



# THE HISTORY OF MEDICAL MARIJUANA IN THE U.S. AND ITS IMPLICATIONS FOR THE CURRENT LEGAL IMPEDIMENTS TO THE MEDICAL USE OF MARIJUANA IN THE STATES

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**THE HISTORY OF MEDICAL MARIJUANA IN THE  
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The twenty-five year controversy surrounding the illegal status of medicinal marijuana, which remains unresolved, provides an excellent study of the relationship between the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), and the courts. During this historical chronology the agencies attempt to fulfill their shared duties under the Controlled Substances Act of 1970 (CSA), while the judiciary seeks to enforce principles of administrative law and the U.S. Constitution. Added to the difficulty of defining the boundary of each entity's power is the notion that different standards govern the way each determines what is in the best interest of the American people they serve. The following is a discussion of how legal principles and scientific evidence have been, and are working together toward a resolution of the medical marijuana debate.

Facts regarding the positives and negatives of marijuana inhalation, and an historical account of the pre-1994 debates, lends pertinent background information for understanding the recent actions of medicinal marijuana advocates.

Proponents (such as the National Organization for the Reform of Marijuana Laws (NORML) and the Marijuana Policy Project Foundation) and the United States Government, as the major opponent agree, that marijuana has provided

relief to persons with cancer, AIDS wasting syndrome, and glaucoma.<sup>1</sup> Where cancer is concerned marijuana has been used to alleviate symptoms of nausea and excessive vomiting, while also enhancing the appetite which assists in the maintaining of a stable body weight.<sup>2</sup> It has provided relief of similar symptoms in those suffering from the AIDS wasting syndrome.<sup>3</sup>

Studies from the early 1970s demonstrate that marijuana's affect on glaucoma, characterized by intense pressure within the eye which damages the optic nerve, is to decrease the intraocular pressure in the eye.<sup>4</sup> Proponents also allege that it lessens tremors and the loss of muscle coordination in those with multiple sclerosis, helps relieve the convulsions of persons with epilepsy, and dissipates the pain and muscle spasms of those who suffer from paraplegia and quadriplegia.<sup>5</sup>

Marijuana advocates assert that the cigarette (illegal in the U.S.) has several advantages over the FDA approved synthetic form of the drug delta-9-tetrahydrocannabinol (THC), marijuana's most active ingredient.<sup>6</sup> THC is

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<sup>1</sup>Department of Health & Human Services, Public Health Services, National Cancer Institute Fact Sheet on the Therapeutic Use of Marijuana for Chemotherapy-Induced Nausea and Vomiting; National Eye Institute Fact Sheet on the Therapeutic Use of Marijuana for Glaucoma; National Institute On Allergy and Infectious Diseases Fact Sheet on the Therapeutic Use of Marijuana for Patients With HIV-Wasting Syndrome; provided by Dr. Judy Lawrence Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Agency.

<sup>2</sup>National Cancer Institute Fact Sheet.

<sup>3</sup>National Institute on Allergy and Infectious Diseases Fact Sheet.

<sup>4</sup>National Eye Institute Fact Sheet.

<sup>5</sup>Plaintiff's Opening Brief at 11-14, Dr. Marcus Conant v. Barry R. McCaffrey et al, U.S. District Court for the Northern District of California, (January 1, 1997).

<sup>6</sup>Id. at 11-12.

available in pill form by the brand name Marinol.<sup>7</sup> For cancer patients, inhaled marijuana is deemed better because oral medication often cannot be maintained in the system until dissolved.<sup>8</sup> In the late 1980s experts who testified in favor of legalization before Administrative Law Judge Francis L. Young asserted that cigarettes provide an instant effect, wherein activation of the pill requires hours.<sup>9</sup> Thus because one can feel the effect while smoking, a patient is better able to control dosage through a cigarette.<sup>10</sup> Proponents have also asserted that the unknown chemicals in the marijuana plant combine with the THC to improve the therapeutic effect.<sup>11</sup> Furthermore, it is argued that the plant is far cheaper than the other drugs favored by marijuana opponents.<sup>12</sup>

Clinical research by doctors Steve Sallen and Norman Zinberg supports the contention that smoked marijuana is preferable to Marinol.<sup>13</sup> A study by Rick Doblin and Mark Kleiman, drug policy researchers at Harvard's Kennedy School of Government, demonstrates that a significant percentage of oncologists belonging to the American Society of Clinical Oncology believe the same.<sup>14</sup> In fact they received responses from approximately ten percent of America's on-

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<sup>7</sup>*Id.* at 11.

<sup>8</sup>Gregg A. Bilz, *The Medical Use of Marijuana: The Politics of Medicine*, 13 Hamline Journal of Public Law & Policy 117, 127 (Spring 1992).

<sup>9</sup>*Id.* at 126-127.

<sup>10</sup>*Id.*

<sup>11</sup>*Id.* at 127.

<sup>12</sup>Interview with Rick Doblin, Director, Multidisciplinary Association for Psychedelic Studies (MAPS), January 13, 1997.

<sup>13</sup>S.E. Sallen et al., *Antiemetic Effect of Delta-9-Tetrahydrocannabinol in Patients Receiving Cancer Chemotherapy*, 293 New England Journal of Medicine, 795 (1975).

<sup>14</sup>Gregg A. Bilz, *The Medical Use of Marijuana: The Politics of Medicine*, 13 Hamline Journal of Public Law & Policy 117, 130 (Spring 1992).

cologists. Forty-eight percent of these acknowledged that they would prescribe marijuana cigarettes if it were legal, and forty-four of the oncologists admitted that they had already recommended the illegal form of the drug.<sup>15</sup> Based upon this information proponents conclude that the illegality of plant marijuana hinders the physician's ability to communicate and practice medicine.<sup>16</sup>

The U.S. Government purports a series of counter arguments. A fact sheet published by the National Institutes of Health (NIH) and the Department of Health and Human Services (HHS) asserts that National Cancer Institute scientists disfavor the THC pill when compared with other antiemetics such as ondansetron (brand name Zofran) used alone or together with dexamethasone (a steroid hormone), or metoclopramide (brand name Reglan) together with diphenhydramine and dexamethasone.<sup>17</sup> The article also asserts that over 400 potential carcinogens are found in marijuana smoke, and research has demonstrated that tobacco smoking HIV positive individuals have progressed to AIDS quicker than non-smokers.<sup>18</sup> Also, the cigarettes sold on the black market may house disease-causing agents which would be harmful to patients with weakening immune systems.<sup>19</sup>

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<sup>15</sup>

Id.

<sup>16</sup>Plaintiffs' Brief at 17-18, Conant (1997).

<sup>17</sup>National Cancer Institute Fact Sheet.

<sup>18</sup>Id.

<sup>19</sup>Id.

Currently there are 24 FDA approved drugs for glaucoma.<sup>20</sup> The National Eye Institute admits that side effects may include headaches and respiratory problems, and agrees that a drug may lose its effectiveness over time.<sup>21</sup> However the variety of drugs provides a host of alternative treatments which have been extended to include laser surgery and incisional surgery.<sup>22</sup> The Eye Institute's research of other potential glaucoma drugs has proven that merely decreasing intraocular pressure, an effect of smoked marijuana, is not guaranteed to eliminate the disease.<sup>23</sup> This HHS-Eye Institute study claims that evidence supporting marijuana's use for the spasms and pain which accompany multiple sclerosis are anecdotal rather than scientific in nature.<sup>24</sup> The report makes no mention of epilepsy, paraplegia, or quadriplegia, but a fact sheet produced by NIH and the National Institute on Drug Abuse (NIDA) asserts that marijuana use may cause heart rate alteration, intense anxiety, or paranoia.<sup>25</sup> Additional information critical to the debate, and stipulated by both sides, is that clinical trials of the type that could lead to marijuana's New Drug Application (NDA) status are not yet complete.<sup>26</sup> Research at this level would enable scientists to weigh the positive and negative components of marijuana therapy and determine, through current technology, the extent to which the harmful affects of marijuana could be eliminated, if at all.

