No. 03-40

In the Supreme Court of the United States

JOHN P. WALTERS, ET AL., PETITIONERS

v.

DR. MARCUS CONANT, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, only persons registered with the Drug Enforcement Administration (DEA) may manufacture, distribute, or dispense controlled substances, and they may do so only to the extent authorized by their DEA registration. 21 U.S.C. 822(a) and (b). The CSA also authorizes the DEA to revoke the registration of a physician who "has committed such acts as would render his registration * * * inconsistent with the public interest," 21 U.S.C. 824(a)(4), such as activities that violate the CSA, 21 U.S.C. 823(f)(4), or "may threaten the public health and safety," 21 U.S.C. 823(f)(5). The question presented is:

Whether the court of appeals erred in affirming a district court injunction that bars federal officials from revoking a physician's registration, or even investigating a physician's conduct, based on the physician's recommendation that a patient use marijuana, a Schedule I substance that, as a matter of federal law, 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" even "under medical supervision," 21 U.S.C. 812(b)(1)(A)-(C).

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States (substituted for his predecessor, Janet Reno), Tommy G. Thompson, Secretary of the Department of Health and Human Services (substituted for his predecessor, Donna E. Shalala), John P. Walters, Director of the White House Office of National Drug Control Policy (substituted for his predecessor, Barry R. McCaffrey), and William B. Simpkins, Acting Administrator, United States Drug Enforcement Administration (substituted for his predecessors, Asa Hutchinson and Thomas A. Constantine). The named respondents are Dr. Marcus Conant, Dr. Donald Northfelt, Dr. Debashish Tripathy, Dr. Neil Flynn, Dr. Stephen Follansbee, Dr. Stephen O'Brien, Dr. Milton Estes, Jo Daly, Keith Vines, Judith Cushner, Valerie Corral, Bay Area Physicians for Human Rights, Being Alive: People with HIV/AIDS Action Coalition, Inc., Dr. Howard Maccabee, Daniel Kane, Dr. Allan Flach, and Michael Ferrucci.

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The Solicitor General, on behalf of the Attorney General of the United States, the Secretary of Health and Human Services, the Director of the Office of National Drug Control Policy, and the Acting Administrator of the Drug Enforcement Administration, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-39a) is reported at 309 F.3d 629. The opinion of the district court entering a permanent injunction (App., *infra*, 40a-73a) is unreported, but is available at 2000 WL 1281174. The opinion of the district court entering a preliminary injunction (App., *infra*, 74a-115a) is reported at 172 F.R.D. 681.

JURISDICTION

The judgment of the court of appeals was entered on October 29, 2002. A petition for rehearing was denied on February 6, 2003 (App., *infra*, 116a). On April 29, 2003, Justice O'Connor extended the time within which to file a

petition for a writ of certiorari to and including June 6, 2003. On May 29, 2003, Justice O'Connor granted a further extension to and including July 6, 2003 (a Sunday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, are set forth at App., *infra*, 134a-147a.

STATEMENT

1. The Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. Rep. No. 1444, 91st Cong., 2d Sess., Pt. 1, at 6 (1970); *United States* v. *Moore*, 423 U.S. 122, 141 (1975) (CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal.") (quoting H.R. Rep. No. 1444, *supra*, at 3). The CSA thus makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense," or to "possess," any controlled substance, "[e]xcept as authorized by" the Act itself. 21 U.S.C. 841(a)(1), 844(a); see *Moore*, 423 U.S. at 131, 135.

Under the CSA, each controlled substance is assigned to one of five "schedules" based on factors such as its potential for abuse, the extent to which it produces dependence, and the degree of accepted medical use. 21 U.S.C. 812; *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 491-492 (2001). For example, substances listed in Schedules II through IV may be "dispensed" under a prescription issued by a federally registered physician. 21 U.S.C. 829; see 21 U.S.C. 802, 822-824. A drug is included in Schedule II if it "has a high potential for abuse," but "has a currently accepted medical use in treatment in the United States" or "a currently accepted medical use with severe restrictions." 21 U.S.C. 812(b)(2)(A) and (B). Schedules III through V include drugs that also have "a currently accepted medical use in treatment," 21 U.S.C. 812(b)(3)(B), (4)(B) and

(5)(B), but have a lower potential for abuse and a lesser tendency to induce dependence. 21 U.S.C. 812(b)(3)-(5).

In contrast, controlled substances listed in Schedule I (such as heroin and marijuana) may not be dispensed by physicians under prescription because those substances have been determined as a matter of federal law to have "no currently accepted medical use in treatment." 21 U.S.C. 812(b)(1)(B). Schedule I substances, moreover, have been determined as a matter of federal law to have "a high potential for abuse" and to lack "accepted safety for use" even "under medical supervision." 21 U.S.C. 812(b)(1)(A) and (C). Schedule I substances may be distributed and used only in research that has been registered with the DEA and specifically approved by the Food and Drug Administration (FDA). 21 U.S.C. 823(f); 21 C.F.R. 5.10(a)(9), 1301.18, 1301.32; 28 C.F.R. 0.100(b); *Oakland Cannabis*, 532 U.S. at 490.

Consistent with the "closed" system of distribution established by the CSA, anyone seeking to manufacture, distribute, import, export, dispense, or administer controlled substances must obtain a registration from the Attorney General. 21 U.S.C. 822(a). Registrants must "adhere to certain recordkeeping and reporting requirements," see 21 U.S.C. 827, "that permit monitoring the flow of controlled substances within the 'closed' system" established by the CSA. S. Rep. No. 225, 98th Cong., 1st Sess. 261 (1983).

Registration under the CSA confers a status of special trust and responsibility. The Attorney General may refuse to register a practitioner (including a physician or pharmacy) "if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f). The Attorney General may revoke an existing registration on a number of grounds, including falsification of an application under the CSA, 21 U.S.C. 824(a)(1), conviction of a felony relating to controlled substances, 21 U.S.C. 824(a)(2), or revocation of the practitioner's state license to practice medicine or handle controlled substances, 21 U.S.C. 824(a)(3). In addition, the Attorney General may revoke an

existing registration if the registrant "has committed such acts as would render his registration * * * inconsistent with the public interest as determined under" Section 823. 21 U.S.C. 824(a)(4). Subsection (f) of Section 823 in turn sets out five factors for the Attorney General to consider in determining whether a practitioner's registration is inconsistent with the public interest. Those include the practitioner's compliance with laws relating to controlled substances (including the CSA), 21 U.S.C. 823(f)(4), and any "other conduct that may threaten the public health and safety." 21 U.S.C. 823(f)(5).[1] The Attorney General's authority to revoke registration for "other conduct that may threaten the public health and safety" was added in 1984 to expand the Attorney General's ability to "maintain[] the intended 'closed' system at the practitioner level." S. Rep. No. 225, *supra*, at 262.

Marijuana and tetrahydrocannabinols are Schedule I substances under federal law because they have "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." 21 U.S.C. 812(b)(1)(A)-(C). Physicians thus may not prescribe marijuana to their patients, and marijuana is lawfully available in the United States only through carefully controlled research approved by the DEA and the FDA. Congress classified marijuana as a Schedule I substance when it first enacted the CSA in 1970. See 84 Stat. 1249 (Schedule I(c)(10) and (17)). Although any controlled substance may be transferred to another schedule or removed from the schedules entirely, see 21 U.S.C. 811(a), the Administrator of the DEA has denied petitions to reclassify

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[1] The other factors include the recommendation of the State's licensing board or disciplinary authority, 21 U.S.C. 823(f)(1); the practitioner's experience in dispensing or conducting research with respect to controlled substances, 21 U.S.C. 823(f)(2); and the practitioner's prior conviction record under laws concerning the manufacture, distribution, or dispensing of controlled substances, 21 U.S.C. 823(f)(3).

marijuana, and marijuana accordingly has remained a Schedule I substance since the CSA's enactment. See 21 U.S.C. 812(c) (Schedule I(c)(10) and (17)); *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (D.C. Cir. 1994) (upholding decision declining to transfer marijuana from Schedule I to Schedule II); 66 Fed. Reg. 20,038 (2001), petition for review dismissed, *Gettman* v. *DEA*, 290 F.3d. 430 (D.C. Cir. 2002).[2]

b. In 1996, the voters of the State of California adopted Proposition 215 to decriminalize possession and cultivation of marijuana by individuals for putative medical purposes "upon the written or oral recommendation or approval of a physician." Cal. Health & Safety Code § 11362.5(d) (West Supp. 2003). Proposition 215 purports to give "seriously ill" Californians the right, under state law, to obtain and use marijuana for medical purposes where that medical use is "deemed appropriate" and "recommended" by a physician who has determined that "the person's health would benefit from the use of marijuana." *Id.* § 11362.5(b)(1)(A). The initiative states that it was designed to ensure that patients and their "primary caregivers" who obtain and use marijuana upon the "recommendation" of a physician "are not subject

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[2] Under 21 U.S.C. 811, "any interested party" who believes that medical, scientific, or other relevant data warrant transferring marijuana (or any other controlled substance) to a less restrictive schedule may petition the Attorney General to initiate a rulemaking proceeding to do so. 21 U.S.C. 811(a). Before initiating such a proceeding, the Administrator of the DEA, to whom the Attorney General has delegated his authority under the CSA (see 28 C.F.R. 0.100(b)), must request from the Secretary of Health and Human Services a scientific and medical evaluation and a recommendation as to whether the substance should be reclassified or decontrolled. The recommendations of the Secretary are binding on the Administrator with respect to scientific and medical matters. 21 U.S.C. 811(b). If the Administrator concludes that there is substantial evidence that the substance should be reclassified or decontrolled, he shall institute a public rulemaking proceeding on the record. 21 U.S.C. 811(b). Any party aggrieved by a final decision of the Administrator may seek review in a court of appeals. 21 U.S.C. 877; see *Gettman*, 290 F.3d at 432.

to criminal prosecution or sanction." *Id.* § 11362.5(b)(1)(B). The statute thus gives physician "recommendations" or "approvals" of marijuana legally operative effect under state law: Although a user may not possess or cultivate marijuana consistent with California law if the user lacks a physician's "recommendation," Proposition 215 makes possession and cultivation permissible for purposes of state law if he has such a recommendation. Other States have enacted similar legislation.[3]

Following the passage of Proposition 215 and a similar initiative in Arizona (see note 3, *supra*), the federal government announced the "Administration's Response to the Pas-

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[3] See Alaska Stat. §§ 11.71.090, 11.37.010 (2002) (exempting from state marijuana prosecution patients who file with the State "a statement signed by the patient's physician * * * that the physician has considered other approved medications and treatments * * * [and] has concluded that the patient might benefit from the medical use of marijuana"); Ariz. Rev. Stat. § 13-3412.01 (Supp. 2002) (providing that "any medical doctor * * * may prescribe a controlled substance included in Schedule I * * * to treat a disease, or to relieve the pain and suffering of a seriously ill patient"); Colo. Const. Art. XVIII, § 14 (requiring "a statement signed by a patient's physician or * * * pertinent medical records" indicating "the physician's conclusion that the patient might benefit from the medical use of marijuana"); Haw. Rev. Stat. § 329-122 (Supp. 2002) (requiring a physician to certify "in writing that, in the physician's professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks"); Me. Rev. Stat. Ann. tit. 22, § 2383-B.5 (West Supp. 2001) (requiring "written documentation from a physician * * * [advising] that the person might benefit from the medical use of marijuana to relieve pain or alleviate symptoms of the person's condition"); Nev. Rev. Stat. § 453A.210 (Supp. 2001) (requiring "[v]alid, written documentation from the person's attending physician stating that * * * [t]he medical use of marijuana may mitigate the symptoms or effects of that condition"); Or. Rev. Stat. §§ 475.309, 475.306 (2001) (requiring that the State receive "[v]alid, written documentation from the * * * attending physician stating that the person has been diagnosed with a debilitating medical condition and that the medical use of marijuana may mitigate the symptoms or effects"); Wash. Rev. Code §§ 69.51A.040, 69.51A.010 (Supp. 2003) (requiring a "statement signed by a qualifying patient's physician * * * that, in the physician's professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks").

sage of California Proposition 215 and Arizona Proposition 200." App., *infra*, 118a-129a. The Administration's Response informed the public that the possession and cultivation of marijuana remain illegal under federal law notwithstanding the changes in state law, and it identified a number of objectives to combat unlawful marijuana use and distribution. For example, the Response stated that the "Department of the Treasury and the Customs Service will continue to protect the nation's borders and take strong and appropriate enforcement action against imported or exported marijuana and other illegal drugs," *id.* at 121a; the Postal Service will "pursue aggressively the detection and seizure of Schedule I controlled substances mailed through the US mails," *id.* at 122a; and various federal agencies will continue their drug-free workplace and safety programs, *id.* at 124a-126a. To protect children from increased marijuana availability and use, the Response proposed education campaigns, increased study and data collection, and reliance on the Safe and Drug Free Schools Act. *Id.* at 127a-128a.

The Administration's Response also stated that, to protect the public health and ensure the integrity of the medical-scientific process, "evaluations of the medical usefulness of any controlled substance should be conducted through the Congressionally established research and approval process managed by the National Institutes of Health and the Food and Drug Administration" in the Department of Health and Human Services (HHS). App., *infra*, 123a. It explained that HHS will examine the current "medical and scientific evidence relevant to the perceived medical usefulness of marijuana," identifying "gaps in knowledge and research," and determine whether and how further research might provide additional scientific insight. *Ibid.*

In a section dedicated to preserving the effectiveness of the framework created by the CSA and the Federal Food, Drug and Cosmetic Act, the Administration's Response also stated that the "Department of Justice's position is that a practitioner's action of recommending or prescribing

Schedule I controlled substances is not consistent with the 'public interest' (as that phrase is used in the federal Controlled Substances Act) and will lead to administrative action by the Drug Enforcement Administration to revoke the practitioner's registration." App., *infra*, 119a-120a. In addition, the Response stated that the Department of Justice and HHS "will send a letter to national, state, and local practitioner associations and license boards which states unequivocally that DEA will seek to revoke DEA registrations of physicians who recommend or prescribe Schedule I controlled substances." *Id.* at 122a.

On February 27, 1997, the Department of Justice and HHS sent such a letter to national, state, and local practitioner associations (the "Medical Leader letter") to explain and clarify the government's position regarding discussions between physicians and patients about marijuana. App., *infra*, 130a-133a. The letter began by expressing concern about "several misperceptions" that had "developed concerning the federal government's response" to California's and Arizona's marijuana initiatives. *Id.* at 130a. "Before the[] enactment" of those initiatives, the letter observed, "nothing in federal law prevented a physician, in the context of a legitimate physician-patient relationship, from merely discussing with a patient the risks and alleged benefits of the use of marijuana to relieve pain or alleviate symptoms." *Id.* at 130a-131a. "This," the letter assured the medical profession, "continues to be true." *Id.* at 131a. The letter noted that "patients look to their physicians as their primary source of knowledge about a wide variety of potential health hazards and treatments." *Ibid.* Accordingly, the letter "encourage[d] physicians to talk with patients about their concerns and answer inquiries about any procedure, treatment, substance or device that may affect a patient's health," and to "share their knowledge and professional expertise regarding the risks, benefits, and legality of any potential medical treatment or modality." *Ibid.*

At the same time, the letter made clear that physicians registered under the CSA are under a duty not to assist patients in circumventing the CSA's closed system of controlled substance distribution. App., *infra*, 131a. The letter thus warned that physicians "may not intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law." *Ibid.* "Physicians who do so," the letter continued, "risk revocation of their DEA prescription authority, criminal prosecution, and exclusion from participation in the Medicare and Medicaid programs." *Ibid.*

The Medical Leader letter stressed that "[f]ederal law establishes the specific criteria that every potential medication must meet before it can be sold to the public or prescribed by doctors," and that "[f]or decades this process of federal drug approval has protected the American public from dangerous drugs and ineffective treatments." App., *infra*, 131a. "[T]his process," the letter continued, "must be preserved," and the determination of whether a drug has "an accepted medical use" therefore "should continue to be determined through rigorous scientific testing." *Ibid.* The letter explained that testing to date has not shown that "marijuana is a safe and effective drug with an accepted medical use," and that "the weight of current scientific evidence shows that marijuana can significantly harm" various physiological and mental functions. *Id.* at 132a. Nonetheless, the letter assured the medical community that the "federal government is undertaking additional steps to analyze carefully the state of all available scientific knowledge." *Ibid.* But "unless and until" marijuana is reclassified, the letter concluded, "current federal law remains in effect." *Id.* at 133a.

2. In early 1997, respondents (ten physicians, a physician organization, six patients with terminal illnesses, and an organization comprised of people with HIV/AIDS) filed this suit on behalf of a class of California patients and physicians to enjoin the federal government from bringing administra-

tive or criminal actions against physicians who recommend that their patients use marijuana. App., *infra*, 5a, 47a. Respondents also sought a declaration that the government's alleged "threats" to enforce federal law "in a manner that would punish or penalize physicians for communicating with their patients * * * regarding potential risks and benefits of medical use of marijuana" violate the First Amendment. C.A. E.R. 136 (Second Amended Compl., Prayer for Relief, ¶ B).

The district court certified a class and entered a preliminary injunction on April 30, 1997. See App., *infra*, 74a-115a. On September 7, 2000, the district court entered a permanent injunction. *Id.* at 40a-73a. The district court rejected the government's argument that respondents cannot bring a pre-enforcement overbreadth challenge to the government's statements regarding the circumstances that could result in the revocation of physician registrations, concluding that the Administration's Response sufficiently threatened to chill free expression.[4]

On the merits, the district court agreed with the government that the text of 21 U.S.C. 823(f)(5) and principles of deference under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), support the government's position. By permitting the DEA to revoke a physician's registration for "such other conduct which may threaten the public health and safety," the district court acknowledged, Congress "presumably" sought to reach "conduct apart from that already listed in the previous four factors," such as "convictions * * * and violations of the law relating to controlled substances." App., *infra*, 64a. The district court also agreed that "[r]ecommending the medical use of a prohibited substance" such as marijuana "might

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[4] The district court rejected respondents' request for an injunction against enforcement of criminal laws and potential exclusion from Medicare/Medicaid. App., *infra*, 57a. Respondents did not seek review of that ruling.

arguably fall within such 'other conduct'" and thus constitute a proper basis for revoking a physician's registration. *Ibid.*

Nonetheless, relying on the First Amendment and the doctrine of constitutional avoidance, the district court construed the CSA to prohibit the revocation of a physician's registration on that ground. The court held that what it regarded as physicians' "legitimate need to discuss with and to recommend to their patients all medically acceptable forms of treatment" outweighs the government's "legitimate interest in suppressing and controlling the flow of dangerous drugs and controlled substances within the United States." App., *infra*, 67a. The court noted that, in the government's view, physicians may "'discuss' the pros and cons of marijuana therapy with their patients." *Id.* at 68a. But it concluded that the DEA could not revoke the registration of physicians who recommend that their patients smoke marijuana, even though such recommendations have legally operative effect under California law. In the court's view, "mere recommendation will [not] necessarily lead to the commission of a federal offense," because patients can rely on the recommendation to participate in DEA-registered and FDA-approved research, move to a country without marijuana prohibitions, or petition Congress to change the laws. *Id.* at 68a-70a. The court also expressed concern that physicians might be deterred from speaking with their patients candidly because the line between permissible discussions of the "pros and cons" of marijuana use and impermissible "recommendations" is uncertain. *Id.* at 71a.

Accordingly, the district court permanently enjoined the government "from (i) revoking a class-member physician's DEA registration merely because the doctor recommends medical marijuana to a patient based on a sincere medical judgment and (ii) from initiating any investigation solely on that ground." App., *infra*, 73a. The injunction "applies whether or not the physician anticipates that the recommen-

dation will, in turn, be used by the patient to obtain marijuana in violation of federal law." *Ibid.*

3. The United States Court of Appeals for the Ninth Circuit affirmed. App., *infra*, 1a-40a. The Ninth Circuit first rejected the government's argument that a physician's recommendation that a patient use marijuana is, by virtue of California law, analogous to a "prescription" for a controlled substance. *Id.* at 9a. A physician issuing a prescription, the court reasoned, intends for the patient to fill it and obtain the substance, while physicians recommending marijuana do not necessarily have that intent. *Ibid.* The court of appeals also observed that the injunction excepts from its scope physician conduct that amounts to criminal aiding and abetting or conspiracy to violate the CSA, *i.e.*, instances in which the physician acts with the specific intent of facilitating the commission of an offense. *Id.* at 9a-10a. A recommendation would not necessarily constitute such criminal conduct, the court stated, because the physician could lawfully seek to place the patient in a federally approved clinical trial, or the patient might rely on the recommendation to petition the government to change the law. See *id.* at 8a-9a.

The Ninth Circuit also rejected the government's challenge to the injunction against even initiating an investigation based on a physician's recommendation that his patients use marijuana. It reasoned that "[b]ecause a doctor's recommendation does not itself constitute illegal conduct, the portion of the injunction barring investigations solely on that basis does not interfere with the federal government's ability to enforce its laws." App., *infra*, 12a.

Finally, the court of appeals held that the revocation of a physician's registration under the CSA in the circumstances identified in the government's statements would be inconsistent with the First Amendment. Emphasizing the importance of doctor-patient communications, the court stated that—notwithstanding the extensive regulation of the practice of medicine—"professional speech may be entitled to 'the strongest protection our Constitution has to offer.'"

App., *infra*, 13a (quoting *Florida Bar* v. *Went For It, Inc.*, 515 U.S. 618, 634 (1995)). The court of appeals characterized the government's statements as "condemn[ing] the expression of a particular viewpoint, i.e., that medical marijuana would likely help a particular patient." *Id.* at 14a. And the court held that, given the First Amendment interests at stake, the government's policy was not sufficiently tailored. Although the policy allowed physicians to discuss the pros and cons of marijuana, the court stated that the government had not provided a clear definition of what constitutes a prohibited "recommendation" of marijuana. *Id.* at 17a. That failure to "articulate exactly what speech is proscribed," the court held, chills free expression by causing physicians to refrain from "speech that would not rise to the level of that which the government constitutionally may prohibit." *Id.* at 17a-18a (internal quotation marks omitted). Finally, the court invoked "principles of federalism," under which States are "the primary regulators of professional conduct." *Ibid.*

In a concurring opinion, Judge Kozinski expressed the view that patients have a strong First Amendment interest in receiving candid advice about the medical uses of marijuana, a subject concerning which there exists a "genuine difference of expert opinion." App., *infra*, 26a. Judge Kozinski further expressed the view that, by restricting the ability of doctors to make "recommendations" under Proposition 215, the federal government has "commandeer[ed]" the State to defeat California's decision to decriminalize medical marijuana under state law. *Id.* at 29a-36a.

REASONS FOR GRANTING THE PETITION

The Ninth Circuit's decision in this case affirms a sweeping injunction that forbids the DEA from taking administrative action to revoke a physician's registration —and bars the DEA even from initiating an investigation —based on the physician's recommendation that his patients use marijuana as a medical treatment. The court upheld that injunction even though it is illegal to manufacture,

distribute, dispense, or possess marijuana under federal law, and even though that drug has been determined, pursuant to the same federal statute under which physicians are registered, to have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and not to be safe for use even "under medical supervision," 21 U.S.C. 812(b)(1)(A)-(C). That judicial intrusion into the DEA's regulatory and investigatory authority cannot be sustained. A State's decision to lift criminal sanctions for the possession of marijuana based on a physician's recommendation does not limit the federal government's independent regulatory authority with respect to physicians who chose to obtain registration under the CSA.

The Ninth Circuit's holding that the First Amendment forbids the federal government from exercising its statutory authority is an issue of exceptional and continuing importance that warrants review by this Court, especially since seven States in the Ninth Circuit have enacted laws that purport to lift marijuana prohibitions based on physician advice. First, by holding that the First Amendment bars the DEA from invoking 21 U.S.C. 823(f)(5) to investigate or revoke a physician's registration for conduct that "may threaten the public health and safety" unless the physician is committing a criminal offense, the court of appeals held unconstitutional a provision of an Act of Congress as applied in this important setting. That holding is of particular significance, because Congress added Section 823(f)(5) to ensure that the DEA could revoke registrations even absent a criminal conviction. Second, the Ninth Circuit's decision impairs the Executive's authority to enforce the law in an area vital to the public health and safety. Third, by ignoring the fundamental distinction between speech and conduct in the context of physician-patient interactions, the Ninth Circuit effectively licensed physicians to treat patients with prohibited substances outside the CSA's "closed" system of controlled substance distribution. And fourth, the decision ignores fundamental separation of powers concerns by im-

posing sweeping and unprecedented restrictions on the government's ability even to investigate possible violations of the law.

1. The Ninth Circuit erred in holding that the DEA would violate the First Amendment by revoking a physician's registration, or by even initiating an investigation of physician conduct, based on a physician's recommendation to his patients that they use marijuana as a medical treatment. The practice of medicine is subject to reasonable licensing and regulation, even where that practice involves speech. See *Planned Parenthood* v. *Casey*, 505 U.S. 833, 884 (1992) (opinion of O'Connor, Kennedy, and Souter, JJ.) (physician's First Amendment interest in not speaking subject to the State's reasonable licensing and regulation of the practice of medicine); *id.* at 967 (opinion of Rehnquist, C.J.) (requirement to furnish information permissible because it is rationally related to assuring a fully informed decision). Any First Amendment rights of doctors in the course of their practice of medicine, like the rights of other highly regulated professionals, must be "balance[d] * * * against the State's legitimate interest in regulating the activity in question." *Gentile* v. *State Bar*, 501 U.S. 1030, 1075 (1991).

Here, the CSA establishes a closed system for the distribution of controlled substances, prohibits physicians from prescribing such substances absent registration with the DEA, and authorizes the DEA to revoke such registration if a physician violates the CSA, 21 U.S.C. 823(f)(4), or engages in "other conduct" that "may threaten the public health and safety," 21 U.S.C. 823(f)(5); see 21 U.S.C. 824(a)(4). It is beyond dispute that a physician's recommendation that a patient take Schedule I controlled substances such as heroin or LSD would be a threat to public health and safety and justify investigation and potential revocation of the physician's registration. There is no statutory or First Amendment basis for treating marijuana, another Schedule I substance, differently. The government's ability to enforce the CSA cannot vary from one Schedule I substance to another

based on the public policy views adopted by States or the courts. See *Oakland Cannabis*, 532 U.S. at 493 (holding that marijuana "should not be treated any less restrictively than other schedule I drugs.").

