harm the federal drug approval process; the medical cannabis movement is a cynical ploy to legalize marijuana and other drugs. With strong opinions being expressed on all sides of this complex issue, the debate over medical marijuana does not appear to be approaching resolution.

This report will be updated as legislative activity and other developments occur.

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Medical Marijuana: Review and Analysis of Federal and State Policies

Introduction: The Issue Before Congress

The issue before Congress is whether to continue the federal prosecution of medical marijuana[1] patients and their providers, in accordance with marijuana's status as a Schedule I drug under the Controlled Substances Act, or whether to relax federal marijuana prohibition enough to permit the medicinal use of botanical cannabis[2] products when recommended by a physician, especially in those states that have created medical marijuana programs under state law.

The first action on medical marijuana in the current Congress occurred on April 18, 2007, at markup of the Prescription Drug User Fee Act (S. 1082). The Senate Committee on Health, Education, Labor, and Pensions adopted an amendment requiring "that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration." Intended to squelch the medical use of cannabis products that has been approved by the voters or legislatures of 12 states since 1996, the actual effect of this amendment, if signed into law, is not entirely clear and may be subject to legal interpretation, as discussed below.

Bills with the opposite intent — to allow patients who appear to benefit from medical cannabis to use it in accordance with the various state regulatory schemes that have been created — have been introduced in recent Congresses and are expected to be reintroduced in the 110th Congress. These include the States' Rights to Medical Marijuana Act, which would move marijuana from Schedule I to Schedule II of the Controlled Substances Act and make it available under federal law for medical use in the states with medical marijuana programs, and the Steve McWilliams Truth in Trials Act, which would make it possible for defendants in federal court to reveal to juries that their marijuana activity was medically related and legal under state law.

The Hinchey-Rohrabacher Amendment, which would prohibit the use of federal funds to arrest and prosecute medical marijuana patients and providers whose

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[1] The terms *medical marijuana* and *medical cannabis* are used interchangeably in this report to refer to marijuana (scientific name: Cannabis sativa) and to marijuana use that qualifies for a medical use exception under the laws of certain states and under the federal Investigational New Drug Compassionate Access Program.

[2] The terms *botanical cannabis*, *botanical marijuana*, and *herbal cannabis*, used interchangeably in this report, signify the whole marijuana plant and therapeutic products derived therefrom, as opposed to drugs based on molecules found in the marijuana plant that are produced synthetically in the laboratory.

activities are permitted by the laws of their states, is also expected to be offered again in the current Congress. This and other congressional actions relating to the issue of medical marijuana are discussed below in greater detail.

Background: Medical Marijuana Prior to 1937

The Cannabis sativa plant has been used for healing purposes throughout history. According to written records from China and India, the use of marijuana to treat a wide range of ailments goes back more than 2,000 years. Ancient texts from Africa, the Middle East, classical Greece, and the Roman Empire also describe the use of cannabis to treat disease.

For most of American history, growing and using marijuana was legal under both federal law and the laws of the individual states. By the 1840s, marijuana's therapeutic potential began to be recognized by some U.S. physicians. From 1850 to 1941 cannabis was included in the *United States Pharmacopoeia* as a recognized medicinal.[3] By the end of 1936, however, all 48 states had enacted laws to regulate marijuana.[4] Its decline in medicine was hastened by the development of aspirin, morphine, and then other opium-derived drugs, all of which helped to replace marijuana in the treatment of pain and other medical conditions in Western medicine.[5]

Federal Medical Marijuana Policy

All three branches of the federal government play an important role in formulating federal policy on medical marijuana. Significant actions of each branch are highlighted here, beginning with the legislative branch.

Congressional Actions

The Marihuana[6] Tax Act of 1937. Spurred by spectacular accounts of marijuana's harmful effects on its users, by the drug's alleged connection to violent crime, and by a perception that state and local efforts to bring use of the drug under

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[3] Gregg A. Bliz, "The Medical Use of Marijuana: The Politics of Medicine," *Hamline Journal of Public Law and Policy*, vol. 13, spring 1992, p. 118.

[4] Oakley Ray and Charles Ksir, *Drugs, Society, and Human Behavior*, 10th ed. (New York: McGraw-Hill, 2004), p. 456.

[5] Bill Zimmerman, *Is Marijuana the Right Medicine for You? A Factual Guide to Medical Uses of Marijuana* (New Canaan, CT: Keats Publishing, 1998), p. 19.

[6] In Spanish, the letter "j" carries the sound of "h" in English. This alternative spelling of marijuana (with an "h") was formerly used by the federal government and is still used by some writers today.

control were not working, Congress enacted the Marihuana Tax Act of 1937.[7] Promoted by Harry Anslinger, Commissioner of the recently established Federal Bureau of Narcotics, the act imposed registration and reporting requirements and a tax on the growers, sellers, and buyers of marijuana. Although the act did not prohibit marijuana outright, its effect was the same. (Because marijuana was not included in the Harrison Narcotics Act in 1914,[8] the Marihuana Tax Act was the federal government's first attempt to regulate marijuana.)

Dr. William C. Woodward, legislative counsel of the American Medical Association (AMA), opposed the measure. In oral testimony before the House Ways and Means Committee, he stated that "there are evidently potentialities in the drug that should not be shut off by adverse legislation. The medical profession and pharmacologists should be left to develop the use of this drug as they see fit."[9] Two months later, in a letter to the Senate Finance Committee, he again argued against the act:

> There is no evidence, however, that the medicinal use of these drugs ["cannabis and its preparations and derivatives"] has caused or is causing cannabis addiction. As remedial agents they are used to an inconsiderable extent, and the obvious purpose and effect of this bill is to impose so many restrictions on their medicinal use as to prevent such use altogether. Since the medicinal use of cannabis has not caused and is not causing addiction, the prevention of the use of the drug for medicinal purposes can accomplish no good end whatsoever. How far it may serve to deprive the public of the benefits of a drug that on further research may prove to be of substantial value, it is impossible to foresee.[10]

Despite the AMA's opposition, the Marihuana Tax Act was approved, causing all medicinal products containing marijuana to be withdrawn from the market and leading to marijuana's removal, in 1941, from *The National Formulary* and the *United States Pharmacopoeia*, in which it had been listed for almost a century.

Controlled Substances Act (1970). With increasing use of marijuana and other street drugs during the 1960s, notably by college and high school students, federal drug-control laws came under scrutiny. In July 1969, President Nixon asked Congress to enact legislation to combat rising levels of drug use.[11] Hearings were

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[7] P.L. 75-238, 50 Stat. 551, Aug. 2, 1937. In *Leary* v. *United States* (395 U.S. 6 (1968)), the Supreme Court ruled the Marihuana Tax Act unconstitutional because it compelled self-incrimination, in violation of the Fifth Amendment.

[8] P.L. 63-223, Dec. 17, 1914, 38 Stat. 785. This law was passed to implement the Hague Convention of 1912 and created a federal tax on opium and coca leaves and their derivatives.

[9] U.S. Congress, House Committee on Ways and Means, *Taxation of Marihuana*, hearings on H.R. 6385, 75th Cong., 1st sess., May 4, 1937 (Washington: GPO, 1937), p. 114.

[10] U.S. Congress, Senate Committee on Finance, Taxation of Marihuana, hearing on H.R. 6906, 75th Cong., 1st sess., July 12, 1937 (Washington: GPO, 1937), p. 33.

[11] U.S. President, 1969-1974 (Nixon), "Special Message to the Congress on Control of Narcotics and Dangerous Drugs," July 14, 1969, *Public Papers of the Presidents of the*

(continued...)

held, different proposals were considered, and House and Senate conferees filed a conference report in October 1970.[12] The report was quickly adopted by voice vote in both chambers and was signed into law as the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513).

Included in the new law was the Controlled Substances Act (CSA),[13] which placed marijuana and its derivatives in Schedule I, the most restrictive of five categories. Schedule I substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety standards for use of the drug under medical supervision.[14] Other drugs used recreationally at the time also became Schedule I substances. These included heroin, amphetamine, methamphetamine, LSD, mescaline, peyote, and psilocybin. Drugs with recognized medical uses, such as cocaine, were assigned to Schedules II through V, depending on their potential for abuse.[15] Despite its placement in Schedule I, marijuana use increased, as did the number of health-care professionals and their patients who believed in the plant's therapeutic value.

The CSA does not distinguish between the medical and recreational use of marijuana. Under federal statute, simple possession of marijuana for personal use, a misdemeanor, can bring up to one year in federal prison and up to a $100,000 fine for a first offense.[16] Growing marijuana is considered *manufacturing* a controlled substance, a felony.[17] A single plant can bring an individual up to five years in federal prison and up to a $250,000 fine for a first offense.[18]

The CSA is not preempted by state medical marijuana laws, under the federal system of government, nor are state medical marijuana laws preempted by the CSA. States can statutorily create a medical use exception for botanical cannabis and its derivatives under their own, state-level controlled substance laws. At the same time, federal agents can investigate, arrest, and prosecute medical marijuana patients, caregivers, and providers in accordance with the federal Controlled Substances Act,

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[11] (...continued)
United States 1969 (Washington: GPO, 1971), pp. 513-518.

[12] U.S. Congress, Conference Committees, *Comprehensive Drug Abuse Prevention and Control Act of 1970*, conference report to accompany H.R. 18583, 91st Cong., 2nd sess., H.Rept. 91-1603 (Washington: GPO, 1970).

[13] Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, P.L. 91-513, Oct. 27, 1970, 84 Stat. 1242, 21 U.S.C. §801, *et seq*.

[14] Ibid., Sec. 202, 84 Stat. 1247, 21 U.S.C. §812.

[15] Amphetamine and methamphetamine have since been moved to Schedule II, in recognition of their accepted medical use in treatment. Cocaine was initially put in Schedule II in 1970 and remains there today.

[16] Sec. 404 of the CSA (21 U.S.C. §844) and 18 U.S.C. §3571. Sec. 404 also calls for a minimum fine of $1,000, and Sec. 405 (21 U.S.C. §844a) permits a civil penalty of up to $10,000.

[17] Sec. 102(15), (22) of the CSA (21 U.S.C. §802(15), (22)).

[18] Sec. 401(b)(1)(D) of the CSA (21 U.S.C. §841(b)(1)(D)).

even in those states where medical marijuana programs operate in accordance with state law.

Anti-Medical Marijuana Legislation in the 105th Congress (1998). In September 1998, the House debated and passed a resolution (H.J.Res. 117) declaring that Congress supports the existing federal drug approval process for determining whether any drug, including marijuana, is safe and effective and opposes efforts to circumvent this process by legalizing marijuana, or any other Schedule I drug, for medicinal use without valid scientific evidence and without approval of the Food and Drug Administration (FDA). With the Senate not acting on the resolution and adjournment approaching, this language was incorporated into the FY1999 omnibus appropriations act under the heading "Not Legalizing Marijuana for Medicinal Use."[19]

In a separate amendment to the same act, Congress prevented the District of Columbia government from counting ballots of a 1998 voter-approved initiative that would have allowed the medical use of marijuana by persons suffering from serious diseases, including cancer and HIV infection. The amendment was challenged and overturned in District Court, and the ballots were counted. Nevertheless, despite further court challenges, Congress continues to prohibit implementation of the initiative.[20]

The Hinchey-Rohrabacher Amendment (2003-2006).[21] In the first session of the 108th Congress, in response to federal Drug Enforcement Administration (DEA) raids on medical cannabis users and providers in California and other states that had approved the medical use of marijuana if recommended by a physician, Representatives Hinchey and Rohrabacher offered a bipartisan amendment to the FY2004 Commerce, Justice, State appropriations bill (H.R. 2799). The amendment would have prevented the Justice Department from using appropriated funds to interfere with the implementation of medical cannabis laws in the nine states that had approved such use. The amendment was debated on the floor of the House on July 22, 2003. When brought to a vote on the following day, it was defeated 152 to 273 (66 votes short of passage).[22]

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[19] Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, P.L. 105-277, Oct. 21, 1998, 112 Stat. 2681-760.

[20] Ibid., District of Columbia Appropriations Act, 1999, Sec. 171, 112 Stat. 2681-150. See CRS Report RL33563, *District of Columbia: Appropriations for 2007*, by Eugene Boyd and David P. Smole. This recurring provision of D.C. appropriations acts is known as the Barr Amendment because it was offered by Rep. Bob Barr. Since leaving Congress in 2003, Barr changed his position on medical marijuana and is now working in support of it as a lobbyist for the Marijuana Policy Project. See his website [http://www.bobbarr.org].

[21] When last considered in June 2006, the amendment stated: "None of the funds made available in this Act to the Department of Justice may be used to prevent the States of Alaska, California, Colorado, Hawaii, Maine, Montana, Rhode Island, Nevada, Oregon, Vermont, or Washington from implementing State laws authorizing the use of medical marijuana in those States." The wording in previous versions of the amendment was similar.

[22] "Amendment No. 1 offered by Mr. Hinchey," *Congressional Record*, daily edition, vol.

(continued...)

The amendment was offered again in the second session of the 108th Congress. It was debated on the House floor on July 7, 2004, during consideration of H.R. 4754, the Commerce, Justice, State appropriations bill for FY2005. This time it would have applied to 10 states, with the recent addition of Vermont to the list of states that had approved the use of medical cannabis. It was again defeated by a similar margin, 148 to 268.[23]

The amendment was voted on again in the first session of the 109th Congress and was again defeated, 161-264, on June 15, 2005. During floor debate on H.R. 2862, the FY2006 Science, State, Justice, Commerce appropriations bill, a Member stated in support of the amendment that her now-deceased mother had used marijuana to treat her glaucoma. Opponents of the amendment argued, among other things, that its passage would undermine efforts to convince young people that marijuana is a dangerous drug.[24]

Despite an extensive pre-vote lobbying effort by supporters, the amendment gained only two votes in its favor over the previous year when it was debated and defeated (163 to 259) on June 28, 2006.[25] The bill under consideration this time was H.R. 5672, the FY2007 Science, State, Justice, Commerce appropriations bill.

The amendment is expected to be offered again in the 110th Congress as an ongoing measure of sentiment in the House for marijuana law reform.

Medical Marijuana Bills in the 109th Congress (2005). Bills have been introduced in recent Congresses to allow patients who appear to benefit from medical cannabis to use it in accordance with the various regulatory schemes that have been approved, since 1996, by the voters or legislatures of 12 states. This legislative activity continued in the 109th Congress.