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<sup>20</sup>National Eye Institute Fact Sheet.

<sup>21</sup>Id.

<sup>22</sup>Id.

<sup>23</sup>Id.

<sup>24</sup>National Institute of Neurological Disorders and Stroke Fact Sheet.

<sup>25</sup>*The Facts About Marijuana*, A Fact Sheet Prepared by NIDA and NIH; provided by Dr. Judith Lawrence, Drug Enforcement Agency.

<sup>26</sup>*Q's and A's on Medical Marijuana Policy*, HHS; provided by Dr. Judith Lawrence, Drug Enforcement Agency.

Presently there is no federally funded medicinal marijuana research.<sup>27</sup> Dr. Donald Abrams (Chairman, Community Consortium, Assistant Director AIDS Program San Francisco General Hospital, and Professor of Clinical Medicine at the University of California San Francisco), a marijuana proponent eager to conduct privately funded research, has been unable to secure a supply of marijuana from NIDA (the only legal source of the drug in the U.S.) despite FDA approval of his protocol under 21 U.S.C. § 823(f).<sup>28</sup> This standstill has been a reality since 1994 and became one of the catalysts which sparked the California voter referendum that legalized medicinal marijuana at the state level.

A study of historical developments will enhance one's understanding of a more detailed account of the current issues. Marijuana was declared a prohibited substance in the Marijuana Tax Act of 1937.<sup>29</sup> In the 1970 Controlled Substances Act (CSA) it was classified as Schedule I. 21 U.S.C. § 812(b)(1) defines such drugs as follows:

- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
- (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.<sup>30</sup>

The characteristics of Schedule II drugs include:

- (A) The drug or other substance has a high potential for abuse.

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<sup>27</sup>Id.

<sup>28</sup>Dr. Donald Abrams, Letter to Alan Leshner Ph.D., Director of NIDA, <http://www.maps.org/mmj/abrams.html> (visited Jan. 12, 1997).

<sup>29</sup>Bilz, *Medical Use of Marijuana*, 13 Hamline Journal of Public Law & Policy 117, 118 (Spring 1992).

<sup>30</sup>21 U.S.C. § 812(b)(1).

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

© Abuse of the drug or other substances may lead to severe psychological or physical dependence.<sup>31</sup>

Since Schedule I drugs have no accepted medical use and are deemed unsafe even with doctor supervision, domestic distribution is banned.<sup>32</sup> Schedule II drugs, however, do have medical value and may be prescribed. Thus medicinal marijuana proponents have always battled for a change of schedule.

21 U.S.C.A. § 811(a)-(c) enables the Attorney General, the Secretary of HHS, or any interested party to initiate a rescheduling. Regardless of who requests the change, in addition to complying with the rulemaking procedures of the Administrative Procedure Act, the DEA Administrator (to whom the Attorney General has delegated her powers under the CSA<sup>33</sup>) must request from the Secretary a scientific and medical evaluation, and her recommendations as to whether the substance should be rescheduled.<sup>34</sup> These recommendations are binding on the DEA insofar as they address medical and scientific information. If the Secretary recommends that a substance not be controlled, the statute does not permit the DEA to control it. Aside from this power limitation, provided DEA has considered the HHS recommendations, the DEA has freedom to determine whether the drug should be rescheduled.<sup>35</sup>

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<sup>31</sup>21 U.S.C. § 812(b)(2).

<sup>32</sup> Peter Barton Hutt & Richard A. Merrill, Food and Drug Law 536 (1991).

<sup>33</sup>28 C.F.R. § 0.100(b).

<sup>34</sup> 21 U.S.C.A. § 811(b)

<sup>35</sup> Id.

Litigation between the National Organization for the Reform of Marijuana Laws (NORML) and the DEA from 1974 to 1994 demonstrates that the agencies governed by the CSA have, in some instances, evaded statutory requirements. It also is evidence of the expected agency partiality to Presidential opinion. During these years it was the judiciary which insisted upon compliance with the letter of the law.

Immediately prior to the litigation era NORML found an ally in the government's own National Commission on Marihuana. In 1972 the Commission unleashed its report entitled, *Marihuana: A Signal of Misunderstanding*.<sup>36</sup> Its recommended that marijuana be thoroughly researched for its potential medical uses, that states which still recognized marijuana as a narcotic should change their laws, and that possession of marijuana for personal use should not be a federal offense.<sup>37</sup> President Nixon divorced himself from the Commission having already decided that he was adamantly opposed to marijuana's legalization.<sup>38</sup> Prior to the release of the report President Nixon declared, Even if the commission does recommend that it [marijuana] be legalized, I will not follow the recommendation.<sup>39</sup>

In line with the President the DEA denied NORML's first request that mari-

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<sup>36</sup>Bilz, *Medical Use of Marijuana*, 13 Hamline Journal of Public Law & Policy 117, 122 (Spring 1992).

<sup>37</sup>Id., 122-123.

<sup>38</sup>Id.

<sup>39</sup>Id.

juana be recognized as having a medical value.<sup>40</sup> The U.S. Court of Appeals for the D.C. Circuit, in NORML v. Ingersoll, remanded the case because the Bureau of Narcotics and Dangerous Drugs (BNDD), the precursor of the DEA, had refused to hold an administrative hearing as was required under 21 U.S.C.A. § 811(a).<sup>41</sup> The court asserted, it was not the kind of agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process.<sup>42</sup>

Following the hearing the DEA again rejected NORML's request for rescheduling and the court, in NORML v. DEA, remanded. This time the DEA had not referred the petition to the Secretary for medical and scientific evaluation and recommendation as is required by 21 U.S.C.A. § 811(b).<sup>43</sup> The petition was still denied following HHS input, and the court again remanded because FDA had not considered new evidence regarding possible medical uses of THC as distinguished from the full marijuana plant.<sup>44</sup>

The D.C. Circuit's actions demonstrate a Court whose objective was to ensure statutory compliance. It realized, however, that it could not control the agencies once they began evaluating scientific evidence behind closed doors. Still, general court oversight has facilitated the advance of medicinal marijuana.

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<sup>40</sup> 37 Fed. Reg. 10897 (Sept. 1, 1972).

<sup>41</sup> NORML v. Ingersoll, 497 F.2d 654, 659 (D.C. Cir. 1974).

<sup>42</sup> Id. at 659.

<sup>43</sup> NORML v. DEA, 559 F.2d 735 (D.C. Cir. 1977).

<sup>44</sup> NORML v. DEA, No. 79-1660 (D.C. Cir., October 16, 1980).

The year after NORML v. DEA the FDA granted marijuana investigative new drug (IND) status through its IND Compassionate Access Program.<sup>45</sup> This project enabled individuals to receive a legal supply of marijuana cigarettes contingent upon a recommendation from their physicians.<sup>46</sup> Following investigation of synthetic THC, the government agreed to market the THC pill (brand name Marinol) in 1985, and transferred this new drug from Schedule I to Schedule II in April of 1986.<sup>47</sup>

There is additional evidence that the court was merely following its duty to uphold the law as already established either by statute or by principles of administrative law. In Alliance for Cannabis Therapeutics (ACT) v. DEA, 930 F.2d 936, 938-39 (D.C. Cir. 1991), the court sustained the DEA Administrator's decision to reject Administrative Law Judge Francis Young's 1988 recommendation that marijuana become a Schedule II drug.