As a matter of federal law, *all* Schedule I substances have "a high potential for abuse," have "no currently accepted medical use in treatment in the United States," and are not "accepted" as safe "for use" even "under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C). Consequently, just as a physician engages in "conduct which may threaten the public health and safety" within the meaning of 21 U.S.C. 823(f)(5) by recommending Schedule I substances like LSD and heroin to his patients as medical treatments, a physician may likewise threaten the public health and safety by recommending, as medical advice, that his patients use marijuana. Such recommendations promote illegal drug use, jeopardize the patient's health, do not have an accepted medical purpose, and circumvent the "closed" system of controlled substances distribution created by the CSA. See 21 U.S.C. 801(2) ("The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.").

The States and registered physicians, of course, may disagree with the federal government's decision to classify marijuana as a Schedule I substance. Physicians may voice that disagreement to the public or to their patients. And they may seek to have marijuana removed from Schedule I through administrative petitions and judicial review under 21 U.S.C. 877, or by urging an amendment of the CSA. But any such contrary views do not give physicians registered under the CSA a license to bypass the CSA's closed system of controlled substance distribution, of which they form an integral part, by prescribing or recommending treatment regimens in which patients purchase Schedule I substances like heroin, LSD, or marijuana on the street.

a. The Ninth Circuit's decision in this case holds Sections 823(f)(5) and 824(a)(4) of the CSA unconstitutional as applied to revocation of registration based on such recommendations —even when they have an operative effect under state law similar to a prescription—unless the government can establish a federal criminal violation of aiding and abetting or conspiracy. See App., *infra*, 5a-6a, 9a (declaring that the government may proceed only if "officials in good faith believe that they have 'probable cause to charge under the federal aiding and abetting and/or conspiracy statutes'"); see also *id.* at 11a-12a ("[T]he government may not initiate an investigation of a physician solely on the basis of a recommendation of marijuana * * * unless the government in good faith believes it has substantial evidence of criminal conduct."). Congress clearly did not intend for the DEA's authority to deny or revoke registration to be so limited. Physicians and other registrants under the CSA have a position of special trust and responsibility, and they therefore are properly held to a higher standard than merely avoiding criminal violations of the Act. For that reason, the CSA expressly provides that the DEA may revoke a physician's registration if the physician "commit[s] such acts as would render his registration under Section 823 * * * inconsistent with the public interest," 21 U.S.C. 824(a)(4), including not only noncompliance with controlled substances laws, 21 U.S.C. 823(f)(4), but also "such other conduct which may threaten the public health and safety," 21 U.S.C. 823(f)(5). And there can be no doubt that such "other conduct" includes *non*-criminal behavior, since criminal conduct is covered by other provisions. See, *e.g.*, 21 U.S.C. 824(a)(2) (revocation for conviction of a felony relating to controlled substances); 21 U.S.C. 823(f)(3) and (4) (public interest considerations of "conviction record" and "compliance with applicable State, Federal, or local laws relating to controlled substances"); App., *infra*, 64a.

The Ninth Circuit's decision is of particular significance given Section 823(f)(5)'s purpose. Before 1984, a physician's

registration could be revoked only if the physician materially falsified his application, was convicted of a felony, or lost his state registration or license. S. Rep. No. 225, 98th Cong., 1st Sess. 266 (1983). But Congress concluded that such "overly limited bases * * * for denial or revocation" failed to "operate in the public interest." *Ibid.* Requiring the government to wait for state regulatory action, a conviction, or criminal conduct prevented the government from exercising "strong regulatory authority to maintain a 'closed' distribution chain * * * at the practitioner level," *id.* at 261—the level at which "80 to 90 percent of all" illegal drug diversion was taking place. *Id.* at 261-262. It was to close that gap that Congress added Section 823(f)(5)'s reference to "other conduct" that may "threaten the public health and safety." See *id.* at 262, 266-267. By prohibiting investigations of physician conduct and revocations of physician registrations in the absence of criminal conduct, the Ninth Circuit's decision has re-established as a matter of constitutional law the very gap that Section 823(f)(5) was designed to close.

b. The Ninth Circuit's First Amendment analysis rests on the erroneous premise that a physician's recommendation that a patient smoke marijuana is pure speech that cannot form the basis of government action. Physician recommendations like those at issue here are not pure speech. The recommendation of what the patient should do—and which drugs to take in particular—are part of the treatment of disease, a medical service the government may regulate. See *Casey*, 505 U.S. at 884 (opinion of O'Connor, Kennedy, and Souter, JJ.) ("practice of medicine" is "subject to reasonable licensing and regulation by the State"). Indeed, physician recommendations are especially significant precisely because patients are not only prone but expected to follow them.

For that very reason, courts have routinely rejected First Amendment challenges to regulatory or judicial actions against medical practitioners who prescribe or recommend treatments contrary to state licensing laws or public health

and safety. See, *e.g.*, *Nebraska Dep't of Health* v. *Hinze*, 441 N.W.2d 593, 595 (Neb. 1989) (rejecting First Amendment challenge to criminal contempt citation against doctor of "naturopathy" who recommended various homeopathic and naturopathic treatments for individual patients without state license and in violation of injunction); *Shea* v. *Board of Med. Exam'rs*, 146 Cal. Rptr. 653, 662 (1978) (upholding revocation of physician's medical license for unprofessional conduct; finding that "the First Amendment is not an umbrella shielding the type of verbal conduct in which the doctor engaged. It does not insulate the verbal charlatan from responsibility for his conduct; nor does it impede the State in the proper exercise of its regulatory functions"); cf. *People* v. *Jeffers*, 690 P.2d 194, 198 (Colo. 1984) ("The practice of medicine itself is not protected by the First Amendment. Therefore, reasonable regulation of medical practice does not conflict with First Amendment protections."). Moreover, physicians who provide incompetent advice even in good faith have long been subject to malpractice claims. Such claims are unobjectionable because they do not challenge speech but rather the adequacy of care, even if that care is provided through speech (*e.g.*, diagnosis and recommendations).

California's passage of Proposition 215 in no way diminishes the federal government's authority to investigate and take appropriate action under the CSA in response to registrant conduct that relates to controlled substances and that threatens public health and safety. To the contrary, because Proposition 215 gives a physician's "recommendation" legal effect for purposes of California law and makes it "analogous to a prescription," *Pearson* v. *McCaffrey*, 139 F. Supp. 2d 113, 121 (D.D.C. 2001) (rejecting First Amendment challenge parallel to that presented here), it magnifies the potential threat to public health and safety posed by physician recommendations that their patients use marijuana. Absent a physician recommendation, an individual may not legally possess or use marijuana under California law; with such a

recommendation, an individual may do both. See Cal. Health & Safety Code § 11362.5(d) (West Supp. 2002).

More fundamentally, the recommendation represents the course of treatment the physician has proposed for the patient. As such, it is subject to reasonable regulation. Congress and the DEA (in consultation with HHS) have made the determination under the CSA that there is no currently accepted medical use for marijuana, that marijuana has a high potential for abuse, and that it is not accepted as safe for use even under medical supervision. A physician who nevertheless recommends to a patient that he use marijuana contravenes that controlling determination under the CSA just as if he had recommended the use of LSD or heroin. It has never been thought to be an abridgment of free speech to make a course of conduct sanctionable merely because it was initiated or carried out by means of language, whether spoken, written or printed. See *Giboney* v. *Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949); *Ohralik* v. *Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978) ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity."). A fortiori, it does not violate the First Amendment to revoke the registration of a physician under an Act of Congress if that physician recommends that patients engage in conduct that both contravenes that Act *and* threatens the public health and safety.

The concerns resulting from physician recommendations to use marijuana are heightened by the fact that, in California and other States having similar laws, they often are used to obtain marijuana illegally. See *Oakland Cannabis*, 532 U.S. at 486 (explaining that to become a member of the Oakland Cannabis Cooperative, "a patient *must provide a written statement from a treating physician assenting to marijuana therapy* * * *. If accepted as a member, the patient receives an identification card entitling him to obtain marijuana from the Cooperative.") (emphasis added). Indeed, respondents emphasized in their Second

Amended Complaint that "the recommendation or approval of a physician" is a "precondition" to permissible use of marijuana under Proposition 215, because "[w]ithout this clinical recommendation or approval, patients and their 'primary caregivers' are unable to invoke [Proposition 215's] protections from criminal prosecution or sanction under state law." C.A. E.R. 128 (Compl. ¶ 38).

In these circumstances, the government's efforts in 1996 and 1997 to warn physicians against conduct that is substantially likely to facilitate and promote the acquisition and use of an unsafe controlled substance having a high potential for abuse and no accepted medical use under federal law do not abridge any First Amendment rights. Instead, those efforts legitimately sought to ensure that physicians—who occupy a special position of trust and responsibility in maintaining the CSA's closed system of distribution for controlled drugs—exercise their authority in a manner that is consistent with the tight regulation of controlled substances that Congress established to protect the public.

c. Perhaps recognizing that difficulty, the Ninth Circuit and the district court hypothesized that patients may use physician recommendations for lawful purposes, such as enrollment in a clinical trial approved by the DEA and the FDA or petitioning Congress to change the law. App., *infra*, 8a-9a, 68a-70a. That speculation blinks reality. First, it is hard to imagine that many patients seeking such "recommendations" or physicians making them realistically expect the recommendation to be used for those purposes, rather than to establish an exemption from state law for conduct that still violates federal law. Yet the injunction prohibits administrative investigation and enforcement even if "the doctor anticipates that the patient will, in turn, use his or her recommendation to obtain marijuana in violation of federal law." *Id.* at 6a-7a; see *id.* at 10a-11a.

Second, nothing in the CSA or the Administration's Response and Medical Leader letter prevents physicians from pursuing lawful courses of action such as seeking to enroll

their patients in lawful medical research, urging expansion of such research, or urging patients to lobby for political change. What physicians may not do is to recommend the use of marijuana to their patients so as to exempt them from state law prohibitions, carelessly disregarding the substantial likelihood that the patients will follow the recommendations by using marijuana in violation of federal law.

The Ninth Circuit's rationale, moreover, reflects a misunderstanding of the statements in the Administration's Response and Medical Leader letter—a misunderstanding that likely results from the abstract nature of this anticipatory challenge. A physician "recommendation" is not a basis for revoking a federal registration except insofar as it may threaten the public health and safety or violate the CSA. Moreover, physicians are fiduciaries and occupy a position of trust and responsibility as integral parts of the closed system established by the CSA. Accordingly, they have a duty to ensure that they do not use their authority in a way that promotes the use of marijuana in violation of the CSA.

A physician who genuinely wishes to express his opinion to a patient regarding marijuana, and who at the same time genuinely wishes to avoid treating the patient with marijuana or promoting contravention of the CSA, could be expected to warn his patient that the distribution and possession of marijuana are illegal under federal law; to inform the patient that Congress and the responsible federal agencies have 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," 21 U.S.C. 812(b)(1)(A)-(C); and to advise the patient that the physician's comments about marijuana are not to be considered a recommendation or approval of the use of marijuana except through enrollment in a DEA-registered and FDA-approved clinical trial. It is extraordinarily unlikely that a physician who forthrightly and genuinely offers such information and warnings to a patient would be found to have engaged in

conduct that threatens the public health and safety, and therefore to warrant revocation of his registration. If the physician is uncertain about what might be said, one answer (as in other contexts) may be more speech rather than less. See *Casey*, 505 U.S. at 884 (plurality opinion) (sustaining law requiring warning of consequences of an abortion).

Indeed, with that basic point in mind, the February 1997 Medical Leader letter, in responding to the California and Arizona initiatives, emphasized that "nothing in federal law prevent[s] a physician * * * from merely discussing with a patient the risks and alleged benefits of the use of marijuana to relieve pain or alleviate symptoms," and it "encouraged" physicians to "share their knowledge and professional expertise regarding the risks, benefits, *and legality* of any potential medical treatment or modality." App., *infra*, 130a-131a (emphasis added). As the court in *Pearson* recognized in evaluating the same government admonitions concerning the California and Arizona laws, 139 F. Supp. 2d at 120, "doctors, patients, and researchers may freely discuss the benefits and risks of the use of marijuana without fearing that the federal government will proceed against them with criminal, civil, or administrative penalties." Respondents may not be satisfied with the mere expression of opinions by physicians in California, or with physician discussions about marijuana that include the sort of warnings described above, if what they seek is a legally operative recommendation that will exempt patients from California's marijuana laws. But even with such a recommendation, a patient's conduct in obtaining and using marijuana would remain illegal as a matter of federal law. See *Oakland Cannabis*, *supra.* There is no legitimate interest, protected by the First Amendment, in enabling physicians to facilitate such illegal conduct by their patients. Cf. *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 388-389 (1973).

For similar reasons, the Ninth Circuit erred in asserting that the government's admonitions impermissibly chill speech because they did not define "recommendation." App.,

infra, 16a-17a. The term "recommendation" has no independent significance as a matter of federal law; the government used the words "recommendation" and "prescribing" because they were used in the state laws that triggered the government's concerns. Under federal law, the question is whether the physician's conduct "may threaten the public health and safety." 21 U.S.C. 823(f)(5). Nor was the federal government required to provide precise guidance on what physicians in diverse settings throughout the Nation should or should not say about marijuana, *id.* at 17a; the DEA could reasonably determine not to impose that sort of scripting of doctor-patient discussions out of a respect for physician autonomy and to preserve the openness of the exchange between physician and patient.

In any event, all that is required is for the law to give persons "of ordinary intelligence a reasonable opportunity to know what is prohibited" and "provide explicit standards for those who apply them." *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). Context is also important, for the standards in question in this case apply to physicians, who practice under pervasive regulation of their professional conduct, especially on matters concerning public health and safety. Here, the statutory standards of the CSA, together with the Administration's Response and Medical Leader letter, give physicians ample guidance.

Even in the context of electoral politics, this Court has concluded that the distinction between a "discussion" of a candidate and "express advocacy" in favor of that candidate's election is sufficiently precise to withstand constitutional scrutiny. *Buckley* v. *Valeo*, 424 U.S. 1, 43-44, 80 (1976); *Federal Election Comm'n* v. *Furgatch*, 807 F.2d 857, 862-864 (9th Cir.), cert. denied, 484 U.S. 850 (1987); see *Master Printers of Am.* v. *Donovan*, 751 F.2d 700, 711 (4th Cir. 1984) (holding that "persuade" is not impermissibly vague), cert. denied, 474 U.S. 818 (1985). The courts upheld those distinctions even though the challenged terminology (unlike the term "recommendation") had controlling signifi-

cance as a matter of federal law and even though electoral politics (unlike doctor recommendations to patients) stand at the very core of First Amendment protections.

In the present context, California physicians of ordinary intelligence and professional training can understand the difference between a discussion by a physician of the risks and alleged benefits of various treatment options, and a recommendation by the physician that the patient use one of those options, especially where using that particular treatment would be a crime under federal law. Physicians thus place their registration under the CSA at risk if they recommend the use of Schedule I substances in disregard of the substantial risk that their patients will follow their recommendation in violation of federal law by obtaining and using those substances outside the closed system established by the CSA. With respect to a drug that 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" even "under medical supervision," 21 U.S.C. 812(b)(1)(A)-(C), such conduct unquestionably "may threaten the public health and safety." 21 U.S.C. 823(f)(5).

By contrast, no such threat to the public health and safety arises if physicians in California merely express their views on marijuana—even views directly contrary to the judgments thus far made by Congress, the DEA, and the FDA—particularly if they make good faith efforts to prevent the expression of their views from becoming a recommendation that may promote or facilitate unlawful marijuana use. See pp. 22-23, *supra*. Any lingering uncertainty about the line between conduct by the physician that may lead to revocation of registration and discussions that would not can be avoided if the physician makes reasonable efforts to ensure that his statements are not invoked as a recommendation of unlawful conduct in derogation of the CSA, such as by furnishing the warnings and disclaimers identified above. See pp. 22-23, *supra*. Physicians are often under a professional duty to provide medical warnings (such as

warnings about side-effects), and the Ninth Circuit nowhere identified any harm that would result to physician-patient discourse in California if a physician gave similar medical and legal warnings with respect to controlled substances listed in Schedule I of the CSA. See *Casey*, 505 U.S. at 884 (opinion of O'Connor, Kennedy, and Souter, JJ.); *id.* at 967 (opinion of Rehnquist, C.J.).

For the same reason, respondents have not shown the substantial overbreadth necessary to support this anticipatory challenge to possible future revocation of a physician's registration by pointing to the statements in the Administration's Response and Medical Leader letter, which focused specifically on recently passed state laws that gave legally operative effect to physician recommendations and prescriptions for the use of marijuana. Indeed, respondents have not shown that the DEA would *ever* revoke the registration of a physician "engaged in constitutionally protected speech." See *Virginia* v. *Hicks*, 123 S. Ct. 2191, 2197, 2198 (2003).

2. The Ninth Circuit independently erred—and grossly intruded on the authority of the Executive Branch to investigate possible CSA violations—by prohibiting the government from "initiating any investigation solely on [the basis of a physician recommendation], unless the government has substantial evidence of criminal conduct." App., *infra*, 5a, 11a-12a. The court of appeals justified that prohibition with a single sentence: "Because a doctor's recommendation does not itself constitute illegal conduct, the portion of the injunction barring investigations solely on that basis does not interfere with the federal government's ability to enforce its laws." *Id.* at 12a. That reasoning, however, rests on an obviously false premise. Even if conduct is not itself criminal, it still can provide suspicion of criminal conduct or form a reasonable basis for investigation. A publication advocating non-payment of income taxes is not illegal, and may be protected speech, but nothing in the First Amendment or any other principle of law prohibits the

government from verifying whether the author has filed tax returns. See, *e.g.*, *Alliance to End Repression* v. *City of Chicago*, 742 F.2d 1007, 1014, 1015-1016 (7th Cir. 1984) (en banc). Moreover, by enjoining the Executive from even investigating, the injunction unnecessarily interferes with the discovery and prosecution of potentially serious crimes.

This Court reversed a Ninth Circuit decision that made the same mistake just two Terms ago in *United States* v. *Arvizu*, 534 U.S. 266 (2002). In that case, the Ninth Circuit held that certain actions by a motorist were entitled to no weight in establishing reasonable suspicion because each was "readily susceptible to an innocent explanation." *Id.* at 272, 274. Reversing, this Court explained that even acts that may appear "innocent" by themselves may cumulatively warrant "further investigation." *Id.* at 274.

In the present context, DEA officials investigating cannabis clubs sometimes find a large number of written marijuana recommendations from particular physicians. Even assuming *arguendo* that such recommendations could properly be regarded as "innocent" by themselves—and that some physicians who issued them were acting within the bounds of the CSA—certainly the DEA has a legitimate interest in investigating further so as to distinguish the physicians who were behaving responsibly from those who were not. Indeed, the injunction's primary effect is not to protect physicians acting in good faith (who are unlikely to be the subject of administrative or criminal proceedings), but to protect those who effectively "sell" marijuana recommendations en masse, cf. *Moore*, 423 U.S. at 126-127, since such sales are most likely to come to the DEA's attention when searches of cannabis clubs and similar trafficking locations uncover the recommendations themselves.

In any event, the Ninth Circuit's ruling on this point is utterly inconsistent with the broad discretion agencies have to investigate potential violations of federal law. There is a strong general presumption against judicial intervention in criminal and administrative investigations. See, *e.g.*, *Jobs*,

Training & Servs., Inc. v. *East Tex. Council*, 50 F.3d 1318, 1324-1325 (5th Cir. 1995); *O'Brien, Inc.* v. *SEC*, 704 F.2d 1065, 1067 n.6 (9th Cir. 1983). Other courts of appeals have refused to preclude the government from merely gathering information or investigating on First Amendment grounds. See, *e.g.*, *Reporters Comm.* v. *AT&T*, 593 F.2d 1030, 1065 (D.C. Cir. 1978) (holding that the First Amendment neither bars "good faith" investigations "by means which accord with Fourth and Fifth Amendment protections" nor "insulate[s]" citizens "from the general and subjective inhibitions that naturally arise from the prospect of such investigation"), cert. denied, 440 U.S. 949 (1979); see also *Socialist Workers Party* v. *Attorney General of the United States*, 510 F.2d 253, 256 (2d Cir. 1974). As one court explained, a decree that purports to deprive the government of power "to investigate anything that cannot be punished"—such as one that bars the government from commencing an investigation "solely on the basis of activities protected by the First Amendment"—represents a "remarkable judicial intervention in vital executive functions" that "trifles with the public safety" and the Executive's "constitutional obligation to 'take Care that the Laws be faithfully executed.'" *Alliance to End Repression*, 742 F.2d at 1010, 1014-1015. Yet the Ninth Circuit has upheld precisely such a decree here, requiring probable cause to believe a crime has occurred before the government can even *investigate*. And such a threshold requirement is particularly out of place where the investigations concern civil administrative enforcement of provisions addressing non-criminal conduct. See pp. 17-18, *supra*.

In *Reno* v. *American-Arab Antidiscrimination Committee*, 525 U.S. 471, 488 (1999), this Court rejected the similar argument that the deportation policy at issue there had an unconstitutional "chilling effect" on First Amendment rights. Referring to the rules governing selective prosecution claims in the criminal context, the Court explained that, "[b]ecause such claims invade a special

province of the Executive—its prosecutorial discretion—we have emphasized that the standard for proving them is particularly demanding, requiring a criminal defendant to introduce 'clear evidence' displacing the presumption that a prosecutor has acted lawfully." *Id.* at 489. In this case, the Ninth Circuit and district court went even further by enjoining the Executive from exercising its authority even to *investgate* conduct, based solely on the unsupported and erroneous assertion that the government would not be injured thereby.

3. The Ninth Circuit's decision in this case holds unconstitutional important provisions of an Act of Congress designed to protect the public health and safety as applied in the context of physician recommendations that patients use Schedule I controlled substances. In so doing, the decision seriously undermines the integrity of the registration process under the CSA: It requires the DEA to maintain the registration of physicians, who occupy a special position of responsibility and trust under the CSA, even though they have (1) recommended that their patients use marijuana—a substance that has a high potential for abuse, no accepted medical use, and is not safe for use even under medical supervision—as a medical treatment, and (2) disregarded the substantial likelihood that their patients will follow those recommendations in violation of federal law by obtaining that controlled substance outside the closed system of distribution established by the CSA. The decision also constitutes an unprecedented judicial intrusion on the Executive Branch's investigatory authority. The decision, moreover, now represents governing precedent for the entire Ninth Circuit, which includes seven of the nine States that have enacted laws that legalize the possession of marijuana based on the opinions of physicians. See note 3, *supra*. Given the decision's significant legal, programmatic, and practical consequences, this Court's review is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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JULY 2003

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 00-17222

D.C. No. CV-97-00139-WHA

MARCUS CONANT, DR.; DONALD NORTHFELT, DR.; DEBASHISH TRIPATHY, DR.; NEIL FLYNN, DR.; STEPHEN FOLLANSBEE, DR.; STEPHEN O'BRIEN, DR.; MILTON ESTES, DR.; JO DALY; KEITH VINES; JUDITH CUSHNER; VALERIE CORRAL; BAY AREA PHYSICIANS FOR HUMAN RIGHTS; BEING ALIVE: PEOPLE WITH HIV/AIDS ACTION COALITION, INC.; HOWARD MACCABEE, DR.; DANIEL KANE; ALLAN FLACH, DR.; MICHAEL FERRUCCI, PLAINTIFFS-APPELLEES

v.

JOHN P. WALTERS,[*] DIRECTOR OF THE OFFICE OF NATIONAL DRUG CONTROL POLICY; ASA HUTCHINSON,[**] ADMINISTRATOR, U.S. DEA;

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[*] John P. Walters is substituted for his predecessor, Barry R. McCaffrey, as Director of the White House Office of National Drug Control Policy. Fed. R. App. P. 43(c)(2).

[**] Asa Hutchinson is substituted for his predecessor, Thomas A. Constantine, as Administrator of the U.S. DEA. Fed. R. App. P. 43(c)(2).

JOHN ASHCROFT,[***] ATTORNEY GENERAL OF THE UNITED STATES; TOMMY G. THOMPSON,[****] SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEFENDANTS-APPELLANTS

Argued and Submitted: April 8, 2002
Filed: Oct. 29, 2002

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

WILLIAM H. ALSUP, DISTRICT JUDGE, PRESIDING

Before: SCHROEDER, Chief Judge, B. FLETCHER and KOZINSKI, Circuit Judges.

SCHROEDER, Chief Judge.

This is an appeal from a permanent injunction entered to protect First Amendment rights. The order enjoins the federal government from either revoking a physician's license to prescribe controlled substances or conducting an investigation of a physician that might lead to such revocation, where the basis for the government's action is solely the physician's professional "recommendation" of the use of medical marijuana. The district court's order and accompanying opinion are at

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[***] John Ashcroft is substituted for his predecessor, Janet Reno, as Attorney General of the United States. Fed. R. App. P. 43(c)(2).

[****] Tommy G. Thompson is substituted for his predecessor, Donna E. Shalala, as Secretary of the Department of Health and Human Services. Fed. R. App. P. 43(c)(2).

Conant v. McCaffrey, 2000 WL 1281174 (N.D. Cal. Sept. 7, 2000). The history of the litigation demonstrates that the injunction is not intended to limit the government's ability to investigate doctors who aid and abet the actual distribution and possession of marijuana. 21 U.S.C. § 841(a). The government has not provided any empirical evidence to demonstrate that this injunction interferes with or threatens to interfere with any legitimate law enforcement activities. Nor is there any evidence that the similarly phrased preliminary injunction that preceded this injunction, *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997), which the government did not appeal, interfered with law enforcement. The district court, on the other hand, explained convincingly when it entered both the earlier preliminary injunction and this permanent injunction, how the government's professed enforcement policy threatens to interfere with expression protected by the First Amendment. We therefore affirm.