The States' Rights to Medical Marijuana Act (H.R. 2087/Frank) would have transferred marijuana from Schedule I to Schedule II of the Controlled Substances Act. It also would have provided that, in states in which marijuana may legally be prescribed or recommended by a physician for medical use under state law, no provisions of the Controlled Substances Act or the Federal Food, Drug, and Cosmetic Act could prohibit or otherwise restrict a physician from prescribing or recommending marijuana for medical use, an individual from obtaining and using marijuana if prescribed or recommended by a physician for medical use, a pharmacy from obtaining and holding marijuana for such a prescription or recommendation, or an entity established by a state from producing and distributing marijuana for such

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[22] (...continued)
149 (July 22, 2003), pp. H7302-H7311 and vol. 149 (July 23, 2003), pp. H7354-H7355.

[23] "Amendment No. 6 Offered by Mr. Farr," *Congressional Record*, daily edition, vol. 150 (July 7, 2004), pp. H5300-H5306, H5320.

[24] "Amendment Offered by Mr. Hinchey," *Congressional Record*, daily edition, vol. 151 (July 15, 2005), pp. H4519-H4524, H4529.

[25] "Amendment Offered by Mr. Hinchey," *Congressional Record*, daily edition, vol. 152 (June 28, 2006), pp. H4735-H4739.

a prescription or recommendation. Versions of this bill have been introduced in every Congress since the 105th in 1997 but have not seen action beyond the committee referral process.

Medical marijuana defendants in federal court are not permitted to introduce evidence showing that their marijuana-related activities were undertaken for a valid medical purpose under state law. The Steve McWilliams Truth in Trials Act (H.R. 4272/Farr) would have amended the Controlled Substances Act to provide an affirmative defense for the medical use of marijuana in accordance with the laws of the various states. First introduced in the 108th Congress, this version of the bill was named for a Californian who took his own life while awaiting federal sentencing for marijuana trafficking. At his trial, the jurors were not informed that he was actually providing marijuana to seriously ill patients in San Diego in compliance with state law. The bill also would have limited the authority of federal agents to seize marijuana authorized for medical use under state law and would have provided for the retention and return of seized plants pending resolution of a case involving medical marijuana.

Neither bill saw action beyond the committee referral process, and both bills are expected to be reintroduced in the 110th Congress.

Legislative Activity in the 110th Congress. The first action on medical marijuana in the current Congress occurred on April 18, 2007, at markup of the Prescription Drug User Fee Act (S. 1082). The Senate Committee on Health, Education, Labor, and Pensions adopted, in an 11-9 vote, an amendment offered by Senator Coburn that attempts to shut down state medical marijuana programs. The amendment states:

> The Secretary of Health and Human Services shall require that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration, including a risk evaluation and mitigation strategy and all other requirements of the Federal Food, Drug, and Cosmetic Act regarding safe and effective reviews, approval, sale, marketing, and use of pharmaceuticals.

Herbal cannabis products are not, in fact, being marketed in the United States as pharmaceuticals, nor are they being developed as investigational new drugs due largely to federal restrictions on marijuana research. Because of this and other possibly complicating factors, the validity and actual effect of this amendment, if signed into law, are unclear and may be subject to legal interpretation and judicial review.[26] The bill cleared the Senate and was sent to the House on May 9.

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[26] For a legal analysis of the amendment, see CRS Congressional Distribution Memorandum, "Possible Legal Effects of the Medical Marijuana Amendment to S. 1082," by Vanessa Burrows and Brian Yeh.

Executive Branch Actions and Policies

IND Compassionate Access Program (1978). In 1975, a Washington, DC, resident was arrested for growing marijuana to treat his glaucoma. He won his case by using the medical necessity defense,[27] forcing the government to find a way to provide him with his medicine. In 1978, FDA created the Investigational New Drug (IND) Compassionate Access Program,[28] allowing patients whose serious medical conditions could be relieved only by marijuana to apply for and receive marijuana from the federal government. Over the next 14 years, other patients, less than 100 in total, were admitted to the program for conditions including chemotherapy-induced nausea and vomiting (emesis), glaucoma, spasticity, and weight loss. Then, in 1992, in response to a large number of applications from AIDS patients who sought to use medical cannabis to increase appetite and reverse wasting disease, the George H.W. Bush Administration closed the program to all new applicants. Several previously approved patients remain in the program today and continue to receive their monthly supply of government-grown medical marijuana.

Approval of Marinol (1985). Marinol is the only cannabis-based drug approved by the FDA for use in the United States. Made by Unimed, Marinol is the trade name for dronabinol, a synthetic form of delta-9-tetrahydrocannabinol (THC), one of the principal psychoactive components of botanical marijuana. It was approved in May 1985 for nausea and vomiting associated with cancer chemotherapy in patients who fail to respond to conventional antiemetic treatments. In December 1992, it was approved by FDA for the treatment of anorexia associated with weight loss in patients with AIDS. Marketed as a capsule, Marinol was originally placed in Schedule II.[29] In July 1999, in response to a rescheduling petition from Unimed, it was moved administratively by DEA to Schedule III to make it more widely available to patients.[30] The rescheduling was granted after a review by DEA and the Department of Health and Human Services found little evidence of illicit abuse of the drug. In Schedule III, Marinol is now subject to fewer regulatory controls and lesser criminal sanctions for illicit use.

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[27] The Common Law *Doctrine of Necessity* argues that the illegal act committed (in this case, growing marijuana) was necessary to avert a greater harm (blindness).

[28] Despite the program's name, it was not a clinical trial to test the drug for eventual approval, but a means for the government to provide medical marijuana to patients demonstrating necessity. Some have criticized the government for its failure to study the safety and efficacy of the medical-grade marijuana it grew and distributed to this patient population.

[29] U.S. Dept. of Justice, Drug Enforcement Administration, "Schedules of Controlled Substances: Rescheduling of Synthetic Dronobinol in Sesame Oil and Encapsulation in Soft Gelatin Capsules From Schedule I to Schedule II; Statement of Policy," 51 *Federal Register* 17476, May 13, 1986.

[30] Ibid., "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," 64 *Federal Register* 35928, July 2, 1999.

Administrative Law Judge Ruling to Reschedule Marijuana (1988). Congressional passage of the Controlled Substances Act in 1970 and its placement of marijuana in Schedule I provoked controversy at the time because it strengthened the federal policy of marijuana prohibition and forced medical marijuana users to buy marijuana of uncertain quality on the black market at inflated prices, subjecting them to fines, arrest, court costs, property forfeiture, incarceration, probation, and criminal records. The new bureaucratic controls on Schedule I substances were also criticized because they would impede research on marijuana's therapeutic potential, thereby making its evaluation and rescheduling through the normal drug approval process unlikely.

These concerns prompted a citizens' petition to the Bureau of Narcotics and Dangerous Drugs (BNDD) in 1972 to reschedule marijuana and make it available by prescription. The petition was summarily rejected.[31] This led to a long succession of appeals, hearing requests, and various court proceedings. Finally, in 1988, after extensive public hearings on marijuana's medicinal value, the chief administrative law judge of the Drug Enforcement Administration (the BNDD's successor agency) ruled on the petition, stating that "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man."[32] Judge Francis L. Young also wrote:

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

Judge Young found that "the provisions of the [Controlled Substances] Act permit and require the transfer of marijuana from schedule I to schedule II," which would recognize its medicinal value and permit doctors to prescribe it. The Judge's findings and recommendation were soon rejected by the DEA Administrator because "marijuana has not been demonstrated as suitable for use as a medicine."[33] Subsequent rescheduling petitions were also rejected, and marijuana remains a Schedule I substance.

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[31] Ibid., 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," 37 *Federal Register* 18097, Sept. 7, 1972.

[32] Ibid., Drug Enforcement Administration, "In the Matter of Marijuana Rescheduling Petition, Docket No. 86-22, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge," Francis L. Young, Administrative Law Judge, Sept. 6, 1988. This quote and the following two quotes are at pp. 58-59, 68, and 67, respectively. This opinion is online at [http://www.druglibrary.net/olsen/MEDICAL/YOUNG/young.html].

[33] Ibid., "Marijuana Scheduling Petition; Denial of Petition," 54 *Federal Register* 53767 at 53768, Dec. 29, 1989. The petition denial was appealed, eventually resulting in yet another DEA denial to reschedule. See Ibid., "Marijuana Scheduling Petition; Denial of Petition; Remand," 57 *Federal Register* 10499, Mar. 26, 1992.

NIH-Sponsored Workshop (1997). NIH convened a scientific panel on medical marijuana composed of eight nonfederal experts in fields such as cancer treatment, infectious diseases, neurology, and ophthalmology. Over a two-day period in February, they analyzed available scientific information on the medical uses of marijuana and concluded that "in order to evaluate various hypotheses concerning the potential utility of marijuana in various therapeutic areas, more and better studies would be needed." Research would be justified, according to the panel, into certain conditions or diseases such as pain, neurological and movement disorders, nausea of patients undergoing chemotherapy for cancer, loss of appetite and weight related to AIDS, and glaucoma.[34]

Institute of Medicine Report (1999). In January 1997, shortly after passage of the California and Arizona medical marijuana initiatives, the Director of the Office of National Drug Control Policy (the federal drug czar) commissioned the Institute of Medicine (IOM) of the National Academy of Sciences to review the scientific evidence on the potential health benefits and risks of marijuana and its constituent cannabinoids. Begun in August 1997, IOM's 257-page report, *Marijuana and Medicine: Assessing the Science Base*, was released in March 1999.[35] A meta-analysis of all existing studies of the therapeutic value of cannabis, the IOM Report was also based on public hearings and consultations held around the country with biomedical and social scientists and concerned citizens.

For the most part, the IOM Report straddled the fence and provided sound bites for both sides of the medical marijuana debate. For example, "Until a nonsmoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from *chronic* conditions that might be relieved by smoking marijuana, such as pain or AIDS-wasting" (p. 179) and "Smoked marijuana is unlikely to be a safe medication for any chronic medical condition" (p. 126). For another example, "There is no conclusive evidence that marijuana causes cancer in humans, including cancers usually related to tobacco use" (p. 119) and "Numerous studies suggest that marijuana smoke is an important risk factor in the development of respiratory disease" (p. 127).

The IOM Report did find more potential promise in synthetic cannabinoid drugs than in smoked marijuana (p. 177):

> The accumulated data suggest a variety of indications, particularly for pain relief, antiemesis, and appetite stimulation. For patients such as those with AIDS or who are undergoing chemotherapy, and who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication.

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[34] National Institutes of Health. The Ad Hoc Group of Experts. *Workshop on the Medical Utility of Marijuana: Report to the Director*, Aug. 1997. (Hereafter cited as NIH Workshop.) [http://www.nih.gov/news/medmarijuana/MedicalMarijuana.htm]

[35] Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., eds., *Marijuana and Medicine: Assessing the Science Base* (Washington: National Academy Press, 1999). (Hereafter cited as the IOM Report.) [http://www.nap.edu/books/0309071550/html/]

In general, the report emphasized the need for well-formulated, scientific research into the therapeutic effects of marijuana and its cannabinoid components on patients with specific disease conditions. To this end, the report recommended that clinical trials be conducted with the goal of developing safe delivery systems.

Denial of Petition to Reschedule Marijuana (2001). In response to a citizen's petition to reschedule marijuana submitted to the DEA in 1995, DEA asked the Department of Health and Human Services (HHS) for a scientific and medical evaluation of the abuse potential of marijuana and a scheduling recommendation. HHS concluded that marijuana has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. HHS therefore recommended that marijuana remain in Schedule I. In a letter to the petitioner dated March 20, 2001, DEA denied the petition.[36]

FDA Statement That Smoked Marijuana Is Not Medicine (2006). On April 20, 2006, the FDA issued an interagency advisory restating the federal government's position that "smoked marijuana is harmful" and has not been approved "for any condition or disease indication." The one-page announcement did not refer to new research findings. Instead, it was based on a "past evaluation" by several agencies within HHS that "concluded that no sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of marijuana for general medical use."[37]

Media reaction to this pronouncement was largely negative, asserting that the FDA position on medical marijuana was motivated by politics, not science, and ignored the findings of the 1999 Institute of Medicine Report.[38] In Congress, 24 House Members, led by Representative Hinchey, sent a letter to the FDA acting commissioner requesting the scientific evidence behind the agency's evaluation of the medical efficacy of marijuana and citing the FDA's IND Compassionate Access Program as "an example of how the FDA could allow for the legal use of a drug, such as medical marijuana, without going through the 'well-controlled' series of steps that other drugs have to go through if there is a compassionate need."[39]

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[36] U.S. Dept. of Justice, Drug Enforcement Administration, "Notice of Denial of Petition," 65 *Federal Register* 20038, Apr. 18, 2001.

[37] U.S. Food and Drug Administration, "Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine," press release, Apr. 20, 2006, p. 1. Although not cited in the press release, the "past evaluation" referred to is apparently the 2001 denial of the petition to reschedule marijuana discussed above.

[38] See, for example, "The Politics of Pot," editorial, *New York Times*, Apr. 22, 2006, p. A26, which calls the FDA statement "disingenuous" and concludes: "It's obviously easier and safer to issue a brief, dismissive statement than to back research that might undermine the administration's inflexible opposition to the medical use of marijuana.".

[39] The text of the letter, dated April 27, 2006, is available at Rep. Hinchey's website [http://www.house.gov/hinchey].

Administrative Law Judge Ruling to Grow Research Marijuana (2007). Since 1968, the only source of marijuana available for scientific research in the United States has been tightly controlled by the federal government. Grown at the University of Mississippi under a contract administered by the National Institute on Drug Abuse, the marijuana is difficult to obtain even by scientists whose research protocols have been approved by the FDA. Not only is the federal supply of marijuana largely inaccessible, but researchers also complain that it does not meet the needs of research due to its inferior quality and lack of multiple strains.[40] Other Schedule I substances — such as LSD, heroin, and MDMA (Ecstasy) — can be provided legally by private U.S. laboratories or imported from abroad for research purposes, with federal permission. Only marijuana is limited to a single, federally controlled provider.