Following a two year hearing Judge Young concluded,

It would be unreasonable, arbitrary, and capricious for the DEA to continue to stand between those sufferers and the benefit of this substance in light of the evidence in this record.<sup>48</sup>

Yet despite this judge's determination that the DEA's policy was arbitrary and capricious, usually an administrative law ground for invalidating an agency action, the Circuit Court upheld the DEA Administrator's rationale for rejecting Judge Young's decision.

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<sup>45</sup> Q's and A's on Medicinal Marijuana Policy, HHS Fact Sheet.

<sup>46</sup> Id.

<sup>47</sup> Bilz, *Medical Uses of Marijuana*, 13 Hamline Journal of Public Law & Policy 117, 124-125 (Spring 1992).

<sup>48</sup> 2 Robert C. Randall, *Marijuana, Medicine, and the Law* 445 (1989).

The point of contention between Judge Young and the Administrator turned upon what determines whether a drug has a currently accepted medical use, a requirement for Schedule II status. Since the Circuit Court found the statutory phrase ambiguous and its legislative history scant, it deemed rational the Administrator's eight-point list of characteristics necessary for a substance to be classified as having an accepted medical use.<sup>49</sup> The Court made this determination in light of Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837, 843-45 (1984) (a court may not substitute its own construction of an ambiguous statutory provision for an agency's reasonable interpretation if the statute in question is one Congress enacted to establish the parameters of the agency's activities).

Ironically, in ACT v. DEA after finding the eight-point test rational the Court remanded the case for an explanation as to how [the test] had been utilized by the Administrator in reaching his decision. The Court did this because it felt three of the criteria were impossible for a Schedule I drug to meet.<sup>50</sup> All three had in common an assumption that the drug would be readily available, a fact which was untrue for Schedule I substances.<sup>51</sup> On remand the Administrator asserted that two of the three criteria had not been relied upon in the decision to refuse rescheduling. As for the third, he provided an explanation which satisfied the Court that the agency's decision was still fair.<sup>52</sup> In addition

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<sup>49</sup>ACT v. DEA, 930 F.2d at 937 (D.C. Cir. 1991).

<sup>50</sup>ACT & NORML v. DEA, 15 F.3d 1131, 1133-1134 (D.C. Cir. 1994).

<sup>51</sup>Id.

<sup>52</sup>Id.

he published in the Federal Register a Final Order listing only five criteria which must be met for a substance to be considered as having an accepted medical use.<sup>53</sup> Based upon the new list the Administrator again refused to alter marijuana scheduling. The change from the list of eight to the list of five, without notification to marijuana proponents, became the subject of the next appeal. The Court of Appeals for the D.C. Circuit still considered the Administrator's actions rational.<sup>54</sup>

Although court interference in analysis and interpretation of agency research is minimal or none, HHS has on occasion increased research in response to Congressional requests and popular pressure. In 1991, medicinal marijuana proponents publicized the IND Compassionate Access Program as a no cost supply of marijuana cigarettes for AIDS patients.<sup>55</sup> Since the increased demand would have depleted the national supply, then Assistant Secretary for Health, James O. Mason, M.D., called for a policy review and further NIH research on marijuana's efficacy. During that time no action was taken on the new applications.<sup>56</sup>

NIH considered available research in order to determine marijuana's affect on five diseases. The study, presented in 1993 at the Ninth International AIDS Conference in Berlin, revealed that marijuana provided no relief beyond that of other already approved drugs.<sup>57</sup> It also indicated a relationship between

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<sup>53</sup>Id.

<sup>54</sup>Id.

<sup>55</sup>HHS - Public Health Service Fact Sheet on Therapeutic Marijuana Policy, Jan. 12, 1994.

<sup>56</sup>Id.

<sup>57</sup>Id.

smoked marijuana and bacterial pneumonia in HIV positive persons.<sup>58</sup>

As a result of these findings, and the realization that the IND Compassionate Access Program could not produce the type of research necessary to move marijuana toward satisfaction of the FDA new drug application requirements (NDA), the HHS Secretary closed the Program to new applicants and provided them with information on other medications. The agency continued to supply marijuana to its earlier patients which still desired it.<sup>59</sup>

Although the grassroots effort to publicize FDA dispersment of marijuana produced unfavorable results for the medical marijuana movement, pressure from government insiders and agency negotiations with medical marijuana proponents have also been ineffective in the quest for legalization. An article by Representative Newt Gingrich published in the March 19, 1982 issue of the Journal of the American Medical Association commended the AMA's Council on Scientific Affairs piece, Marihuana: Its Health Hazards and Therapeutic Potential.<sup>60</sup> However Mr. Gingrich did not hesitate to add,

Federal policies do not reflect a factual or balanced assessment of marijuana's use as a medicant. The Council, by thoroughly investigating the available materials, might well discover that its own assessment of marijuana's therapeutic value has, in the past, been more than slightly shaded by federal policies that are less than neutral.<sup>61</sup>

It is apparent that despite this article and the earlier discussed 1971 report by the government's National Commission on Marihuana, federal agencies have not

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<sup>58</sup>Id.

<sup>59</sup>Id.

<sup>60</sup>Bilz, 13 Hamline Journal of Public Law & Policy 117, 121-122.

<sup>61</sup>Id.

varied from their entrenched belief that any medicinal value found in marijuana has already been located in other drugs.

A letter from Representative Barney Frank and other congressmen requesting a review of Dr. Mason's decision to close the Compassionate Access Program did cause his successor, Dr. Philip Lee, to reconsider.<sup>62</sup> Dr. Lee maintained his predecessor's position and claimed that the grand error of the project was that it could not yield the type of evidence necessary to suggest whether the FDA should approve or disapprove of marijuana as a new drug.<sup>63</sup>

Even the attempt by advocates Valerie Corral and Elvy Musikka to negotiate a moratorium on the prosecution of diseased persons arrested for possession of marijuana has been unsuccessful. A letter from Assistant Attorney General Jo Ann Harris reconfirmed the current policy and declared that the Department of Justice was not willing or able to grant the request. It also stated that the Attorney General would not reverse the DEA Administrator's position that marijuana is a Schedule I drug.<sup>64</sup>

The current dispute surrounding medical marijuana, which involves Dr. Donald Abrams' research protocol, began with a challenge from former DEA Administrator Mr. Robert Bonner who declared,

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<sup>62</sup>Rick Doblin, *The Medicinal Use of Marijuana - A Progress Report On Dr. Donald Abrams' Pilot Study Comparing Smoked Marijuana and the Oral THC Capsule for the Promotion of Weight Gain In Patients Suffering from the AIDS Wasting Syndrome*, <http://www.maps.org/news-letters/v5n1/abrams.html> (visited Jan. 12, 1997).

<sup>63</sup> Id.

<sup>64</sup> Id.

Those who insist that marijuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money and rhetoric into lobbying, public relations campaigns and perennial litigation.<sup>65</sup>

In support of this statement both HHS and the Department of Justice (which oversees DEA policy) have agreed that what is necessary are clinical trials.<sup>66</sup> Such trials must produce scientific evidence warranting FDA approval of marijuana as a prescription drug. In fact the HHS published Question and Answers on Medicinal Marijuana Policy provides,

Should a private group propose to do a study on the therapeutic use of smoked marijuana, the FDA is prepared to follow its customary practice of discussing with the potential sponsors of such a study the federal regulations governing the use in humans of investigational new drug substances and the requirements of approval for a new medication. FDA has a history of working with Schedule I drugs for potential medical use.<sup>67</sup>

The FDA has demonstrated its commitment to this statement by granting approval of Dr. Abrams protocol under 21 U.S.C.A. § 823(f) and 21 C.F.R. § 1301.42.<sup>68</sup> Yet this is only one of the requirements necessary to perform research. Dr. Abrams also needs a legal supply of marijuana, and a DEA registration to possess and distribute the marijuana.<sup>69</sup> As mentioned above, NIDA, the organization with a monopoly on the government supply of marijuana, has refused Dr. Abrams request for the drug because it claims Dr. Abrams did not follow proper protocol.<sup>70</sup>

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<sup>65</sup>

Id.