I. The Federal Marijuana Policy

The federal government promulgated its policy in 1996 in response to initiatives passed in both Arizona and California decriminalizing the use of marijuana for limited medical purposes and immunizing physicians from prosecution under state law for the "recommendation or approval" of using marijuana for medical purposes. *See* Cal. Health & Safety Code § 11362.5. The federal policy declared that a doctor's "action of recommending or prescribing Schedule I controlled substances is not consistent with the 'public interest' (as that phrase is used in the federal Controlled Substances Act)" and that such action would lead to revocation of the physician's registration to prescribe controlled sub-

stances.[1] The policy relies on the definition of "public interest" contained in 21 U.S.C. § 823(f), which provides:

> In determining the public interest, the following factors shall be considered: (1) The recommendation of the appropriate State licensing board or professional disciplinary authority. (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances. (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances. (4) Compliance with applicable State, Federal, or local laws relating to controlled substances. (5) Such other conduct which may threaten the public health and safety.

The policy also said that the DOJ and the HHS would send a letter to practitioner associations and licensing boards informing those groups of the policy. The federal agencies sent a letter two months later to national, state, and local practitioner associations outlining the Administration's position ("Medical Leader Letter"). The Medical Leader Letter cautioned that physicians who "intentionally provide their pa-

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[1] The policy was entitled "The Administration's Response to the Passage of California Proposition 215 and Arizona Proposition 200" and was released on December 30, 1996, by Barry R. McCaffrey, the Director of the Office of National Drug Control Policy ("ONDCP") at the time. The Administration's Response was promulgated by an interagency working group that included the ONDCP; the Drug Enforcement Administration ("DEA"); the Department of Justice ("DOJ"); the Department of Health and Human Services ("HHS"); the Nuclear Regulatory Commission; and the Departments of Treasury, Defense, Transportation, and Education.

tients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law . . . risk revocation of their DEA prescription authority."

II. Litigation History

Plaintiffs are patients suffering from serious illnesses, physicians licensed to practice in California who treat patients with serious illnesses, a patient's organization, and a physician's organization. The patient organization is Being Alive: People with HIV/AIDS Action Coalition, Inc. The physician's organization is the Bay Area Physicians for Human Rights. Plaintiffs filed this action in early 1997 to enjoin enforcement of the government policy insofar as it threatened to punish physicians for communicating with their patients about the medical use of marijuana. The case was originally assigned to District Judge Fern Smith, who presided over the case for more than two years. After Judge Smith received the parties' briefs, she issued a temporary restraining order, certified a plaintiff class, denied the government's motion to dismiss, issued a preliminary injunction, awarded interim attorney's fees to plaintiffs, and set the briefing schedule for discovery.

Judge Smith entered the preliminary injunction on April 30, 1997. It provided that the government "may not take administrative action against physicians for recommending marijuana unless the government in good faith believes that it has substantial evidence" that the physician aided and abetted the purchase, cultivation, or possession of marijuana, 18 U.S.C. § 2, or engaged in a conspiracy to cultivate, distribute, or possess marijuana, 21 U.S.C. § 846. *Id.* at 700. Judge Smith specifically enjoined the "defendants, their

agents, employees, assigns, and all persons acting in concert or participating with them, from threatening or prosecuting physicians, [or] revoking their licenses . . . based upon conduct relating to medical marijuana that does not rise to the level of a criminal offense." *Id.* at 701. The preliminary injunction covered not only "recommendations," but also "non-criminal activity related to those recommendations, such as providing a copy of a patient's medical chart to that patient or testifying in court regarding a recommendation that a patient use marijuana to treat an illness." *Id.* at 701 n. 8.

The government did not appeal the preliminary injunction, and it remained in effect after the case was transferred more than two years later to Judge Alsup on August 19, 1999. Judge Alsup in turn granted a motion to modify the plaintiff class, held a hearing on motions for summary judgment, granted in part and denied in part the cross-motions for summary judgment, dissolved the preliminary injunction, and entered a permanent injunction. The class was modified to include only those patients suffering from specific symptoms related to certain illnesses and physicians who treat such patients. The permanent injunction appears to be functionally the same as the preliminary injunction that Judge Smith originally entered. It provides that the government is permanently enjoined from:

> (i) revoking any physician class member's DEA registration merely because the doctor makes a recommendation for the use of medical marijuana based on a sincere medical judgment and (ii) from initiating any investigation solely on that ground. The injunction should apply whether or not the doctor anticipates that the patient will, in turn, use

> his or her recommendation to obtain marijuana in violation of federal law.

Conant, 2000 WL 1281174, at *16.

In explaining his reasons for entering the injunction, Judge Alsup pointed out that there was substantial agreement between the parties as to what doctors could and could not do under the federal law. *Id.* at *11. The government agreed with plaintiffs that revocation of a license was not authorized where a doctor merely discussed the pros and cons of marijuana use. *Id.* The court went on to observe that the plaintiffs agreed with the government that a doctor who actually prescribes or dispenses marijuana violates federal law. The fundamental disagreement between the parties concerned the extent to which the federal government could regulate doctor-patient communications without interfering with First Amendment interests. *Id.* This appeal followed.

III. Discussion

It is important at the outset to observe that this case has been litigated independently of contemporaneous litigation concerning whether federal law exempts from prosecution the dispensing of marijuana in cases of medical necessity. The Supreme Court in that litigation eventually held that it does not, reversing this court. *See United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001), *rev'g United States v. Oakland Cannabis Buyers' Coop.*, 190 F.3d 1109 (9th Cir. 1999). When the district court entered the permanent injunction in this case, it pointed out that it was doing so without regard to this Circuit's decision in the *Oakland Cannabis* litigation. *Conant*, 2000 WL 1281174, at *15 n.7.

The dispute in the district court in this case focused on the government's policy of investigating doctors or initiating proceedings against doctors only because they "recommend" the use of marijuana. While the government urged that such recommendations lead to illegal use, the district court concluded that there are many legitimate responses to a recommendation of marijuana by a doctor to a patient. There are strong examples in the district court's opinion supporting the district court's conclusion. For example, the doctor could seek to place the patient in a federally approved, experimental marijuana-therapy program. *Id.* at *15. Alternatively, the patient upon receiving the recommendation could petition the government to change the law. *Id.* at *14. By chilling doctors' ability to recommend marijuana to a patient, the district court held that the prohibition compromises a patient's meaningful participation in public discourse. *Id.* The district court stated:

> Petitioning Congress or federal agencies for redress of a grievance or a change in policy is a time-honored tradition. In the marketplace of ideas, few questions are more deserving of free-speech protection than whether regulations affecting health and welfare are sound public policy. In the debate, perhaps the status quo will (and should) endure. But patients and physicians are certainly entitled to urge their view. To hold that physicians are barred from communicating to patients sincere medical judgments would disable patients from understanding their own situations well enough to participate in the debate. As the government concedes, . . . many patients depend upon discussions with their physicians as their primary or only source of sound

> medical information. Without open communication with their physicians, patients would fall silent and appear uninformed. The ability of patients to participate meaningfully in the public discourse would be compromised.

Id.

On appeal, the government first argues that the "recommendation" that the injunction may protect is analogous to a "prescription" of a controlled substance, which federal law clearly bars. We believe this characterizes the injunction as sweeping more broadly than it was intended or than as properly interpreted. If, in making the recommendation, the physician intends for the patient to use it as the means for obtaining marijuana, as a prescription is used as a means for a patient to obtain a controlled substance, then a physician would be guilty of aiding and abetting the violation of federal law. That, the injunction is intended to avoid. Indeed the predecessor preliminary injunction spelled out what the injunction did not bar; it did not enjoin the government from prosecuting physicians when government officials in good faith believe that they have "probable cause to charge under the federal aiding and abetting and/or conspiracy statutes." 172 F.R.D. at 701.

The plaintiffs themselves interpret the injunction narrowly, stating in their brief before this Court that, "the lower court fashioned an injunction with a clear line between protected medical speech and illegal conduct." They characterize the injunction as protecting "the dispensing of information," not the dispensing of controlled substances, and therefore assert that the injunction does not contravene or undermine federal law.

As Judge Smith noted in the preliminary injunction order, conviction of aiding and abetting requires proof that the defendant "associate[d] himself with the venture, that he participate[d] in it as something that he wishe[d] to bring about, that he [sought] by his actions to make it succeed." 172 F.R.D. at 700 (quoting *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 190, 114 S. Ct. 1439, 128 L. Ed. 2d 119 (1994) (internal quotation marks and citation omitted)). This is an accurate statement of the law. We have explained that a conviction of aiding and abetting requires the government to prove four elements: "(1) that the accused had the specific intent to facilitate the commission of a crime by another, (2) that the accused had the requisite intent of the underlying substantive offense, (3) that the accused assisted or participated in the commission of the underlying substantive offense, and (4) that someone committed the underlying substantive offense." *See United States v. Gaskins*, 849 F.2d 454, 459 (9th Cir. 1988). The district court also noted that conspiracy requires that a defendant make "an agreement to accomplish an illegal objective and [that he] knows of the illegal objective and intends to help accomplish it." 172 F.R.D. at 700-01 (citing *United States v. Gil*, 58 F.3d 1414, 1423 & n. 5 (9th Cir. 1995)).

The government on appeal stresses that the permanent injunction applies "whether or not the doctor anticipates that the patient will, in turn, use his or her recommendation to obtain marijuana in violation of federal law," and suggests that the injunction thus protects criminal conduct. A doctor's anticipation of patient conduct, however, does not translate into aiding and abetting, or conspiracy. A doctor would aid and abet by acting with the specific intent to provide a

patient with the means to acquire marijuana. *See Gaskins*, 849 F.2d at 459. Similarly, a conspiracy would require that a doctor have knowledge that a patient intends to acquire marijuana, agree to help the patient acquire marijuana, and intend to help the patient acquire marijuana. *See Gil*, 58 F.3d at 1423. Holding doctors responsible for whatever conduct the doctor could anticipate a patient *might* engage in after leaving the doctor's office is simply beyond the scope of either conspiracy or aiding and abetting.

The government also focuses on the injunction's bar against "investigating" on the basis of speech protected by the First Amendment and points to the broad discretion enjoyed by executive agencies in investigating suspected criminal misconduct. The government relies on language in the permanent injunction that differs from the exact language in the preliminary injunction. The permanent injunction order enjoins the government "from initiating any investigation solely on" the basis of "a recommendation for the use of medical marijuana based on a sincere medical judgment." *Conant*, 2000 WL 1281174, at *16. The preliminary injunction order provided that "the government may not take administrative action against physicians for recommending marijuana unless the government in good faith believes that it has substantial evidence of [conspiracy or aiding and abetting]." 172 F.R.D. at 701.

The government, however, has never argued that the two injunctive orders differ in any material way. Because we read the permanent injunction as enjoining essentially the same conduct as the preliminary injunction, we interpret this portion of the permanent injunction to mean only that the government 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. Because a doctor's recommendation does not itself constitute illegal conduct, the portion of the injunction barring investigations solely on that basis does not interfere with the federal government's ability to enforce its laws.

The government policy does, however, strike at core First Amendment interests of doctors and patients. An integral component of the practice of medicine is the communication between a doctor and a patient. Physicians must be able to speak frankly and openly to patients. That need has been recognized by the courts through the application of the common law doctor-patient privilege. *See* Fed. R. Evid. 501.

The doctor-patient privilege reflects "the imperative need for confidence and trust" inherent in the doctor-patient relationship and recognizes that "a physician must know all that a patient can articulate in order to identify and to treat disease; barriers to full disclosure would impair diagnosis and treatment." *Trammel v. United States*, 445 U.S. 40, 51, 100 S. Ct. 906, 63 L. Ed. 2d 186 (1980). The Supreme Court has recognized that physician speech is entitled to First Amendment protection because of the significance of the doctor-patient relationship. *See Planned Parenthood of Southeastern Pennsylvania v. Casey,* 505 U.S. 833, 884, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992) (plurality) (recognizing physician's First Amendment right not to speak); *Rust v. Sullivan,* 500 U.S. 173, 200, 111 S. Ct. 1759, 114 L. Ed. 2d 233 (1991) (noting that regulations on physician speech may "impinge upon the doctor-patient relationship").

This Court has also recognized the core First Amendment values of the doctor-patient relationship. In *Nat'l Ass'n for the Advancement of Psychoanalysis v. California Bd. of Psychology*, 228 F.3d 1043 (9th Cir. 2000), we recognized that communication that occurs during psychoanalysis is entitled to First Amendment protection. *Id.* at 1054. We upheld California's mental health licensing laws that determined when individuals qualified as mental health professionals against a First Amendment challenge. *Id.* at 1053-56. Finding the laws content-neutral, we noted that California did not attempt to "dictate the content of what is said in therapy" and did not prevent licensed therapists from utilizing particular "psycho-analytical methods." *Id.* at 1055-56.

Being a member of a regulated profession does not, as the government suggests, result in a surrender of First Amendment rights. *See Thomas v. Collins*, 323 U.S. 516, 531, 65 S. Ct. 315, 89 L. Ed. 430 (1945) ("the rights of free speech and a free press are not confined to any field of human interest"). To the contrary, professional speech may be entitled to "the strongest protection our Constitution has to offer." *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 634, 115 S. Ct. 2371, 132 L. Ed. 2d 541 (1995). Even commercial speech by professionals is entitled to First Amendment protection. *See Bates v. Arizona*, 433 U.S. 350, 382-83, 97 S. Ct. 2691, 53 L. Ed. 2d 810 (1977). Attorneys have rights to speak freely subject only to the government regulating with "narrow specificity." *NAACP v. Button*, 371 U.S. 415, 433, 438-39, 83 S. Ct. 328, 9 L. Ed. 2d 405 (1963).

In its most recent pronouncement on regulating speech about controlled substances, *Thompson v. West-*

ern States Medical Ctr., 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002), the Supreme Court found that provisions in the Food and Drug Modernization Act of 1997 that restricted physicians and pharmacists from advertising compounding drugs violated the First Amendment. *Id.* at 1500. The Court refused to make the "questionable assumption that doctors would prescribe unnecessary medications" and rejected the government's argument that "people would make bad decisions if given truthful information about compounded drugs." *Id.* at 1507. The federal government argues in this case that a doctor-patient discussion about marijuana might lead the patient to make a bad decision, essentially asking us to accept the same assumption rejected by the Court in *Thompson*. *Id.* We will not do so. Instead, we take note of the Supreme Court's admonition in *Thompson:* "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try." *Id.*

The government's policy in this case seeks to punish physicians on the basis of the content of doctor-patient communications. Only doctor-patient conversations that include discussions of the medical use of marijuana trigger the policy. Moreover, the policy does not merely prohibit the discussion of marijuana; it condemns expression of a particular viewpoint, i.e., that medical marijuana would likely help a specific patient. Such condemnation of particular views is especially troubling in the First Amendment context. "When the government targets not subject matter but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant." *Rosen-*

berger v. Rector, 515 U.S. 819, 829, 115 S. Ct. 2510, 132 L. Ed. 2d 700 (1995). Indeed, even content-based restrictions on speech are "presumptively invalid." *R.A.V. v. St. Paul*, 505 U.S. 377, 382, 112 S. Ct. 2538, 120 L. Ed. 2d 305 (1992).

The government's policy is materially similar to the limitation struck down in *Legal Services Corp. v. Velazquez*, 531 U.S. 533, 121 S. Ct. 1043, 149 L. Ed. 2d 63 (2001), that prevented attorneys from "present[ing] all the reasonable and well-grounded arguments necessary for proper resolution of the case." 531 U.S. at 545, 121 S. Ct. 1043. In *Velazquez*, a government restriction prevented legal assistance organizations receiving federal funds from challenging existing welfare laws. *Id.* at 537-38, 121 S. Ct. 1043. Like the limitation in *Velazquez*, the government's policy here "alter[s] the traditional role" of medical professionals by "prohibit[ing] speech necessary to the proper functioning of those systems." *Id.* at 544, 121 S. Ct. 1043.

The government relies upon *Rust* and *Casey* to support its position in this case. *Rust*, 500 U.S. 173, 111 S. Ct. 1759, 114 L. Ed. 2d 233; *Casey*, 505 U.S. 833, 112 S. Ct. 2791, 120 L. Ed. 2d 674. However, those cases did not uphold restrictions on speech itself. *Rust* upheld restrictions on federal funding for certain types of activity, including abortion counseling, referral, or advocacy. *See Rust*, 500 U.S. at 179-80, 111 S. Ct. 1759. In *Casey*, a plurality of the Court upheld Pennsylvania's requirement that physicians' advice to patients include information about the health risks associated with an abortion and that physicians provide information about alternatives to abortion. 505 U.S. at 883-84, 112 S. Ct. 2791. The plurality noted that physicians did not have to comply if they had a reasonable belief

that the information would have a "severely adverse effect on the physical or mental health of the patient," and thus the statute did not "prevent the physician from exercising his or her medical judgment." *Id.* The government's policy in this case does precisely that.

The government seeks to justify its policy by claiming that a doctor's "recommendation" of marijuana may encourage illegal conduct by the patient, which is not unlike the argument made before, and rejected by, the Supreme Court in a recent First Amendment case. *See Ashcroft v. Free Speech Coalition*, 535 U.S. 234, 122 S. Ct. 1389, 1403, 152 L. Ed. 2d 403 (2002). In *Free Speech Coalition*, the government defended the Child Pornography Prosecution Act of 1996 by arguing that, although virtual child pornography does not harm children in the production process, it threatens them in "other, less direct, ways." *Id.* at 1397. For example, the government argued pedophiles might use such virtual images to encourage children to participate in sexual activity. *Id.* The Supreme Court rejected such justifications, holding that the potential harms were too attenuated from the proscribed speech. "Without a significantly stronger, more direct connection, the Government may not prohibit speech on the ground that it may encourage . . . illegal conduct." *Id.* at 1403. The government's argument in this case mirrors the argument rejected in *Free Speech Coalition.*

The government also relies on a case in which a district court refused to order an injunction against this federal drug policy. *See Pearson v. McCaffrey*, 139 F. Supp. 2d 113, 125 (D.D.C. 2001). The court did so, however, because the plaintiffs in that case did not factually support their claim that the policy chilled their speech. *See id.* at 120. In this case, the record is re-

plete with examples of doctors who claim a right to explain the medical benefits of marijuana to patients and whose exercise of that right has been chilled by the threat of federal investigation. The government even stipulated in the district court that a "reasonable physician would have a genuine fear of losing his or her DEA registration to dispense controlled substances if that physician were to recommend marijuana to his or her patients."

To survive First Amendment scrutiny, the government's policy must have the requisite "narrow specificity." *See Button*, 371 U.S. at 433, 83 S. Ct. 328. Throughout this litigation, the government has been unable to articulate exactly what speech is proscribed, describing it only in terms of speech the patient believes to be a recommendation of marijuana. Thus, whether a doctor-patient discussion of medical marijuana constitutes a "recommendation" depends largely on the meaning the patient attributes to the doctor's words. This is not permissible under the First Amendment. *See Thomas v. Collins*, 323 U.S. 516, 535, 65 S. Ct. 315, 89 L.Ed. 430 (1945). In *Thomas*, the court struck down a state statute that failed to make a clear distinction between union membership, solicitation, and mere "discussion, laudation, [or] general advocacy." The distinction rested instead on the meaning the listeners attributed to spoken words. *Id.* The government's policy, like the statute in *Thomas*, leaves doctors and patients "no security for free discussion." *Id.* As Judge Smith appropriately noted in granting the preliminary injunction, "when faced with the fickle iterations of the government's policy, physicians have been forced to suppress speech that would not rise to

the level of that which the government constitutionally may prohibit." 172 F.R.D. at 696.

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"). We must "show[ ] respect for the sovereign States that comprise our Federal Union. That respect imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country." *Oakland Cannabis*, 532 U.S. at 501, 121 S. Ct. 1711 (Stevens, J., concurring) (internal quotation marks omitted).

For all of the foregoing reasons, we affirm the district court's order entering a permanent injunction.

AFFIRMED.

KOZINSKI, Circuit Judge, concurring:

I am pleased to join Chief Judge Schroeder's opinion. I write only to explain that for me the fulcrum of this dispute is not the First Amendment right of the doctors. That right certainly exists and its impairment justifies the district court's injunction for the reasons

well explained by Chief Judge Schroeder. But the doctors' interest in giving advice about the medical use of marijuana is somewhat remote and impersonal; they will derive no direct *benefit* from giving this advice, other than the satisfaction of doing their jobs well. At the same time, the *burden* of the federal policy the district court enjoined falls directly and personally on the doctors: By speaking candidly to their patients about the potential benefits of medical marijuana, they risk losing their license to write prescriptions, which would prevent them from functioning as doctors. In other words, they may destroy their careers and lose their livelihoods.[1]

This disparity between benefits and burdens matters because it makes doctors peculiarly vulnerable to intimidation; with little to gain and much to lose, only the most foolish or committed of doctors will defy the federal government's policy and continue to give patients candid advice about the medical uses of marijuana.[2] Those immediately and directly affected by the

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[1] Dr. Neil M. Flynn, Professor at the University of California at Davis School of Medicine, offers one perspective:

> AIDS medicine is my profession and my passion. I have dedicated myself to this disease since 1983 when I opened the Clinic at U.C. Davis. Thus, I am deeply concerned about civil and criminal sanctions that loom over me. . . . If I lost my Schedule II license, my ability to provide care for people with AIDS—80% of my patients—would be severely compromised. I write 30-50 narcotic prescriptions per month for my seriously ill patients. I would no longer be able to do so if my DEA license were revoked.

[2] As Alice Pasetta Mead explained in her expert report:

> [P]hysicians are particularly easily deterred by the threat of governmental investigation and/or sanction from engaging in conduct that is entirely lawful and medically appropriate. . . .

federal government's policy are the patients, who will be denied information crucial to their well-being, and the State of California, whose policy of exempting certain patients from the sweep of its drug laws will be thwarted. In my view, it is the vindication of these latter interests—those of the patients and of the state—that primarily justifies the district court's highly unusual exercise of discretion in enjoining the federal defendants from even investigating possible violations of the federal criminal laws.

> [A] physician's practice is particularly dependent upon the physician's maintaining a reputation of unimpeachable integrity. A physician's career can be effectively destroyed merely by the fact that a governmental body has investigated his or her practice. . . .

The federal government's policy had precisely this effect before it was enjoined by the district court. Dr. Milton N. Estes, Associate Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Medicine at the University of California-San Francisco (UCSF), reports:

> As a result of the government's public threats, I do not feel comfortable even discussing the subject of medical marijuana with my patients. I feel vulnerable to federal sanctions that could strip me of my license to prescribe the treatments my patients depend upon, or even land me behind bars. . . . Because of these fears, the discourse about medical marijuana has all but ceased at my medical office. . . . My patients bear the brunt of this loss in communication.

And Dr. Stephen O'Brien, former co-director of UCSF HIV Managed Care, similarly notes:

> Due to fear caused by these threats, I feel compelled and coerced to withhold information, recommendations, and advice to patients regarding use of medical marijuana. . . . I am fearful and reluctant to engage in even limited communications regarding medical marijuana.

In 1996, the people of California, acting by direct initiative, adopted a narrow exemption from their laws prohibiting the cultivation, sale and use of marijuana. The exemption applies only to patients whose physicians recommend or prescribe the drug for medical purposes. To those unfamiliar with the issue, it may seem faddish or foolish for a doctor to recommend a drug that the federal government finds has "no currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1)(B). But the record in this case, as well as the public record, reflect a legitimate and growing division of informed opinion on this issue. A surprising number of health care professionals and organizations have concluded that the use of marijuana may be appropriate for a small class of patients who do not respond well to, or do not tolerate, available prescription drugs.[3]

Following passage of the California initiative, the White House Office of National Drug Control Policy commissioned the National Institute of Medicine of the National Academy of Sciences (IOM) to review the scientific evidence of the therapeutic application of cannabis. *See* Inst. of Med., *Marijuana and Medicine: Assessing the Science Base* (Janet E. Joy et al. eds., 1999) [hereinafter IOM Report], *available at* http://www.nap.edu/books/0309071550/html. The year-long study included scientific workshops, analysis of relevant scientific literature and extensive consultation with biomedical and social scientists. *Id.* at 15. It resulted in a 250-plus-page report which concluded that

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[3] I am indebted to the brief of amici American Public Health Association et al. for its lucid and forceful analysis of this issue. Much of the discussion in the text is plagiarized from that brief. For ease of readability, I dispense with further attribution.

"[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation," *id.* at 179.

The IOM Report found that marijuana can provide superior relief to patients who suffer these symptoms as a result of certain illnesses and disabilities, in particular metastic cancer, HIV/AIDS, multiple sclerosis (MS), spinal cord injuries and epilepsy, and those who suffer the same symptoms as side effects from the aggressive treatments for such conditions. *See id.* at 53, 142, 153-54, 157, 160. As a consequence, the IOM Report cautiously endorsed the medical use of marijuana. *See id.* at 179.[4]

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[4] The IOM Report concluded:

> Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions: failure of all approved medications to provide relief has been documented, the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs, such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and [the treatment] involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

Id. at 179.

The IOM limited its recommendation to six months primarily because of health concerns about damage from smoking the drug for a prolonged period of time. *See id.* at 126, 179. This concern may be less alarming to patients suffering critical or terminal illnesses. As Dr. Debasish Tripathy, Assistant Clinical Professor of Medicine at UCSF, explains, "Any discussion of adverse consequences appears to focus on the effects of long-term use (*e.g.*,

At about the time the IOM study got underway, the British House of Lords—a body not known for its wild and crazy views—opened public hearings on the medical benefits and drawbacks of cannabis. Like the IOM, the Lords concluded that "cannabis almost certainly does have genuine medical applications, especially in treating the painful muscular spasms and other symptoms of MS and in the control of other forms of pain." Select Comm. on Sci. & Tech., House of Lords, Sess. 1997-98, Ninth Report, *Cannabis: The Scientific and Medical Evidence: Report* § 8.2 (Nov. 4, 1998), *available at* http://www.publications.parliament.uk/pa/ld199798/ldselect/ldsctech/151/15101.htm. The Lords recommended that the British government act immediately "to allow doctors to prescribe an appropriate preparation of cannabis, albeit as an unlicensed medicine." *Id.* § 8.6.