In response to this situation, Dr. Lyle Craker, a professor of plant biology and director of the medicinal plant program at the University of Massachusetts at Amherst, applied in 2001 for a DEA license to cultivate research-grade marijuana. The application was filed in association with the Multidisciplinary Association for Psychedelic Studies (MAPS), a nonprofit drug research organization headed by Dr. Rick Doblin, whose stated goal is

> to break the government's monopoly on the supply of marijuana that can be used in FDA-approved research, thereby creating the proper conditions for a $5 million, 5 year drug development effort designed to transform smoked and/or vaporized marijuana into an FDA-approved prescription medicine.[41]

The DEA rejected the Craker/MAPS application in December 2004, after being sued for "unreasonable delay" in the DC Circuit Court of Appeals, and the rejection was appealed administratively. Nine days of hearings were held over a five-month period in 2005, at which researchers testified that their requests for marijuana had been rejected, making it impossible to conduct their FDA-approved research. On February 12, 2007, DEA's Administrative Law Judge Mary Ellen Bittner found that "an inadequate supply" of marijuana is available for research and ruled that it "would be in the public interest" to allow Dr. Craker to create the proposed marijuana production facility.[42] The ruling, however, is nonbinding, and a decision by the DEA Administrator on whether to accept or reject the Craker decision is pending.

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[40] Jessica Winter, "Weed Control: Research on the Medicinal Benefits of Marijuana May Depend on Good Gardening — and Some Say Uncle Sam, the Country's Only Legal Grower of the Cannabis Plant, Isn't Much of a Green Thumb," *Boston Globe*, May 28, 2006.

[41] "The UMass Amherst MMJ Production Facility Project," on the MAPS website at [http://www.maps.org/mmj/mmjfacility.html]. See the entry for Feb. 8, 2005. (Numerous documents related to the Craker/MAPS application are linked here.)

[42] U.S. Dept. of Justice, Drug Enforcement Administration, "In the Matter Lyle E. Craker, Ph.D., Docket No. 05-16, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of Administrative Law Judge," Mary Ellen Bittner, Administrative Law Judge, Feb. 12, 2007, p. 87. This opinion is online at [http://www.maps.org/mmj/DEAlawsuit.html].

DEA Enforcement Actions Against Medical Marijuana Providers. Most arrests in the United States for marijuana possession are made by state and local police, not the DEA. This means that patients and their caregivers in the states that permit medical marijuana mostly go unprosecuted, because their own state's marijuana prohibition laws do not apply to them and because federal law is not usually enforced against them.

Federal agents do, however, move against medical cannabis growers and distributors in states with medical marijuana programs. In recent years, DEA agents have conducted many raids of medical marijuana dispensaries, especially in California, where the law states that marijuana providers can receive "reasonable compensation" on a nonprofit basis. The DEA does not provide statistics on its moves against medical marijuana outlets because the agency does not distinguish between criminal, non-medical marijuana trafficking organizations and locally licensed storefront dispensaries that are legal under state law. They are all felony criminal operations under the Controlled Substances Act. As a practical matter, however, the DEA reportedly targets larger, for-profit medical marijuana providers who are engaged in "nothing more than high-stakes drug dealing, complete with the same high-rolling lifestyles."[43] A few high-profile medical marijuana patients are also being prosecuted under federal law.[44]

DEA's actions to shut down medical marijuana growing and distribution operations have provoked lawsuits and other responses. In April 2003, for example, the city and county of Santa Cruz, CA, along with seven medical marijuana patients, filed a lawsuit in San Jose federal district court in response to DEA's earlier raid on the Wo/Men's Alliance for Medical Marijuana (WAMM). The court granted the plaintiffs' motion for a preliminary injunction, thereby allowing WAMM to resume growing and producing marijuana medications for its approximately 250 member-patients with serious illnesses, pending the final outcome of the case.[45] The suit is said to be the first court challenge brought by a local government against the federal war on drugs.

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[43] Rone Tempest, "DEA Targets Larger Marijuana Providers," *Los Angeles Times*, Jan. 1, 2007.

[44] These include medical marijuana activist and author Ed Rosenthal, whose first jury renounced its guilty verdict when it learned after the trial that he was legally helping patients under state law and who is being tried again. See Paul Elias, "Federal Prosecutors Will Retry Ed Rosenthal Against Judge Recommendation," *Associated Press*, Apr. 15, 2007.

[45] *County of Santa Cruz* v. *Ashcroft*, 314 F.Supp.2d 1000 (N.D.Cal. 2004); the decision, however, rests on the 9th Circuit's ruling in *Raich*, subsequently reversed by the Supreme Court, as described below.

Medical Cannabis in the Courts: Major Cases

Because Congress and the executive branch have not acted to permit seriously ill Americans to use botanical marijuana medicinally, the issue has been considered by the judicial branch, with mixed results. Three significant cases have been decided so far, and other court challenges are moving through the judicial pipeline.[46]

***U.S.* v. *Oakland Cannabis Buyers' Cooperative* (2001).** The U.S. Department of Justice filed a civil suit in January 1998 to close six medical marijuana distribution centers in northern California. A U.S. district court judge issued a temporary injunction to close the centers, pending the outcome of the case. The Oakland Cannabis Buyers' Cooperative fought the injunction but was eventually forced to cease operations and appealed to the Ninth Circuit Court of Appeals. At issue was whether a medical marijuana distributor can use a medical necessity defense against federal marijuana distribution charges.[47]

The Ninth Circuit's decision found in September 1999 that medical necessity is a valid defense against federal marijuana trafficking charges if a trial court finds that the patients to whom the marijuana was distributed are seriously ill, face imminent harm without marijuana, and have no effective legal alternatives.[48] The Justice Department appealed to the Supreme Court.

The Supreme Court held, 8-0, that "a medical necessity exception for marijuana is at odds with the terms of the Controlled Substances Act" because "its provisions leave no doubt that the defense is unavailable."[49] This decision had no effect on state medical marijuana laws, which continued to protect patients and primary caregivers from arrest by state and local law enforcement agents in the states with medical marijuana programs.

***Conant* v. *Walters* (2002).** After the 1996 passage of California's medical marijuana initiative, the Clinton Administration threatened to investigate doctors and revoke their licenses to prescribe controlled substances and participate in Medicaid and Medicare if they recommended medical marijuana to patients under the new state law. A group of California physicians and patients filed suit in federal court, early in 1997, claiming a constitutional free-speech right, in the context of the doctor-patient relationship, to discuss the potential risks and benefits of the medical use of cannabis. A preliminary injunction, issued in April 1997, prohibited federal officials from threatening or punishing physicians for recommending marijuana to patients suffering from HIV/AIDS, cancer, glaucoma, or seizures or muscle spasms associated

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[46] For a legal analysis of all three cases mentioned here, see CRS Report RL31100, *Marijuana for Medical Purposes: The Supreme Court's Decision in* United States *v.* Oakland Cannabis Buyers' Cooperative *and Related Legal Issues*, by Charles Doyle.

[47] The necessity defense argues that the illegal act committed (distribution of marijuana in this instance) was necessary to avert a greater harm (withholding a helpful drug from seriously ill patients).

[48] 523 U.S. 483 (2001).

[49] Ibid. at 494 n. 7.

with a chronic, debilitating condition.[50] The court subsequently made the injunction permanent in an unpublished opinion.

On appeal, the Ninth Circuit affirmed the district court's order entering a permanent injunction. The federal government, the opinion states, "may not initiate an investigation of a physician solely on the basis of a recommendation of marijuana within a bona fide doctor-patient relationship, unless the government in good faith believes that it has substantial evidence of criminal conduct."[51] The Bush Administration appealed, but the Supreme Court refused to take the case.

***Gonzales* v. *Raich* (2005).** In response to DEA agents' destruction of their medical marijuana plants, two patients and two caregivers in California brought suit. They argued that applying the Controlled Substances Act to a situation in which medical marijuana was being grown and consumed locally for no remuneration in accordance with state law exceeded Congress's constitutional authority under the Commerce Clause, which allows the federal government to regulate interstate commerce. In December 2003, the Ninth Circuit Court of Appeals in San Francisco agreed, ruling that states are free to adopt medical marijuana laws so long as the marijuana is not sold, transported across state lines, or used for nonmedical purposes.[52] Federal appeal sent the case to the Supreme Court.

The issue before the Supreme Court was whether the Controlled Substances Act, when applied to the *intra*state cultivation and possession of marijuana for personal use under state law, exceeds Congress's power under the Commerce Clause. The Supreme Court, in June 2005, reversed the Ninth Circuit's decision and held, in a 6-3 decision, that Congress's power to regulate commerce extends to purely local activities that are "part of an economic class of activities that have a substantial effect on interstate commerce."[53]

Raich does not invalidate state medical marijuana laws. The decision does mean, however, that DEA may continue to enforce the CSA against medical marijuana patients and their caregivers, even in states with medical marijuana programs.

[redacted][54] The majority

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[50] *Conant* v. *McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997).

[51] *Conant* v. *Walters*, 309 F.3d 629, 636 (9th Cir. 2002); the parties agreed that "a doctor who actually prescribes or dispenses marijuana violates federal law," ibid. at 634.

[52] *Raich* v. *Ashcroft*, 352 F.3d 1222 (9th Cir. 2003).

[53] *Gonzales* v. *Raich*, 125 S.Ct. 2195, 2205 (2005).

[54] Ibid. at 2211 n. 37. For a legal analysis of this case, see CRS Report RS22167, Gonzales *v*. Raich: *Congress's Power Under the Commerce Clause to Regulate Medical Marijuana*,

(continued...)

opinion, in closing, notes that in the absence of judicial relief for medical marijuana users there remains "the democratic process, in which the voices of voters allied with these respondents may one day be heard in the halls of Congress."[55]

Thus, the Supreme Court reminds that Congress has the power to reschedule marijuana, thereby recognizing that it has accepted medical use in treatment in the United States. Congress, however, does not appear likely to do so. Neither does the executive branch, which could reschedule marijuana through regulatory procedures authorized by the Controlled Substances Act. In the meantime, actions taken by state and local governments continue to raise the issue, as discussed below.

Americans for Safe Access (ASA) Lawsuit Against HHS. The federal Data Quality Act of 2001 (DQA) requires the issuance of guidelines "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies" and allows "affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines."[56]

In October 2004, Americans for Safe Access (ASA), a California-based patient advocacy group, formally petitioned HHS, under the DQA, to correct four erroneous statements about medical marijuana made by HHS in its 2001 denial of the marijuana rescheduling petition discussed above. Specifically, ASA requested that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition" be replaced with "[a]dequate and well-recognized studies show the efficacy of marijuana in the treatment of nausea, loss of appetite, pain and spasticity"; that "it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana" be replaced with "[t]here is substantial consensus among experts in the relevant disciplines that marijuana is effective in treating nausea, loss of appetite, pain and spasticity. It is accepted as medicine by qualified experts"; that "complete scientific analysis of all the chemical components found in marijuana has not been conducted" be replaced with "[t]he chemistry of marijuana is known and reproducible"; and [redacted] The petition claimed that "HHS's statements about the lack of medical usefulness of marijuana harms these individuals [ill persons across the United States] in that it contributes to denying them access to medicine which will alleviate their suffering."[57]

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[54] (...continued)
by Todd B. Tatelman.

[55] Ibid. at 2215.

[56] P.L. 106-554, 114 Stat. 2763A-153, 44 U.S.C. § 3516 note. For background on the DQA see CRS Report RL32532, *The Information Quality Act: OMB's Guidance and Initial Implementation*, by Curtis W. Copeland.

[57] The original petition and all subsequent documents relating to the case can be found at [http://www.safeaccessnow.org/article.php?id=4401]. See also Carolyn Marshall, "U.S. Is Sued Over Position on Marijuana," *New York Times*, Feb. 22, 2007.

Were HHS to accept the ASA petition, the revised statements would set the preconditions for placing marijuana in a schedule other than I. HHS denied the petition in 2005 and rejected ASA's subsequent appeal in 2006 on just those grounds: that HHS is already in the process of reviewing a rescheduling petition submitted to DEA in October 2002 and will be evaluating all of the publicly available peer-reviewed literature on the medicinal efficacy of marijuana in that context.

State and Local Referenda and Legislation

In the face of federal intransigence on the issue, advocates of medical marijuana have turned to state and local governments in a mostly successful effort, as outlined here, to pass laws and establish programs that enable patients to obtain and use botanical marijuana therapeutically in a legal and regulated manner.

States Allowing Use of Medical Marijuana[58]

All of these states have in place, or are developing, programs to regulate the use of medical marijuana by approved patients. Patients in state programs (except for New Mexico) may be assisted by caregivers, persons who are authorized to help patients grow, acquire, and use the drug. Physicians in these states are immune from liability and prosecution for discussing or recommending medical cannabis to their patients in accordance with state law.

Nine of the 12 states that have legalized medical marijuana are in the West: Alaska, California, Colorado, Hawaii, Montana, Nevada, New Mexico, Oregon, and Washington. Of the 37 states outside the West, only three, all in the Northeast — Maine, Rhode Island, and Vermont — have adopted medical cannabis statutes. Hawaii, New Mexico, Rhode Island, and Vermont have the only programs initiated by acts of their state legislatures. The medical marijuana programs in the other eight

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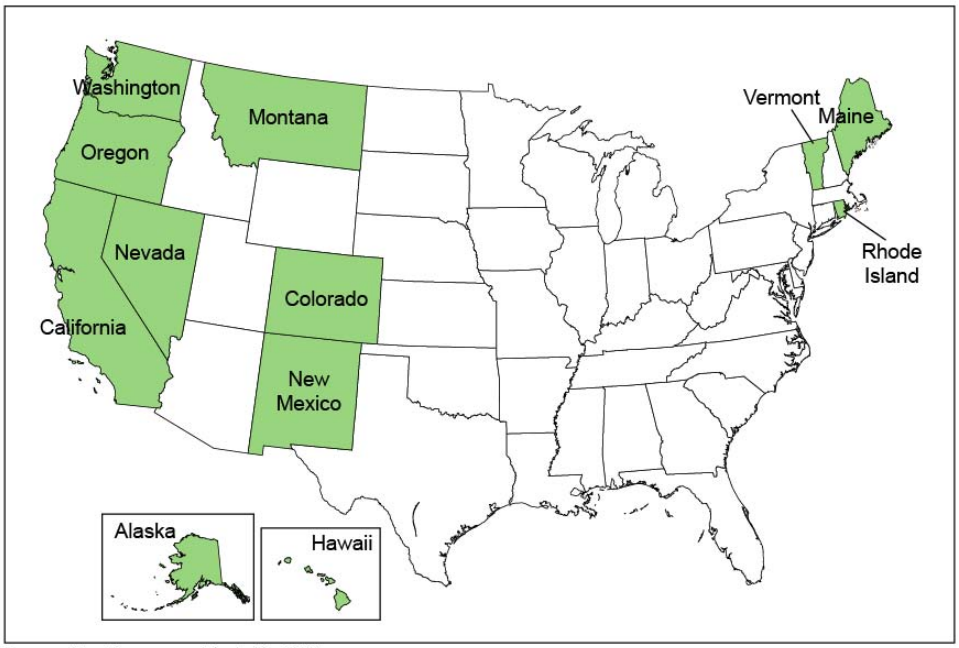
[58] The information in this and the following section is drawn largely from: *State-by-State Medical Marijuana Laws: How to Remove the Threat of Arrest*, Marijuana Policy Project, July 2004, available at [http://www.mpp.org/statelaw/index.html]. More recent information is from press reports.