*Q's and A's on Medicinal Marijuana*, HHS.

<sup>67</sup>Id.

<sup>68</sup>Rick Doblin, *The Medical Use of Marijuana*, <http://www.maps.org/newsletters/v5n1/abrams.html> (visited Jan. 12, 1997).

<sup>69</sup>*Q's and A's on Medicinal Marijuana Policy*, HHS.

<sup>70</sup>Dr. Alan Leshner, Director NIDA, Letter to Dr. Donald Abrams,

From an administrative law perspective the issue is to what extent can this organization, which along with the FDA is under the wing of HHS, refuse to release the marijuana? NIDA was established within the National Institute of Mental Health, Health, Education, and Welfare Department by an act of March 21, 1972 (86 Stat. 85).<sup>71</sup> It was then removed from within the National Institute of Mental Health and became a part of the Alcohol, Drug Abuse, and Mental Health Administration under a statute of May 14, 1974 (88 Stat. 136). Its duties were next assigned to HHS by an October 17, 1979 act (93 Stat. 695). The Institute was abolished on July 10, 1992 (106 Stat. 331), and reestablished on July 10, 1992, again as part of HHS, under the Public Health Service Act (106 Stat. 361, 42 U.S.C. § 285o).<sup>72</sup>

The general purpose of the Institute is,

[to] conduct and support biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.<sup>73</sup>

In addition to this statutory statement that NIDA's objective is to research and assist development of drug abuse treatments, an HHS fact sheet asserts, NIDA conducts research on the effects of drug abuse, it does not study the possible medicinal effects of drugs.<sup>74</sup>

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<http://www.maps.org/mmj/leshner.html> (visited Jan. 12, 1997).

<sup>71</sup>Richard L. Claypoole, & John W. Carlin, *The United States Government Manual* 774 (1996/1997).

<sup>72</sup>*Id.*

<sup>73</sup>42 U.S.C. § 285(o)(a) (1994).

<sup>74</sup>*Q's and A's on Medicinal Marijuana Policy*, HHS.

Nevertheless, NIDA's director, Alan I. Leshner, Ph.D., made the following statement in his letter of rejection to Dr. Abrams.

As you know, decisions for the commitment of limited NIH resources are based upon scientific principles, so as to ensure the most effective use of our research sources. Our decision here is based upon issues of design, scientific merit and rationale. We believe that your study will not adequately answer the question posed.<sup>75</sup>

Dr. Judith Lawrence (a Ph.D. in the DEA's Drug and Chemical Evaluation Section of the Office of Diversion Control) who has testified before Congress on the marijuana issue, confirmed that NIDA's rejection was based upon its scarce resources.<sup>76</sup> She also held that NIDA was designed to do limited preliminary research regarding drug abuse, and was not designed to supply the magnitude of any drug needed for clinical trials of the type which lead to FDA new drug application approval.<sup>77</sup>

Even the proponents of medical marijuana agree that usually once the FDA has approved a protocol the researchers may conduct the studies.<sup>78</sup> Only because NIDA is the sole supply of legal marijuana did Dr. Abrams have to contact the Institute. Yet proponents also contend that NIDA has required them to request the marijuana through a National Institute of Health (NIH) grant application process.<sup>79</sup> This process enables NIH to evaluate the efficacy

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<sup>75</sup>Alan Leshner, Letter to Dr. Abrams, <http://www.maps.org/mmj/leshner.html> (visited Jan. 12, 1997).

<sup>76</sup>Telephone interview with Dr. Lawrence, Jan. 17, 1997.

<sup>77</sup>Id.

<sup>78</sup>*NIDA Obstructs Medicinal Marijuana Research*, Pamphlet by Marijuana Policy Project Foundation, Oct. 1996.

<sup>79</sup>Id.

of the protocol in a manner similar to Dr. Leshner's. Proponents also claim that prior to the early 1980s NIDA did not require researchers to submit requests in this manner.<sup>80</sup>

The major point of dispute between Dr. Abrams and Dr. Leshner is the extent to which the proposed protocol will demonstrate marijuana's effectiveness in 40 patients suffering from AIDS Wasting Syndrome.<sup>81</sup> Dr. Leshner contends that the study sample is too small to yield statistically relevant data regarding the relationship between dose and effect. Dr. Leshner also questions the lack of dosing control.<sup>82</sup>

With respect to the latter, Dr. Abrams contends that it was not mandatory for patients in the Marinol trials to receive the same dose each day.<sup>83</sup> Rather, patients were evaluated if they used any amount over 75% of their daily allotment of medication.<sup>84</sup> He also argued that patients who smoke marijuana can self-titrate, and would be required to provide a daily record of the quantity smoked and time of day smoked.<sup>85</sup>

Dr. Abrams has rebutted the former argument by stating that neither he nor the FDA expect this initial study to produce a statistically significant difference in weight gain among those who receive high and medium potency marijuana,

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<sup>80</sup>Id.

<sup>81</sup>Rick Doblin, *NIDA Blocks Medical Marijuana Research*, <http://www.maps.org/mmj/ricklelesh.html> (visited Jan. 12, 1997).

<sup>82</sup>Id. and Dr. Leshner's Letter to Dr. Abrams, <http://www.maps.org/mmj/leshner.html> (visited Jan. 12, 1997).

<sup>83</sup>Id.

<sup>84</sup>Rick Doblin, *NIDA Blocks Medical Marijuana Research*, <http://www.maps.org/mmj/ricklelesh.html/>

<sup>85</sup>Id.

as compared to those groups which receive low potency marijuana or the THC capsule. Rather, the protocol is intended only to evince trends suggesting marijuana's usefulness which hopefully will merit approval to conduct larger studies.<sup>86</sup>

Descriptions of FDA regulations concerning Phase I, Phase II, and Phase III clinical studies in humans to some extent lend support to Dr. Abrams argument that he should begin with a smaller study. In Phase II, relatively small numbers of patients are investigated intensively with specialized studies tailored to the type of drug and the disease to be treated.<sup>87</sup> In Phase III, hundreds and even thousands of patients are investigated.<sup>88</sup> However, it is apparent that the two doctors have different interpretations of what constitutes a small initial study and the degree of efficacy which needs to be demonstrated at this stage in the research.

Part of the confusion might stem from the different objectives of NIDA and FDA when approving an Investigational New Drug (IND). FDA's review of Phase 1 submissions focuses on determining the safety of these investigations, whereas review of Phases 2 and 3 submissions concentrate increasingly on the quality of the study and the prospects for eventual New Drug Application

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<sup>86</sup>

Id.

<sup>87</sup>

Hutt & Merrill, Food and Drug Law 516 (1991).

<sup>88</sup>

Id.

(NDA) approval.<sup>89</sup> NIDA, to the contrary, because its marijuana resources are limited, may desire greater proof of efficacy at an earlier stage in the process than the FDA. The difficulty is that wherein Dr. Abrams classifies his study as being in the beginning stages, and thus he just desires to find a general trend that marijuana is helpful to AIDS patients, his study does provide the drug to diseased persons which is technically a Phase II research project. Thus, although the FDA may not object to the study producing only general, statistically irrelevant data, NIDA's sources are being absorbed and NIDA wants the research to get at the heart of resolving the effectiveness of marijuana for the AIDS Wasting Syndrome. The degree to which a research protocol must be designed to demonstrate the drug's usefulness should be consistent between FDA and NIDA. This will require intra-agency negotiations.