In June 2001, Canada promulgated its Marihuana Medical Access Regulations after an extensive study of the available evidence. *See* Marihuana Medical Access Regulations, SOR 2001-227 (June 14, 2001), *available at* http://laws.justice.gc.ca/en/C-38.8/SOR-2001-227/index.html. The new regulations allow certain persons to cultivate and possess marijuana for medical use, and authorize doctors to recommend and prescribe marijuana to patients who are suffering from severe pain,

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adverse effects on the lungs), and even those concerns are speculative. . . . In populations with short life expectancies, the risks become less imminent and the benefits more paramount." *See also* Jerome P. Kassirer, M.D., Editorial, *Federal Foolishness and Marijuana*, New Eng. J. Med., Jan. 30, 1997, at 366, 366 ("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.").

muscle spasms, anorexia, weight loss or nausea, and who have not found relief from conventional therapies. *See* Office of Cannabis Med. Access, Health Canada, *Medical Access to Marijuana—How the Regulations Work*, *at* http://www.hc-sc.gc.ca/hecs-sesc/ocma/bckdr_1-0601.htm (last visited Aug. 23, 2002).[5]

Numerous other studies and surveys support the use of medical marijuana in certain limited circumstances.[6]

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[5] In 1988, an Administrative Law Judge of the Drug Enforcement Administration similarly concluded that certain patients should have access to medical marijuana. *See In re Marijuana Rescheduling Petition*, No. 86-22 (Drug Enforcement Admin. Sept. 6, 1988). ALJ Young found:

> 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.

Id. at 68. The DEA Administrator did not endorse the ALJ's findings. *See* 54 Fed. Reg. 53,767 (Dec. 29, 1989).

[6] *See, e.g.*, Clive Cookson, *High Hopes for Cannabis To Relieve Pain*, Fin. Times, Sept. 4, 2001, National News, at 4 ("Cannabis extract is proving remarkably effective at relieving severe pain in patients with multiple sclerosis and spinal injury. . . ."); David Baker et al., *Cannabinoids Control Spasticity and Tremor in a Multiple Sclerosis Model*, 404 Nature 84 (2000) (finding therapeutic potential in the use of cannabis to control the debilitating symptoms of MS); William J. Martin, *Basic Mechanisms of Cannabinoid-Induced Analgesia*, Int'l Ass'n for the Study of Pain Newsletter, Summer 1999, *available at* http://www.halcyon.com/iasp/TC99Summer.html (noting that cannabinoids can reduce pain); Richard E. Doblin & Mark A.R. Kleiman, *Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes*, 9 J. Clinical Oncology 1314 (1991) (reporting that a majority of oncologists surveyed thought marijuana should be

The federal government itself has conducted studies on the subject, and continues to fund and provide the marijuana for studies conducted by private researchers. *See, e.g.*, Bill Workman, *Pot Study in Spotlight: San Mateo County's Clinical Trial Is a First in U.S.*, S.F. Chron., July 25, 2001, at A13; *see also* University of California Center for Medicinal Cannabis Research, *Research, at* http://www.cmcr.ucsd.edu/geninfo/research.htm (last visited Aug. 23, 2002) (listing eleven studies, nine of which have received regulatory approval, that will use federally supplied marijuana). Finally, the medical histories of individuals who have received and continue to receive medical marijuana from the federal government (reproduced in the Appendix) provide compelling support for the view that medical marijuana can make the difference between a relatively normal life and a life marred by suffering.

No doubt based on this and similar evidence, seven states (Alaska, Arizona, Colorado, Maine, Nevada, Oregon and Washington) have followed California in enacting medical marijuana laws by voter initiative, *see* Alaska Stat. Ann. §§ 11.71.090, 17.37.010-.080; Ariz. Rev. Stat. § 13-3412.01; Colo. Const. art. XVIII, § 14; Me. Rev. Stat. Ann. tit. 22, § 2383-B5; Nev. Const. art. 4, § 38; Or. Rev. Stat. §§ 475.300-.346; Wash. Rev. Code §§ 69.51A.005-.902; one other state (Hawaii) has

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available by prescription); H.M. Meinck et al., *Effect of Cannabinoids on Spasticity and Ataxia in Multiple Sclerosis*, 236 J. Neurology 120 (1989) (concluding from a neurological study that herbal cannabis provided relief from both muscle spasms and ataxia, a combined benefit not found in other available medications); Vincent Vinciguerra et al., *Inhalation Marijuana as an Antiemetic for Cancer Chemotherapy*, 88 N.Y. St. J. Med. 525 (1988) (finding that 78% of patients who were unresponsive to standard antiemetics responded positively to cannabis).

done so by legislative enactment, *see* Haw. Rev. Stat. §§ 329-121 to 128. The total number of states that have approved marijuana for medical purposes now stands at nine.

The evidence supporting the medical use of marijuana does not prove that it is, in fact, beneficial. There is also much evidence to the contrary, and the federal defendants may well be right that marijuana provides no additional benefit over approved prescription drugs, while carrying a wide variety of serious risks.[7] What matters, however, is that there is a genuine difference of expert opinion on the subject, with significant scientific and anecdotal evidence supporting both points of view. *See (Medical) MarijuanaInfo.org*, *at* http://www.marijuanainfo.org (last visited Aug. 27, 2002) (exhaustive catalog of information and expert opinion on both sides of the medical marijuana debate). For the great majority of us who do not suffer from debilitating pain, or who have not watched a loved one waste away as a result of AIDS-induced anorexia, *see* IOM Report at 154, it doesn't much matter who has the better of this debate. But for patients suffering from MS, cancer, AIDS or one of the other afflictions listed in the IOM report, and their loved ones, obtaining candid and reliable information about a possible avenue of relief is of vital importance.

It is well established that the right to hear—the right to receive information—is no less protected by the First Amendment than the right to speak. *See*, *e.g.*, *Bd. of Educ. v. Pico*, 457 U.S. 853, 866-67, 102 S. Ct. 2799, 73 L. Ed. 2d 435 (1982); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756-57,

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[7] *See* 66 Fed. Reg. 20,038 (Apr. 18, 2001) (citing sources).

96 S. Ct. 1817, 48 L. Ed. 2d 346 (1976); *Kleindienst v. Mandel*, 408 U.S. 753, 762-63, 92 S. Ct. 2576, 33 L. Ed. 2d 683 (1972). Indeed, the right to hear and the right to speak are flip sides of the same coin. As Justice Brennan put it pithily, "It would be a barren marketplace of ideas that had only sellers and no buyers." *Lamont v. Postmaster General*, 381 U.S. 301, 308, 85 S. Ct. 1493, 14 L. Ed. 2d 398 (1965) (Brennan, J., concurring), *quoted with approval in Pico*, 457 U.S. at 867, 102 S. Ct. 2799. This does not mean, however, that the right to speak and the right to listen always carry the same weight when a court exercises its equitable discretion. In this case, for instance, it is perfectly clear that the harm to patients from being denied the right to receive candid medical advice is far greater than the harm to doctors from being unable to deliver such advice.[8] While denial of the right to speak is never trivial, the simple fact is that if the injunction were denied, the doctors would be able to continue practicing

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[8] Dr. Stephen Eliot Follansbee, Chief of Staff at Davies Medical Center, noted the importance of this information to patients:

> Patients who seek my advice regarding the benefits of medical marijuana are evidence that there is hope. They have a very strong desire to survive their illness and to function as normally and productively as possible. . . . These patients ask me about marijuana not because they want to get high, but because they are fighting for their lives, which includes an honest search for the best available means to do so. Government threats against the physicians who struggle with these patients will inevitably thwart the patients' efforts. They may, in fact, remove their doctors from the healing process when vulnerable individuals are most in need of their counsel. Denying information and treatment advice to a seriously ill patient, when that medicine could promote and facilitate critical medical treatment, may needlessly hasten the patient's death.

medicine and go on with their lives more or less as before. It is far different for patients who suffer from horrible disabilities, such as plaintiff Judith Cushner, a mother of two and the director of a preschool program, who has fought breast cancer since 1989, and who only found relief from the debilitating effects of chemotherapy by smoking cannabis to counteract nausea, retching and chronic mouth sores; plaintiff Keith Vines, an Assistant District Attorney, decorated Air Force officer and father, whose bout with AIDS had caused him to lose more than 40 pounds of lean body mass, which he was only able to recover by using cannabis to stimulate his appetite; and many others like them. Enforcement of the federal policy will cut such patients off from competent medical advice and leave them to decide on their own whether to use marijuana to alleviate excruciating pain, nausea, anorexia or similar symptoms. But word-of-mouth and the Internet are poor substitutes for a medical doctor; information obtained from chat rooms and tabloids cannot make up for the loss of individualized advice from a physician with many years of training and experience.

A few patients may be deterred by the lack of a doctor's recommendation from using marijuana for medical purposes, but I suspect it would be very few indeed, because the penalties under state law for possession of small amounts of the drug are trivial. *See* Cal. Health & Safety Code § 11357(b) (making small-quantity possession a misdemeanor carrying a maximum $100 fine). A far more likely consequence is that, in the absence of sound medical advice, many patients desperate for relief from debilitating pain or nausea would self-medicate, and wind up administering the wrong dose or frequency, or use the drug where a

physician would advise against it. Whatever else the parties may disagree about, they agree that marijuana is a powerful and complex drug, the kind of drug patients should *not* use without careful professional supervision.[9] The unintended consequence of the federal government's policy—a policy no doubt adopted for laudable reasons—will be to dry up the only reliable source of advice and supervision critically ill patients have, and drive them to use this powerful and dangerous drug on their own.

Which points to the second important interest impaired by the federal government's policy: California's interest in legalizing the use of marijuana in certain limited circumstances, so that critically ill patients may

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[9] Patients who use marijuana for medical purposes must strike a delicate balance; they must take enough of the drug so that they get needed relief from pain or other symptoms, but not so much as to induce the drug's well-known hallucinogenic side-effects, which interfere with daily life activities. Valerie A. Corral, who suffered from severe seizures before using medical marijuana, explains that she only needs "a few puffs of marijuana" to find relief that over fifteen pills a day could not provide. Judith Cushner recalls that smoking small amounts of marijuana as part of her cancer treatment was neither "a regular part of [her] day, nor did it become a habit." She states: "I smoked it only when nausea or retching commenced or worsened, usually in conjunction with a treatment session. There were weeks when I smoked it every few days. There were also periods when I didn't smoke for weeks at a time. Each time I felt a wave of nausea coming on, I inhaled just two or three puffs and it subsided." Similarly, Assistant District Attorney Keith Vines, countering AIDS-induced wasting syndrome, found that "it took only two or three puffs from a marijuana cigarette for my appetite to return. . . . Because I only required a small dose to stimulate my appetite, I did not need to get stoned in order to eat." Patients lacking the benefit of medical guidance may well take more than appropriate to alleviate their symptoms, unnecessarily suffering the drug's powerful side-effects.

use it if and only if it is medically advisable for them to do so. The state relies on the recommendation of a state-licensed physician to define the line between legal and illegal marijuana use. The federal government's policy deliberately undermines the state by incapacitating the mechanism the state has chosen for separating what is legal from what is illegal under state law. Normally, of course, this would not be a problem, because where state and federal law collide, federal law prevails. *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108, 112 S. Ct. 2374, 120 L. Ed. 2d 73 (1992); *cf. United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001). In the circumstances of this case, however, I believe the federal government's policy runs afoul of the "commandeering" doctrine announced by the Supreme Court in *New York v. United States*, 505 U.S. 144, 112 S. Ct. 2408, 120 L. Ed. 2d 120 (1992), and *Printz v. United States*, 521 U.S. 898, 117 S. Ct. 2365, 138 L. Ed. 2d 914 (1997).

New York and *Printz* stand for the proposition that "[t]he 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." *Printz*, 521 U.S. at 935, 117 S. Ct. 2365. Applied to our situation, this means that, much as the federal government may prefer that California keep medical marijuana illegal,[10] it cannot force the state to

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[10] 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 ob-

do so. Yet, the effect of the federal government's policy is precisely that: By precluding doctors, on pain of losing their DEA registration, from making a recommendation that would legalize the patients' conduct under state law, the federal policy makes it impossible for the state to exempt the use of medical marijuana from the operation of its drug laws. In effect, the federal government is forcing the state to keep medical marijuana illegal. But preventing the state from repealing an existing law is no different from forcing it to pass a new one; in either case, the state is being forced to regulate conduct that it prefers to leave unregulated.

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jectives. 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) [hereinafter Judiciary Hearing] (statement of Thomas A. Constantine); *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.").

It is true that by removing state penalties for the use of marijuana, a doctor's recommendation may embolden patients to buy the drug, and others to sell it to them, in violation of federal law. But the doctors *only* help patients obtain the drug by removing state penalties for possession and sale; they do not purport to exempt patients or anyone else from federal law, nor could they. 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.[11] 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.

Nor does the state have another mechanism available to distinguish lawful from unlawful conduct. The state law in question does not legalize use of marijuana by anyone who believes he has a medical need for it. Rather, state law is closely calibrated to exempt from regulation only patients who have consulted a physician. And the physician may only recommend mari-

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[11] Federal defendants concede that this is their goal, arguing that the doctors' actions are illegal because "[w]ithout [the doctors'] clinical recommendation or approval, patients and their primary caregivers are unable to invoke [Proposition 215's] protections from criminal prosecution or sanction *under state law*." Appellants' Reply Br. at 6 (internal quotation marks omitted) (emphasis added). General Barry McCaffrey, Director of the Office of National Drug Control Policy, made the same point: "Federal law is not at stake; the actions of local law enforcement are." Judiciary Hearing, *supra,* at 40.

juana when he has made an individualized and bona fide determination that the patient is within the small group that may benefit from its use. If medical doctors are unable or unwilling to make this determination because they fear losing their DEA registration, there is no one who can take their place. Nurses and paramedics aren't qualified to do it, which is why they don't have authority to write prescriptions in the first place. Lawyers, judges and police can't do it, except by asking the advice of physicians. State administrators can't do it. If doctors are taken out of the picture—as the federal policy clearly aims to do—the state's effort to withdraw its criminal sanctions from marijuana use by the small group of patients who could benefit from such use is bound to be frustrated. The federal government's attempt to target doctors—eliminating the only viable mechanism for distinguishing between legal and illegal drug use—is a backdoor attempt to "control or influence the manner in which States regulate private parties." *Reno v. Condon*, 528 U.S. 141, 150, 120 S. Ct. 666, 145 L. Ed. 2d 587 (2000) (internal quotation marks omitted).

This is not a situation like *United States v. Moore*, 423 U.S. 122, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975), where a doctor used his prescriptions license to circumvent the federal drug laws. Moore conducted inadequate or no medical examinations, ignored the results of the few tests he did perform, prescribed however many tablets the "patient" asked for and graduated his fee according to the number he prescribed. *See id.* at 142-43, 120 S. Ct. 666. The Court concluded that Moore had abandoned his professional role and effectively become a drug dealer. Here, by contrast, doctors are performing their normal function

as doctors and, in so doing, are determining who is exempt from punishment under state law. If a doctor abuses this privilege by recommending marijuana without examining the patient, without conducting tests, without considering the patient's medical history or without otherwise following standard medical procedures, he will run afoul of state as well as federal law. But doctors who recommend medical marijuana to patients after complying with accepted medical procedures are not acting as drug dealers; they are acting in their professional role in conformity with the standards of the state where they are licensed to practice medicine. The doctor-patient relationship is an area that falls squarely within the states' traditional police powers. The federal government may not force the states to regulate that relationship to advance federal policy.

The commandeering problem becomes even more acute where Congress legislates at the periphery of its powers. The Constitution authorizes Congress to regulate activities that affect interstate commerce. But that authority is not boundless. As the Supreme Court recently reminded us, Congress must exercise its power so as to preserve "the Constitution's distinction between national and local authority." *United States v. Morrison*, 529 U.S. 598, 615, 120 S. Ct. 1740, 146 L. Ed. 2d 658 (2000). That distinction, in turn, was designed "so that the people's rights would be secured by the division of power." *Id.* at 616 n. 7, 120 S. Ct. 1740; *see also U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 838, 115 S. Ct. 1842, 131 L. Ed. 2d 881 (1995) (Kennedy, J., concurring) ("The Framers split the atom of sovereignty. It was the genius of their idea that our citizens would have two political capacities, one state

and one federal, each protected from incursion by the other."). The Supreme Court's recent Commerce Clause jurisprudence is cut from the same cloth as the commandeering principle; both protect the duality of our unique system of government. The Commerce Clause limits the scope of national power, while the commandeering doctrine limits how Congress may use the power it has. These checks work in tandem to ensure that the federal government legislates in areas of truly national concern, while the states retain independent power to regulate areas better suited to local governance.

Medical marijuana, when grown locally for personal consumption, does not have any direct or obvious effect on interstate commerce. *Cf. Oakland Cannabis Buyers' Coop.*, 532 U.S. at 495 n. 7, 121 S. Ct. 1711 (reserving "whether the Controlled Substances Act exceeds Congress' power under the Commerce Clause"). Federal efforts to regulate it considerably blur the distinction between what is national and what is local. But allowing the federal government, already nearing the outer limits of its power, to act through unwilling state officials would "obliterate the distinction" entirely. *United States v. Lopez*, 514 U.S. 549, 557, 115 S. Ct. 1624, 131 L. Ed. 2d 626 (1995) (internal quotation marks omitted).[12]

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[12] The reluctance of state officials to enforce federal drug policies against medical marijuana patients is not merely theoretical. *See* William Booth, *Santa Cruz Defies U.S. on Marijuana: City Officials Vow To Defend Medical Uses*, Wash. Post, Sept. 18, 2002, at A3. It is precisely such conflicts between state and federal officials that the commandeering doctrine is designed in part to prevent.

It may well be, as our opinion holds, that interference with the rights of doctors to speak is sufficient to support the district court's injunction. Nevertheless, it remains a significant step for a court to enjoin the prosecution and even investigation of what federal officials believe may be a violation of federal law. *See, e.g., Bresgal v. Brock*, 843 F.2d 1163, 1171 (9th Cir. 1987); *Jett v. Castaneda*, 578 F.2d 842, 845 (9th Cir. 1978). In affirming the district court, I therefore find comfort in knowing that the interests of the patients, and those of the state, provide significant additional support for the district court's exercise of discretion.

Appendix

From 1978 to 1992, the federal government conducted its own medical marijuana program. Today, the government continues to supply individuals who participated in this program with marijuana under its Compassionate Care program; they are among the few people in the country who can use the drug legally. Together with the American Public Health Association and other health care and medical organizations, individuals in this group filed an amicus brief supporting the plaintiffs. The following are their personal statements, taken from that brief.

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.

Elvy Musikka was diagnosed with glaucoma in 1975 at the age of 36. She tried conventional medications to treat her condition, but could not tolerate them. Reluctantly, in 1976, she decided to try herbal cannabis at the advice of her physician. The cannabis provided her immediate relief, substantially lowering her intraocular pressure as no other medication had, with few

side effects. Ms. Musikka ingests cannabis by smoking it, as well as eating it in baked goods and olive oil. Fearful of the legal consequences of smoking cannabis, Ms. Musikka underwent several risky surgeries in an attempt to correct her condition, but they were unsuccessful and left her blind in one eye. In 1988, Ms. Musikka was arrested in Florida and charged with cannabis possession. She challenged her conviction in the Florida Supreme Court, where she prevailed, becoming the first person in that state to establish a medical necessity defense for cannabis. Shortly thereafter, the federal government enrolled Ms. Musikka in its medical cannabis program and has provided her with one and one-half pounds of herbal cannabis on a quarterly basis ever since. Ms. Musikka and her physician believe that if she were deprived of cannabis she would go blind.

Irvin Henry Rosenfeld was diagnosed at age 10 with multiple congenital cartilaginous exostosis, a disease causing the continuous growth of bone tumors, and the generation of new tumors, on ends of most of the long bones in his body. He was told he would not survive into adulthood. In an attempt to treat the painful symptoms of this disease, he was prescribed high doses of opioid analgesics, muscle relaxants and anti-inflammatory medications, which he took on a daily basis, but which had minimal efficacy and produced debilitating side effects. In 1971, Mr. Rosenfeld began using smoked herbal cannabis with the approval and under the supervision of a team of physicians. Mr. Rosenfeld found the cannabis highly efficacious in alleviating pain, reducing swelling, relaxing muscles and veins that surround the bone tumors, and preventing hemorrhaging. In 1982, the United States government,

operating under the Compassionate Care IND Program, at the request of his physicians, began supplying Mr. Rosenfeld with herbal cannabis to treat his condition. For the past 19 years, the government has consistently provided him with a 75-day supply of herbal cannabis, totaling 33 ounces per shipment. Mr. Rosenfeld smokes 12 marijuana cigarettes a day to control the symptoms of his disease. In the 30 years that Mr. Rosenfeld has used herbal cannabis as a medicine, he has experienced no adverse side effects (including no "high"), has been able to discontinue his prescription medications, and has worked successfully for the past 13 years as a stockbroker handling multi-million dollar accounts. Mr. Rosenfeld and his physicians believe that but for herbal cannabis, Mr. Rosenfeld might not be alive, or, at the very least, would be bed-ridden.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 97-00139 WHA

DR. MARCUS CONANT, ET AL., PLAINTIFFS

v.

BARRY R. MCCAFFREY, ET AL., DEFENDANTS

Sept. 7, 2000

ORDER GRANTING IN PART AND DENYING IN PART CROSS-MOTIONS FOR SUMMARY JUDGMENT; DISSOLVING PRELIMINARY INJUNCTION; ENTERING PERMANENT INJUNCTION

ALSUP, District J.

INTRODUCTION

This class action challenges the lawfulness of the federal government's policy to punish physicians who "recommend" marijuana to patients. The parties have filed cross-motions for summary judgment both as to justiciability and the merits. This order holds that the relevant federal statute does not authorize the government to revoke a physician's license to dispense con-

trolled substances merely because a physician "recommends" marijuana as a therapy to a patient. Any contrary holding would raise severe First Amendment doubts.

STATEMENT

1. The Compassionate Use Act

On November 5, 1996, the voters of California passed Proposition 215, the Compassionate Use Act of 1996, also known as the Medical Marijuana Initiative, adding Section 11362.5 to California's Health and Safety Code. The law took effect at 12:01 a.m., on Wednesday, November 6, 1996. The Compassionate Use Act provides, in relevant part, that:

> seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

Cal. Health & Safety Code § 11362.5(a) (West 2000). The Compassionate Use Act specifically protects physicians who recommend medical marijuana: "[No] physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes."

2. Federal Regulation of Controlled Substances

The Controlled Substances Act, 21 U.S.C. 801, et seq., established a comprehensive regulatory scheme governing the manufacture and distribution of dangerous drugs. The Controlled Substances Act classifies these drugs in one of five "Schedules," depending upon such factors as potential for abuse, the extent to which they lead to psychological or physical dependence, whether there is an accepted level of safety for their use under medical supervision, and whether they have a currently accepted medical use in the United States.

Schedule I controlled substances are subject to the most strict regulation because the federal government has determined that they have 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." 21 U.S.C. 812(b)(1). The Controlled Substances Act prohibits physicians from prescribing Schedule I drugs. Schedule I drugs may be dispensed in the United States only through strictly-controlled, federally-approved research programs. Marijuana is classified as a Schedule I drug.

Drugs in Schedules II through V may be prescribed. The federal government has determined both that they have some currently accepted medical uses in treatment in the United States and that they are safe for use under medical supervision. *Id.*, §§ 812(b)(2)-(5). A Schedule I drug may be reclassified only if the Food and Drug Administration approves a new drug application. The FDA has not done so for marijuana (Joint Stmt. Undisputed Facts ¶ 21).

In order to prescribe any controlled substances, a physician first must obtain a registration from the Attorney General (hereinafter "DEA registration"). The Controlled Substances Act confers authority on the Attorney General not only to grant registrations, but also to deny or revoke a physician's DEA registration if the physician "has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest. . . ." 21 U.S.C. 824(a)(4). The Attorney General has delegated this authority to the Administrator of the Drug Enforcement Agency. 28 C.F.R. 0.100(b).

3. The Federal Government's Response to the Compassionate Use Act

On December 30, 1996, less than two months after the Compassionate Use Act took effect, the Director of the Office of National Drug Control Policy[1] issued "The Administration's Response to the Passage of California Proposition 215 and Arizona Proposition 200" (hereinafter the "Administration's Response") (Joint Stmt. Undisputed Facts ¶ 3). The Administration's Response

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[1] The Office of National Drug Control Policy and the Drug Enforcement Agency are related but distinct federal entities. The ONDCP establishes policies, priorities, and objectives for the nation's drug control program, the goals of which are to reduce illicit drug use, manufacturing and trafficking; drug-related crime and violence; and drug-related health consequences. To achieve these goals, the Director produces the National Drug Control Strategy, which directs the nation's anti-drug efforts and establishes a program, a budget, and guidelines for cooperation among federal, state, and local entities. 21 U.S.C. § 1701, *et seq*. The Drug Enforcement Agency, on the other hand, is charged with enforcing federal drug laws. Among its other powers, the DEA may grant, deny, or revoke registrations under the Controlled Substances Act.

stated "that a practitioner's action of recommending or prescribing Schedule I controlled substances is not consistent with the 'public interest' (as that phrase is used in the federal Controlled Substances Act), and will lead to administrative action by the Drug Enforcement Administration to revoke the practitioner's registration" (*id.* at ¶ 4). The Administration's Response focused on the term "recommend" in response to that term's inclusion in the Compassionate Use Act (*id.* at ¶ 8).

The Administration's Response stated that the Department of Justice and the Department of Health and Human Services would send a letter to national, state, and local practitioner associations and licensing boards, stating unequivocally that the DEA would seek to revoke the registrations of physicians who recommended or prescribed Schedule I controlled substances. The letter, according to the Administration's Response, would also outline the authority of the Inspector General for HHS to exclude specified individuals or entities from participation in the Medicare and Medicaid programs (*id.* at ¶ 5).