[59] Alaska (Stat. §11.71.090); California (Cal.Health & Safety Code Ann. §11362.5) and (2003 CA S.B. 420 (SN)); Colorado (Colo.Const. Art. XVIII §14); Hawaii (Rev.Stat. §§329-121 to 329-128); Maine (Me.Rev.Stat.Ann. tit.22 §1102 or 2382-B(5)); Montana (Mont.Code Ann. §§50-46-101 to 50-46-210); Nevada (Nev.Rev.Stat.Ann. §§453A.010 to 453A.400); New Mexico (S.B. 523); Oregon (Ore.Rev.Stat. §§475.300 to 475.346); Rhode Island (RI ST §§21-28.6-1); Vermont (Vt.Stat.Ann. tit. 18, §§4472-4474d); Washington (Wash.Rev.Code Ann. §§69.51A.005 to 69.51A.902).

states were approved by the voters in statewide referenda or ballot initiatives, beginning in 1996 with California. Since then, voters have approved medical marijuana initiatives in every state where they have appeared on the ballot with the exception of South Dakota, where a medical marijuana initiative was defeated in 2006 by 52% of the voters. Bills to create medical marijuana programs have been introduced in the legislatures of additional states — Alabama, Connecticut, Illinois, Maryland, Minnesota, New Hampshire, New Jersey, among others — and have received varying levels of consideration but have so far not been enacted.

Figure 1. States With Medical Marijuana Programs



Source: Map Resources. Adapted by CRS.

Effective state medical marijuana laws do not attempt to overturn or otherwise violate federal laws that prohibit doctors from writing prescriptions for marijuana and pharmacies from distributing it. In the 12 states with medical marijuana programs, doctors do not actually prescribe marijuana, and the marijuana products used by patients are not distributed through pharmacies. Rather, doctors *recommend* marijuana to their patients, and the cannabis products are grown by patients or their caregivers, or they are obtained from cooperatives or other alternative dispensaries. The state medical marijuana programs do, however, contravene the federal prohibition of marijuana. Medical marijuana patients, their caregivers, and other marijuana providers can, therefore, be arrested by federal law enforcement agents, and they can be prosecuted under federal law.

Statistics on Medical Marijuana Users. Determining exactly how many patients use medical marijuana with state approval is difficult. According to a 2002 study published in the *Journal of Cannabis Therapeutics*, an estimated 30,000 California patients and another 5,000 patients in eight other states possessed a

physician's recommendations to use cannabis medically.[60] More recent estimates are much higher. The *New England Journal of Medicine* reported in August 2005, for example, that an estimated 115,000 people have obtained marijuana recommendations from doctors in the states with programs.[61]

Although 115,000 people may be approved medical marijuana users, the number of patients who have actually registered is much lower. A July 2005 CRS telephone survey of the state programs revealed a total of 14,758 registered medical marijuana users in eight states.[62] (Maine and Washington do not maintain state registries, and Rhode Island and New Mexico had not yet passed their laws.) This number vastly understates the number of medical marijuana users, however, because California's state registry was in pilot status, with only 70 patients so far registered.

A brief description of each state's medical marijuana programs follows. The programs are discussed in the order in which they were approved by voters or passed by the state legislatures.

California (1996). Proposition 215, approved by 56% of the voters in November, removed the state's criminal penalties for medical marijuana use, possession, and cultivation by patients with the "written or oral recommendation or approval of a physician" who has determined that the patient's "health would benefit from medical marijuana." Called the Compassionate Use Act, it legalized cannabis for "the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief." The law permits possession of an amount sufficient for the patient's "personal medical purposes." A second statute (Senate bill 420), passed in 2003, allows "reasonable compensation" for medical marijuana caregivers and says that distribution should be done on a nonprofit basis.

Oregon (1998). Voters in November removed the state's criminal penalties for use, possession, and cultivation of marijuana by patients whose physicians advise that marijuana "may mitigate the symptoms or effects" of a debilitating condition. The law, approved by 55% of Oregon voters, does not provide for distribution of cannabis but allows up to seven plants per patient (changed to 24 plants by act of the state legislature in 2005). The state registry program is supported by patient fees. (In the November 2004 election, Oregon voters rejected a measure that would have expanded the state's existing program.)

Alaska (1998). Voters in November approved a ballot measure to remove state-level criminal penalties for patients diagnosed by a physician as having a

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[60] Dale Gieringer, "The Acceptance of Medical Marijuana in the U.S.," *Journal of Cannabis Therapeutics*, vol. 3, no. 1 (2003), pp. 53-67. The author later estimated that there were more than 100,000 medical marijuana patients in California alone (personal communication dated Apr. 30, 2004).

[61] Susan Okie, "Medical Marijuana and the Supreme Court," *New England Journal of Medicine*, vol. 353, no. 7 (Aug. 18, 2005), p. 649.

[62] The telephone survey was conducted for this report by CRS summer intern Broocks Andrew Meade.

debilitating medical condition for which other approved medications were considered. The measure was approved by 58% of the voters. In 1999, the state legislature created a mandatory state registry for medical cannabis users and limited the amount a patient can legally possess to 1 ounce and six plants.

Washington (1998). Approved in November by 59% of the voters, the ballot initiative exempts from prosecution patients who meet all qualifying criteria, possess no more marijuana than is necessary for their own personal medical use (but no more than a 60-day supply), and present valid documentation to investigating law enforcement officers. The state does not issue identification cards to patients.

Maine (1999). Maine's ballot initiative, passed in November by 61% of the voters, puts the burden on the state to prove that a patient's medical use or possession is not authorized by statute. Patients with a qualifying condition, authenticated by a physician, who have been "advised" by the physician that they "might benefit" from medical cannabis, are permitted 1¼ ounces and six plants. There is no state registry of patients.

Hawaii (2000). In June, the Hawaii legislature approved a bill removing state-level criminal penalties for medical cannabis use, possession, and cultivation of up to seven plants. A physician must certify that the patient has a debilitating condition for which "the potential benefits of the medical use of marijuana would likely outweigh the health risks." This was the first state law permitting medical cannabis use that was enacted by a legislature instead of by ballot initiative.

Colorado (2000). A ballot initiative to amend the state constitution was approved by 54% of the voters in November. The amendment provides that lawful medical cannabis users must be diagnosed by a physician as having a debilitating condition and be "advised" by the physician that the patient "might benefit" from using the drug. A patient and the patient's caregiver may possess 2 usable ounces and six plants.

Nevada (2000). To amend the state constitution by ballot initiative, a proposed amendment must be approved by the voters in two separate elections. In November, 65% of Nevada voters passed for the second time an amendment to exempt medical cannabis users from prosecution. The amendment requires the state legislature to develop a program that allows qualified patients to use, possess, and grow marijuana for medicinal purposes.

Vermont (2004). In May, Vermont became the second state to legalize medical cannabis by legislative action instead of ballot initiative. Vermont patients are allowed to grow up to three marijuana plants in a locked room and to possess 2 ounces of manicured marijuana under the supervision of the Department of Public Safety, which maintains a patient registry. The law went into effect without the signature of the governor, who declined to sign it but also refused to veto it, despite pressure from Washington.

Montana (2004). In November, 62% of state voters passed Initiative 148, allowing qualifying patients to use marijuana under medical supervision. Eligible medical conditions include cancer, glaucoma, HIV/AIDS, wasting syndrome,

seizures, and severe or chronic pain. A doctor must certify that the patient has a debilitating medical condition and that the benefits of using marijuana would likely outweigh the risks. The patient may grow up to six plants and possess 1 ounce of dried marijuana. The state public health department registers patients and caregivers.

Rhode Island (2006). In January, the state legislature overrode the governor's veto of a medical marijuana bill, allowing patients to possess up to 12 plants or 2½ ounces to treat cancer, HIV/AIDS, and other chronic ailments. The law includes a sunset provision and will expire on July 1, 2007, unless renewed by the legislature.

New Mexico (2007). Passed by the legislature and signed into law by the governor in April, the Lynn and Erin Compassionate Use Medical Marijuana Act goes into effect on July 1, 2007. It requires the state's Department of Health to set rules governing the distribution of medical cannabis to state-authorized patients. Unlike other state programs, patients and their caregivers cannot grow their own marijuana; rather, it will be provided by state-licensed "cannabis production facilities."

Other State and Local Medical Marijuana Laws

Arizona (1996). Arizona's law,[63] approved by 65% of the voters in November, permits marijuana prescriptions, but there is no active program in the state because federal law prohibits doctors from *prescribing* marijuana. Patients cannot, therefore, obtain a valid prescription. (Other states' laws allow doctors to "recommend" rather than "prescribe.")

Maryland (2003). Maryland's General Assembly became the second state legislature, after Hawaii, to protect medical cannabis patients from the threat of jail when it approved a bill, later signed by the governor, providing that patients using marijuana preparations to treat the symptoms of illnesses such as cancer, AIDS, and Crohn's disease would be subject to no more than a $100 fine.[64] The law falls short of full legalization and does not create a medical marijuana program, but it allows for a medical necessity defense for people who use marijuana on their own for medical purposes. If patients arrested for possession in Maryland can prove in court that they use cannabis for legitimate medical needs, they escape the maximum penalty of one year in jail and a $1,000 fine.

Other State Laws. Laws favorable to medical marijuana have been enacted in 36 states since 1978.[65] Except for the state laws mentioned above, however, these laws do not currently protect medical marijuana users from state prosecution. Some laws, for example, allow patients to acquire and use cannabis through therapeutic

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[63] Ariz.Rev.Stat.Ann. §13-3412.01(A).

[64] Md. Crim.Code Ann. §5-601.

[65] *State-by-State Medical Marijuana Laws: How to Remove the Threat of Arrest*, Marijuana Policy Project, July 2004, p. 3. The laws in some of these states have expired or been repealed.

research programs, although none of these programs has been operational since 1985, due in large part to federal opposition. Other state laws allow doctors to prescribe marijuana or allow patients to possess marijuana if it has been obtained through a prescription, but the federal Controlled Substances Act prevents these laws from being implemented. Several states have placed marijuana in a controlled drug schedule that recognizes its medical value. State legislatures continue to consider medical marijuana bills, some favorable to its use by patients, others not.

District of Columbia (1998). In the nation's capital, 69% of voters approved a medical cannabis initiative to allow patients a "sufficient quantity" of marijuana to treat illness and to permit nonprofit marijuana suppliers. Congress, however, has blocked the initiative from taking effect.[66]

Local Measures. Medical cannabis measures have been adopted in several localities throughout the country. San Diego is the country's largest city to do so. One day after the Supreme Court's anti-marijuana ruling in *Gonzales* v. *Raich* was issued, Alameda County in California approved an ordinance to regulate medical marijuana dispensaries, becoming the 17th locality in the state to do so. Localities in nonmedical marijuana states have also acted. In November 2004, for example, voters in Ann Arbor, MI, and Columbia, MO, approved medical cannabis measures. Although largely symbolic, such local laws can influence the priorities of local law enforcement officers and prosecutors.

Public Opinion on Medical Marijuana

Voters in nine states have approved medical marijuana initiatives to protect patients from arrest under state law. Likewise, American public opinion has consistently favored access to medical marijuana by seriously ill patients. ProCon.org, a nonprofit and nonpartisan public education foundation, has identified 21 national public opinion polls that asked questions about medical marijuana from 1995 to the present. Respondents in every poll were in favor of medical marijuana by substantial margins, ranging from 60% to 80%.[67]

The *Journal of the American Medical Association* analyzed public opinion on the War on Drugs in a 1998 article. The authors' observations concerning public attitudes toward medical marijuana remain true today:

> While opposing the use or legalization of marijuana for recreational purposes, the public apparently does not want to deny very ill patients access to a potentially helpful drug therapy if prescribed by their physicians. The public's

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[66] For more information on the situation in the District of Columbia, see CRS Report RL33563, *District of Columbia: Appropriations for 2007*, by Eugene Boyd and David P. Smole.

[67] The questions asked and the results obtained can be viewed at [http://www.medicalmarijuanaprocon.org/pop/votesNat.htm].

support of marijuana for medical purposes is conditioned by their belief that marijuana would be used only in the treatment of serious medical conditions.[68]

Analysis of Arguments For and Against Medical Marijuana

At least in public opinion polls, the majority of Americans appear to hold that seriously ill or terminal patients should be able to use marijuana if recommended by their doctors. In 8 of the 12 states with medical marijuana programs, a majority has supported that belief in the voting booth. The federal government and most state governments, however, remain strongly opposed to medical marijuana.

In the ongoing debate over cannabis as medicine, certain arguments are frequently made on both sides of the issue. These arguments are briefly stated below and are analyzed in turn. Equal weight is not given to both sides of every argument. Instead, the analysis is weighted according to the preponderance of evidence as currently understood. CRS takes no position on the claims or counterclaims in this debate.

What follows, then, is an attempt to analyze objectively the claims frequently made about the role that herbal cannabis might or might not play in the symptomatic treatment of certain diseases and about the possible societal consequences should its role in the practice of modern medicine be expanded beyond the handful of states where it is now permitted.

Marijuana Is Harmful and Has No Medical Value

Suitable and superior medicines are currently available for treatment of all symptoms alleged to be treatable by crude marijuana.

— Brief of the Drug Free America Foundation, et al., 2004[69]

The federal government — along with many state governments and private antidrug organizations — staunchly maintains that botanical marijuana is a dangerous drug without any legitimate medical use. Marijuana intoxication can impair a person's coordination and decision-making skills and alter behavior. Chronic marijuana smoking can adversely affect the lungs, the cardiovascular system, and possibly the immune and reproductive systems.[70]

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[68] Robert J. Blend on and John T. Young, "The Public and the War on Illicit Drugs," *Journal of the American Medical Association*, vol. 279, no. 11 (Mar. 18, 1998), p. 831.

[69] Brief for the Drug Free America Foundation, Inc. et al. as Amici Curiae Supporting Petitioners at 13, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454). The amici curiae briefs filed in *Raich* contain a wealth of information and arguments on both sides of the medical marijuana debate. They are available online at [http://www.angeljustice.org].

[70] See, for example, "Exposing the Myth of Medical Marijuana," on the DEA website at [http://www.usdoj.gov/dea/ongoing/marijuanap.html].