This description of the dispute between Dr. Abrams and Dr. Leshner facilitates an understanding of whether the DEA has been correct in its refusal to grant Dr. Abrams a license. Mr. Gene Haislip, Deputy Assistant Administrator, Office of Diversion Control, is the DEA official designated authority over the issuance of DEA Schedule I licenses.<sup>90</sup> He has sent to the FDA documentation of his concerns with Dr. Abrams research, scientific and otherwise.<sup>91</sup>

According to 21 U.S.C.A. § 823(f) the Attorney General, who in these matters has delegated her authority to the DEA Administrator, may refuse to license

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<sup>89</sup>21 C.F.R. § 312.22(a) (1996).

<sup>90</sup> Rick Doblin, *The Medicinal Use of Marijuana*, <http://www.maps.org/newsletters/v5n1/abrams.html> (visited Jan. 12, 1997).

<sup>91</sup> Id.

a researcher who has FDA approval of his protocol only if issuance of the license would violate section 824(a).

Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary [of HHS] may be denied by the Attorney General only on a ground specified in section 824(a) of this title.<sup>92</sup>

Of the factors listed in 824(a) only the fourth seems applicable to the discussion of the legalization of medicinal marijuana. That factor states that a license to distribute a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant- has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.<sup>93</sup>

Although the CSA generally encourages the FDA and the DEA to work together to regulate controlled substances, section 823(f) does not give the DEA official latitude to deny a license because he disagrees with scientific aspects of the protocol. Hence, only if Mr. Haislip's other grounds for disapproval involve a fear that Mr. Abrams proposal is somehow inconsistent with the public interest would he have a legal basis for objection. In fact this is the argument the government is currently using to denounce the California state law legalizing medicinal marijuana.<sup>94</sup>

Both the federal government's response to Dr. Abrams and the complete cessa-

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<sup>92</sup>21 U.S.C. § 823(f) (1994).

<sup>93</sup> 21 U.S.C.A. § 824(a)(4) (1994).

<sup>94</sup>General Barry R. McCaffrey, Director of the Office of National Drug Control Policy, *Administration Rejects Use of Marijuana For Medicinal Purposes*, <http://www.marijuana.org/dw3.htm> (visited Jan. 12, 1997).

tion of the IND Compassionate Access Program could be categorized as catalysts which helped to ignite the November 5, 1996 passage of California's Proposition 215 Medical Marijuana Initiative by 56 to 44 percent. However it must be noted that there was already existing in that state a breadth of strong willed grassroots individuals and organizations including Dr. Abrams and Californians for Medical Rights.

A study of the California initiative will enhance the discussion of how federal agencies and federal courts fulfill their duty to uphold federal statutory law, and permits some introductory speculation as to how they will work to enforce the U.S. Constitution.

The California initiative, entitled Compassionate Use Act (ACT) of 1996, asserts,

...that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician...<sup>95</sup>

Here to recommend is not to prescribe as pharmacies may not shelve what is still an illegal Schedule I drug. Furthermore, although the statute does list the usual illnesses for which marijuana has been considered helpful (cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, and migraine), a guide distributed by the Californians for Medical Rights warns that an individual is not protected under the Act simply because he or she has a mentioned

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<sup>95</sup>

California Health and Safety Code Section 1. Section 11362.5.

illness.<sup>96</sup> Rather a doctor must have specifically recommended the drug.<sup>97</sup>

Other noteworthy aspects of the initiative include the fact that patients and their primary caregivers may possess and cultivate marijuana.<sup>98</sup> Yet although they may be arrested, they cannot be prosecuted by state authorities. Doctors who have recommended marijuana for medical purposes may not be punished or denied any right or privilege for doing so. The Act also prohibits any patient from engaging in conduct that endangers others, such as driving under the influence, and the Act prohibits the diversion of marijuana for nonmedical purposes.

California Attorney General Dan Lungren has admitted that an initiative which receives a majority of the popular vote can only be changed by another vote of the people. Our job is to correctly apply the 'medicinal use' law as narrowly as possible – as close as possible to what the voters' intentions were, conceded Mr. Lungren. Yet he also has acknowledged that because the law is so loosely written it is difficult to determine exactly what is within and outside the scope of legality.<sup>99</sup> He has therefore concentrated his efforts on ensuring that marijuana is sold exclusively for medicinal purposes, working with associations such as the California Medical Association with respect to usage of marijuana by children under Proposition 215, and declaring that the physician working in an incarcer-

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<sup>96</sup>Californians for Medical Rights, *Proposition 215 and You: A Guide for Medical Marijuana Patients and Others*, <http://www.prop215.org/brochur1.html> (visited Jan. 14, 1997).

<sup>97</sup>*Id.*

<sup>98</sup>California Health and Safety Code Section 1. Section 113362.5(d).

<sup>99</sup>News Release– AG Dan Lungren, California Dept. of Justice, <http://www.prop215.org/allzone2.html> (visited Jan. 14, 1997).

ation facility independently determines whether an inmate should be provided marijuana, consistent with facility security policies.<sup>100</sup>

Much of the federal response has come from General Barry R. McCaffrey, Director of the Office of National Drug Control Policy. His four objectives are as follows:

1. Maintain effective enforcement efforts within the framework created by the Federal Controlled Substance Act and the Food, Drug, and Cosmetic Act;
2. Ensure the integrity of the medical-scientific process by which substances are approved as safe and effective medicines;
3. Preserve federal drug-free workplace and safety programs; and
4. Protect children from increased marijuana availability and use.<sup>101</sup>

When outlining these principles he proclaimed two major White House concerns, the illicit distribution of marijuana under the pretext of medical need, and easier access to controlled substances by minors.<sup>102</sup>

The Department of Justice has sought to protect these concerns by suggesting that physicians who prescribe or recommend (a newly enacted Arizona law has sanctioned prescriptions) Schedule I controlled substances may have their licenses revoked under 21 U.S.C. § 824(a).<sup>103</sup> Of the five factors listed as basis for revocation, the fourth is relevant for a discussion of conflicting state and federal laws, as this is the section of the Code the Justice Department asserts

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<sup>100</sup>Id.

<sup>101</sup> Administration Rejects Use of Marijuana For Medicinal Purposes, <http://www.marijuana.org/dw3.htm> (visited Jan. 12, 1997).

<sup>102</sup> Id.

<sup>103</sup>Id.

as supporting its position.

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant...

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.<sup>104</sup>

Again, child susceptibility to drug abuse and public safety, both on the highway and in the workplace, constitute the public interest. To what extent will the government be able to protect these interests under the federal statute using principles of administrative law and/or the U.S. Constitution?

Insofar as marijuana is still a Schedule I drug legally it has no medicinal value and will continue to be considered in this light as long as marijuana proponents and opponents both stipulate that there currently exists no clinical research which can pass the FDA new drug application (NDA) standard. Hence, under 21 U.S.C.A. § 823(f)(5) experimentation with marijuana by anyone other than a DEA licensed researcher would be an illegal diversion.

The administrative law theory of deference to the agency would permit the Justice Department, through DEA, to define inconsistent with the public interest as described above. In Leslie v. DEA, 92 F.3d 1192 (Ninth Cir. 1996) (an unpublished opinion, the text of which is only available on Westlaw) the Court held that when the DEA decides to revoke a license because the licensee has acted inconsistent with the public interest, the standard of review is arbitrary

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<sup>104</sup>21 U.S.C.A. § 824(a) and § 824(a)(5) pamphlet supplement (1996).

and capricious.