The Administration's Response stated that the Department of Justice would "continue existing enforcement programs," and specified the criteria that would be used by the five United States Attorneys in Arizona and California to "review cases for prosecution," the Administration's Response stated. Those criteria were described as follows:

> (a) the absence of a bona fide doctor-patient relationship; (b) a high volume of prescriptions or recommendations of Schedule I controlled substances; (c) the accumulation of significant profits or

> assets from the prescription or recommendation of Schedule I controlled substances; (d) Schedule I controlled substances being provided to minors; and/or (e) special circumstances, such as when death or serious bodily injury results from drugged driving.

On February 27, 1997, the Department of Justice and the Department of Health and Human Services sent a letter to national, state and local practitioner associations to clarify the government's position (*id.* at ¶ 7). That letter, the so-called Medical Leader Letter, assured, among other things, that "nothing in federal law prevents a physician, in the context of a legitimate physician-patient relationship, from merely discussing with a patient the risks and alleged benefits of the use of marijuana to relieve pain or alleviate symptoms." At the same time, the letter stated that physicians "may not intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law" (*ibid.*).

Dr. Robert Mastroianni, a physician in Pollock Pines, California, was interviewed on or about January 27, 1997, by a DEA agent (*id.* at ¶ 20). The agent presented Dr. Mastroianni with a copy of a written marijuana recommendation which allegedly had been created by Dr. Mastroianni. The agent asked questions about Dr. Mastroianni's medical practices, his recommendations of marijuana, and his familiarity with research on the medical efficacy of marijuana. The agent also requested to review Dr. Mastroianni's prescription records at a local pharmacy (*ibid.*).

4. The Plaintiffs

The plaintiff class is defined by stipulation and order as follows:

> (1) All licensed physicians practicing in the State of California who treat patients suffering from severe nausea (commonly associated with HIV/AIDS and cancer), wasting syndrome or anorexia (commonly associated with HIV/AIDS), increased intraocular pressure (commonly associated with glaucoma), seizures or muscle spasms associated with a chronic, debilitating condition (commonly associated with epilepsy, multiple sclerosis, and paraplegia/quadriplegia/hemiplegia), and/or severe, chronic pain (commonly associated with paraplegia/quadriplegia/hemiplegia, HIV/AIDS, metastasized cancers, and cervical disk disease), and who, in the context of a bona fide physician-patient relationship, discuss, approve, or recommend the medical use of marijuana for these patients based on the physician's best medical judgment; and
>
> (2) All patients in the State of California suffering from severe nausea (commonly associated with HIV/AIDS and cancer), wasting syndrome or anorexia (commonly associated with HIV/AIDS), increased intraocular pressure (commonly associated with glaucoma), seizures or muscle spasms associated with a chronic, debilitating condition (commonly associated with epilepsy, multiple sclerosis, and paraplegia/quadriplegia/hemiplegia), and/or severe, chronic pain (commonly associated with paraplegia/quadriplegia/hemiplegia, HIV/AIDS, metastasized cancers, and cervical disk disease), who, in the context of a bona fide

physician-patient relationship, communicate with their physicians about the medical use of marijuana.

The named plaintiffs in this action include ten physicians, a physicians' organization, six patients with terminal illnesses, and an organization comprised of people with AIDS. They are Dr. Marcus Conant, Dr. Donald Northfelt, Dr. Arnold Leff, Dr. Debasish Tripathy, Dr. Neil Flynn, Dr. Stephen Follansbee, Dr. Robert Scott, III, Dr. Stephen O'Brien, Dr. Milton Estes, Dr. Howard Maccabee, Dr. Allan Joseph Flach, Bay Area Physicians for Human Rights, Keith Vines, Judith Cushner, Valerie Corral, Dan Kane, Michael Ferrucci, and Being Alive: People with HIV/AIDS Action Coalition, Inc. Plaintiff Jo Daily, a victim of cancer, died after this suit was filed. In a declaration she submitted in support of plaintiffs' request for a preliminary injunction, she requested that her name be left on the complaint should she not outlive this case.

Dr. Marcus Conant, to take an example of the physician plaintiffs, has practiced medicine in San Francisco for over thirty years (Conant Decl. ¶ 1). Dr. Conant is the Medical Director of the Conant Medical Group, a large private AIDS practice. He is a Professor at the University of California medical center in San Francisco and is the author or co-author of over seventy publications on treatment of AIDS (*id.* at ¶ 5). He and his colleagues provide primary care for over 5,000 HIV infected patients, including approximately 2,000 patients with active AIDS (*id.* at ¶ 1).

In his AIDS practice, Dr. Conant prescribes aggressive treatments combining several different drugs that are recently emerging as the first effective treatment for AIDS (*id.* at ¶ 10). Dr. Conant has found, however, that these drugs often cause severe nausea and

vomiting, a particular worry when the patient is suffering from AIDS wasting syndrome, which causes a steady, uncontrolled weight loss. For many patients, traditional anti-nausea drugs and appetite stimulants are effective. Dr. Conant believes, however, that for some patients medical marijuana proves to be the best if not the only viable, treatment option. Prior to the Administration's Response, he recommended marijuana to some patients (*ibid.*). In reaction to the Administration's Response, Dr. Conant limited his conversations with patients, curtailing information regarding the risks and benefits of medical marijuana (*id.* at ¶¶ 16-17). He directed his staff likewise to curtail their discussions with patients (*ibid.*).

Keith Vines is an AIDS patient who credits medical marijuana with helping to save his life (Vines Decl. ¶ 4). He has been HIV positive since 1983, and by 1990 his health began to deteriorate (*id.* at ¶ 7). In 1993, he was diagnosed with AIDS wasting syndrome. He lost more than forty pounds of lean body mass. His bones became brittle and his joints, for lack of nourishment, ached (*ibid.*). Mr. Vines was prescribed a series of medications to help fight his disease, including ddI, AZT, d4T, 3TC, Saquinavir, Crixavan, Septra and Acyclorir. Many of these medications suppressed his appetite (*id.* at ¶ 8).

Not only did Mr. Vines need food to stave off AIDS wasting syndrome, but his experimental growth-hormone therapy required that he eat regularly (*id.* at ¶ 9). His doctors told him it was essential that he eat three full meals a day for this treatment to be effective (*id.* at ¶ 11). To stimulate his appetite, one of his physicians prescribed Marinol, a synthetic derivative of THC, which is one of the primary active ingredients of

marijuana (*id.* at ¶ 12). He found that he could not tolerate the side effects, though he tried to endure them despite only a small gain in appetite. A single Marinol capsule could make him feel "stoned" for several hours such that he could not function competently. Other times the Marinol put him to sleep. The side effects affected his performance as an assistant district attorney (*ibid.*).

When Mr. Vines informed his doctors that he could no longer tolerate the Marinol, two of them suggested that he try marijuana (*id.* at ¶ 13). They told him that they had observed that for many AIDS patients, smoking marijuana stimulated appetite better than Marinol, and did so without many of the side effects (*ibid.*). Mindful of his career in law enforcement, Mr. Vines was reluctant to use marijuana because it was illegal (*id.* at¶ 14). Nevertheless, he obtained a small amount from a cannabis buyers' club and tried it (*ibid.*). He found that he needed very little for his appetite to return (*id.* at ¶ 15). The beneficial effect took place within minutes rather than the hours he sometimes waited after swallowing a Marinol capsule. Because he needed so little marijuana, he did not need to get stoned in order to eat (*ibid.*).

Mr. Vines believes that the government's threats jeopardize his relationships with his doctors (*id.* at ¶ 18). He believes the policy hinders him from receiving the best and most reliable medical advice (*ibid.*). Like Mr. Vines, many patients depend upon discussions with their physicians as their primary or only source of sound medical advice and information (Joint Stmt. Undisputed Facts ¶ 17).

5. The Reaction to the Government's Statements

All of the physician plaintiffs believe that their discussion and recommendation of medical use of marijuana is appropriate or potentially appropriate for some of their patients (*id.* at ¶ 1). Prior to the Administration's Response, Drs. Tripathy, Maccabee, Conant, Estes, Flynn, Leff, Scott, O'Brien, Follansbee, Brody, and Stalcup had discussed with and recommended to certain of their patients the medical use of marijuana (*id.* at ¶ 10).

After the Administration's Response, numerous California physicians contacted their professional organizations seeking guidance and clarification regarding its meaning (*id.* at ¶ 6). Drs. Estes, Follansbee, Scott, O'Brien, Maccabee, Tripathy, Conant, and Flynn self-censored their conversations with patients by withholding information, recommendations or advice regarding use of medical marijuana (*id.* at ¶ 11). Drs. Flynn, Conant and O'Brien omitted medically relevant information from some patient medical records (*id.* at ¶ 12).[2]

Drs. Estes, Follansbee, Scott, O'Brien, Maccabee, Tripathy, Conant, and Flynn subjectively fear that they will be prosecuted or lose their DEA registrations to

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[2] As a normal part of medical practice, physicians record their diagnoses and recommendations, and their patients' reactions to such diagnoses and recommendations, on patients' individual medical charts, as is required by California Business & Professions Code Sections 2234, 2266 (*id.* at ¶ 18). The parties agree that accurate charts are necessary to provide sound medical care to the patient in the future, either by the same physician or by a different physician, and the failure to accurately chart a patient's care could jeopardize the patient's life and health (*id.* at ¶ 19).

dispense controlled substances if they engage in any discussion of medical marijuana, and/or that they will be prosecuted if they recommend a patient's medical use of marijuana (*id.* at ¶ 14). Drs. Estes, Follansbee, Scott, O'Brien, Maccabee, Tripathy, Conant, and Flynn continue to fear prosecution and loss of their DEA registrations, even after this Court entered a preliminary injunction in April 1997, the scope of which is described below (*id.* at ¶ 15).

Significantly, the government concedes that in reaction to the Administration's Response, a reasonable physician would have a genuine fear of losing his or her DEA registration to dispense controlled substances if that physician were to recommend marijuana to his or her patients (*id.* at ¶ 13).

6. The Procedural History

The named plaintiffs filed this suit on January 14, 1997, against the following federal officials in their official capacities: Barry McCaffrey as the Director of the United States Office of National Drug Control Policy; Thomas Constantine as the Administrator of the United States Drug Enforcement Administration; Janet Reno as the Attorney General of the United States; and Donna Shalala as the Secretary of Health and Human Services. Plaintiffs sought a preliminary and permanent injunction enjoining the government from enforcing or threatening to enforce any federal statute, regulation or other provision of law in a manner that would punish or penalize California physicians for communicating with their patients in the context of a bona fide physician-patient relationship regarding potential risks and benefits of medical use of marijuana. Plaintiffs further sought a declaration that the govern-

ment's threats to enforce federal provisions of law in a manner that would punish or penalize physicians for communicating with their patients, using their best medical judgment in the context of a bona fide physician-patient relationship, regarding potential risks and benefits of medical use of marijuana violate the First Amendment on their face. Their initial complaint only leveled a facial challenge, not an as-applied challenge.

The case was first assigned to the Honorable Fern M. Smith, who issued a preliminary injunction and denied the government's motion to dismiss on April 30, 1997. *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997). The preliminary injunction provided that the government could "only prosecute physicians who recommend medical marijuana to their patients if the physicians are liable for aiding and abetting or conspiracy" under 18 U.S.C. 2 or 21 U.S.C. 846. *Id.* at 700. The preliminary injunction also prohibited the government from taking administrative action against physicians "for recommending marijuana unless the government in good faith believes that it has substantial evidence" of aiding and abetting or conspiracy under 18 U.S.C. 2 or 21 U.S.C. 846. *Id.* at 701. Finding the controversy ripe for review, Judge Smith denied the government's motion to dismiss. The government did not appeal the preliminary injunction.

Along with issuing the preliminary injunction, Judge Smith certified a class of physicians, patients and organizations. On August 6, 1997, plaintiffs amended their complaint to include an as-applied challenge to the Administration's Response. Two years later, in August 1999, this case was reassigned to the undersigned. On May 25, 2000, the Court granted plaintiffs' motion to

modify the class. The current class definition is stated above. Now before the Court are cross-motions for summary judgment.

ANALYSIS

Federal Rule of Civil Procedure 56(c) provides that a party shall be entitled to summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." In this case, the parties have stipulated to the material facts; what remains for the Court is to resolve the issues of law.

This case presents three central legal issues: (1) whether the case is justiciable; (2) whether the government's policy exceeds the authority of the Controlled Substances Act; and (3) whether the government's policy violates plaintiffs' First Amendment rights. As discussed below, the Court holds that plaintiffs' challenges to the government's DEA deregistration policy is justiciable but their challenges to the government's policies on criminal prosecutions and Medicare/Medicaid participation are not. The DEA deregistration policy exceeds the scope of the Controlled Substances Act because it raises grave constitutional doubts. Although the Court engages in a First Amendment analysis to show serious constitutional doubts, the Court need not hold that the policy in fact violates the First Amendment. It is sufficient to hold that the policy lacks statutory authority.

1. Justiciability

Judge Smith examined justiciability at the preliminary injunction stage. At the summary judgment stage, however, Judge Smith's findings are not strictly law of the case. Also, the circumstances have changed. Specifically, plaintiffs added an as-applied challenge to their complaint, the government has not criminally prosecuted any physician in the interim years, and the Ninth Circuit issued an *en banc* opinion on the justiciability of pre-enforcement challenges to statutes based on First Amendment grounds. *See Thomas v. Anchorage Equal Rights Comm'n*, Nos. 97-35220, 97-35221, 2000 WL 1069977 (9th Cir. Aug. 4, 2000). Guided by Judge Smith's analysis, but taking into account these changes, the Court holds that plaintiffs' challenge to the government's interpretation of the Controlled Substances Act regarding revocation of DEA registrations is justiciable but that the criminal-prosecution and Medicare/Medicaid policies are not. The constitutional and prudential components of the justiciability inquiry are addressed in turn below.

A. Constitutional Component

To satisfy the case-or-controversy requirement of Article III of the United States Constitution, plaintiffs must demonstrate that they have suffered an actual or threatened injury as a result of the challenged conduct, and that the injury will be redressed by favorable decision. *See Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982). This inquiry, often treated under the rubric of standing, holds for both facial and as-applied challenges. *Flast v. Cohen*, 392 U.S. 83, 94-101 (1968).

The Court first turns to the question of actual or threatened injury. Standing to bring a pre-enforcement challenge exists when a plaintiff "faces a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979). The Ninth Circuit very recently addressed what constitutes a credible threat of prosecution in the context of a pre-enforcement challenge based on the First Amendment. In *Thomas v. Anchorage Equal Rights Commission*, Nos. 97-35220, 97-35221, 2000 WL 1069977 (9th Cir. Aug. 4, 2000), the court held that landlords failed to meet the constitutional component of the justiciability because any threat of enforcement or prosecution against them for refusing to rent to unmarried couples, although theoretically possible, was not "reasonable or imminent." *Id.* at *5. In evaluating the genuineness of the claimed threat, the court looked to the following three factors: "whether the plaintiffs had articulated a 'concrete plan' to violate the law in question, whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings, and the history of past prosecution or enforcement under the challenged statute." *Id.* at *4 (quoting *San Diego County*, 98 F.3d at 1126-27). Applying these factors to this case, the Court finds that plaintiffs face a credible threat of DEA registration revocation, though not of criminal prosecution or exclusion from Medicare and Medicaid programs.

The "concrete plan" factor plays out differently in this case than in *Thomas*. There, the landlords could not articulate to whom, when, where, or under what circumstances they had refused to rent to unmarried couples in the past, and although they pledged to

violate the law in the future, they could not articulate when, to whom, where, or under what circumstances. 2000 WL 1069977, at *4. Here, while plaintiffs have not pointed to a specific "plan" to violate the Administration's Response, they have shown that they are at immediate risk of violating it because the government's distinction between "discussions" (permissible, according to the government) and "recommendations" (impermissible, according to the government) is vague and unclear. Physicians have a very concrete and ever-present professional obligation to treat their patients. In a very palpable way, physicians will inevitably confront the government's ban on marijuana recommendations.

Moving to the next factor, "the prosecuting authorities" in this case "have communicated a specific warning or threat." DEA de-registrations will attend any physician who recommends marijuana. The government reaffirmed this position at the recent hearing on these cross motions. The warning appears serious. In January 1997, during the short period between the issuances of the Administration's Response and the preliminary injunction, a DEA agent interviewed Dr. Mastroianni. The agent presented a copy of a written marijuana recommendation allegedly created by Dr. Mastroianni, asked questions regarding Dr. Mastroianni's medical practices, recommendations of marijuana and familiarity with research on the medical efficacy of marijuana, and requested to review Dr. Mastroianni's prescription records at a local pharmacy. In light of the preliminary injunction, which issued just months after the Administration's Response, the absence of any *subsequent* threats is immaterial. The

Court finds in favor of a threatened injury based on the government's DEA de-registration policy.

The analysis differs, however, with respect to the government's criminal-prosecution and Medicare/Medicaid policies. As to criminal prosecutions, the Administration's Response stated only "that the DOJ will continue existing enforcement programs regarding criminal possession or conspiracy to possess marijuana." This threat, while troubling to the plaintiff physicians, was not as clear or specific as the government's threat to revoke DEA registrations. A mere recommendation alone was *not* enough to initiate prosecution. A list of factors was relevant, such as the absence of bona-fide doctor-patient relationships and the accumulation of profits from the prescription or recommendation of marijuana (see full list of factors above). The Administration's Response said that the Department of Justice would merely "continue existing enforcement programs."

In the case of the Medicare and Medicaid programs, the Administration's Response stated only that the government "will send a letter" that "will outline the authority of the Inspector General for HHS to exclude specified individuals or entities from participation in the Medicare and Medicaid programs." Such a letter has never been prepared or released. The parties can only speculate as to what such a letter would contain, and what effect it would have on plaintiffs. The Administration's Response alone does not amount to a specific threat. This factor is fatal to plaintiffs' challenge of the Medicare/Medicaid policy. "Unadorned speculation" is "insufficient to invoke federal judicial power." *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990).

Finally, the history of enforcement also weighs in favor of justiciability of the DEA de-registration policy but against justiciability of the criminal-prosecution policy. Unlike *Thomas*, this case does not present a situation in which a policy has languished on the books, unenforced or very rarely enforced, for a period of years or decades. The Administration's Response was issued in December 1996, the case was filed in January 1997, and the preliminary injunction was issued in April 1997. Given this four-month time frame and the existence of the preliminary injunction, it is not significant that there have been no DEA registration revocation proceedings. On balance, this factor weighs in favor of plaintiffs regarding the credible threat of DEA registration revocation for recommendations of marijuana, given the investigation of Dr. Mastroianni noted above, although it is clear that an investigation is not tantamount to an enforcement proceeding. In light of the three *Thomas* factors, the record supports that there is a credible threat of DEA registration revocation.

As for the criminal-prosecution policy, however, there have been no signs of enforcement. The government has not pursued any criminal prosecutions in the years since the Administration's Response, despite the clear authority under Judge Smith's preliminary injunction allowing prosecutions for conspiracy and aiding and abetting. Nor had the government pursued any prosecutions before the preliminary injunction. The *Thomas* factors counsel against adjudicating plaintiffs' challenge to this policy, given the general, rather than specific, threat of criminal prosecution, and the lack of actual prosecutions.

There still remains the question of whether plaintiffs have suffered a[n] *actual* injury. A chilling effect on protected speech is an adequate actual injury to establish standing for facial overbreadth challenges because the "alleged danger . . . is, in large measure, one of self-censorship; a harm that can be realized even without an actual prosecution." *San Diego County Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1129 (1996) (quoting *Virginia v. American Booksellers Ass'n*, 484 U.S. 383, 393 (1988)). The chilling effect caused by the government's DEA de-registration policy is alone a sufficient injury for the purposes of an overbreadth challenge. This conclusion flows inexorably from the stipulated facts. Plaintiff physicians believe that recommendation of marijuana is appropriate for some patients; before the Administration's Response plaintiff physicians discussed marijuana with and recommended for some patients; the Administration's Response threatens that merely recommending marijuana will lead to revocation of DEA registrations; plaintiff physicians responded to the Administration's Response by withholding discussions and advice regarding medical use of marijuana. *Even the government concedes that a reasonable physician would have a genuine fear of losing his or her DEA registration to dispense controlled substances if that physician were to recommend marijuana to his or her patients* (Joint Stmt. Undisputed Facts ¶ 13).[3] As discussed above, however,

[3] There is no inconsistency in the Court's holding that physicians are both chilled from speaking about marijuana *and* at immediate risk of violating the government's DEA de-registration policy. As noted above, the vague nature of "recommend" puts plaintiffs in danger of violating the Administration's Response even while they are engaging in self-censorship.

the same is not true for criminal prosecution and exclusion from Medicare/Medicaid. Just as there is no credible threat that the government will criminally prosecute physicians or exclude them from Medicare or Medicaid programs, so too is there no reasonable chill from the Administration's Response on these points.

The second prong of the constitutional component of justiciability is redressability. It seems clear that a favorable ruling would redress the injury caused by the government's DEA de-registration policy. A declaration that the government has exceeded its statutory authority or has violated the First Amendment, along with a tailored injunction, can prevent unauthorized sanctions or unconstitutional limitations of protected speech. *Conant*, 172 F.R.D. at 686. In summary, plaintiffs may challenge the government's stated intent to initiate DEA registration revocation proceedings for doctors who recommend medical marijuana.

B. Prudential Component

The evaluation of the prudential component of justiciability is guided by two primary considerations: "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Thomas*, 2000 WL 1069977, at *5 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). A case is fit for review if there is a sufficient factual record and the challenged administrative action is final. *See Trustees for Alaska v. Hodel*, 806 F.2d 1378, 1381 (9th Cir. 1986) (citing *Abbott Labs.*, 387 U.S. at 149). In order to demonstrate hardship, plaintiffs must demonstrate a realistic possibility of sustaining an injury as a result of enforcement. *See O'Shea v. Littleton*, 414 U.S. 488, 494 (1974).

The finality of the administrative action and the factual record, both previously evaluated by Judge Smith, render this case fit for review. Moreover, as detailed by Judge Smith, the plaintiffs would suffer significant hardship were this Court to withhold review. The Court adopts the analysis on these points set forth in *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997). Plaintiffs' challenge to the DEA de-registration policy is justiciable.

2. The Government's Construction of the Controlled Substances Act

The Controlled Substances Act vests power in the Attorney General to deny or revoke a physician's DEA registration to prescribe controlled substances. 21 U.S.C. 824. The Attorney General has delegated that authority to the Administrator of the Drug Enforcement Agency. 28 C.F.R. 0.100(b). One of the permissible grounds for revocation is a finding that the physician "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." 21 U.S.C. 824(a)(4). In turn, Section 823 states that "public interest" should be determined by the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing or conducting research with respect to controlled substances.

> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Based on this statutory language, the government construes Factor Five to allow the Administrator of the Drug Enforcement Agency to revoke a physician's registration if he or she merely recommends marijuana to a patient.

Significantly, the government admits that revocation is *not* authorized where a doctor discusses the pros and cons of marijuana use with a patient. Yet the government claims the doctor crosses a statutory line when the discussion melds into a recommendation. Also of significance, both sides acknowledge that a doctor may not, under the statute, actually prescribe or dispense marijuana. Plaintiffs do not seek to do so. The focus is on "recommend" and whether a statutory line can really be drawn between discussions of pros and cons versus recommendations.

Referring to Section 823 for the definition of "public interest" (as directed by Section 824), the government concludes that recommending marijuana falls within Factor Five—"[s]uch other conduct which may threaten the public health and safety." Factor Five, according to the government's construction, must be something beyond controlled-substance convictions and/or violations, since such conduct already is covered by Factors Three and Four. There is no caselaw

precedent. There is no legislative history on point. The issue is of first impression.

When a court reviews an agency's construction of the statute which it administers, it must first look to see whether Congress addressed the precise question at issue. *Chevron U.S.A. v. Natural Resources Def. Council*, 467 U.S. 837, 842-43 (1984). If the intent of Congress is clear, the court must give effect to that intent, unless it is unconstitutional, even if it is inconsistent with the agency's construction. If Congress is silent on the issue, on the other hand, the court normally defers to the agency's interpretation if it is reasonable. *Ibid.* A court will reject an agency interpretation that would ordinarily receive deference under *Chevron*, however, if it believes the agency's reading raises serious constitutional doubts. *Williams v. Babbitt*, 115 F.3d 657, 661-63 (9th Cir. 1997) *cert. denied sub nom. Kawerak Reindeer Herders Ass'n v. Williams*, 523 U.S. 1117 (1998) (citing *DeBartolo Corp. v. Florida Gulf Coast Trades Council*, 485 U.S. 568 (1988) and *Rust v. Sullivan*, 500 U.S. 173 (1991)). "[I]f Congress meant to push the constitutional envelope, it must do so explicitly." *Williams*, 115 F.3d at 662.

Congress did not address whether the government may revoke a physician's registration based on the physician recommending a Schedule I drug to a patient. The term "recommend" does not appear in Section 824 of the statute. The legislative history is silent as to whether Congress intended that such conduct could constitute a ground for revocation. As stated, no caselaw addresses the point. No regulations have been issued. All that exist are statements by the government, including the Administration's Response, giving its current view of the statute.

Were it not for First Amendment considerations, the government's interpretation of the Controlled Substances Act might be permissible under *Chevron.* As the government notes, Factor Five's "[s]uch other conduct which may threaten the public health and safety" presumably includes conduct apart from that already listed in the previous four factors. That previously listed conduct includes convictions relating to controlled substances and violations of the law relating to controlled substances. Recommending the medical use of a prohibited substance might arguably fall within such "other conduct." As discussed below, however, the constitutional doubts raised by such an interpretation are most serious.

3. The First Amendment

The practice of the learned professions such as medicine and law necessarily involve communications with patients, clients and others. While such communications implicate First Amendment concerns, no one would claim that the professions are immunized from regulation merely because speech is incident to the trade. For the professional, "[o]bedience to ethical precepts may require abstention from what in other circumstances might be constitutionally protected speech." *In re Sawyer*, 360 U.S. 622, 646-47 (1959) (Stewart, J., concurring). A lawyer, for example, may not counsel a client to violate the law or to commit perjury. The First Amendment would not prohibit the lawyer's disbarment for doing so. A doctor, to take another example, may not counsel a patient to rely on quack medicine. The First Amendment would not prohibit the doctor's loss of license for doing so. *E.g.*, *Shea v. Board of Medical Examiners*, 81 Cal. App. 3d. 564, 577 (3rd Dist. 1978) (affirming revocation of license

to practice medicine where physician "treated" patients by luridly and salaciously describing sexual foreplay and intercourse). As stated in *Shea*, "[the First Amendment] does not insulate the verbal charlatan from responsibility for his conduct." *Ibid.* Speech protected on the street corner might not be protected in the professional's venue.