Of course, FDA's 1985 approval of Marinol proves that the principal psychoactive ingredient of marijuana — THC — has therapeutic value. But that is not the issue in the medical marijuana debate. Botanical marijuana remains a plant substance, an herb, and its opponents say it cannot substitute for legitimate pharmaceuticals. Just because one molecule found in marijuana has become an approved medicine, they argue, does not make crude marijuana a medicine. The Drug Free America Foundation calls medical marijuana "a step backward to the times of potions and herbal remedies."[71]

The federal government's argument that marijuana has no medical value is straightforward. A drug, in order to meet the standard of the Controlled Substances Act as having a "currently accepted medical use in treatment in the United States," must meet a five-part test:

(1) The drug's chemistry must be known and reproducible,
(2) there must be adequate safety studies,
(3) there must be adequate and well-controlled studies proving efficacy,
(4) the drug must be accepted by qualified experts, and
(5) the scientific evidence must be widely available.[72]

According to the DEA, botanical marijuana meets none of these requirements. First, marijuana's chemistry is neither fully known nor reproducible. Second, adequate safety studies have not been done. Third, there are no adequate, well-controlled scientific studies proving marijuana is effective for any medical condition. Fourth, marijuana is not accepted by even a significant minority of experts qualified to evaluate drugs. Fifth, published scientific evidence concluding that marijuana is safe and effective for use in humans does not exist.[73]

The same DEA Final Order that set forth the five requirements for currently accepted medical use also outlined scientific evidence that would be considered irrelevant by the DEA in establishing currently accepted medical use. These include individual case reports, clinical data collected by practitioners, studies conducted by persons not qualified by scientific training and experience to evaluate the safety and effectiveness of the substance at issue, and studies or reports so lacking in detail as to preclude responsible scientific evaluation. Such information is inadequate for experts to conclude responsibly and fairly that marijuana is safe and effective for use as medicine.[74] The DEA and other federal drug control agencies can thereby disregard medical literature and opinion that claim to show the therapeutic value of marijuana because they do not meet the government's standards of proof.

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[71] Ibid at 25.

[72] This test was first formulated by the DEA in 1992 in response to a marijuana rescheduling petition. See U.S. Department of Justice, Drug Enforcement Administration, "Marijuana Scheduling Petition; Denial of Petition; Remand," 57 *Federal Register* 10499, Mar. 26, 1992, at 10506.

[73] Ibid., p. 10507.

[74] Ibid., pp. 10506-10507.

The official view of medical marijuana is complicated by the wider War on Drugs. It is difficult to disentangle the medical use of locally grown marijuana for personal use from the overall policy of marijuana prohibition, as the Supreme Court made clear in *Raich*. To make an exemption for medical marijuana, the Court decided, "would undermine the orderly enforcement of the entire regulatory scheme ... The notion that California law has surgically excised a discrete activity that is hermetically sealed off from the larger interstate marijuana market is a dubious proposition..."[75]

It remains the position of the federal government, then, that the Schedule I substance marijuana is harmful — not beneficial — to human health. Its use for any reason, including medicinal, should continue to be prohibited and punished. Despite possible signs of a more tolerant public attitude toward medical marijuana, its therapeutic benefits, if any, will continue to be officially unacknowledged and largely unrealized in the United States so long as this position prevails at the federal level.

Marijuana Effectively Treats the Symptoms of Some Diseases

> *[I]t cannot seriously be contested that there exists a small but significant class of individuals who suffer from painful chronic, degenerative, and terminal conditions, for whom marijuana provides uniquely effective relief.*
>
> — Brief of the Leukemia & Lymphoma Society, et al., 2004[76]

Proponents of medical marijuana point to a large body of reports and journal articles from around the world that support the therapeutic value of marijuana in treating a variety of disease-related problems, including:

- relieving nausea,
- increasing appetite,
- reducing muscle spasms and spasticity,
- relieving chronic pain,
- reducing intraocular pressure, and
- relieving anxiety.[77]

Given these properties, marijuana has been used successfully to treat the debilitating symptoms of cancer and cancer chemotherapy,[78] AIDS, multiple

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[75] *Gonzales* v. *Raich*, 125 S.Ct. 2195, at 2212 and 2213 (2005).

[76] Brief for the Leukemia & Lymphoma Society, et al. as Amici Curiae Supporting Respondents at 4, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[77] Ibid., at 1-2.

[78] A 1990 survey of oncologists found that 54% of those with an opinion on medical marijuana favored the controlled medical availability of marijuana and 44% had already broken the law by suggesting at least once that a patient obtain marijuana illegally. R. Doblin and M. Kleiman, "Marijuana as Antiemetic Medicine," *Journal of Clinical Oncology*, vol. 9 (1991), pp. 1314-1319.

sclerosis, epilepsy, glaucoma, anxiety, and other serious illnesses.[79] As opponents of medical marijuana assert, existing FDA-approved pharmaceuticals for these conditions are generally more effective than marijuana. Nevertheless, as the IOM Report acknowledged, the approved medicines do not work for everyone.[80] Many medical marijuana users report trying the drug only reluctantly and as a last resort after exhausting all other treatment modalities. A distinct subpopulation of patients now relies on whole cannabis for a degree of relief that FDA-approved synthetic drugs do not provide.

Medical cannabis proponents claim that single-cannabinoid, synthetic pharmaceuticals like Marinol are poor substitutes for the whole marijuana plant, which contains more than 400 known chemical compounds, including about 60 active cannabinoids in addition to THC. They say that scientists are a long way from knowing for sure which ones, singly or in combination, provide which therapeutic effects. Many patients have found that they benefit more from the whole plant than from any synthetically produced chemical derivative.[81] Furthermore, the natural plant can be grown easily and inexpensively, whereas Marinol and any other cannabis-based pharmaceuticals that might be developed in the future will likely be expensive — prohibitively so for some patients.[82]

In recognition of the therapeutic benefits of botanical marijuana products, various associations of health professionals have passed resolutions in support of medical cannabis. These include the American Public Health Association, the American Nurses Association, and the California Pharmacists Association. The *New England Journal of Medicine* has editorialized in favor of patient access to marijuana.[83] Other groups, such as the American Medical Association, are more cautious. Their position is that not enough is known about botanical marijuana and that more research is needed.[84]

The recent discovery of cannabinoid receptors in the human brain and immune system provides a biological explanation for the claimed effectiveness of marijuana in relieving multiple disease symptoms. The human body produces its own cannabis-like compounds, called endocannabinoids, that react with the body's cannabinoid receptors. Like the better known opiate receptors, the cannabinoid receptors in the

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[79] There is evidence that marijuana might also be useful in treating arthritis, migraine, menstrual cramps, alcohol and opiate addiction, and depression and other mood disorders.

[80] IOM Report, pp. 3-4: "The effects of cannabinoids on the symptoms studied are generally modest, and in most cases there are more effective medications. However, people vary in their responses to medications, and there will likely always be a subpopulation of patients who do not respond well to other medications."

[81] Brief for the Leukemia & Lymphoma Society et al. as Amici Curiae Supporting Respondents at 18, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[82] Marinol currently sells at retail for about $17 per pill.

[83] "Federal Foolishness and Marijuana," *New England Journal of Medicine*, vol. 336, no. 5 (Jan. 30, 1997), pp. 366-367.

[84] The website "Medical Marijuana ProCon" [http://www.medicalmarijuanaprocon.org] contains information on organizations that both support and oppose medical marijuana.

brain stem and spinal cord play a role in pain control. Cannabinoid receptors, which are abundant in various parts of the human brain, also play a role in controlling the vomiting reflex, appetite, emotional responses, motor skills, and memory formation. It is the presence of these natural, endogenous cannabinoids in the human nervous and immune systems that provides the basis for the therapeutic value of marijuana and that holds the key, some scientists believe, to many promising drugs of the future.[85]

The federal government's own IND Compassionate Access Program, which has provided government-grown medical marijuana to a select group of patients since 1978, provides important evidence that marijuana has medicinal value and can be used safely. A scientist and organizer of the California medical marijuana initiative, along with two medical-doctor colleagues, has written:

> Nothing reveals the contradictions in federal policy toward marijuana more clearly than the fact that there are still eight patients in the United States who receive a tin of marijuana 'joints' (cigarettes) every month from the federal government. ... These eight people can legally possess and use marijuana, at government expense and with government permission. Yet hundreds of thousands of other patients can be fined and jailed under federal law for doing exactly the same thing.[86]

Smoking Is an Improper Route of Drug Administration

> *Can you think of any other untested, home-made, mind-altering medicine that you self-dose, and that uses a burning carcinogen as a delivery vehicle?*
>
> — General Barry McCaffrey, U.S. Drug Czar, 1996-2000[87]

That medical marijuana is smoked is probably the biggest obstacle preventing its acceptance. Opponents of medical marijuana argue that smoking is a poor way to take a drug, that inhaling smoke is an unprecedented drug delivery system, even though many approved medications are marketed as inhalants. DEA Administrator Karen Tandy writes:

> The scientific and medical communities have determined that smoked marijuana is a health danger, not a cure. There is no medical evidence that smoking marijuana helps patients. In fact, the Food and Drug Administration (FDA) has approved no medications that are smoked, primarily because smoking is a poor way to deliver medicine. Morphine, for example has proven to be a

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[85] For a summary of the growing body of research on endocannabinoids, see Roger A. Nicoll and Bradley N. Alger, "The Brain's Own Marijuana," *Scientific American*, Dec. 2004, pp. 68-75, and Jean Marx, "Drugs Inspired by a Drug," *Science*, Jan. 20, 2006, pp. 322-325.

[86] Bill Zimmerman, *Is Marijuana the Right Medicine For You? A Factual Guide to Medical Uses of Marijuana* (Keats Publishing, New Canaan, CT: 1998), p. 25.

[87] Barry R. McCaffrey, "We're on a Perilous Path," *Newsweek*, Feb. 3, 1997, p. 27.

medically valuable drug, but the FDA does not endorse smoking opium or heroin.[88]

Medical marijuana opponents argue that chronic marijuana smoking is harmful to the lungs, the cardiovascular system, and possibly the immune and reproductive systems. These claims may be overstated to help preserve marijuana prohibition. For example, neither epidemiological nor aggregate clinical data show higher rates of lung cancer in people who smoke marijuana.[89] The other alleged harms also remain unproven. Even if smoking marijuana is proven harmful, however, the immediate benefits of smoked marijuana could still outweigh the potential long-term harms — especially for terminally ill patients.[90]

The therapeutic value of *smoked* marijuana is supported by existing research and experience. For example, the following statements appeared in the American Medical Association's "Council on Scientific Affairs Report 10 — Medicinal Marijuana,"[91] adopted by the AMA House of delegates on December 9, 1997:

- "Smoked marijuana was comparable to or more effective than oral THC [Marinol], and considerably more effective than prochlorperazine or other previous antiemetics in reducing nausea and emesis." (p. 10)

- "Anecdotal, survey, and clinical data support the view that smoked marijuana and oral THC provide symptomatic relief in some patients with spasticity associated with multiple sclerosis (MS) or trauma." (p. 13)

- "Smoked marijuana may benefit individual patients suffering from intermittent or chronic pain." (p. 15)

The IOM Report expressed concerns about smoking (p. 126): "Smoked marijuana is unlikely to be a safe medication for any chronic medical condition." Despite this concern, the IOM Report's authors were willing to recommend smoked marijuana under certain limited circumstances. For example, the report states (p. 154):

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[88] Karen Tandy, "Marijuana: The Myths Are Killing Us," *Police Chief Magazine*, Mar. 2005, available at [http://www.usdoj.gov/dea/pubs/pressrel/pr042605p.html].

[89] Lynn Zimmer and John P. Morgan, *Marijuana Myths Marijuana Facts* (New York: Lindesmith Center, 1997), p. 115.

[90] Medicines do not have to be completely safe to be approved. In fact, no medicine is completely safe; every drug has toxicity concerns. All pharmaceuticals have potentially harmful side effects, and it would be startling, indeed, if botanical marijuana were found to be an exception. The IOM Report states that "except for the harms associated with smoking, the adverse effects of marijuana use are within the range of effects tolerated for other medications." (p. 5)

[91] American Medical Association, Council on Scientific Affairs Report: *Medical Marijuana (A-01)*, June 2001. An unpaginated version of this document can be found on the Web at [http://www.mfiles.org/Marijuana/medicinal_use/b2_ama_csa_report.html].

> 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. It is possible that the harmful effects of smoking marijuana for a limited period of time might be outweighed by the antiemetic benefits of marijuana, at least for patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis. Such patients should be evaluated on a case-by-case basis and treated under close medical supervision.

The IOM Report makes another exception for terminal cancer patients (p. 159):

> Terminal cancer patients pose different issues. For those patients the medical harm associated with smoking is of little consequence. For terminal patients suffering debilitating pain or nausea and for whom all indicated medications have failed to provide relief, the medical benefits of smoked marijuana might outweigh the harm.

Smoking can actually be a preferred drug delivery system for patients whose nausea prevents them from taking anything orally. Such patients *need* to inhale their antiemitic drug. Other patients *prefer* inhaling because the drug is absorbed much more quickly through the lungs, so that the beneficial effects of the drug are felt almost at once. This rapid onset also gives patients more control over dosage. For a certain patient subpopulation, then, these advantages of inhalation may prevail over both edible marijuana preparations and pharmaceutical drugs in pill form, such as Marinol.

Moreover, medical marijuana advocates argue that there are ways to lessen the risks of smoking. Any potential problems associated with smoking, they argue, can be reduced by using higher potency marijuana, which means that less has to be inhaled to achieve the desired therapeutic effect. Furthermore, marijuana does not have to be smoked to be used as medicine. It can be cooked in various ways and eaten.[92] Like Marinol, however, taking marijuana orally can be difficult for patients suffering from nausea. Many patients are turning to vaporizers, which offer the benefits of smoking — rapid action, ease of dose titration — without having to inhale smoke. Vaporizers are devices that take advantage of the fact that cannabinoids vaporize at a lower temperature than that required for marijuana to burn. Vaporizers heat the plant matter enough for the cannabinoids to be released as vapor without having to burn the marijuana preparation. Patients can thereby inhale the beneficial cannabinoids without also having to inhale the potentially harmful by-products of marijuana combustion.[93]

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[92] Cannabis preparations are also used topically as oils and balms to soothe muscles, tendons, and joints.