We may not substitute our judgment for that of the agency. We must consider only whether the agency's decision was based upon a consideration of the relevant factors and whether there has been a clear error of judgment.<sup>105</sup>

Although the ruling court declared that this case has no precedential value, the decision hinges on a well known legal principle and is an indication of the Court's opinion in this area.

Humphreys, M.D. v. DEA, 96 F.3d 658, 661 (Third Cir. 1996), was a license revocation case which turned on the definition of inconsistent with the public interest. Although the Court asserted that the DEA bears the burden of proving that a registration would not be in the public interest, a court must uphold any reasonable agency construction of a statute it is entrusted to enforce.

In Humphreys the DEA did not sufficiently bear its burden. The doctor's alleged violation was the prescribing of drugs to his patient using another person's name in order to safeguard his patient's privacy. The Court held that it is common and acceptable practice for the doctor to take such action when the patient is a public figure.<sup>106</sup> Illicit use of a Schedule I drug has never been common and acceptable practice.

Public safety and concern for child development are deemed reasonable in American culture, thus there is a greater likelihood that the government will have met its burden of proof. Marijuana proponents of course would argue that a child

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<sup>105</sup>Leslie v. DEA, 92 F.3d 1192 (Ninth Cir. 1996).

<sup>106</sup>Id. at 662-663.

can learn the difference between the proper and improper use of a drug. Education and individual will power could reduce the chances of car and workplace accidents. Patients will die a more rapid death if marijuana is denied them. To this the government would argue that there already exist approved drugs (discussed above) which satisfy the same needs without the negative side effects. If price is a difficulty, there are government programs such as Medicaid to assist. The government would rather pay for a safe form of treatment than approve a drug which is less beneficial.

On January 14, 1997 medicinal marijuana proponents, supported by Californians for Medical Rights and the American Civil Liberties Union, filed a class action suit against the U.S. Government in the United States District Court for the Northern District of California. They seek injunctive relief for patients and physicians who have been threatened with prosecution and revocation of federal prescription drug licenses.<sup>107</sup> Named as defendants are: General McCaffrey, as Director of the Office of National Drug Control Policy, Thomas A. Constantine, as Administrator, United States Drug Enforcement Administration, Janet Reno, as Attorney General of the United States, and Donna Shalala, as Secretary of Health and Human Services. Plaintiffs include: Dr. Marcus Conant, Dr. Donald Northfelt, Dr. Arnold Leff, Bay Area Physicians for Human Rights, and Being Alive: People with AIDS/HIV Action Coalition, Inc.

Although the brief provides a detailed discussion of the numerous diseases for

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<sup>107</sup>Plaintiffs' Brief at 17-18, Canant (1997).

which marijuana has provided relief and gives anecdotal testimonies of patients who have been treated, the proponents assert only one legal argument.

This class action seeks a declaration that physicians and patients have the right, protected by the First Amendment to the Constitution, to communicate in the context of a bona fide physician-patient relationship, without government interference or threats of punishment, about the potential benefits and risks of the medical use of marijuana.<sup>108</sup>

It is not unusual for an attorney to assert one major theory in support of a case. It is striking, however, that the attorneys for these plaintiffs add no legal citations to precedents as supportive of their position, nor do they attempt to explain and distinguish negative precedents.

Brandenburg v. Ohio, 395 U.S. 444 (1969), is the leading Supreme Court case which addresses a defendant's First Amendment right to advocate illegal action through speech. According to Brandenburg speech is not protected when,

...Such advocacy is directed to inciting or producing imminent lawless action and is likely to incite or produce such action.<sup>109</sup>

A physician who has recommended the use of marijuana has encouraged criminal conduct under federal law since possession of a Schedule I drug is an offense. The plaintiff's brief itself, by asserting that doctors are worried about the possible revocation of their licenses due to marijuana recommendations<sup>110</sup>, is evidence that advocacy of marijuana use is likely to incite or produce [that] action. If the defendants raise the Brandenburg argument in their reply brief it

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<sup>108</sup> Id. at 2.

<sup>109</sup>William B. Lockhart & Yale Kamisar, *Constitutional Law Cases - Comments - Questions* 657 (1996), citing Brandenburg v. Ohio, 395 U.S. 444 (1969).

<sup>110</sup>Plaintiffs' Brief at 17-18, Conant (1997).

is feasible that the court might rule in their favor.

Still, underlying the recommendation issue is the greater question of whether marijuana has an acceptable medical use which the FDA should recognize. If it does then the drug's Schedule I status does inhibit the doctor's ability to speak truthfully to the patient. The issue of what is the truth concerning the marijuana issue is one which can only be answered through unbiased research. Until such research is permitted it is likely that the courts will decide whether the DEA's notion of public interest is reasonable. The United States Court of Appeals for the Ninth Circuit addressed this issue in U.S. v. Rodriguez-Camacho, 468 F.2d 1220 (1972).

Congress has concluded that '...controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.' Appellant urges that this assertion is inapplicable to marijuana. This is a matter, however, whose ultimate resolution lies in the legislature and not in the courts. It is sufficient that Congress had a rational basis for making its findings.<sup>111</sup>

This holding is significant not only because of its content, but of equal importance is the fact that it is a Ninth Circuit appellate opinion. Since medicinal marijuana advocates filed in California District Court, this opinion has set the precedent which they must counterbalance.

In an E-mail message forwarded to top advocates, those involved in the suit specified that they purposely rejected other possible Constitutional claims such

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<sup>111</sup>U.S. v. Rodriguez - Camacho, 468 F.2d 1220 at 1222 (Ninth Cir. 1972).

as due process, cruel and unusual punishment, and right to privacy.<sup>112</sup>

Nevertheless, it is worth reviewing those alternatives in relation to marijuana because they have already been addressed at the federal level, and the court adjudicating the plaintiffs' claims will be aware of how one of its constituents dealt with the contention that marijuana does not meet the criteria for Schedule I substances.

That constituent was the District Court for the District of Columbia in NORML v. Bell, 488 F.Supp. 123 (1980). Besides upholding the Congressional classification of marijuana as Schedule I in the CSA, this Court also addressed the right to privacy, equal protection, and cruel and unusual punishment as they relate to marijuana.

In NORML v. Bell, NORML contested the provisions of the CSA which prohibit the private possession and use of marijuana, the exact situation California has legalized for persons with medical needs. With regard to privacy, the court contended that such a right exists only in relation to specific, fundamental constitutional guarantees.<sup>113</sup> A right is fundamental if it is explicitly or implicitly guaranteed by the Constitution. The Bell Court cited earlier cases to support its holding that smoking marijuana is not Constitutionally protected because it was used primarily as a recreational drug and few would believe they have been deprived of something of critical importance if deprived of marijuana. <sup>114</sup>

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<sup>112</sup>E-mail message to Rick Doblin addressed Complaint for Declaratory and Injunctive Relief.

<sup>113</sup>NORML v. Bell, 488 F.Supp. 123 at 131-132 (D.C. Dist. Ct. 1980).

<sup>114</sup>Id. at 133.

Wherein this argument was plausible in early 1980, the evidence and strong claims currently being made by medicinal marijuana proponents does seem to undermine the court's assertion. If medicinal marijuana does provide relief not achievable through any other source, and this relief prolongs the life of terminally ill individuals, then the use of marijuana may indeed be a fundamental right. Yet, until marijuana is rescheduled, legally it remains a substance with no medical value and thus the Bell opinion would remain valid.

The Court also rejected NORML's equal protection challenge by asserting that legislation which does not affect a fundamental right or a suspect class will not be strictly scrutinized.<sup>115</sup> That there is no fundamental right to smoke marijuana has already been addressed.