Still, there is First Amendment protection in the practice of the learned professions. As the government itself recognizes, when a governmental regulation of professional practice "implicates First Amendment rights, the Court must balance those interests against the State's legitimate interest in regulating the activity in question" (Br. 4, citing *Gentile v. State Bar of Nevada*, 501 U.S. 1030, 1075 (1991)). In *Gentile*, the Supreme Court reviewed a First Amendment challenge to a state-bar sanction against a criminal defense attorney who had given a press conference on the particulars of his client's defense while the case was pending. The rule under which the sanction issued prohibited a lawyer from making "an extrajudicial statement . . . if the lawyer knows or reasonably should know that it will have a substantial likelihood of materially prejudicing an adjudicative proceeding." The Court held that the "substantial likelihood" standard was constitutional, rejecting the argument that the First Amendment required the state to demonstrate a "clear and present danger" of actual prejudice or "an imminent threat" before any sanction could be imposed based on an attorney's speech. *Id.* at 1071-76. In reaching its decision, the Court weighed the state's interest in protecting the integrity and fairness of the state's judicial system against the attorney's interest in free speech, and found that the state's regulation of

speech was sufficiently limited to pass constitutional muster, particularly given that it was content neutral. *Id.* at 1076.

Likewise, the Supreme Court has recognized the First Amendment interests in discussions between doctors and patients. In *Rust v. Sullivan*, 500 U.S. 173, 200 (1990), the Court suggested, but did not hold, that individual doctor-patient relationships, in contrast to family-planning clinics, might enjoy First Amendment protection even when subsidized by the government. Although the Court did not decide whether the doctor-patient relationship is entitled to special First Amendment protection from the state's purse strings, its discussion presupposed First Amendment interests in discussions between doctors and patients.

In *Planned Parenthood v. Casey*, 505 U.S. 833, 884 (1992), the Supreme Court again acknowledged the First Amendment interests in doctor-patient discussions, but suggested that a rational basis would justify regulation of speech as part of the practice of medicine. There, the petitioners challenged a provision that required doctors to inform abortion patients of the nature of the procedure, the health risks of the abortion and of childbirth, and the probable gestational age of the unborn child. *Id.* at 881. A plurality rejected a First Amendment challenge to the informed-consent provision.[4] *Id.* at 884. The state may compel physicians

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[4] The following paragraph comprises the full extent of the plurality's First Amendment analysis:

> All that is left of petitioners' argument is an asserted First Amendment right of a physician not to provide information about the risks of abortion, and childbirth, in a manner mandated by the State. To be sure, the physician's First Amendment rights not to speak are implicated, see *Wooley v.*

to provide health-related information so long as it is true and reasonable.

The *Casey* regulation merely compelled disclosure of information about a medical procedure, much like warning labels disclose the side effects and risks of pharmaceuticals. In this case, by contrast, the government would punish physicians for voicing their professional opinions based on their best medical judgment. Like *Gentile*, this case involves punishment of affirmative professional speech. Given the stark differences, the balancing framework of *Gentile* is more appropriate than the "reasonable regulation" framework of *Casey*.

In striking the appropriate balance in this case, the Court recognizes that the government has a legitimate interest in suppressing and controlling the flow of dangerous drugs and controlled substances within the United States. A recommendation by a doctor may (or may not) be used by a patient to obtain marijuana under the Compassionate Use Act. On the other side of the scale, physicians have a legitimate need to discuss with and to recommend to their patients all medically acceptable forms of treatment. In California and seven other states,[5] recommending marijuana to treat certain debilitating illnesses is recognized as legitimate in

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Maynard, 430 U.S. 705 (1977), but only as part of the practice of medicine, subject to reasonable licensing and regulation by the State, cf. *Whalen v. Roe*, 429 U.S. 589, 603 (1977). We see no constitutional infirmity in the requirement that the physician provide the information mandated by the State here. *Id.* at 884.

[5] Alaska, Arizona, Hawaii, Maine, Nevada, Oregon and Washington have passed laws similar to California's Compassionate Use Act.

medically appropriate circumstances. The government itself would allow physicians to "discuss" the pros and cons of marijuana therapy with their patients. In some cases, however, it will be the professional opinion of doctors that marijuana is the best therapy or at least should be tried. If such recommendations could not be communicated, then the physician-patient relationship would be seriously impaired. Patients need to know their doctors' recommendations.

Contrary to the government's argument, it is not true that a mere recommendation will necessarily lead to the commission of a federal offense. To the contrary, such recommendations can lead to lawful and legitimate responses. *First,* a cancer or AIDS victim so advised may choose to honor the federal law but, armed with the doctor's recommendation, may urge the federal government to change that law. Petitioning Congress or federal agencies for redress of a grievance or a change in policy is a time-honored tradition. In the marketplace of ideas, few questions are more deserving of free-speech protection than whether regulations affecting health and welfare are sound public policy. In the debate, perhaps the status quo will (and should) endure. But patients and physicians are certainly entitled to urge their view. To hold that physicians are barred from communicating to patients sincere medical judgments would disable patients from understanding their own situations well enough to participate in the debate. As the government concedes, and as Mr. Vines exemplifies, many patients depend upon discussions with their physicians as their primary or only source of sound medical information. Without open communication with their physicians, patients would fall silent and appear uninformed. The ability of patients to partici-

pate meaningfully in the public discourse would be compromised. This factor alone persuades the Court that the balance of considerations ought to be struck firmly on the side of protecting sincere medical recommendations.

Second, a cancer or AIDS victim may well be able to obtain medical marijuana without violating federal law. There are three possible ways. One is to enroll in a federally-approved experimental marijuana therapy program.[6] Another is to travel to a country where marijuana is legally dispensed. Finally, the Ninth Circuit has recently recognized the "medical necessity" defense for cannabis-club distribution of marijuana to patients requiring marijuana as a medical necessity.[7]

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[6] Schedule I substances may be dispensed in strictly-controlled research projects registered with the DEA, and approved by the Secretary of Health and Human Services, acting through the Food and Drug Administration. *See* 21 U.S.C. § 823(f). The government conceded at oral argument that some patients may seek to enroll in its experimental marijuana therapy programs.

[7] In *United States v. Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109, 1113-15 (9th Cir. 1999), the Ninth Circuit held that the district court had the equitable discretion to modify an injunction to allow continuing cannabis distribution to patients whose physicians certify that (1) the patient suffers from a serious medical condition; (2) if the patient does not have access to cannabis, the patient will suffer imminent harm; (3) cannabis is necessary for the treatment of the patient's medical condition or that cannabis will alleviate the medical condition or symptoms associated with it; (4) there is no legal alternative to cannabis for the effective treatment of the patient's medical condition because the patient has tried other legal alternatives to cannabis and has found them ineffective in treating his or her condition or has found that such alternatives result in intolerable side effects. The panel noted that these factors were modeled on the Ninth Circuit's recognition of a necessity defense to violations of federal law in

The point is that a recommendation for marijuana therapy does not translate, as night follows day, into a violation of federal law. To the contrary, a recommendation for marijuana may lead to actions by patients all of which are lawful under federal law and some of which are themselves protected, such as petitioning the government for a change in the prohibition itself, by the First Amendment.

To be sure, some patients may use sincere medical recommendations to obtain marijuana from cannabis clubs in circumstances illegal under federal law. A doctor, for example, may sincerely believe that a cancer victim, having exhausted other medications without success, should try marijuana. Such a circumstance may or may not qualify as a medical necessity. Even though the doctor warns of the illegal status of marijuana, the patient may use the doctor's recommendation to obtain marijuana under the Compassionate Use Act. If so, however, the acquisition of marijuana is committed by the patient, not the doctor. A sincere recommendation alone is not a federal crime, even if the doctor foresees it could be used to facilitate a federal crime. The federal interest in enforcing the marijuana prohibition in the United States is a legitimate concern, but it pales by comparison to the free speech concerns.

What is more, the government's position is weakened by the artificial line it would draw. "Discussions of pros and cons" with patients are proper, the government

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United States v. Aguilar, 883 F.2d 662, 692 (9th Cir. 1989). The government is still in the process of seeking review in the Supreme Court of the United States. This Court's judgment, however, does not depend upon *Oakland Cannabis Buyers' Cooperative* for the reasons stated above.

concedes, but "recommendations" drawn therefrom are not. The government's test is wholly unworkable. The government would define "recommend" as "to present as worthy of confidence, acceptance, use, etc." or "to suggest" (Reply Br. 13). It would be impossible to discuss even the pros and cons without, at least in some cases, the patient concluding that the doctor is suggesting marijuana or "presenting it as worthy of acceptance." This would be so even if the doctor never used the term "recommend" or "suggest." Accordingly, prudent doctors wishing to retain their DEA registrations would plainly be deterred from even discussing the pros and cons of marijuana. In other words, the vagueness of the government's proposed test exacerbates the compromise of First Amendment interests. *See NAACP v. Button,* 371 U.S. 415, 433 (1963).

When a doctor recommends marijuana, a patient who is accepting of the idea may well ask how to obtain it. Here, doctors must be honest. The First Amendment is not a license to circumvent the federal drug laws. If the doctor addresses the subject, he or she must be truthful and advise on the unavailability of marijuana under the present federal drug laws and on the availability of the federal experimental programs and overseas laws (to the extent the doctor is knowledgeable).

Turning to written recommendations, the same balance of considerations controls—with one exception. Patients have a legitimate need to know that their doctors will back them up if and when federal authorities question their "medical necessity" defense or if and when they choose to urge publically a change in the law. A writing from a physician memorializing a recommendation serves those uses. Where those uses do not apply, however, physicians should proceed more

cautiously. If (and only if) a physician concludes that the sole use and reason for the writing (as opposed to the recommendation itself) would be simply to obtain marijuana in violation of federal law, it would be hard to see how the extra step of a writing in and of itself serves any purpose other than to facilitate an illegal transaction, and hard to see why the writing itself deserves free-speech protection. The "public interest" comprehends regulation of communication with no purpose other than to facilitate violations of the Controlled Substances Act. A doctor would be well advised to state in his or her own records the reason for each recommendation and the reason for each written certification.

The government is legitimately concerned that a physician might in bad faith issue recommendations that would then be used to enlarge the distribution of marijuana to those who really do not need it. From time to time, physicians registered under the Controlled Substances Act abuse their privileges, dispensing, for example, excessive controlled substances or otherwise circumventing the Act. *See, e.g., United States v. Moore*, 423 U.S. 122 (1975). Physicians who issue insincere recommendations without a medical basis and with knowledge that they would be used to illegally obtain marijuana would be subject to DEA revocation. On the other hand, doctors are entitled to be confident that their good-faith recommendations based on honest medical judgments will not be the basis for DEA revocations even when they forsee their recommendations might be used by the patients to obtain marijuana from sources illegal under federal law.

Given the doctrine of constitutional doubt, the government's construction of the Controlled Sub-

stances Act cannot stand. The government should be permanently enjoined from (i) revoking any physician class member's DEA registration merely because the doctor makes a recommendation for the use of medical marijuana based on a sincere medical judgment and (ii) from initiating any investigation solely on that ground. The injunction should apply whether or not the doctor anticipates that the patient will, in turn, use his or her recommendation to obtain marijuana in violation of federal law.

CONCLUSION

Plaintiffs' motion for summary judgment is **GRANTED IN PART** and **DENIED IN PART**. Defendants' motion for summary judgment is **GRANTED IN PART** and **DENIED IN PART**. The government's interpretation of the registration-revocation provision of the Controlled Substances Act exceeds the statute's authority. The government is permanently **ENJOINED** from (i) revoking a class-member physician's DEA registration merely because the doctor recommends medical marijuana to a patient based on a sincere medical judgment and (ii) from initiating any investigation solely on that ground. This injunction applies whether or not the physician anticipates that the recommendation will, in turn, be used by the patient to obtain marijuana in violation of federal law. The Court finds that all other issues tendered are not justiciable. All claims having been resolved, the preliminary injunction is **DISSOLVED** and superceded by this permanent injunction. The Clerk shall close the file and enter judgment.

IT IS SO ORDERED.

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 97-0139 FMS

DR. MARCUS CONANT, ET AL., PLAINTIFFS

v.

BARRY R. MCCAFFREY, AS DIRECTOR, UNITED STATES OFFICE OF NATIONAL DRUG CONTROL POLICY, ET AL., DEFENDANTS

April 30, 1997

ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION, CLASS CERTIFICATION; DENYING DEFENDANTS' MOTION TO DISMISS; SCHEDULING ORDER

FERN M. SMITH, District Judge.

INTRODUCTION

Pending are plaintiffs' motions for class certification and a preliminary injunction, and defendants' motion to dismiss. Plaintiffs' motion for a preliminary injunction requires a determination whether plaintiffs have raised serious questions about whether the government's response to California's Compassionate Use Act violates the First Amendment rights of physicians and

patients who communicate with each other about the use of medical marijuana to treat disease. It must also be determined whether plaintiffs have demonstrated that the balance of hardship tips in their favor. Plaintiffs' motion for class certification requires a determination whether plaintiff physicians and patients have fulfilled the prerequisites for maintaining their case as a class action.[1]

Plaintiffs have raised serious questions as to whether the government's medical marijuana policy is impermissibly vague. Further, because the policy may infringe on plaintiffs' First Amendment rights and is affecting physicians' treatment of patients suffering from life-threatening diseases, the balance of hardships tips in plaintiffs' favor. For these reasons, the Court issues a preliminary injunction limiting the government's ability to prosecute physicians, revoke their prescription licenses, or bar their participation in Medicare and Medicaid because they recommend medical use of marijuana. The Court also grants plaintiffs' motion for class certification.

BACKGROUND

In November 1996, the citizens of California passed an initiative known as Proposition 215 or the Compassionate Use Act. The initiative took legal effect at

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[1] Because defendants attached to their motion to dismiss a document that was outside the scope of the pleadings, that motion is procedurally improper, and the Court is precluded from considering it under Federal Rule of Civil Procedure 12(b)(6). Because it is incorporated by reference into defendants' opposition to plaintiffs' motion for a preliminary injunction, however, all the arguments raised in defendants' motion to dismiss are analyzed as part of this order.

12:01 a.m. on Wednesday, November 6, 1996. It provides, in pertinent part, that

> seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

Cal. Health & Safety Code § 11362.5(a) (West 1997). Under the Act, neither patients nor physicians may be punished or denied any right or privilege for conduct relating to medical use of marijuana. *Id.* at § 11362.5(b)(1)(B) & 11362.5(d).

Before considering the issues raised by the parties, it is important to recognize what this case is about. It is not about doctors prescribing, growing, or distributing marijuana, nor is it about giving free rein to patients to make massive purchases of marijuana for distribution. Instead, this case is about the ability of doctors, on an individualized basis, to give advice and recommendations to bona fide patients suffering from serious, debilitating illnesses regarding the possible benefits of personal, medical use of small quantities of marijuana.

Although the Drug Enforcement Agency has determined that marijuana has "no currently accepted medical use in treatment in the United States," 57 Fed. Reg. 10,499 (1992), and the Court of Appeals for the District of Columbia Circuit affirmed that determination, see *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131, 1137 (D.C.

Cir. 1994),[2] a majority of Californians, and many physicians, apparently believe that medical marijuana may be a safe and effective treatment for certain diseases. Proposition 215 passed by a wide margin, and plaintiff physicians claim to have recommended medical marijuana to patients for many years.

According to the complaint, prior to passage of the Compassionate Use Act, the federal government had neither punished nor threatened physicians in any way for recommending the medical use of marijuana to seriously ill patients. As the election approached, however, and polls indicated that Proposition 215 would likely pass, defendant Barry McCaffrey, the director of the United States Office of Drug Control Policy, first suggested that the federal government would take action against physicians for conduct protected by the Act. Soon after Proposition 215's enactment, the government confirmed that it would prosecute physicians, revoke their prescription licenses, and deny them participation in Medicare and Medicaid for recommending medical marijuana. In the months since the election, federal officials have made at least fifteen separate statements verifying the government's intent.

On February 14, 1997, plaintiffs—ten physicians, five patients, and two nonprofit organizations—filed this case, contending that the government's medical marijuana policy infringes on the First Amendment rights of both physicians and patients. Plaintiffs proffered declarations indicating that some physicians are suffi-

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[2] Since *Alliance* in 1994, the government apparently has conducted no scientific studies to determine the medical efficacy of marijuana, nor has it granted permission for anyone else to conduct such studies.

ciently worried by the government's threats that they are afraid to offer patients their best medical judgment regarding the use of marijuana to treat disease, and have begun to censor their communications with patients. Plaintiffs claim that physicians' self-censoring threatens the integrity of the physician-patient relationship and prevents proper patient care. Equally important, plaintiffs contend that the "chilling" of physician-patient communication violates the First Amendment rights of physicians and patients alike. Plaintiffs filed a motion for a preliminary injunction, asking the Court to declare that because physician-patient communication is protected speech under the First Amendment, the government may neither prosecute nor administratively sanction physicians for recommending medical use of marijuana. Seeking to protect the rights of all California physicians and patients, plaintiffs also filed a motion for class certification.

On February 28, 1997, defendants filed their opposition to plaintiffs' motion for a preliminary injunction, and a motion to dismiss the complaint. Defendants' opposition and motion are based in large part on a February 27, 1997 letter from the Assistant Secretary for Health and the Acting Assistant Attorney General purporting to clarify the government's medical marijuana policy. The letter states that physicians may discuss medical marijuana with their patients but may not "intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law." (Declaration of Kathleen Moriarty Mueller ("Mueller Decl.") Ex. 7.) Defendants argue that this clarification is consistent with First Amendment jurisprudence and

eliminates any case or controversy because it delineates the limits of permissible behavior for physicians.

The motions were heard and fully argued on April 11, 1997. Although the parties differed to some degree about the parameters of constitutional government policy, the Court believed these differences might be resolved without further litigation and that such resolution would be in the public interest. It therefore ordered the parties to a settlement conference before the Honorable Eugene F. Lynch. In the interim, the Court issued a temporary restraining order preventing the government from taking action against physicians.

The parties met with Judge Lynch for the first time on April 17, 1997. On April 21, 1997, the temporary restraining order was extended so that the parties could meet again with Judge Lynch on April 29, 1997. Because the parties have been unable to resolve their differences, these rulings on the pending motions now issue.

DISCUSSION

I. Legal Standard for Preliminary Injunctions

In order for the Court to issue a preliminary injunction, plaintiffs must show "either (1) a combination of probable success on the merits and the possibility of irreparable harm, or (2) that serious questions are raised and the balance of hardships tips sharply in the moving party's favor." *Rodeo Collection, Ltd. v. West Seventh*, 812 F.2d 1215, 1217 (9th Cir. 1987) (citing *Sardi's Restaurant Corp. v. Sardie*, 755 F.2d 719, 723 (9th Cir. 1985)). These two standards do not represent separate tests for the grant of a preliminary injunction but are rather two ends of "a continuum in which the

required showing of harm varies inversely with the required showing of meritoriousness." *San Diego Comm. Against Registration and The Draft (Card) v. Governing Bd. of the Grossmont Union High Sch. Dist.*, 790 F.2d 1471, 1473 n.3 (9th Cir. 1986).

In determining which test to apply, the Court first considers the parties' relative hardships. *See Gilder v. PGA Tour, Inc.*, 936 F.2d 417, 422 (9th Cir. 1991). "If the balance of harm tips decidedly toward the plaintiff, then the plaintiff need not show as robust a likelihood of success on the merits as when the balance tips less decidedly." *Id.* (internal citation and quotation marks omitted). Deprivation of First Amendment freedoms "unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373, 96 S. Ct. 2673, 2690, 49 L. Ed. 2d 547 (1976). Because plaintiffs allege unconstitutional chilling of free speech, the test to be applied in determining whether an injunction is warranted tends more toward the "serious questions" side of the continuum. *See Gilder*, 936 F.2d at 422. The "serious questions" approach requires the Court to determine only that the questions raised by plaintiffs are a "'fair ground for litigation.'" *Id.* (citation omitted). "Serious questions need not promise a certainty of success, nor even present a probability of success, but must involve a fair chance of success on the merits." *Id.* (internal citation and quotation marks omitted).

II. Analysis

Following the passage of Proposition 215 in California, the federal government made numerous declarations regarding its position on the limits that federal drug laws impose on physician-patient discussions about marijuana, notwithstanding the state voter initiative. High ranking administration officials, in-

cluding defendants, have given varied public interpretations of the limits of federal authority—in formal documents, during congressional committee hearings, and in interviews with the press.

On December 2, 1996, defendant Thomas A. Constantine, the administrator of the Drug Enforcement Administration ("DEA"), appeared before the Senate Judiciary Committee to discuss the DEA's response to the Compassionate Use Act. Constantine testified that the DEA will "[t]ake both administrative and criminal actions against physicians who violate the terms of their DEA drug registrations that authorize them to prescribe controlled substances." Constantine stated that physicians who prescribe or recommend Schedule I substances violate federal law. (Declaration of Jonathan Weissglass ("Weissglass Decl.") Ex. C at C28-C31.)

On December 30, 1996, numerous Clinton administration officials, including defendants McCaffrey, Janet Reno, and Donna Shalala, convened a news conference to delineate "officially" the administration's policy. (Declaration of Graham A. Boyd ("Boyd Decl.") Ex. B.) At the conference, defendants distributed a seven-page memorandum entitled "The Administration's Response to the Passage of California Proposition 215 and Arizona Proposition 200" ("Administration Response"). *See* 62 Fed. Reg. 6164 (1997); Boyd Decl. Ex. C. The Administration Response described specific sanctions that the federal government would impose on physicians "who recommend or prescribe Schedule I controlled substances," including: (1) revocation of medical licenses, (2) exclusion from Medicare and Medicaid programs, and (3) criminal prosecution. *See id.* at 6164.

Subsequent to the filing of plaintiffs' law suit, the Department of Health and Human Services ("DHHS") and the Department of Justice ("DOJ") issued a joint letter to "clarify" the scope of the Administration Response and eliminate misperceptions that had developed regarding the federal government's interpretation of federal drug laws ("Clarification to Administration Response" or "Clarification"). The Clarification states that federal law does not prohibit physicians from discussing the risks and benefits of marijuana, and that the federal government did not intend to establish a "gag rule" to prevent physicians from communicating their professional judgments regarding the risks and benefits of any course of treatment. *See* Mueller Decl. Ex. 7 at 1. The Clarification also states, however, that "[p]hysicians may not intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law. Physicians who do so risk revocation of their DEA prescription authority, criminal prosecution, and exclusion from participation in the Medicare and Medicaid programs." *Id.*

Since issuance of the Clarification, federal officials have continued to promote the administration's position. For example, at the April 1997 American Methadone Treatment Association ("AMTA") conference in Chicago, defendant McCaffrey, a keynote speaker, and his staff distributed a folder entitled "Office of National Drug Control Policy, Executive Office of the President" to all conference participants. (Declaration of Daniel N. Abrahamson re: Defendants' Ex Parte Motion for Clarification of the 4/11/97 TRO ("Abrahamson Decl.") ¶ 4.) The folder included the December 30, 1996 Administration Response to Pro-

position 215 but made no mention of the Clarification to the Administration Response. *Id.* It unequivocally stated that the administration would seek to revoke practitioners' licenses, prevent practitioners from participating in Medicare and Medicaid programs, and impose criminal sanctions on practitioners for "recommending" marijuana to their patients.[3] *Id.*

A. Ripeness

Despite the varying interpretations of the federal government's policy given by administration officials, defendants insist that the Clarification has eliminated any confusion about the policy. Because the policy is clear, defendants argue, there can be no case or controversy over its interpretation.

1. Legal Standard

Article III of the Constitution prohibits courts from engaging in hypothetical or abstract legal disputes; courts may decide only cases that present real and substantial controversies between parties which can result in actual and adverse consequences. *See Babbitt v. United Farm Workers Nat'l Union,* 442 U.S. 289, 297-98, 99 S. Ct. 2301, 2308-09, 60 L. Ed. 2d 895 (1979); *Railway Mail Ass'n v. Corsi*, 326 U.S. 88, 93, 65 S. Ct. 1483, 1487, 89 L. Ed. 2072 (1945). This "ripeness" inquiry focuses on two distinct elements, "the fitness of

[3] Plaintiffs have provided the Court with a chronology of press reports on the administration's position on medical marijuana. The articles present varying interpretations of the administration's policy. Many of the statements are impermissible hearsay; however, the chronology demonstrates the shifting sands of the government's policy. *See* Plaintiffs' Reply Memorandum of Points and Authorities in Support of Motion for Preliminary Injunction ("Pls.' Reply") App. A.

the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S. Ct. 1507, 1515, 18 L. Ed. 2d 681 (1967). If either element is not established, a dispute is not ripe for resolution. *See Socialist Labor Party v. Gilligan*, 406 U.S. 583, 589, 92 S. Ct. 1716, 1720, 32 L. Ed. 2d 317 (1972) (holding that a dispute was not ripe because of the lack of an adequate record).

a. Fitness of the Issues

A claim attacking an administrative action is fit for decision if the parties present a sufficient factual record and establish that the challenged administrative action is final. *See Trustees for Alaska v. Hodel*, 806 F.2d 1378, 1381 (9th Cir. 1986) (citing *Abbott Labs.*, 387 U.S. at 149, 87 S. Ct. at 1515-16). Facial attacks on statutes, raising issues of law, do not require a significant development of the factual record prior to judicial determination. *See Freedom to Travel Campaign v. Newcomb*, 82 F.3d 1431, 1434 (9th Cir. 1996). "If it is inevitable that the challenged rule will operate to the plaintiff's disadvantage—if the court can make a firm prediction" that the harm will occur—there is a justiciable controversy. *See id.* at 1436 (quoting *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 69, 113 S. Ct. 2485, 2501, 125 L. Ed. 2d 38 (1993) (O'Connor, J., concurring)) (internal quotation marks omitted).