[93] Several companies offer vaporizers for sale in the United States, but their marketing is complicated by marijuana prohibition and by laws prohibiting drug paraphernalia. The advantages of the vaporizer were brought to the attention of the IOM panel. The IOM Report, however, devoted only one sentence to such devices, despite its recommendation for research into safe delivery systems. The IOM Report said, "Vaporization devices that permit inhalation of plant cannabinoids without the carcinogenic combustion products found

(continued...)

Marijuana Should Be Rescheduled To Permit Medical Use

> *[T]he administrative law judge concludes that the provisions of the [Controlled Substances] Act permit and require the transfer of marijuana from Schedule I to Schedule II. The Judge realizes that strong emotions are aroused on both sides of any discussion concerning the use of marijuana. Nonetheless it is essential for this Agency [DEA], and its Administrator, calmly and dispassionately to review the evidence of record, correctly apply the law, and act accordingly.*
>
> — Francis L. Young, DEA Administrative Law Judge, 1988[94]

Proponents of medical marijuana believe its placement in Schedule I of the CSA was an error from the beginning. Cannabis is one of the safest therapeutically active substances known.[95] No one has ever died of an overdose.[96] Petitions to reschedule marijuana have been received by the federal government, and rejected, ever since the original passage of the Controlled Substances Act in 1970.

Rescheduling can be accomplished administratively or it can be done by an act of Congress. Administratively, the federal Department of Health and Human Services (HHS) could find that marijuana meets sufficient standards of safety and efficacy to warrant rescheduling. Even though THC, the most prevalent cannabinoid in marijuana, was administratively moved to Schedule III in 1999, no signs exist that botanical marijuana will similarly be rescheduled by federal agency ruling anytime soon.

An act of Congress to reschedule marijuana is only slightly less likely, although such legislation has been introduced in recent Congresses including the 109th.[97] The States' Rights to Medical Marijuana Act (H.R. 2087/Frank), which would move marijuana from Schedule I to Schedule II of the Controlled Substances Act, has seen no action beyond committee referral.[98]

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[93] (...continued)
in smoke are under development by several groups; such devices would also require regulatory review by the FDA." (p. 216)

[94] U.S. Dept. of Justice, Drug Enforcement Administration, "In the Matter of Marijuana Rescheduling Petition, Docket No. 86-22, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge," Francis L. Young, Administrative Law Judge, Sept. 6, 1988, p. 67. This opinion is online at [http://www.druglibrary.net/olsen/MEDICAL/YOUNG/young.html].

[95] Ibid., pp. 58-59.

[96] Ibid., p. 56.

[97] When Congress directly schedules a drug, as it did marijuana in 1970, it is not bound by the criteria in section 202(b) of the CSA (21 U.S.C. 812(b)).

[98] Congress could also follow the lead of some states that have a dual scheduling scheme for botanical marijuana whereby its recreational use is prohibited (Schedule I) but it is permitted when used for medicinal purposes (Schedules II or III). Congress could achieve the same effect by leaving marijuana in Schedule I but removing criminal penalties for the medical
(continued...)

Schedule II substances have a high potential for abuse and may lead to severe psychological or physical dependence but have a currently accepted medical use in treatment in the United States. Cocaine, methamphetamine, morphine, and methadone are classified as Schedule II substances. Many drug policy experts and laypersons alike believe that marijuana should also reside in Schedule II.

Others think marijuana should be properly classified as a Schedule III substance, along with THC and its synthetic version, Marinol. Substances in Schedule III have less potential for abuse than the drugs in Schedules I and II, their abuse may lead to moderate or low physical dependence or high psychological dependence, and they have a currently accepted medical use in treatment in the United States.

Rescheduling seems to be supported by public opinion. A nationwide Gallup Poll conducted in March 1999 found that 73% of American adults favor "making marijuana legally available for doctors to prescribe in order to reduce pain and suffering." An AARP poll of American adults age 45 and older conducted in mid-November 2004 found that 72% agree that adults should be allowed to legally use marijuana for medical purposes if recommended by a physician.[99]

Few Members of Congress, however, publicly support the rescheduling option. The States' Rights to Medical Marijuana Act (H.R. 2087/Frank), which would move marijuana from Schedule I to Schedule II of the Controlled Substances Act, currently has 37 cosponsors.

State Medical Marijuana Laws Increase Illicit Drug Use

> *The natural extension of this myth [that marijuana is good medicine] is that, if marijuana is medicine, it must also be safe for recreational use.*
> — Karen P. Tandy, DEA Administrator, 2005[100]

It is the position of the federal government that to permit the use of medical marijuana affords the drug a degree of legitimacy it does not deserve. America's youth are especially vulnerable, it is said, and state medical marijuana programs send

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[98] (...continued)
use of marijuana, commonly called *decriminalization*. Congress could also opt for *legalization* by removing marijuana from the CSA entirely and subjecting it to federal and state controls based on the tobacco or alcohol regulatory models or by devising a regulatory scheme unique to marijuana. None of these options seem likely given the current political climate in which both political parties support marijuana prohibition.

[99] These and other poll results can be consulted at [http://www.medicalmarijuanaprocon.org/pop/votes.htm]. This website states: "Because 100% of the voter initiatives and polls we located were favorable (50.01% or more pro) towards the medical use of marijuana, we contacted several organizations decidedly 'con' to medical marijuana — two of which were federal government agencies — and none knew of any voter initiatives or polls that were 'con' (50.01% or more con) to medical marijuana."

[100] Karen Tandy, "Marijuana: The Myths Are Killing Us," *Police Chief Magazine*, Mar. 2005, available at [http://www.usdoj.gov/dea/pubs/pressrel/pr042605p.html].

the wrong message to our youth, many of whom do not recognize the very real dangers of marijuana.

Studies show that the use of an illicit drug is inversely proportional to the perceived harm of that drug. That is, the more harmful a drug is perceived to be, the fewer the number of people who will try it.[101] Opponents of medical marijuana argue that "surveys show that perception of harm with respect to marijuana has been dropping off annually since the renewal of the drive to legalize marijuana as medicine, which began in the early 1990s when legalization advocates first gained a significant increase in funding and began planning the state ballot initiative drive to legalize crude marijuana as medicine."[102] They point to the 1999 National Household Survey on Drug Abuse (NHSDA), which "reveals that those states which have passed medical marijuana laws have among the highest levels of past-month marijuana use, of past-month other drug use, of drug addiction, and of drug and alcohol addiction."[103]

Indeed, all 11 states that have passed medical marijuana laws ranked above the national average in the percentage of persons 12 or older reporting past-month use of marijuana in 1999, as shown in **Table 3**. It is at least possible, however, that this analysis confuses cause with effect. It is logical to assume that the states with the highest prevalence of marijuana usage would be more likely to approve medical marijuana programs, because the populations of those states would be more knowledgeable of marijuana's effects and more tolerant of its use.

It is also the case that California, the state with the largest and longest-running medical marijuana program, ranked 34th in the percentage of persons age 12-17 reporting marijuana use in the past month during the period 2002-2003, as shown in **Table 2**. In fact, between 1999 and 2002-2003, of the 10 states with active medical marijuana programs, five states (AK, HI, ME, MT, VT) rose in the state rankings of past-month marijuana use by 12- to 17-year-olds and five states fell (CA, CO, NV, OR, WA).[104] Of the five states that had approved medical marijuana laws before 1999 (AK, AZ, CA, OR, WA), only Alaska's ranking rose between 1999 and 2002-2003, from 7th to 4th, with 11.08% of youth reporting past-month marijuana use in 2002-2003 compared with 10.4% in 1999. No clear patterns are apparent in the state-level data. Clearly, more important factors are at work in determining a state's

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[101] See, for example, J.G. Bachman et al., "Explaining Recent Increases in Students' Marijuana Use: Impacts of Perceived Risks and Disapproval, 1976 through 1996," *American Journal of Public Health*, vol. 88 (1998), pp. 887-892.

[102] Brief for the Drug Free America Foundation, Inc. et al. as Amici Curiae Supporting Petitioners at 26, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[103] Ibid., at 27. The 1999 NHSDA was the first to include state-level estimates for various measures of drug use. Unfortunately, comprehensive state-level data prior to 1999 are not available from other sources.

[104] Care should be taken in comparing NHSDA data for 1999 with NSDUH data for 2002 and after, due to changes in survey methodology made in 2002. The trend observations drawn here from these data should therefore be considered suggestive rather than definitive.

prevalence of recreational marijuana use than whether the state has a medical marijuana program.

The IOM Report found no evidence for the supposition that state medical marijuana programs lead to increased use of marijuana or other drugs (pp. 6-7):

> Finally, there is a broad social concern that sanctioning the medical use of marijuana might increase its use among the general population. At this point there are no convincing data to support this concern. The existing data are consistent with the idea that this would not be a problem if the medical use of marijuana were as closely regulated as other medications with abuse potential. ... [T]his question is beyond the issues normally considered for medical uses of drugs and should not be a factor in evaluating the therapeutic potential of marijuana or cannabinoids.

The IOM Report further states (p. 126):

> Even if there were evidence that the medical use of marijuana would decrease the perception that it can be a harmful substance, this is beyond the scope of laws regulating the approval of therapeutic drugs. Those laws concern scientific data related to the safety and efficacy of drugs for individual use; they do not address perceptions or beliefs of the general population.

The IOM Report also found (p. 102): "No evidence suggests that the use of opiates or cocaine for medical purposes has increased the perception that their illicit use is safe or acceptable." Doctors can prescribe cocaine, morphine, amphetamine, and methamphetamine, but this is not seen as weakening the War on Drugs. Why is doctors' recommending medical marijuana to their patients any different?

A June 2005 editorial in the *Washington Examiner* had a slightly different take on this issue:

> Studies show higher increases in overall marijuana use in states that have passed medical marijuana initiatives. The solution is to go after the estimated 15 million people who smoke marijuana for recreation, not the sick people these laws were intended to help.[105]

The so-called "Gateway Theory" of marijuana use is also cited to explain how medical marijuana will increase illicit drug use. With respect to the rationale behind the argument that marijuana serves as a "gateway" drug, the IOM Report offered the following (p. 6):

> 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.

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[105] "Congress Should Amend Drug Laws," *Washington Examiner* editorial, June 16, 2005.

Tables 1 and 2. States Ranked by Percentage of Youth Age 12-17 Reporting Past-Month Marijuana Use, 1999 and 2002-2003

Table 1. 1999

Rank	State	%
1	Delaware	13.9
2	Massachusetts	11.9
3	**Nevada**	11.6
4	**Montana**	11.4
5	Rhode Island	10.8
6	New Hampshire	10.7
7	**Alaska**	10.4
8	**Colorado**	10.3
9	Minnesota	9.9
9	**Washington**	9.9
11	**Oregon**	9.6
	District of Columbia	9.6
12	Illinois	9.2
12	New Mexico	9.2
14	Maryland	8.8
15	Indiana	8.7
16	Connecticut	8.6
17	**Vermont**	8.4
18	**Hawaii**	8.3
18	Wisconsin	8.3
20	Michigan	7.8
20	Wyoming	7.8
22	**California**	7.7
23	North Dakota	7.6
	National	7.4
24	South Carolina	7.4
27	**Arizona**	7.3
27	Arkansas	7.3
27	New Jersey	7.3
28	**Maine**	7.2
29	West Virginia	7.1
31	Ohio	6.9
31	South Dakota	6.9
33	New York	6.8
33	North Carolina	6.8
34	Mississippi	6.7
37	Kansas	6.6
37	Louisiana	6.6
37	Missouri	6.6
38	Georgia	6.4
40	Oklahoma	6.3
40	Pennsylvania	6.3
41	Florida	6.2
43	Nebraska	6.1
43	Utah	6.1
45	Idaho	5.9
45	Virginia	5.9
46	Texas	5.7
47	Alabama	5.6
48	Kentucky	5.3
50	Iowa	5.2
50	Tennessee	5.2

Source: SAMHSA, Office of Applied Studies, National Household Survey on Drug Abuse, 1999, Table 3B, at [http://www.oas.samhsa.gov/ NHSDA/99 StateTabs/tables2.htm]. Rankings calculated by CRS.

Table 2. 2002-2003

Rank	State	%
1	**Vermont**	13.32
2	**Montana**	12.07
3	New Hampshire	11.79
4	**Alaska**	11.08
5	Rhode Island	10.86
6	**Maine**	10.56
7	Massachusetts	10.53
8	New Mexico	10.35
9	**Hawaii**	10.23
10	**Colorado**	9.82
11	**Nevada**	9.58
12	South Dakota	9.57
13	Delaware	9.41
14	**Oregon**	9.31
15	Michigan	9.23
16	Connecticut	9.22
17	Nebraska	9.13
18	**Washington**	9.11
19	Minnesota	8.92
20	New York	8.76
21	Ohio	8.74
22	West Virginia	8.62
23	Florida	8.52
24	North Carolina	8.44
25	Virginia	8.43
26	Pennsylvania	8.18
27	Kentucky	8.16
28	Oklahoma	8.13
	National	8.03
29	Arkansas	7.97
30	Idaho	7.92
31	Maryland	7.87
32	**Arizona**	7.74
33	Wisconsin	7.71
34	**California**	7.66
35	Illinois	7.61
36	North Dakota	7.58
37	Missouri	7.43
	District of Columbia	7.43
38	Kansas	7.39
39	Indiana	7.37
40	New Jersey	7.33
41	South Carolina	7.25
42	Wyoming	7.14
43	Iowa	7.10
44	Louisiana	6.92
45	Georgia	6.87
46	Texas	6.38
47	Alabama	6.37
47	Tennessee	6.37
49	Mississippi	6.04
50	Utah	5.30

Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2002 and 2003, Table B.3, at [http://www.oas.samhsa.gov/2k3State/appB.htm#tabB.3]. Rankings calculated by CRS.