The Court did mention the phrase suspect classification but failed to explore it, possibly because NORML did not allege that a specific group was discriminatorily harmed by marijuana's illegality. To the contrary, the recent California lawsuit explicitly asserts that individuals with certain terminal and/or chronic illnesses are being denied a beneficial product because their physicians fear the federal repercussions of making a recommendation. Could plaintiffs' attorneys allege that their clients are a suspect class which has been discriminated against?

A law challenged by a suspect class must endure the highest level of scrutiny

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<sup>115</sup>Id. at 134-135.

by the reviewing court if it is to be upheld. To date the Supreme Court has only accepted race and national origin as fully suspect classes meriting the strictest scrutiny whereby a law must be closely tailored to serve a compelling government interest if it is to remain valid.<sup>116</sup> Gender and illegitimacy have been granted intermediate scrutiny whereby any classification based upon these characteristics must be substantially related to an important government objective.<sup>117</sup> All other equal protection challenges have been resolved by the court through a rational basis review.<sup>118</sup>

Ralph K. Winter, Jr. in his article *Poverty, Economic Equality, and the Equal Protection Clause*, argues in part that because there is an enormous amount of legislation to help the poor, the impoverished would not qualify as a suspect class.<sup>119</sup> The analogy could be drawn that the FDA and DEA have worked together to approve a variety of other drugs and treatments which offer the same relief as marijuana. This coupled with the fact that marijuana is denied to everyone, serves as proof that the plaintiffs have not been discriminated against.

Winters also asserts that common to each of the accepted suspect and semi-suspect classes is an unalterable human quality.<sup>120</sup> Poverty is not necessarily

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<sup>116</sup>William B. Lockhart, and Yale Kamisar, *Constitutional Law Cases - Comments - Questions* 1258 (1996); see also Richmond v. Croson Co., 488 U.S. 469 (1989) and Hernandez v. Texas, 347 U.S. 475 (1954).

<sup>117</sup>Lockhart, *Constitutional Law* 1310 (1996); see also Clark v. Jeter, 486 U.S. 456 (1988) and Craig v. Boren, 429 U.S. 190 (1976).

<sup>118</sup>Lockhart, *Constitutional Law* 1310 (1996).

<sup>119</sup>Lockhart, *Constitutional Law* 1321 (1996).

<sup>120</sup>Id.

a permanent status and since individuals can sometime escape, that is another reason why poverty should not be considered a suspect class.<sup>121</sup> On the other hand, most of the illnesses for which marijuana is useful are terminal. If research demonstrated that this substance offered the best relief, one might argue that those for whom marijuana has been beneficial have become a suspect class, or semi-suspect class because the government was denying only those persons the best available and affordable medicine.

If courts do not view those requesting medical marijuana as a suspect or semi-suspect class, the substance's Schedule I status will be upheld provided there is a rational relationship to a legitimate state interest. When engaged in a rational relationship analysis the court presumes the legislature acted as a reasonable person would. The statute can only be invalidated if no grounds can be conceived to justify it.<sup>122</sup> Given the cases already discussed which have affirmed that Congress and the agencies have been rational in not varying the marijuana classification, the equal protection argument would not be easily won today.

NORML, in NORML v. Bell, also challenged punishment for possession of marijuana as a violation of the Eighth Amendment. The Court responded with an explanation of the Supreme Court's framework for reviewing the fairness of a criminal statute. First, the severity of the offense and the sentence is compared

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<sup>121</sup>Id.

<sup>122</sup>NORML v. Bell, 488 F.Supp. 123 at 134-135 (Dist. Ct. D.C. 1980).

both to penalties for other crimes in the same jurisdiction, and to penalties for the same crime in other jurisdictions.<sup>123</sup> Second, evolving standards of decency that mark the progress of a maturing society, are the criteria used to assess the fairness of the punishment in relation to the crime. However, in this democratic society the Court assumes that the legislature's rules are representative of society's evolving standards of decency.<sup>124</sup>

The legislature is not compelled to choose the least severe punishment. Rather, as long as the penalty given is not cruelly inhumane or disproportionate to the crime involved, the burden remains with the one who has challenged the people's choice as it is established in the statute.<sup>125</sup>

The Bell Court held that the punishment for possession of marijuana did not violate the Eighth Amendment's protection from cruel and unusual punishment. The one year incarceration period was not considered extreme when compared to other possession related federal penalties.<sup>126</sup> Since Congress still controls the sanctions for substance abuse, it is not likely that a court today would rule differently on an Eighth Amendment claim.

Despite the numerous Constitution based precedents which disfavor the California plaintiffs there are two remaining avenues for a possible victory. The first

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<sup>123</sup>Id. at 142.

<sup>124</sup>Id.

<sup>125</sup>Id.

<sup>126</sup>Id. at 142.

is based upon a January 8, 1997 decision of the San Francisco Superior Court. Judge David A. Garcia agreed to lift the restraining order against San Francisco's Cannabis Club, an organization run by Dennis Peron which cultivated and distributed marijuana cigarettes to individuals claiming a medical need.<sup>127</sup> Although state charges are still pending against Peron for selling marijuana, Judge Garcia referred to the Compassionate Use Act when he decided in favor of the will of the people.<sup>128</sup>

The California Act does permit a primary caregiver to obtain and possess marijuana for a patient.<sup>129</sup> However the state supreme court will ultimately have to determine whether one man, Dennis Peron, can be the legal caregiver for every terminally ill person in the San Francisco area whose physician has recommended marijuana.

The Act defines a primary caregiver as the individual designated by the... [patient] who has consistently assumed responsibility for the housing, health or safety of that person.<sup>130</sup> One group of medical marijuana proponents, Californians for Medical Rights, asserts that family members, very close friend, and roommates of patients fit under this definition most readily.<sup>131</sup> In one of their publications they advise patients to be conservative in designating a

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<sup>127</sup>Glen Martin, *Medical Pot Users Light Up*, San Francisco Chronicle, <http://www.marijuana.org/cc2.htm> (visited Jan. 16, 1997); E-mail message to Rick Doblin, Subject: Details on San Francisco Cannabis Cultivators Club Opening (Jan. 9, 1997).

<sup>128</sup>E-Mail to Rick Doblin, Subject: Details on San Francisco.

<sup>129</sup>California Health and Safety Code, Section 1. Section 11362.5(d).

<sup>130</sup>Id.

<sup>131</sup>Californians for Medical Rights, *Proposition 215 and You: A Guide for Medical Marijuana Patients and Others*, <http://www.prop215.org/brochur1.html>.

caregiver, and to place emphasis on the statutory phrase consistently assumed responsibility, for they concede that it will be a judge who will decide each case individually.<sup>132</sup>

If California's highest Court, which has the final word on matters of interpreting state law, does not deem Peron a valid primary caregiver then patients will have to resort to cultivating their own small quantities of the drug, or continue to purchase on the black market. Yet this could be a victory in disguise because patients with the right to smoke and cultivate under California law cannot be prosecuted in federal courts.<sup>133</sup> Since the DEA, like all federal agencies, has limited resources that agency must decide whether searching for individual medical marijuana users is the best allocation of its resources.

If, on the other hand, the California Supreme Court upholds Judge Garcia's decision, that likewise would be favorable to the proponents with the exception that the Compassionate Use Act did not legalize the sale of marijuana. Another vote by the populous would then be needed to amend the statute to allow an exception for pre-approved suppliers such as the Cannabis Club.

A claim of necessity is the other tactic available to medical marijuana advocates, and because it is a common law criminal defense it can be used by patients in states without a favorable statute. The Superior Court of the District of Columbia, in U.S. v. Randall, Criminal Docket No. 65923-75 (1976),

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<sup>132</sup>Id.