A controversy is ripe if the challenged administrative decision is final within the meaning of section 10 of the Administrative Procedure Act, 5 U.S.C. § 704 ("APA"). The APA defines final agency action as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or pre-

scribe law or policy." *Abbott Labs.*, 387 U.S. at 149, 87 S. Ct. at 1516 (quoting 5 U.S.C. §§ 551(4), 551(13)) (internal quotation marks omitted). Courts employ a flexible and pragmatic test to ascertain the finality of an administrative action. *See Assiniboine & Sioux Tribes of the Fort Peck Indian Reservation v. Board of Oil & Gas Conservation of Mont.*, 792 F.2d 782, 789 (9th Cir. 1986). They look to numerous factors, including: whether the action is a definitive statement of any agency's position; whether the action has an effect on the day-to-day business of the complaining parties; and whether the agency expects immediate compliance. *See Municipality of Anchorage v. United States*, 980 F.2d 1320, 1323 (9th Cir. 1992) (citing *Mt. Adams Veneer Co. v. United States*, 896 F.2d 339, 343 (9th Cir. 1989)). The agency action must represent "the final administrative word to insure that judicial review will not interfere with the agency's decision making process." *State of Cal., Dep't of Educ. v. Bennett*, 833 F.2d 827, 833 (9th Cir. 1987).

b. Hardship to Parties

Plaintiffs challenging a statute, regulation, or policy must demonstrate a realistic possibility of sustaining an injury as a result of its enforcement, *see O'Shea v. Littleton*, 414 U.S. 488, 494, 94 S. Ct. 669, 675, 38 L. Ed. 2d 674 (1974); however, they need not wait for "the consummation of threatened injury to obtain preventive relief." *Pennsylvania v. West Virginia*, 262 U.S. 553, 593, 43 S. Ct. 658, 663, 67 L. Ed. 1117 (1923). "If injury is certainly impending, that is enough." *Id.*; *see Bland v. Fessler*, 88 F.3d 729, 736-37 (9th Cir.), cert. denied, 519 U.S. 1009, 117 S. Ct. 513, 136 L. Ed .2d 403 (1996).

Plaintiffs contesting criminal statutes do not have to expose themselves to "actual arrest or prosecution" prior to challenging the constitutionality of a statute. See *Steffel v. Thompson*, 415 U.S. 452, 459, 94 S. Ct. 1209, 1215-16, 39 L. Ed. 2d 505 (1974); *Doe v. Bolton*, 410 U.S. 179, 188, 93 S. Ct. 739, 745, 35 L. Ed. 2d 201 (1973) (holding that a plaintiff "should not be required to await and undergo a criminal prosecution as the sole means of seeking relief"). Additionally, challenges to statutes based on the First Amendment receive special consideration because "free expression—of transcendent value to all society, and not merely to those exercising their rights—might be the loser." *Bland*, 88 F.3d at 737 (quoting *Dombrowski v. Pfister*, 380 U.S. 479, 486, 85 S. Ct. 1116, 1121, 14 L. Ed. 2d 22 (1965)). If the plaintiffs cannot establish that a prosecution is likely to occur, however, a constitutional challenge is not justiciable. *See Younger v. Harris*, 401 U.S. 37, 42, 91 S. Ct. 746, 749-50, 27 L. Ed. 2d 669 (1971).

2. Analysis of Plaintiffs' Claims

a. Fitness of the Issues Presented

Defendants maintain that the Court cannot entertain plaintiffs' challenge because the complaint and surrounding factual circumstances do not create a sufficiently concrete record. Defendants contend that without an actual prosecution, the Court cannot properly determine whether the government interprets the term "recommendation" in a manner violative of physicians' free speech right. The Court finds to the contrary. Plaintiffs have shown that because the government continues to vacillate in its description of sanctionable conduct, its policy is subject to numerous interpretations. Plaintiffs have also demonstrated that

the government policy "chills" speech. Because this is a facial challenge involving questions of First Amendment law, no further factual development is required. *See Newcomb*, 82 F.3d at 1434.

Under the factors set forth by the Ninth Circuit in *Mt. Adams Veneer Co.*, the government's various statements represent a final administrative action with the meaning of the APA. *See* 896 F.2d at 343. First, defendants are the highest ranking officials in their respective agencies. Their statements equate to federal agency interpretations of federal drug law. Second, plaintiff physicians and patients are being affected adversely by the government's conflicting statements of law—they allege a chilling of free speech. Finally, the agencies expect immediate compliance with their policy pronouncements: at different times, each agency has declared that, notwithstanding Proposition 215, it would take immediate action against physicians and others who violate federal drug policies.[4]

b. Plaintiffs' Hardships

Because they fear prosecution or administrative sanction, plaintiff physicians contend they have censored their medical advice to patients, refusing to provide guidance regarding the risks and benefits of medical marijuana. *See, e.g.*, Declaration of Stephen O'Brien, M.D. ("O'Brien Decl.") ¶ 11. Despite defendants' alleged clarification of federal policy, the physicians remain unsure as to whether bona fide discussions regarding medical marijuana will result in federal punishment. *See, e.g.*, Complaint ¶¶ 7, 8, 9, 10; Declara-

[4] The swiftness of the government's response to the proposition is evidenced by the January 27, 1997 threats to Dr. Mastroianni. See discussion *infra* part II.A.2.b.

tion of Neil M. Flynn, M.D. ("Flynn Decl.") ¶ 5. Their fears are corroborated by the testimony of Robert Mastroianni, M.D. ("Dr.Mastroianni"). Dr. Mastroianni has been interrogated by DEA agents who questioned his medical education and training, confronted a pharmacist regarding prescriptions he has dispensed, and informed him that it was illegal to "recommend or prescribe" marijuana. (Declaration of Robert Mastroianni ("Mastroianni Decl.") ¶¶ 5, 7, 10.)

Plaintiff patients allege that as a result of the government's policy, they no longer trust in their physicians' advice, and can no longer comfortably communicate with their physicians about medical marijuana. *See, e.g., Complaint* ¶¶ 16-20; Declaration of Daniel J. Kane ("Kane Decl.") ¶ 7-8; Decl. of Jo Daly ("Daly Decl.") ¶ 15. Both patients and physicians agree that patient care is threatened by this lack of confidence and communications. (Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Preliminary Injunction ("Mot. for Prelim. Inj.") at 8-10.) Plaintiffs describe various results of the decrease in open communication: patients are less likely to tell their physicians about marijuana use; physicians, in turn, are unable to advise patients about safe use of marijuana or guide proper use of marijuana for treatment; and physicians are discouraged from recording their patients' full medical histories and progress on medical charts. *See id.* at 9-10.

Defendants contend that because the Administration Response and Clarification do not change the law, but only interpret it, no justiciable controversy exists. Defendants reiterate that the government's approach does not place physicians in any type of danger of criminal sanctions for merely discussing the potential

risks or benefits of the medical use of marijuana; according to defendants, physicians must refrain only from giving recommendations intended to facilitate their patients' acquisition or possession of marijuana in violation of federal law. The Court finds these arguments unpersuasive.

The government persists in issuing ambiguous and conflicting interpretations of medical marijuana policy. Indeed, at the hearing on these motions, the government's attorneys were unable clearly to articulate the contours of federal policy on the subject. In light of this confusion, and the harms demonstrated by plaintiffs, the Court finds this case ripe for review. *See Bolton*, 410 U.S. at 188, 93 S. Ct. at 745-46.

B. Class Certification

In conjunction with the motion for a preliminary injunction, plaintiffs have moved for class certification. Because Federal Rule of Civil Procedure 23(c)(1) requires that the Court make an initial determination regarding class certification "as soon as practicable," the Court considers plaintiffs' motion at this time.

1. Legal Standard

The burden of proving that a class action is appropriate rests with the proponent of the class. *See In re Northern Dist. of Cal., Dalkon Shield IUD Prods. Liab. Litig.*, 693 F.2d 847, 854 (9th Cir. 1982); *Shields v. Smith*, [1992 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 97,001, 94,376, 1992 WL 295179 (N.D. Cal. 1992). The party seeking to maintain the action as a class suit must, therefore, establish a prima facie showing of each of the four certification prerequisites and demonstrate that appropriate grounds for a class action exist. *See*

Blackie v. Barrack, 524 F.2d 891, 901 (9th Cir. 1975). The failure to carry this burden as to any one of the requirements precludes the maintenance of the lawsuit as a class action. *See Rutledge v. Electric Hose & Rubber Co.*, 511 F.2d 668, 673 (9th Cir. 1975).

Class certification is governed by Federal Rule of Civil Procedure 23, which provides for a two-step procedure. First, subsection (a) of Rule 23 sets out four conjunctive requirements that must be met in all class actions:

> (1) the class [must be] so numerous that joinder of all members is impracticable, (2) there (must be) questions of law or fact common to the class, (3) the claims or defenses of the representative parties [must be] typical of the claims or defenses of the class, and (4) the representative parties [must] fairly and adequately protect the interests of the class.

If these requirements are met, the proponent must also show that it has met one of the four disjunctive prerequisites of subsection (b) of Rule 23. Under this subsection, the Court must find either: (1) that common questions of law or fact predominate and that a class action is superior to other available methods of adjudication; (2) that the defendant acted or refused to act on grounds generally applicable to the class, so that declaratory or injunctive relief is appropriate with respect to the entire class; (3) that the prosecution of individual actions would create a risk of inconsistent verdicts that would establish incompatible standards of conduct for defendants; or (4) that adjudication of individual claims would be dispositive of the claims of non-party class members, or substantially impede the

ability of non-party class members to pursue their own claims. Fed. R. Civ. P. 23(b)(1)-(3).

Before ordering that a lawsuit may proceed as a class action, the Court must rigorously analyze whether the class action allegations meet the requirements of Rule 23. *See General Tel. Co. of Southwest v. Falcon*, 457 U.S. 147, 161, 102 S. Ct. 2364, 2372-73, 72 L. Ed. 2d 740 (1982); *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 509 (9th Cir. 1992). Because the early resolution of the class certification question requires some degree of speculation, however, the Court need only form a "reasonable judgment" on each certification requirement. In formulating this judgment, the Court may properly consider both the allegations of the class action complaint and the supplemental evidentiary submissions of the parties. *Blackie*, 524 F.2d at 900-01 & n. 17.

2. Analysis

Plaintiffs originally sought certification of a class of:

> (a) All physicians present and future who are licensed by and practicing medicine in California and who, using their best medical judgment in the context of a bona fide physician-patient relationship, have discussed, recommended or approved the medical use of marijuana for their patients, or but for defendants' threats of punishment, would discuss, recommend or approve or consider discussing recommending or approving the medical use of marijuana for their patients; and
>
> (b) All patients in California who seek to communicate with their physicians or receive the recommendation or approval of their physician, in

> the context of a bona fide physician-patient relationship, regarding the medical use of marijuana.

(Notice of Motion and Motion for Class Certification and Memorandum in Support at 1.) In response to defendants' contention that this definition was too broad, plaintiffs narrowed the scope of the proposed class, and now seek certification of the following class:

> (a) All physicians licensed by and practicing in California who recommend or have recommended to a patient the medical use of marijuana or who discuss with or have discussed with a patient the medical use of marijuana; and
>
> (b) All patients to whom those recommendations are or were made or with whom those discussions are or were held.

(Reply Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Class Certification at 1.) This proposed class remains broader than the allegations in plaintiffs' complaint and the evidence submitted by plaintiffs in support of their motion for preliminary injunction.

The record is limited to the recommendation and/or use of medical marijuana in very specific circumstances. Plaintiffs allege that "[f]or at least two decades, hundreds of physicians in California have recommended use of marijuana, often as a medicine of last resort, to seriously ill patients suffering from debilitating conditions including cancer, AIDS and glaucoma." (Complaint ¶ 2.) Although not specifically alleged in the complaint, plaintiff Valerie Corral's experience suggests that physicians in California also recommend use of marijuana for patients suffering from seizures. *See* Com-

plaint ¶ 19; Declaration of Valerie Corral ("Corral Decl.") ¶ 19. These allegations are buttressed by an article submitted by plaintiffs indicating that nearly half of oncologists randomly surveyed report recommending that their patients use marijuana. *See* Declaration of Kevin B. Zeese ("Zeese Decl.") Ex. 23 (Richard E. Doblin & Mark A.R. Kleiman, *Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes*, 9 J. of Clinical Oncology 1314-1319 (1991)).

In his declaration, plaintiffs' witness Kevin B. Zeese, president of Common Sense for Drug Policy, describes the scientific literature supporting the use of marijuana for treatment of cancer, (Zeese Decl. ¶ 1 13); HIV and AIDS, (Zeese Decl. ¶ 14); glaucoma, (Zeese Decl. ¶ 15); and epilepsy (Zeese Decl. ¶ 16). Plaintiffs' complaint describes how marijuana is used to treat diseases other than epilepsy that involve seizures and muscle spasms. (Complaint ¶ 32(e) (multiple sclerosis), ¶ 32(f) (paraplegia and quadriplegia).) Although Mr. Zeese intimates that marijuana may be effective in treating a number of other ailments—including hypertension, peptic ulcers, and asthma, (Zeese Decl. ¶ 8)—neither the record nor the evidence presently supports this suggestion.

Indeed, the proffered class representatives in this case recommend or use marijuana only for a narrow range of illnesses. The physician class representatives include eight clinicians specializing in the treatment of HIV and AIDS, and two oncologists. The patient class representatives include two people living with HIV or AIDS, two cancer patients, and one person suffering from seizures. In their declarations, all of the proffered

class representatives limit their discussion of medical marijuana to its use in connection with these illnesses.

This record does not support certifying a class as broad as the one requested by plaintiffs. Instead, the Court exercises its discretion to limit the definition of the proposed class to provide more appropriate limits, *see Hagen v. City of Winnemucca,* 108 F.R.D. 61, 64 (D. Nev. 1985), and defines the class as follows:

> (1) All licensed physicians practicing in the State of California who treat patients diagnosed with HIV/AIDS, cancer, glaucoma, and/or seizures or muscle spasms associated with a chronic, debilitating condition, and who, in the context of a bona fide physician-patient relationship, discuss, approve, or recommend the medical use of marijuana for these patients based on the physician's best medical judgment; and
>
> (2) All patients in the State of California diagnosed with HIV/AIDS, cancer, glaucoma, and/or seizures or muscle spasms associated with a chronic, debilitating condition, who, in the context of a bona fide physician-patient relationship, communicate with their physicians about the medical use of marijuana.

This class meets the requirements imposed by Federal Rule of Civil Procedure 23. First, the large number of physicians and patients within the defined class, and their residences throughout California, make joinder of all class members impracticable. See *Scholes v. Stone, McGuire & Benjamin,* 143 F.R.D. 181, 184 (N.D. Ill. 1992) (noting that numerosity may be supported by common-sense assumptions). Second, plaintiffs' First Amendment challenge to the government's

medical marijuana policy presents a common and dispositive issue of law. *See Jordan v. County of L.A.*, 669 F.2d 1311, 1321 (9th Cir.) (finding existence of discriminatory policy a common question sufficient to support a class action), *vacated on other grounds*, 459 U.S. 810, 103 S. Ct. 35, 74 L. Ed. 2d 48 (1982). Third, the named plaintiffs' claims are typical, stemming from the same course of conduct that forms the basis of the class action, and based on the same legal theory. *See id.* Fourth, the Court has no reason to question the named plaintiffs' adequacy as representatives, because it cannot identify any conflicts of interest among class members or reasons to question class counsels' competence. *See Falcon*, 457 U.S. at 157 n. 13, 102 S. Ct. at 2370 n. 13 (holding that parties are adequate representatives of absent class members if there are no conflicts of interest between representatives and class members, and counsel for the class will vigorously pursue the action). Finally, because defendants have acted on grounds generally applicable to the class in articulating their medical marijuana policy, injunctive relief is appropriate under Rule 23(b)(2). In fact, as the Advisory Committee's note to the provision states, Rule 23(b)(2) was intended to cover precisely this type of civil rights case. *See* Fed. R. Civ. P. 23(b)(2) advisory committee's note.

Defendants' objection to the breadth of plaintiffs' original proposed class definition was that the class members would not be readily ascertainable. Plaintiffs substantially alleviated this problem by revising the class definition in their reply brief. In further narrowing the definition, the Court has made the class sufficiently ascertainable for purposes of Federal Rule of Civil Procedure 23. Any remaining imprecision is

immaterial. A precise class definition is less important in cases in which plaintiffs are attempting to certify a class for injunctive relief because the representative plaintiffs may move the Court to enforce compliance. *See* 5 *Moore's Federal Practice* 3d § 23.21[6], at 23-59 (Matthew Bender 3d ed. 1997).

Although the Court grants plaintiffs' motion for class certification, "[a] decision as to class certification is not immutable." *Social Servs. Union, Local 535 v. County of Santa Clara*, 609 F.2d 944, 948-49 (9th Cir. 1979). If at any time before, during, or after trial it appears that the class definition is inappropriate, the Court may modify it, expand it, further narrow it, or withdraw certification altogether. *See id.* This authority to shape the litigation will be exercised whenever the circumstances so warrant.

C. First Amendment

Plaintiffs assert, and defendants appear to concede, that the government's policy implicates First Amendment rights. In seeking to restrict what doctors may legally say to their patients concerning the use of medical marijuana, the government seeks to regulate physician-patient dialogue based on the content of that dialogue. "It is axiomatic that the government may not regulate speech based on its substantive content or the message it conveys." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 828, 115 S. Ct. 2510, 2516, 132 L. Ed. 2d 700 (1995) (citing *Police Dep't of Chicago v. Mosley*, 408 U.S. 92, 96, 92 S. Ct. 2286, 2290, 33 L. Ed. 2d 212 (1972)). This proposition is even stronger in situations in which the government targets particular views of the speaker on a given subject. *See Rosenberger*, 515 U.S. at 829, 115 S. Ct. at 2516; *Texas v.*

Johnson, 491 U.S. 397, 414, 109 S. Ct. 2533, 2545, 105 L. Ed.2d 342 (1989) ("If there is a bedrock principle underlying the First Amendment, it is that the government may not prohibit the expression of an idea simply because society finds the idea itself offensive or disagreeable."). This case presents just that situation. Finding itself in disagreement with plaintiff physicians' views about the efficacy of medical marijuana, the government has announced a policy which significantly inhibits communication of those views.

The government concedes that it may not prohibit "discussion" of marijuana, *see*, *e.g.*, Boyd Decl. Ex. D (Letter from Kathleen Moriarty Mueller, Trial Attorney, Federal Programs Branch, United States Department of Justice, to Graham Boyd, Attorney, Altshuler, Berzon, Nussbaum, Berzon & Rubin 1-2 (Feb. 7, 1997)); but the government attempts to justify its policy of sanctioning physicians on the unremarkable and undisputed proposition that the government can regulate distribution and possession of drugs. The government's statutory authority to regulate that conduct, however, does not allow the government to quash protected speech about it. *See NAACP v. Alabama*, 377 U.S. 288, 307, 84 S. Ct. 1302, 1314, 12 L. Ed. 2d 325 (1964) ("[A] governmental purpose to control or prevent activities constitutionally subject to state regulation may not be achieved by means which sweep unnecessarily broadly and thereby invade the area of protected freedoms."). The government's fear that frank dialogue between physicians and patients about medical marijuana might foster drug use, *see* Defendants' Opposition to Motion for Preliminary Injunction ("Defs.' Opp'n") at 19-20, does not justify infringing First Amendment freedoms. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484,

503, 116 S. Ct. 1495, 1508, 134 L. Ed. 2d 711 (1996) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.").[5]

Plaintiffs argue that the First Amendment protects the sanctity of physician-patient dialogue, and, in fact, that physician-patient communications receive heightened First Amendment protection. *See* Mot. for Prelim. Inj. at 15-16. Although the Supreme Court has never held that the physician-patient relationship, as such, receives special First Amendment protection, its case law assumes, without so deciding, that the relationship is a protected one. *See, e.g., Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 884, 112 S. Ct. 2791, 2824, 120 L. Ed. 2d 674 (1992); *City of Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 445, 103 S. Ct. 2481, 2500-01, 76 L. Ed. 2d 687 (1983) (discussing relationship of trust between patient and doctor). Thus, the Court has discussed the physician's right to exercise her best medical judgment, *see Casey*, 505 U.S. at 883-84, 112 S. Ct. at 2823-24, and the patient's right to rely on the medical advice of her physician. *See City of Akron*, 462 U.S. at 445, 103 S. Ct. at 2500-01; *see also Whalen v. Roe*, 429 U.S. 589, 604 n. 33, 97 S. Ct. 869, 879 n. 33, 51 L. Ed. 2d 64 (1977) (commenting on doctor's right to administer medical care and patient's right to receive such care).

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[5] Moreover, the government's fears in this case are exaggerated and without evidentiary support. It is unreasonable to believe that use of medical marijuana by this discrete population for this limited purpose will create a significant drug problem.

The Supreme Court has also indicated that physicians have a First Amendment right not to speak, *see Casey*, 505 U.S. at 884, 112 S. Ct. at 2824, implying that physicians must have the corollary right to speak. *Cf. City of Akron*, 462 U.S. at 445, 103 S. Ct. at 2500-01 (invalidating regulation that placed physicians in "'undesired and uncomfortable straitjacket[s]'" in communicating with their patients) (citation omitted). Although the practice of medicine is subject to state regulation, it does not automatically follow that speech that would otherwise be protected if between two ordinary citizens somehow loses that protection when it occurs in the context of the physician-patient relationship. At the very least, courts confronted with the issue of regulation of physician speech have presupposed that speech between physicians and their patients is protected by the First Amendment. Moreover, sound policy reasons justify special protection of open and honest communication between those groups.

Plaintiffs also argue that defendants may not justify censoring physician speech about medical marijuana on the ground that such speech constitutes incitement to unlawful conduct. Defendants do not contest this proposition. The First Amendment allows physicians to discuss and advocate medical marijuana, even though use of marijuana itself is illegal. What physicians may not do is advocate use of medical marijuana "where such advocacy is directed to inciting or producing imminent lawless action and is likely to incite or produce such action." *Brandenburg v. Ohio*, 395 U.S. 444, 447, 89 S. Ct. 1827, 1829, 23 L. Ed. 2d 430 (1969) (footnote omitted). Defendants make no argument that physicians who discuss or recommend the use of medical marijuana are inciting imminent lawless action, and

the record does not demonstrate that physician speech about medical marijuana could be characterized as incitement and thereby stripped of its First Amendment protection.

For the foregoing reasons, the broad reaches of the government's policy implicate speech that is protected by the First Amendment. Having so found, the Court must now determine whether plaintiffs have raised serious questions as to whether the government's policy violates the First Amendment and whether the balance of hardships tips in favor of plaintiffs.

Plaintiffs argue that the ambiguities in the government's policy render that policy facially invalid and therefore justify entry of a preliminary injunction. (Pls.' Reply at 2 & n. 6.) Vague or overbroad laws may be challenged facially. *See Grayned v. City of Rockford*, 408 U.S. 104, 114, 92 S. Ct. 2294, 2302, 33 L. Ed. 2d 222 (1972). Plaintiffs seem to argue both that the government's policy is void for vagueness and that it is overbroad. The Supreme Court views the doctrines of vagueness and overbreadth as related and similar doctrines, *see Kolender v. Lawson*, 461 U.S. 352, 358 n. 8, 103 S. Ct. 1855, 1858-59, 75 L. Ed. 2d 903 (1983) (citations omitted), and cases involving facial challenges more often than not involve analysis of both doctrines. *See, e.g., Grayned*, 408 U.S. 104, 92 S. Ct. 2294. Because plaintiffs have met their burden of showing that there are serious questions as to whether the government's policy is unconstitutionally vague, no analysis of the overbreadth doctrine need be done at this time.

Due process requires that the prohibitions contained in a government policy, regulation, law, or other enactment be clearly defined. *See Grayned*, 408 U.S. at 108, 92 S. Ct. at 2298-99. In the First Amendment context,

the government may only regulate with "narrow specificity." *NAACP v. Button*, 371 U.S. 415, 433, 83 S. Ct. 328, 338, 9 L. Ed. 2d 405 (1963); *see Buckley v. Valeo*, 424 U.S. 1, 40-41, 96 S. Ct. 612, 645, 46 L. Ed. 2d 659 (1976) ("Close examination of the specificity of the statutory limitation is required where, as here, the legislation imposes criminal penalties in an area permeated by First Amendment interests."). A statute is void for vagueness if it fails to give "the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Grayned*, 408 U.S. at 108, 92 S. Ct. at 2298-99. The First Amendment requires that citizens not be forced to " 'steer far wider of the unlawful zone,' than if the boundaries of the forbidden area were clearly marked." *Baggett v. Bullitt*, 377 U.S. 360, 372, 84 S. Ct. 1316, 1323, 12 L. Ed. 2d 377 (1964) (citation omitted).

Plaintiffs argue that the government's policy sweeps too broadly, leaving physicians confused as to the boundaries of the conduct it prohibits. This vagueness allegedly has led physicians to censor otherwise protected speech in order to ensure that they do not run afoul of conduct for which the government has threatened criminal prosecution and/or administrative sanctions. As discussed above, the government has issued numerous statements regarding its position on medical marijuana since Proposition 215 was passed. Several of those statements indicate that the government means to take action against physicians who simply recommend marijuana to treat disease. *See, e.g.*, Administration Response. In other statements, the government has conceded that physicians may discuss the risks and alleged benefits of medical marijuana, in the context of a bona fide physician-patient relation-

ship, but has stated that they may not recommend marijuana "in order to enable [patients] to obtain controlled substances in violation of federal law." *See, e.g.*, Mueller Decl. Ex. 7 (Clarification). The government's statements range from suggesting that the government will use informers and surveillance to detect physicians who recommend medical marijuana to assuring that simple advice about the risks and benefits of marijuana for a specific patient will not subject physicians to government sanctions. *See* Weissglass Decl. Ex. C at C66, C98; Declaration of Steve Heilig ("Heilig Decl.") ¶ 9.