Tables 3 and 4. States Ranked by Percentage of Persons 12 or Older Reporting Past-Month Marijuana Use, 1999 and 2003-2004

Table 3. 1999

Rank	State	%
1	Maryland	7.9
2	**Colorado**	7.7
3	Massachusetts	7.5
4	Rhode Island	7.4
5	**Alaska**	7.1
	District of Columbia	7.1
6	**Washington**	6.8
7	**Oregon**	6.6
8	Delaware	6.5
8	New Mexico	6.5
10	**California**	6.0
11	**Montana**	5.9
11	New Hampshire	5.9
13	**Hawaii**	5.8
13	**Maine**	5.8
15	**Nevada**	5.6
15	Wyoming	5.6
17	**Vermont**	5.4
18	Michigan	5.3
18	Minnesota	5.3
20	**Arizona**	5.2
21	Wisconsin	5.1
22	Connecticut	5.0
22	Florida	5.0
22	New Jersey	5.0
25	New York	4.9
25	Utah	4.9
	National	4.9
27	Illinois	4.8
29	Missouri	4.7
29	North Carolina	4.7
30	Indiana	4.6
31	Pennsylvania	4.5
32	Ohio	4.3
34	Georgia	4.2
34	Idaho	4.2
35	South Dakota	4.1
36	Virginia	4.0
38	Nebraska	3.9
38	North Dakota	3.9
39	South Carolina	3.8
40	Kansas	3.7
43	Kentucky	3.6
43	Tennessee	3.6
43	West Virginia	3.6
47	Arkansas	3.5
47	Louisiana	3.5
47	Oklahoma	3.5
47	Texas	3.5
50	Alabama	3.3
50	Iowa	3.3
50	Mississippi	3.3

Source: SAMHSA, Office of Applied Studies, National Household Survey on Drug Abuse, 1999, Table 3B, at [http://www.oas.samhsa.gov/NHSDA/99StateTabs/tables2.htm]. Rankings calculated by CRS.

Table 4. 2003-2004

Rank	State	%
1	New Hampshire	10.23
2	**Alaska**	9.78
3	**Vermont**	9.77
	District of Columbia	9.60
4	Rhode Island	9.56
5	**Montana**	9.17
6	**Oregon**	8.88
7	**Colorado**	8.49
8	**Maine**	7.95
9	Massachusetts	7.80
10	**Nevada**	7.62
11	**Washington**	7.41
12	New Mexico	7.37
13	New York	7.34
14	Michigan	7.20
15	**Hawaii**	6.95
16	Connecticut	9.94
17	Delaware	6.89
18	Missouri	6.76
19	Florida	6.58
20	**California**	6.50
21	Ohio	6.49
22	Minnesota	6.37
	National	6.18
23	Indiana	6.12
24	Nebraska	5.97
25	Virginia	5.96
26	North Carolina	5.89
27	Louisiana	5.77
28	Maryland	5.73
29	**Arizona**	5.68
30	South Carolina	5.65
31	Pennsylvania	5.64
32	Arkansas	5.63
33	Kentucky	5.62
34	Illinois	5.60
35	Oklahoma	5.58
36	Wyoming	5.45
37	Wisconsin	5.40
38	North Dakota	5.35
39	South Dakota	5.24
40	West Virginia	5.12
41	Idaho	5.09
42	New Jersey	5.05
43	Georgia	4.93
44	Kansas	4.91
45	Iowa	4.90
46	Texas	4.79
47	Mississippi	4.64
48	Tennessee	4.59
49	Alabama	4.32
50	Utah	4.00

Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2002 and 2003, Table B.3, at [http://www.oas.samhsa.gov/2k3State/appB.htm#tabB.3]. Rankings calculated by CRS.

Medical Marijuana Undermines the War on Drugs

> *The DEA and its local and state counterparts routinely report that large-scale drug traffickers hide behind and invoke Proposition 215, even when there is no evidence of any medical claim. In fact, many large-scale marijuana cultivators and traffickers escape state prosecution because of bogus medical marijuana claims. Prosecutors are reluctant to charge these individuals because of the state of confusion that exists in California. Therefore, high-level traffickers posing as 'care-givers' are able to sell illegal drugs with impunity.*
> — "California Medical Marijuana Information," DEA Web page[106]

It is argued by many that state medical marijuana laws weaken the fight against drug abuse by making the work of police officers more difficult. This undermining of law enforcement can occur in at least three ways: by diverting medical marijuana into the recreational drug market, by causing state and local law enforcement priorities to diverge from federal priorities, and by complicating the job of law enforcement by forcing officers to distinguish medical users from recreational users.

Diversion. Marijuana grown for medical purposes, according to DEA and other federal drug control agencies, can be diverted into the larger, illegal marijuana market, thereby undermining law enforcement efforts to eliminate the marijuana market altogether. This point was emphasized by the Department of Justice (DOJ) in its prepublication review of a report by the Government Accountability Office (GAO) on medical marijuana. DOJ criticized the GAO draft report on the grounds that the "report did not mention that state medical marijuana laws are routinely abused to facilitate traditional illegal trafficking."[107]

GAO responded that in their interviews with federal officials regarding the impact of state medical marijuana laws on their law enforcement efforts, "none of the federal officials we spoke with provided information that abuse of medical marijuana laws was routinely occurring in any of the states, including California."[108] The government also failed to establish this in the *Raich* case. (It is of course possible that significant diversion is taking place yet remains undetected.)

Just as with many pharmaceuticals, some diversion is inevitable. Some would view this as an acceptable cost of implementing a medical marijuana program. Every public policy has its costs and benefits. Depriving seriously ill patients of their medical marijuana is seen by some as a small price to pay if doing so will help to protect America's youth from marijuana. Others balance the harms and benefits of medical marijuana in the opposite direction. Legal analyst Stuart Taylor Jr. recently

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[106] Available at [http://www.usdoj.gov/dea/ongoing/calimarijuanap.html].

[107] U.S. General Accounting Office, *Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes*, GAO-03-189, Nov. 2002, p. 36.

[108] Ibid., p. 37.

wrote, "As a matter of policy, Congress as well as the states should legalize medical marijuana, with strict regulatory controls. The proven benefits to some suffering patients outweigh the potential costs of marijuana being diverted to illicit uses."[109]

Changed State and Local Law Enforcement Priorities. Following the passage of the California and Arizona medical marijuana initiatives in 1996, federal officials expressed concern that the measures would seriously affect the federal government's drug enforcement effort because federal drug policies rely heavily on the state's enforcement of their own drug laws to achieve federal objectives. For instance, in hearings before the Senate Judiciary Committee, the head of the Drug Enforcement Administration stated:

> I have always felt ... that the federalization of crime is very difficult to carry out; that crime, just in essence, is for the most part a local problem and addressed very well locally, in my experience. We now have a situation where local law enforcement is unsure .... The numbers of investigations that you would talk about that might be presently being conducted by the [Arizona state police] at the gram level would be beyond our capacity to conduct those types of individual investigations without abandoning the major organized crime investigations.[110]

State medical marijuana laws arguably feed into the deprioritization movement, by which drug reform advocates seek to influence state and local law enforcement to give a low priority to the enforcement of marijuana laws. This movement to make simple marijuana possession the lowest law enforcement priority has made inroads in such cities as San Francisco, Seattle, and Oakland, but it extends beyond the medical marijuana states to college towns such as Ann Arbor, MI, Madison, WI, Columbia, MO, and Lawrence, KS.[111] Federal officials fear that jurisdictions that "opt out" of marijuana enforcement "will quickly become a haven for drug traffickers."[112]

Distinguishing Between Legal and Illegal Providers and Users. Police officers in medical marijuana states have complained about the difficulty of distinguishing between legitimate patients and recreational marijuana smokers. According to the DEA:

> Local and state law enforcement counterparts cannot distinguish between illegal marijuana grows and grows that qualify as medical

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[109] Stuart Taylor, Jr., "Liberal Drug Warriors! Conservative Pot-Coddlers!," *National Journal*, June 11, 2005, p. 1738.

[110] Testimony of Thomas A. Constantine in U.S. Congress, Senate Committee on the Judiciary, *Prescription for Addiction? The Arizona and California Medical Drug Use Initiatives*, hearing, 104th Cong., 2nd sess., Dec. 2, 1996 (Washington: GPO, 1997), pp. 42-43, 45.

[111] "Marijuana: Lawrence, Kansas, Ponders City Marijuana Ordinance — Impact of HEA Cited," available at [http://stopthedrugwar.org/chronicle/401/lawrence.shtml].

[112] Brief for U.S. Representative Mark E. Souder et al. as Amici Curiae Supporting Petitioners at 20, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

> exemptions. Many self-designated medical marijuana growers are, in fact, growing marijuana for illegal, "recreational" use.[113]

This reasoning is echoed in the *Raich* amici brief of Community Rights Counsel (p. 12):

> Creating an exception for medical use [of marijuana] could undermine enforcement efforts by imposing an often difficult burden on prosecutors of establishing the violator's subjective motivation and intent beyond a reasonable doubt. Given that marijuana used in response to medical ailments is not readily distinguishable from marijuana used for other reasons, Congress rationally concluded that the control of all use is necessary to address the national market for controlled substances.

Patients and caregivers, on the other hand, have complained that their marijuana that is lawful under state statute has been seized by police and not returned. In some cases, patients and caregivers have been unexpectedly arrested by state or local police officers. A November 2002 GAO report on medical marijuana stated that "Several law enforcement officials in California and Oregon cited the inconsistency between federal and state law as a significant problem, particularly regarding how seized marijuana is handled."[114]

The failure of state and local law enforcement officers to observe state medical marijuana laws has especially been a problem in California. The California Highway Patrol (CHP) has, on numerous occasions, arrested patients or confiscated their medical marijuana during routine traffic stops. "Although voters legalized medical marijuana in California nearly nine years ago," reports the *Los Angeles Times*, "police statewide have wrangled with activists over how to enforce the law."[115]

As a result of a lawsuit brought against the CHP by a patient advocacy group, CHP officers will no longer seize patients' marijuana as long as they possess no more than 8 ounces and can show a certified-user identification card or their physician's written recommendation. The CHP's new policy, announced in August 2005, will likely influence the behavior of other California law enforcement agencies.

The Committee on Drugs and the Law of the Bar of the City of New York concluded its 1997 report "Marijuana Should be Medically Available" with this statement: "The government can effectively differentiate medical marijuana and recreational marijuana, as it has done with cocaine. The image of the Federal

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[113] "California Medical Marijuana Information," available on DEA's website at [http://www.usdoj.gov/dea/ongoing/calimarijuanap.html].

[114] U.S. General Accounting Office, *Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes*, GAO-03-189, Nov. 2002, p. 64. GAO interviewed 37 law enforcement agencies and found that the majority indicated that "medical-marijuana laws had not greatly affected their law enforcement activities." (p. 4)

[115] Eric Bailey, "CHP Revises Policy on Pot Seizures," *Los Angeles Times* (national edition), Aug. 28, 2005, p. A12.

authorities suppressing a valuable medicine to maintain the rationale of the war on drugs only serves to discredit the government's effort."[116]

Patients Should Not Be Arrested for Using Medical Marijuana

> *Centuries of Anglo-American law stand against the imposition of criminal liability on individuals for pursuing their own lifesaving pain relief and treatment. ... Because the experience of pain can be so subversive of dignity — and even of the will to live — ethics and legal tradition recognize that individuals pursuing pain relief have special claims to non-interference.*
>
> — Brief of the Leukemia & Lymphoma Society, et al., 2004[117]

Medical marijuana advocates believe that seriously ill people should not be punished for acting in accordance with the opinion of their physicians in a bona fide attempt to relieve their suffering, especially when acting in accordance with state law. Even if marijuana were proven to be more harmful than now appears, prison for severely ill patients is believed to be a worse alternative. Patients have enough problems without having to fear the emotional and financial cost of arrest, legal fees, prosecution, and a possible prison sentence.

The American public appears to agree. The Institute of Medicine found that "public support for patient access to marijuana for medical use appears substantial; public opinion polls taken during 1997 and 1998 generally reported 60-70 percent of respondents in favor of allowing medical uses of marijuana."[118]

The federal penalty for possessing one marijuana cigarette — even for medical use — is up to one year in prison and up to a $100,000 fine,[119] and the penalty for growing a cannabis plant is up to five years and up to a $250,000 fine.[120] That patients are willing to risk these severe penalties to obtain the relief that marijuana provides appears to present strong evidence for the substance's therapeutic effectiveness.

Although the Supreme Court ruled differently in *Raich*, the argument persists that medical marijuana providers and patients are engaging in a class of activity totally different from those persons trafficking in marijuana for recreational use and that patients should not be arrested for using medical marijuana in accordance with the laws of the states in which they reside.

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[116] Committee on Drugs and the Law, "Marijuana Should be Medically Available," *Record of the Association of the Bar of the City of New York*, vol. 52, no. 2 (Mar. 1997), p. 238.

[117] Brief for the Leukemia & Lymphoma Society et al. as Amici Curiae Supporting Respondents at 1,2, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[118] IOM Report, p. 18.

[119] 21 U.S.C. §844 and 18 U.S.C. §3571. 21 U.S.C. §844 also calls for a minimum fine of $1,000, and 21 U.S.C. §844a permits a civil penalty of up to $10,000.

[120] 21 U.S.C. §841(b)(1)(D).

With its position affirmed by *Raich*, however, DEA continues to investigate — and sometimes raid and shut down — medical marijuana distribution operations in California and other medical marijuana states. DEA's position is that:

> [F]ederal law does not distinguish between crimes involving marijuana for claimed "medical" purposes and crimes involving marijuana for any other purpose. DEA likewise does not so distinguish in carrying out its duty to enforce the CSA and investigate possible violations of the Act. Rather, consistent with the agency's mandate, DEA focuses on large-scale trafficking organizations and other criminal enterprises that warrant federal scrutiny. If investigating CSA violations in this manner leads the agency to encounter persons engaged in criminal activities involving marijuana, DEA does not alter its approach if such persons claim at some point their crimes are "medically" justified. To do so would be to give legal effect to an excuse considered by the text of federal law and the United States Supreme Court to be of no moment.[121]

Because nearly all arrests and prosecutions for marijuana possession are handled by state and local law enforcement officers, patients and caregivers in the medical marijuana states can, as a practical matter, possess medical marijuana without fear of arrest and imprisonment. DEA enforcement actions against medical marijuana dispensaries — as occurred in San Francisco shortly after the *Raich* decision was announced[122] — can, however, make it more difficult for patients to obtain the drug. The situation that Grinspoon and Bakalar described in 1995 in the *Journal of the American Medical Association* persists a decade later: "At present, the greatest danger in medical use of marihuana is its illegality, which imposes much anxiety and expense on suffering people, forces them to bargain with illicit drug dealers, and exposes them to the threat of criminal prosecution."[123]

The States Should Be Allowed to Experiment

> *Doctors, not the federal government, know what's best for their patients. If a state decides to allow doctors to recommend proven treatments for their patients, then the federal government has no rightful place in the doctor's office.*
>
> — Attorney Randy Barnett, 2004[124]

Three States — California, Maryland, and Washington — filed an amici curiae brief supporting the right of states to institute medical marijuana programs.

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[121] Communication from DEA Congressional Affairs to author dated Sept. 27, 2005.

[122] Stacy Finz, "19 Named in Medicinal Pot Indictment, More than 9,300 Plants Were Seized in Raids," *San Francisco Chronicle*, June 24, 2005, p. B4.