<sup>133</sup>California Health and Safety Code, Section 1. Section 11362.5(b)(1)(B).

was the first court to accept such a defense. Robert C. Randall, a glaucoma victim, had been arrested and charged with possession of LSD and marijuana in violation of the District of Columbia Code. The court established a three pronged necessity defense.

1. [The actor must have been] reasonably compelled by circumstances to commit the proscribed act.

2. The actor must not have brought the compelling situation upon himself.

3. The consequences the actor sought to avoid must have been greater than the harm done to society.

The defendant satisfied each prong. First, although medical experts could not determine the precise cause of the disease, neither they nor the government alleged that the harm was self-inflicted. The court then engaged in a balancing test weighing the government's interests against the individual's. Evidence demonstrated that the 1937 Tax Act had emerged under economic pressure and with very little to support its effects on smokers. At the time of this case President's Commission reports and data from the Department of Health, Education and Welfare had determined that there was no conclusive scientific evidence of resulting harm and allegations of chromosome damage, reduced immunity to disease, and psychosis were unconfirmed. In contrast to the government's weak assertions the court readily admitted the importance of the individual's right to protect his or her body, and cited Roe v. Wade, 410 U.S. 113 (1973), as support for this contention.

Although the Washington, Florida, and Idaho state courts have also permit-

ted the necessity defense for medical marijuana, other state courts have rejected the defense in an effort to present a united front with their legislatures which have frowned upon use of the drug.<sup>134</sup> For example, the New Jersey Supreme Court ruled that because the legislature labeled marijuana a Schedule I drug (states can reclassify according to a standard different from the federal, however doing so is merely a symbolic act since the U.S. Constitution's Supremacy Clause guarantees that federal law trumps any state law conflict) it had no intentions for a medical use.<sup>135</sup> The Georgia Court of Appeals ruled likewise.<sup>136</sup> The majority of information discussed thus far has demonstrated how principles of constitutional and administrative law have worked together to halt any significant advancement toward a change in medical marijuana's status. Nevertheless, the movement should not be underestimated. In addition to California and the state courts which have adopted the necessity defense in relation to medical marijuana cases, Arizona and Massachusetts have also adopted laws legalizing the medical use of the drug.

The Arizona initiative, entitled the Drug Medicalization, Prevention, and Control Act of 1996, endorses legalization of all Arizona Schedule I drugs for medical purposes despite the Arizona Criminal Justice Commission report that marijuana use doubled among elementary school students between 1990 and

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<sup>134</sup>Marijuana Policy Project Foundation, *How Can a State Legislature Enable Patients to Use Medicinal Marijuana Despite Federal Prohibition?*, <http://www.mpp.org/despite.html> (visited Jan. 7, 1997).

<sup>135</sup> *New Jersey v. Tate*, 505 A2d 941 (1986).

<sup>136</sup> *Spillers v. Ga.*, 245 S.E.2d 54 (1978).

1993 and quadrupled among middle-school students during those years.<sup>137</sup> To counterbalance the seemingly liberal move, the law simultaneously requires that a medical doctor must document that scientific research exists which supports the use of the substance and must also obtain a written second opinion from another medical doctor.<sup>138</sup> Furthermore, the patient must be seriously or terminally ill. Yet another factor which helps to ensure that only medical uses are permitted is the requirement that any person convicted of a violent crime committed while under the influence of a controlled substance must serve his or her sentence and will not be eligible for parole.<sup>139</sup>

Compassion for suffering persons was the motivating spirit behind the initiative measure. Imbedded in the Arizona law is the following,

Thousands of Arizonans suffer from debilitating diseases such as glaucoma, multiple sclerosis, cancer, and AIDS, but cannot have access to the necessary drugs they need. Allowing doctors to Prescribe Schedule I controlled substances could save victims of these diseases from loss of sight, loss of physical capacity, and greatly reduce the pain and suffering of the seriously ill and terminally ill.<sup>140</sup>

Compassion also appears to have been one of the driving forces behind the August 8, 1996 Massachusetts law enacted by the legislature.<sup>141</sup> State public health commissioner David Mulligan has stated, The ethics have to be thought through...If this reduces pain and enables people to keep food down, can we

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<sup>137</sup>Arizona Proposition 200: Drug Medicalization, Prevention, and Control Act of 1996, Section 2 Findings and Declarations.

<sup>138</sup>*Id.* at Title 13 Chapter 13 § 13-3412.01.

<sup>139</sup>*Id.* Title 41, Chapter 11 § 41 -1604.14.

<sup>140</sup>*Id.* Section 2. Findings and Declarations.

<sup>141</sup>Marijuana Policy Project, *How Can a State Legislature Enable Patients to Use Medicinal Marijuana Despite Federal Prohibition?*, <http://www.mpp.org/despite.html> (visited Jan. 7, 1997).

reasonably withhold it?<sup>142</sup>

Although the new law does not enable doctors to write prescriptions, nor does it explicitly endorse a doctor recommendation of marijuana, it does grant a prima facie defense to a charge of possession of marijuana.<sup>143</sup> The person asserting the defense, if certified by the state, should be shielded from punishment.<sup>144</sup> In addition the statute establishes a medical marijuana research program, which also has not been funded by NIDA.<sup>145</sup> Nevertheless, state officials have vowed to ask that federal government agencies not frustrate the state's attempts to study marijuana's medical validity.<sup>146</sup>

In addition to California, Arizona, and Massachusetts which have legalized medical marijuana in various forms, since the 1970s, 24 states have passed legislation creating state-run research programs for marijuana alone or in combination with synthetic THC.<sup>147</sup> Although in six states these laws have expired, and in five others they have been repealed<sup>148</sup>, overall medical marijuana proponents have captured the attention of many within the nation.

Thus far judicial precedent has severely constrained their progress through

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<sup>142</sup>Richard A. Knox, *Mass. Offers Rules Today On Marijuana as Medicine*, The Boston Globe, A1, Jan. 21, 1997.

<sup>143</sup>MA ST 94C § 34 (1996).

<sup>144</sup>Richard A. Knox, *Mass. Offers Rules Today on Marijuana*, The Boston Globe, A1, Jan. 21, 1997.

<sup>145</sup>*Id.*

<sup>146</sup>*Id.*

<sup>147</sup>Marijuana Policy Project, *How Can a State Legislature Enable Patients to Use Medicinal Marijuana Despite Federal Prohibition*, <http://www.mpp.org/despite.html>.

<sup>148</sup>*Id.*

administrative law principles and Constitutional interpretation. While it is true that the higher level courts may continue to uphold the status quo, our system is one of checks and balances. Thus the Chief Executive and his branch agencies should not rely wholly on the Courts to support their position. For if the legalization movement continues to spread this will transfer into constituent pressure on congressional representatives, and one must remain cognizant that Congress has the ultimate authority to reclassify a Schedule I drug.

The issue of medical marijuana will involve difficult decision making which will raise the question, what is the American public interest? Of course it is difficult to deny the terminally ill a supply of what they believe to be the best medication. However, the research is not conclusive as to whether medical marijuana actually is the wonder drug some claim it to be.

There are harmful side affects, but that issue becomes different when the patients are terminally ill. Even the decision to research is complicated because if marijuana does have medicinal value one must become concerned about its availability to the nation's youth. If research is to be done, perhaps a few large private research institutions could conduct the studies with tight government supervision.

Just as each of the thirteen American colonies needed one another to ward off British oppression, the fifty states need leadership in this area as well. That leadership does not necessarily have to be a closed mind to medical marijuana research, however the legalization of a substance which has been deemed harmful

for so long without knowing its ultimate affects could be self-destructive.