[123] Lester Grinspoon and James B. Bakalar, "Marihuana as Medicine: A Plea for Reconsideration," *Journal of the American Medical Association*, vol. 273, no. 23 (June 21, 1995), p. 1876.

[124] Angel Wings Patient OutReach press release, Nov. 29, 2004. Barnett represented Raich et al. in Supreme Court oral argument on this date.

Their brief argued, "In our federal system States often serve as democracy's laboratories, trying out new, or innovative solutions to society's ills."[125]

The *Raich* case shows that the federal government has zero tolerance for state medical marijuana programs. The Bush Administration appealed the decision of the Ninth Circuit Court of Appeals to the Supreme Court, which reversed the Ninth Circuit and upheld the federal position against the states. Framed as a Commerce Clause issue, the case became a battle for states' rights against the federal government.

The *Raich* case created unusual political alliances. Three southern states that are strongly opposed to any marijuana use, medical or otherwise — Alabama, Louisiana, and Mississippi — filed an amici curiae brief supporting California's medical marijuana users on the grounds of states' rights. Their brief argued

> As Justice Brandeis famously remarked, "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[126] Whether California and the other compassionate-use States are "courageous — or instead profoundly misguided — is not the point. The point is that, as a sovereign member of the federal union, California is entitled to make for itself the tough policy choices that affect its citizens.[127]

States' rights advocates argue that authority to define criminal law and the power to make and enforce laws protecting the health, safety, welfare, and morals reside at the state level and that a state has the right to set these policies free of congressional interference.

For Justice O'Connor, the *Raich* case exemplified "the role of States as laboratories."[128] She wrote in her dissenting opinion:

> If I were a California citizen, I would not have voted for the medical marijuana ballot initiative; if I were a California legislator I would not have supported the Compassionate Use Act. But whatever the wisdom of California's experiment with medical marijuana, the federalism principles that have driven our Commerce Clause cases require that room for experiment be protected in this case.[129]

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[125] Brief for the States of California, Maryland, and Washington et al. as Amici Curiae Supporting Respondents at 3, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[126] *New State Ice Co.* v. *Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

[127] Brief for the States of Alabama, Louisiana, and Mississippi et al. as Amici Curiae Supporting Respondents at 3, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[128] *Gonzales* v. *Raich*, 125 S.Ct. 2195, 2220 (2005) (O'Connor, J., dissenting).

[129] Ibid. at 2229.

Medical Marijuana Laws Harm the Drug Approval Process

> *The current efforts to gain legal status of marijuana through ballot initiatives seriously threaten the Food and Drug Administration statutorily authorized process of proving safety and efficacy.*
> — Brief of the Drug Free America Foundation, et al., 2004[130]

Although the individual states regulate the practice of medicine, the federal government has taken primary responsibility for the regulation of medical products, especially those containing controlled substances. Pharmaceutical drugs must be approved for use in the United States by the Food and Drug Administration, an agency of the Department of Health and Human Services. The Federal Food, Drug, and Cosmetics Act gives HHS and FDA the responsibility for determining that drugs are safe and effective, a requirement that all medicines must meet before they can enter interstate commerce and be made available for general medical use.[131] Clinical evaluation is required regardless of whether the drug is synthetically produced or originates from a natural botanical or animal source.

Opponents of medical marijuana say that the FDA's drug approval process should not be circumvented. To permit states to decide which medical products can be made available for therapeutic use, they say, would undercut this regulatory system. State medical marijuana initiatives are seen as inconsistent with the federal government's responsibility to protect the public from unsafe, ineffective drugs.

The Bush Administration argued in its brief in the *Raich* case that "excepting drug activity for personal use or free distribution from the sweep of [federal drug laws] would discourage the consumption of lawful controlled substances and would undermine Congress's intent to regulate the drug market comprehensively to protect public health and safety."[132]

Three prominent drug abuse experts argued in their amici brief:

> This action by the state of California did not create a "novel social and economic experiment," but rather chaos in the scientific and medical communities. Furthermore, under Court of Appeals ruling, such informal State systems could be replicated, and even expanded, in a manner that puts at risk the critical protections so carefully crafted under the national food and drug legislation of the 20th century.[133]

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[130] Brief for the Drug Free America Foundation, Inc. et al. as Amici Curiae Supporting Petitioners at 12, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[131] 21 U.S.C. §351-360

[132] Brief for Petitioners at 11, Gonzales v. Raich, 125 S.Ct. 2195 (2002) (No. 03-1454).

[133] Brief for Robert L. DuPont, M.D. et al. as Amici Curiae Supporting Petitioners at 19, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

The Food and Drug Administration itself has stated that

> FDA is the sole Federal agency that approves drug products as safe and effective for particular indications, and efforts that seek to bypass the FDA drug approval process would not serve the interests of public health. FDA has not approved marijuana for any indication. Only the disciplined, systematic, scientific conduct of clinical trials can establish whether there is any medicinal value to marijuana, smoked or otherwise.[134]

The Drug Free America *Raich* brief elaborates further (pp. 12-13):

> The ballot initiative-led laws create an atmosphere of medicine by popular vote, rather than the rigorous scientific and medical process that all medicines must undergo. Before the development of modern pharmaceutical science, the field of medicine was fraught with potions and herbal remedies. Many of those were absolutely useless, or conversely were harmful to unsuspecting subjects. Thus evolved our current Food and Drug Administration and drug scheduling processes, which Congress has authorized in order to create a uniform and reliable system of drug approval and regulation. This system is being intentionally undermined by the legalization proponents through use of medical marijuana initiatives.

The organizers of the medical marijuana state initiatives deny that it was their intent to undermine the federal drug approval process. Rather, in their view, it became necessary for them to *bypass* the FDA and go to the states because of the federal government's resistance to marijuana research requests and rescheduling petitions.

As for the charge that politics should not play a role in the drug approval and controlled substance scheduling processes, medical marijuana supporters point out that marijuana's original listing as a Schedule I substance in 1970 was itself a political act on the part of Congress.

Scientists on both sides of the issue say more research needs to be done, yet some researchers charge that the federal government has all but shut down marijuana clinical trials for reasons based on politics and ideology rather than science.[135]

In any case, as the IOM Report pointed out, "although a drug is normally approved for medical use only on proof of its 'safety and efficacy,' patients with life-threatening conditions are sometimes (under protocols for 'compassionate use') allowed access to unapproved drugs whose benefits and risks are uncertain."[136] This was the case with the FDA's IND Compassionate Access Program under which a

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[134] FDA, "FDA Statement Re: Marijuana Legislation," provided to Rep. Mark E. Souder on July 7, 2004, available at [http://reform.house.gov/UploadedFiles/Medical%20Marijuana%20Statement.pdf].

[135] See, for example, Lila Guterman, "The Dope on Medical Marijuana, *Chronicle of Higher Education*, June 2, 2000, p. A21.

[136] IOM Report, p. 14.

limited number of patients are provided government-grown medical marijuana to treat their serious medical conditions.

Some observers believe the pharmaceutical industry and some politicians oppose medical marijuana to protect pharmaceutical industry profits. Because the whole marijuana plant cannot be patented, research efforts must be focused on the development of *synthetic* cannabinoids such as Marinol. But even if additional cannabinoid drugs are developed and marketed, some believe that doctors and patients should still not be criminalized for recommending and using the natural substance.

The *New England Journal of Medicine* has editorialized that

> [A] federal policy that prohibits physicians from alleviating suffering by prescribing marijuana for seriously ill patients is misguided, heavy-handed, and inhumane. Marijuana may have long-term adverse effects and its use may presage serious addictions, but neither long-term side effects nor addiction is a relevant issue in such patients. It is also hypocritical to forbid physicians to prescribe marijuana while permitting them to use morphine and meperidine to relieve extreme dyspnea and pain. With both of these drugs the difference between the dose that relieves symptoms and the dose that hastens death is very narrow; by contrast, there is no risk of death from smoking marijuana. To demand evidence of therapeutic efficacy is equally hypocritical. The noxious sensations that patients experience are extremely difficult to quantify in controlled experiments. What really counts for a therapy with this kind of safety margin is whether a seriously ill patient feels relief as a result of the intervention, not whether a controlled trial "proves" its efficacy.[137]

Some observers suggest that until the federal government relents and becomes more hospitable to marijuana research proposals and more willing to consider moving marijuana to a less restrictive schedule, the medical marijuana issue will continue to be fought at state and local levels of governance. As one patient advocate has stated, "As the months tick away, it will become more and more obvious that we need to continue changing state laws until the federal government has no choice but to change its inhumane medicinal marijuana laws."[138]

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[137] "Federal Foolishness and Marijuana," *New England Journal of Medicine*, vol. 336, no. 5 (Jan. 30, 1997), p. 366.

[138] Chuck Thomas, Marijuana Policy Project press release dated Apr. 20, 1999, available at [http://www.mpp.org/releases/nr042099.html].

The Medical Marijuana Movement Is Politically Inspired

> *Advocates have tried to legalize marijuana in one form or another for three decades, and the "medical marijuana" concept is a Trojan Horse tactic towards the goal of legalization.*
>
> — Brief of the Drug Free America Foundation, et al., 2004[139]

Medical marijuana opponents see the movement to promote the use of medical marijuana as a cynical attempt to subvert the Controlled Substances Act and legalize the recreational use of marijuana for all. They see it as a devious tactic in the more than 30-year effort by marijuana proponents to bring an end to marijuana prohibition in the United States and elsewhere.

They point out that between 1972 and 1978, the National Organization for the Reform of Marijuana Laws (NORML) successfully lobbied 11 state legislatures to decriminalize the drug, reducing penalties for possession in most cases to that of a traffic ticket. Also, in 1972, NORML began the first of several unsuccessful attempts to petition DEA to reschedule marijuana from Schedule I to Schedule II on the grounds that crude marijuana had use in medicine.[140]

Later, beginning with California in 1996, "drug legalizers" pushed successfully for passage of medical marijuana voter initiatives in several states, prompting then-Drug Czar Barry McCaffrey, writing in *Newsweek*, to warn that "We're on a Perilous Path." "I think it's clear," he wrote, "that a lot of the people arguing for the California proposition and others like it are pushing the legalization of drugs, plain and simple."[141]

Is it cynical or smart for NORML and other drug reform organizations to simultaneously pursue the separate goals of marijuana decriminalization for all, on the one hand, and marijuana rescheduling for the seriously ill, on the other? It is not unusual for political activists tactically to press for — and accept — half-measures in pursuit of a larger strategic goal. Pro-life activists work to prohibit partial-birth abortions and to pass parental notification laws. Gay rights activists seek limited domestic partner benefits as a stepping stone to full marriage equality. Thus is the tactic used on both sides of the cultural divide in America, to the alarm of those opposed.

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[139] Brief for the Drug Free America Foundation, Inc. et al. as Amici Curiae Supporting Petitioners at 9, Gonzales v. Raich, 125 S.Ct. 2195 (2005) (No. 03-1454).

[140] For example, the amici curiae brief of the Drug Free America Foundation et al. reveals this history to discredit the medical marijuana movement (pp. 9-11). Actually, NORML and some other drug reform organizations are open in acknowledging that they support patient access to marijuana as a first step toward decriminalizing or legalizing marijuana for use by adults in general. See, for example, Joab Jackson, "Medical Marijuana: From the Fringe to the Forefront," *Baltimore City Paper*, Mar. 28, 2002, [http://www.alternet.org/drugreporter/12714].

[141] Barry R. McCaffrey, "We're on a Perilous Path," *Newsweek*, Feb. 3, 1997, p. 27.

It is certainly true that the medical cannabis movement is an offshoot of the marijuana legalization movement. Many individuals and organizations that support medical marijuana also support a broader program of drug law reform. It is also true, however, that many health professionals and other individuals who advocate medical access to marijuana do not support any other changes in U.S. drug control policy. In the same way, not everyone in favor of parental notification laws supports banning abortions for everyone. And not every supporter of domestic partner benefits believes in same-sex marriage.

In these hot-button issues, ideology and emotion often rule. Marijuana users in general, and medical marijuana users in particular, are demonized by some elements of American society. The ideology of the "Drug Warriors" intrudes on the science of medical marijuana, as pointed out by Grinspoon and Bakalar in the *Journal of the American Medical Association*:

> Advocates of medical use of marihuana are sometimes charged with using medicine as a wedge to open a way for "recreational" use. The accusation is false as applied to its target, but expresses in a distorted form a truth about some opponents of medical marihuana: they will not admit that it can be a safe and effective medicine largely because they are stubbornly committed to exaggerating its dangers when used for nonmedical purposes.[142]

The authors of the IOM Report were aware of the possibility that larger ideological positions could influence one's stand on the specific issue of patient access to medical marijuana when they wrote that

> [I]t is not relevant to scientific validity whether an argument is put forth by someone who believes that all marijuana use should be legal or by someone who believes that any marijuana use is highly damaging to individual users and to society as a whole. (p. 14)

In other words, it is widely believed that science should rule when it comes to medical issues. Both sides in the medical marijuana debate claim adherence to this principle. The House Government Reform Committee's April 2004 hearing on medical marijuana was titled "Marijuana and Medicine: The Need for a Science-Based Approach." And medical marijuana advocates plead with the federal government to permit scientific research on medical marijuana to proceed.

Rescheduling marijuana and making it available for medical use and research is not necessarily a step toward legalizing its recreational use. Such a move would put it on a par with cocaine, methamphetamine, morphine, and methadone, all of which are Schedule II substances that are not close to becoming legal for recreational use. Proponents of medical marijuana ask why marijuana should be considered differently than these other scheduled substances.

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[142] Lester Grinspoon and James B. Bakalar, "Marihuana as Medicine: A Plea for Reconsideration," *Journal of the American Medical Association*, vol. 273, no. 23 (June 21, 1995), p. 1876.

It is also arguable that marijuana should indeed be considered differently than cocaine, methamphetamine, morphine, and methadone. Scientists note that marijuana is less harmful and less addictive than these Schedule II substances. Acceptance of medical marijuana could in fact pave the way for its more generalized use. Ethan Nadelmann, head of the Drug Policy Alliance, has observed, "As medical marijuana becomes more regulated and institutionalized in the West, that may provide a model for how we ultimately make marijuana legal for all adults."[143] Medical marijuana opponents have trumpeted his candor as proof of the hypocrisy of those on the other side of the issue. Others note, however, that his comment may be less hypocritical than astute

[143] Quoted in MSNBC.com story, "Western States Back Medical Marijuana," Nov. 4, 2004, available at [http://msnbc.msn.com/id/6406453].