Plaintiff physicians' confusion as to how broadly the government's policy sweeps is understandable. Although the government purported to "clarify" the reach of its policy in the February 27, 1997 letter to the California Medical Association and in the various papers it has filed regarding the pending motions, the government continues to waver on the scope of its policy. *See* discussion *supra* Part II. In oral argument before the Court, when asked where discussion ends and recommendation begins, counsel for defendants answered, "when [physicians] use the word 'recommend.'" Such semantic distinctions are insufficient to render the government's policy constitutionally valid.

The distinction the government attempts to draw between a permissible discussion and an impermissible recommendation may well break down in practical application. *See Buckley v. Valeo*, 424 U.S. at 42, 96 S. Ct. at 646 ("For the distinction between discussion of issues and candidates and advocacy of election or defeat of candidates may often dissolve in practical application."). As in *Thomas v. Collins*, 323 U.S. 516, 65 S. Ct. 315, 89 L. Ed. 430 (1945), the government seems to

be seeking to confine physicians to "innocuous and abstract discussion" about medical marijuana and then to "becloud even this [discussion] with doubt, uncertainty and the risk of penalty." 323 U.S. at 536-37, 65 S. Ct. at 325. In *Thomas*, the Supreme Court invalidated a law on the ground that it was impossible for union members to draw the line between speech that could be found to convey the idea of solicitation and speech that would be classified as mere discussion or general advocacy: "[T]he supposedly clear-cut distinction between discussion, laudation, general advocacy, and solicitation puts the speaker in these circumstances wholly at the mercy of the varied understanding of his hearers. . . . Such a distinction offers no security for free discussion." *Id.* at 535, 65 S. Ct. at 325. Similarly, in this case, when faced with the fickle iterations of the government's policy, physicians have been forced to suppress speech that would not rise to the level of that which the government constitutionally may prohibit. Plaintiffs therefore have raised at least serious questions as to whether the government's policy is unconstitutionally vague.

Having identified serious questions about the constitutionality of the government's policy, the balance of hardships between the parties must now be addressed. Plaintiffs allege that the government's threats of prosecution and administrative sanctions have severely intimidated physicians, leading many physicians to censor any discussion of marijuana with their patients. Some physicians have stopped discussing marijuana altogether. *See, e.g.*, Declaration of Milton N. Estes, M.D. ("Estes Decl.") ¶ 8; Declaration of Stephen Eliot Follansbee, M.D. ("Follansbee Decl.") ¶ 15. Plaintiffs also allege that physicians' self-censorship

jeopardizes patient care, diminishing the trust between doctor and patient. Patients suffer because they are unable to get appropriate information about all potential treatment options. Plaintiffs allege this sometimes may mean the difference between life and death. (O'Brien Decl. ¶ 9.) Moreover, plaintiffs contend that physicians' self-censorship inhibits patients' honesty about marijuana use, which in turn limits physicians' ability to diagnose accurately and to treat effectively patients' illnesses or guide proper use of medical marijuana.

Defendants claim that plaintiffs' fears are speculative and that any chilling is subjective. The Supreme Court faced a similar argument in *Baggett v. Bullitt*, a case in which the State of Washington labeled the plaintiffs' concerns about the possible coverage of challenged loyalty oaths "wholly fanciful." 377 U.S. at 373, 84 S. Ct. at 1323. The Court noted that although the State may have been correct, "the [State's] contention only emphasize[d] the difficulties with the two statutes; for if the oaths do not reach some or any of the behavior suggested, what specific conduct do the oaths cover? Where does fanciful possibility end and intended coverage begin?" *Id.* at 373, 84 S. Ct. at 1323. In this case, it is hard to imagine that in every situation, a physician could easily determine whether a communication with a patient had crossed the line from protected speech to conduct the government has threatened to prosecute. The government cannot force physicians to choose between attempting to comply with a vague and broad policy, thereby limiting protected speech, or discussing medical marijuana with their patients in the exercise of their best medical judgment, thereby incurring the risk of criminal pro-

secution or other sanctions. *See id.* at 374, 84 S. Ct. at 1323-24.

Defendants otherwise counter plaintiffs' claims of injury only by speculating that "between the lines of their papers," plaintiffs may really be claiming that they should be protected from the injury that allegedly occurs when doctors are unable to provide, and patients unable to obtain, marijuana for "treatment." The Court takes plaintiffs' claims at face value rather than reading between the lines.

Because plaintiffs have alleged deprivation of a First Amendment right, irreparable injury is presumed: "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. at 373, 96 S. Ct. at 2690; *American-Arab Anti-Discrimination Comm. v. Reno*, 70 F.3d 1045, 1058 (9th Cir. 1995). Plaintiffs also assert injury to the protected relationship between physicians and patients and potentially to patients' health. *See City of Akron*, 462 U.S. at 445, 103 S. Ct. at 2500 (striking down state regulation that placed "'obstacles' in the path of the doctor upon whom [the patient] is entitled to rely for advice in connection with her decision") (citation omitted).

Defendants claim that a preliminary injunction would be contrary to the public interest because it would interfere with the government's ability to enforce federal drug laws. Defendants worry that the injunction "would authorize physicians to facilitate the cultivation, distribution, dispensing, and possession of marijuana through oral or written 'recommendations' without the corresponding registration, recordkeeping, or reporting requirements that Congress inserted in the Controlled Substances Act to permit the govern-

ment to monitor the distribution of controlled substances." (Defs.' Op'n at 19-20.) Although neither the Court nor plaintiffs dispute the government's authority to enforce federal drug laws, defendants have done nothing to demonstrate that there is anything more than the weakest link between non-criminal physician-patient dialogue about medical marijuana and the government's ability to enforce federal laws. This case involves no more than the ability of physicians to recommend personal use of marijuana to bona fide patients suffering from a narrow range of serious, debilitating diseases.

Because plaintiffs have shown both that there are serious questions as to the constitutionality of the government's policy and that the balance of hardships tips sharply in their favor, the Court may properly enter a preliminary injunction enjoining the government's policy, but only to the extent that such policy is likely unconstitutional. In *Buckley v. Valeo*, 424 U.S. 1, 96 S. Ct. 612, 46 L. Ed. 2d 659, the Supreme Court established a bright line test in order to save a statutory provision from being unconstitutionally vague. *See id.* at 44, 96 S. Ct. at 646-47; *see also Thomas*, 323 U.S. at 535, 65 S. Ct. at 325 (discussing need to draw a "sharp line"). Plaintiffs request that the Court establish a bright line that shifts the focus away from physicians' state of mind and toward a discernible standard defining what physicians can and cannot write and say, and to whom. (Pls.' Reply at 13.) Although it is necessary in this case to establish a bright line test to address the serious questions as to the constitutionality of the government's policy, plaintiffs' theory about where the line should be drawn is problematic.

The First Amendment does not protect speech that is itself criminal because too intertwined with illegal activity. *See Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 498, 69 S. Ct. 684, 688-89, 93 L. Ed. 834 (1949); *United States v. Mendelsohn*, 896 F.2d 1183, 1185 (9th Cir. 1990). If physicians' conduct, which could include speech, rises to the level of aiding and abetting or conspiracy, in violation of valid federal statutes, such conduct is punishable under federal law. *See United States v. Freeman*, 761 F.2d 549, 552 (9th Cir. 1985) ("[W]here speech becomes an integral part of the crime, a First Amendment defense is foreclosed even if the prosecution rests on words alone."). The Court cannot immunize such conduct by eliminating the ability of the government to prosecute physicians if the government can prove in individual situations that a physician had the requisite specific intent to commit the crime of aiding and abetting or conspiracy.[6]

What the Court may and will do, however, is to draw the line at criminal conduct, which plaintiffs concede the government may prosecute. To the extent that the government's definition of "recommend with the intent to facilitate" encompasses only that conduct which would rise to the level of aiding and abetting or conspiracy, such conduct, even if it includes pure speech, is punishable under criminal law. *See United States v. Barnett*, 667 F.2d 835, 841-43 (9th Cir. 1982). The discussion of the Controlled Substances Act and the Medicare statute that follows illustrates how this line also protects the government's administrative power.

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[6] Similarly, the Court cannot restrict the DEA's administrative authority to sanction conduct that violates the Controlled Substances Act or the Medicare statute. *See* discussion *infra* part II.D.

D. Government Authority to Impose Administrative Sanctions

In addition to threatening criminal prosecution, defendants have threatened to take administrative action under the Controlled Substances Act and the Medicare statute against physicians for recommending medical marijuana. The Controlled Substances Act, 21 U.S.C. §§ 801-904, authorizes the government to register physicians and other manufacturers, distributors, and dispensers of controlled substances, 21 U.S.C. §§ 821-828, and to revoke those registrations under certain conditions. 21 U.S.C. § 824. The Medicare Statute, 42 U.S.C. §§ 1301-1324, contains the general provisions for publicly-assisted medical care. Section 1320 guides federal approval of Medicare projects, and includes provisions for excluding physicians from participation in Medicare programs under certain conditions. 42 U.S.C. § 1320a-7. Plaintiffs challenge the government's authority to sanction physicians under either statute for recommending medical marijuana to patients.

1. Controlled Substances Act

Plaintiffs contend that the Controlled Substances Act ("CSA") gives the DEA authority to revoke a physician's license only if that physician commits an illegal act related to the distribution, dispensing, or manufacture of controlled substances. Defendants counter that the CSA provides broad authority to the DEA to revoke a physician's license for any act that violates the public interest. Defendants argue that a physician who recommends marijuana violates the public interest, making such a recommendation grounds for revocation of that physician's license.

In interpreting the CSA, traditional canons of statutory construction first require a consideration of the plain meaning of the terms of the statute. *See Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 48, 107 S. Ct. 1549, 1553, 95 L. Ed. 2d 39 (1987). The meaning of a term, however, "cannot be determined in isolation, but must be drawn from the context in which it is used." *Deal v. United States*, 508 U.S. 129, 132, 113 S. Ct. 1993, 1996, 124 L. Ed. 2d 44 (1993). If, after considering the language of the statute, a term remains ambiguous, the legislative history of the statute must be examined to ascertain the statute's scope and meaning. *See United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 516, 112 S. Ct. 2102, 2109, 119 L. Ed. 2d 308 (1992).

Prior to 1984, the DEA could revoke, deny, or suspend a physician's prescription registration for three reasons: (1) falsification of an application to distribute, dispense, or manufacture controlled substances; (2) a felony conviction related to controlled substances; and (3) the suspension, revocation or denial of a state license or registration by an authorized state authority. *See* 21 U.S.C. § 824(a)(1)-(3). In 1983, as a provision of the Dangerous Drug Diversion Control Act, Congress added a fourth reason for revoking a physician's prescription license—violation of the public interest. *See* 21 U.S.C. § 824(a)(4); *Trawick v. Drug Enforcement Admin.*, 861 F.2d 72, 75 (4th Cir. 1988). Section 823(f) of the CSA provides that the enforcing official should consider the following factors in determining what the public interest includes:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f).

In the abstract, the term "public interest" is broad and may allow the DEA wide latitude to revoke licenses for "recommending" marijuana; however, in the context of sections 823 and 824, the term public interest may be reasonably interpreted to encompass only actual violations of state and federal drug law.[7] *See, e.g.*, *Trawick*, 861 F.2d at 76 ("It is clearly reasonable to interpret this unambiguous language as allowing negative action on a DEA registration based on a misdemeanor possession conviction that is unrelated to the registrant's practice or the diversion concerns of the amendment itself."). The Court has found no case, and defendants submit none, in which a court has concluded that sections 823 and 824 empower the DEA to revoke a physician's license for underlying conduct that did not violate federal, state, or local law, or state licensing

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[7] The Court does not accept as reasonable plaintiffs' extremely narrow interpretation that the DEA has the power to revoke licenses under section 824 only if a physician breaks the law regarding the distribution, dispersement, or manufacture of controlled substances. That interpretation is not consistent with the purpose or plain language of the CSA.

guidelines. *See Humphreys v. DEA*, 96 F.3d 658, 661-62 (3d Cir. 1996) (examining the public interest factors under section 823).

To confirm this interpretation, the legislative history of the statute is instructive. *See Thompson/Center Arms Co.*, 504 U.S. at 516, 112 S. Ct. at 2109. During the debate preceding enactment, Representative Rangel stated that the public interest amendment to the CSA would enable the DEA to revoke registrations of physicians who unscrupulously prescribe potent narcotics for addicts. *See* 130 Cong. Rec. H9682 (daily ed. Sept. 18, 1984) (remarks of Rep. Rangel) (quoted in *Trawick*, 861 F.2d at 75). The Senate Report on the bill explains that the public interest provision would enable the DEA to revoke licenses in instances that involve "violations involving controlled substances but are not punishable as felonies under State law." S. Rep. No. 225, 98th Cong., 2d Sess., *reprinted in* 1984 U.S.C.C.A.N. 3182, 3448-49 (quoted in *Trawick*, 861 F.2d at 75). This legislative history suggests that only convictions or uncharged criminal activity in violation of federal, state, or local law would suffice to establish a violation of the public interest as defined under sections 823 and 824. For these reasons, plaintiffs have raised serious questions as to whether the CSA can be interpreted in a manner that would allow the DEA to revoke a physician's license for merely recommending marijuana. As discussed above, *see supra* part II.C, the balance of harms weighs in favor of plaintiffs, making entry of a preliminary injunction appropriate.

2. Medicare Statute

Section 1320(a)-7 of Title 42 provides that individuals can be excluded from participation in Medicare and

state health care programs under certain circumstances. The circumstances pertinent to this analysis include: (1) conviction for Medicare-related crimes, (2) conviction of a criminal offense relating to neglect or abuse of patients, (3) conviction relating to fraud, (4) conviction relating to obstruction of an investigation of Medicare fraud, (5) conviction relating to the manufacture, distribution, prescription, or dispensing of a controlled substance, and (6) claims for fraud or excess charges. *See* 42 U.S.C. § 1320(a)-7. Nothing in the text of this section supports defendants' argument that the DEA has the authority to exclude physicians from participation in Medicare or Medicaid programs for merely recommending marijuana to their patients without criminal intent.

Plaintiffs also have raised serious questions as to whether the Medicare statute can be interpreted in a manner that would allow the DEA to revoke a physician's Medicare participation solely for recommending medical use of marijuana. As discussed above, *see supra* part II.C, the balance of harms weighs in favor of plaintiffs, making entry of a preliminary injunction appropriate.

CONCLUSION

Defendants argue that if a physician intentionally provides her patients with oral or written statements in order to enable them to obtain controlled substances, that physician may be liable for aiding and abetting a patient's unlawful purchase, cultivation, or possession of marijuana, 18 U.S.C. § 2, or for engaging in a conspiracy to cultivate, distribute, or possess marijuana, 21 U.S.C. § 846. (Defendants' Notice of Motion, Motion to Dismiss, and Memorandum of Points and Authorities

("Defs.' MTD") at 17-18.) Because defendants posit no other grounds for criminal liability, defendants may only prosecute physicians who recommend medical marijuana to their patients if the physicians are liable for aiding and abetting or conspiracy under these statutes.

Under federal law, one who "aids, abets, counsels, commands, induces or procures" the commission of a federal offense "is punishable as a principal." 18 U.S.C. § 2. Criminal aiding and abetting liability under § 2 requires proof that the defendant "in some sort associate[d] himself with the venture, that he participate[d] in it as something that he wishe[d] to bring about, that he [sought] by his action to make it succeed." *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 190, 114 S. Ct. 1439, 1455, 128 L. Ed. 2d 119 (1994) (internal quotation marks and citation omitted).

Under federal law, a person may be guilty of conspiracy if he makes an agreement to accomplish an illegal objective and knows of the illegal objective and intends to help accomplish it. See 21 U.S.C. § 846; *United States v. Gil*, 58 F.3d 1414, 1423 & n. 5 (9th Cir.), *cert. denied*, 516 U.S. 969, 116 S. Ct. 430, 133 L. Ed. 2d 345 (1995); *Ninth Circuit Manual of Model Jury Instructions* 8.05A (West 1995). A defendant may be found guilty of conspiracy even if he does not realize direct benefits from the agreement, but instead conspires to benefit others. *See United States v. Carruth*, 699 F.2d 1017, 1021 (9th Cir. 1983).

Because the First Amendment protects physician-patient communication up until the point that it becomes criminal, defendants may not prosecute California physicians unless the government in good faith

believes that it has probable cause to charge under the federal aiding and abetting and/or conspiracy statutes. This requires that the government believe that it can prove that a physician had the specific intent to aid and abet or conspire. Moreover, because the Court has found serious questions as to whether the Controlled Substances Act and the Medicare statute permit sanctions for conduct relating to medical marijuana which falls short of criminal activity, defendants may not take administrative action against physicians for recommending marijuana unless the government in good faith believes that it has substantial evidence of the above-described criminal activity to support such action.

For the foregoing reasons, the Court PRELIMINARILY ENJOINS defendants, their agents, employees, assigns, and all persons acting in concert or participating with them, from threatening or prosecuting physicians, revoking their licenses, or excluding them from Medicare/Medicaid participation based upon conduct relating to medical marijuana that does not rise to the level of a criminal offense.[8] For the foregoing reasons, the Court also GRANTS plaintiffs' motion for class certification and DENIES defendants' motion to dismiss as moot.

The Court acknowledges that this injunction does not provide physicians with the level of certainty for which

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[8] Although the analysis in this order has focused on physician recommendation of medical marijuana, this preliminary injunction is also intended to cover non-criminal activity related to those recommendations, such as providing a copy of a patient's medical chart to that patient or testifying in court regarding a recommendation that a patient use marijuana to treat an illness. These activities implicate the same legal issues and harms as physician recommendations.

they had hoped; however, it would violate the constitutional separation of powers to limit prosecutorial discretion in the way plaintiffs request. As defendants have argued, the statutes on which the criminal and administrative sanctions proposed by defendants are based have not been challenged in this case as unconstitutionally vague.[9] Plaintiffs must therefore rely on existing case law interpreting these measures in circumscribing their conduct.

The case management conference scheduled for May 23, 1997 is CONTINUED until *June 13, 1997, at 8:30 a.m.*, in Courtroom 9. A joint case management statement shall be filed in advance in accordance with the local rule.

SO ORDERED.

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[9] At least one court has already concluded that the drug conspiracy statute, 21 U.S.C. § 846, is neither vague nor violates the First Amendment. *See United States v. Cooper*, 606 F.2d 96, 98 (5th Cir. 1979).

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 00-17222
D.C. No. CV-97-00139-WHA

MARCUS CONANT, DR.; DONALD NORTHFELT, DR.; DEBU TRIPATHY, DR.; NEIL FLYNN, DR.; STEPHEN POLLANSBEE, DR.; STEPHEN O'BRIEN, DR.; MILTON ESTES, DR.; JO DALY; KEITH VINES; JUDITH CUSHNER; VALERIE CORRAL; BAY AREA PHYSICIANS FOR HUMAN RIGHTS; BEING ALIVE: PEOPLE WITH AIDS/HIV ACTION COALITION, INC.; HOWARD MCCABEE; DANIEL KANE; ALLAN FLACH, DR., PLAINTIFFS-APPELLEES

v.

BARRY R. MCCAFFREY, DIRECTOR; THOMAS A. CONSTANTINE, ADMIN., US DEA; JANET RENO, ATTORNEY GENERAL; DONNA E. SHALALA, SEC. OF HHS, DEFENDANTS-APPELLANTS

Filed: Feb. 6, 2003

ORDER

Before: SCHROEDER, Chief Judge, B. FLETCHER and KOZINSKI, Circuit Judges.

The panel as constituted above has voted to deny the petition for rehearing and the petition for rehearing en banc.

The full court has been advised of the petition for rehearing en banc and no active judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing and the petition for rehearing en banc are denied.

APPENDIX E

[SEAL OMITTED]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

December 30, 1996

STATEMENT RELEASED BY BARRY R. McCAFFREY
DIRECTOR OF THE OFFICE OF NATIONAL DRUG
CONTROL POLICY

THE ADMINISTRATION'S RESPONSE TO THE
PASSAGE OF CALIFORNIA PROPOSITION 215 AND
ARIZONA PROPOSITION 200.

1. General: The recent passage of propositions which make dangerous drugs more available in California and Arizona poses a threat to the National Drug Control Strategy goal of reducing drug abuse in the United States. At the direction of the President, the Office of National Drug Control Policy developed a coordinated administration strategy with the other agencies of the Federal Government to minimize the tragedy of drug abuse in America.

2. Objectives: An interagency working group chaired by ONDCP included the Departments of Justice, Treasury, Defense, Health and Human Services, Transportation, and Education, the Postal Service, and the Nuclear Regulatory Commission. This group met four times in November and December. It developed the following strategic objectives for our coordinated Federal response:

a. Maintain effective enforcement efforts within the framework created by the Federal Controlled Substances Act and the Food, Drug, and Cosmetic Act.

b. Ensure the integrity of the medical-scientific process by which substances are approved as safe and effective medicines.

c. Preserve Federal drug-free workplace and safety programs.

d. Protect children from increased marijuana availability and use.

3. Courses of Action: In developing this strategy, the inter-agency group gave due consideration to two key principles: federal authority *vis á vis* that of the states, and the requirement to ensure American citizens are provided safe and effective medicine. ONDCP and Federal drug control agencies have formed a partnership to undertake the following coordinated courses of action:

A. OBJECTIVE 1—MAINTAIN EFFECTIVE ENFORCEMENT EFFORTS WITHIN THE FRAMEWORK CREATED BY THE FEDERAL CONTROLLED SUBSTANCES ACT AND THE FOOD, DRUG, AND COSMETIC ACT

Department of Justice's position is that a practitioner's action of recommending or prescribing Schedule I controlled substances is not consistent with the "public interest" (as that phrase is used in the federal Controlled Substances Act) and will lead to administrative action by the Drug Enforcement

Administration to revoke the practitioner's registration.

DoJ and Department of Health and Human Services will send a letter to national, state, and local practitioner associations and licensing boards which states unequivocally that DEA will seek to revoke the DEA registrations of physicians who recommend or prescribe Schedule I controlled substances. This letter will outline the authority of the Inspector General for HHS to exclude specified individuals or entities from participation in the Medicare and Medicaid programs.

DoJ will continue existing enforcement programs using the following criteria: (a) the absence of a bona fide doctor-patient relationship; (b) a high volume of prescriptions or recommendations of Schedule I controlled substances; (c) the accumulation of significant profits or assets from the prescription or recommendation of Schedule I controlled substances; (d) Schedule I controlled substances being provided to minors; and/or (e) special circumstances, such as when death or serious bodily injury results from drugged driving. The five U.S. Attorneys in California and Arizona will continue to review cases for prosecution using these criteria.

DEA will adopt seizures of Schedule I controlled substances made by state and local law enforcement officials following an arrest where state and local prosecutors must decline prosecution because of the Propositions. Once in DEA's possession the drugs can be summarily forfeited and destroyed by DEA. State and local law enforcement officials will be encouraged to continue to execute state law to the

fullest extent by having officers continue to make arrests and seizures under state law, leaving defendants to raise the medical use provisions of the Propositions only as a defense to state prosecution.

Department of the Treasury and the Customs Service will continue to protect the nation's borders and take strong and appropriate enforcement action against imported or exported marijuana and other illegal drugs. The Customs Service will continue to: (a) seize unlawfully imported or exported marijuana and other illegal drugs; (2) assess civil penalties against persons violating federal drug laws; (c) seize conveyances facilitating the illegal import or export of marijuana and other illegal drugs, and (d) arrest persons committing Federal drug offenses and refer cases for prosecution to the appropriate Federal or state prosecutor.

Treasury and the Internal Revenue Services will continue the enforcement of existing Federal tax laws which discourage illegal drug activities.

IRS will enforce existing Federal tax laws as it relates to the requirements to report gross income from whatever source derived, including income from activities prohibited under Federal or state law.

Treasury will recommend that the IRS issue a revenue ruling to the extent permissible under existing law, that would deny a medical expense deduction for amounts expended for illegal operations or treatments for drugs, including Schedule I controlled substances, that are illegally procured under Federal or state law.

IRS will enforce existing Federal tax law as it relates to the disallowance of expenditures in connection with the illegal sale of drugs. To the extent that state laws result in efforts to conduct sales of controlled substances prohibited by Federal law, the IRS will disallow expenditures in connection with such sales to the fullest extent permissible under existing Federal tax law.

U.S. Postal Service will continue to pursue aggressively the detection and seizure of Schedule I controlled substances mailed through the US mails, particularly in California and Arizona, and the arrest of those using the mail to distribute Schedule I controlled substances.

DEA together with other Federal, state and local law enforcement agencies will work with private mail, parcel and freight services to ensure continuing compliance with internal company policies dictating that these companies refuse to accept for shipment Schedule I controlled substances and that they notify law enforcement officials of such activities. Federal investigations and prosecutions will be instituted consistent with appropriate criteria.

B. OBJECTIVE 2—ENSURE THE INTEGRITY OF THE MEDICAL-SCIENTIFIC PROCESS BY WHICH SUBSTANCES ARE APPROVED AS SAFE AND EFFECTIVE MEDICINES IN ORDER TO PROTECT PUBLIC HEALTH

The Controlled Substances Act embodies the conclusion of the Congress, affirmed by DEA and HHS, that marijuana, as a Schedule I drug, has "high potential for abuse" *and* "no currently accepted

medical use in treatment in the United States." To protect the public health, all evaluations of the medical usefulness of any controlled substance should be conducted through the Congressionally established research and approval process managed by the National Institutes of Health and the Food and Drug Administration. Currently there are a few patients who receive marijuana through FDA approved investigations.

HHS to ensure the continued protection of the public health will: (a) examine all medical and scientific evidence relevant to the perceived medical usefulness of marijuana; (b) identify gaps in knowledge and research regarding the health effects of marijuana; (c) determine whether further research or scientific evaluation could answer these questions; and (d) determine how that research could be designed and conducted to yield scientifically useful results.

HHS will undertake discussions with medical organizations throughout the nation: (a) to address the "compassionate use" message; and (b) to educate medical and public health professionals by underscoring the dangers of smoked marijuana and explaining the views of NIH that a variety of approved medications are clinically proven to be safe and effective in treating illnesses for which marijuana is purported to provide relief, such as pain, nausea, wasting syndrome, multiple sclerosis, and glaucoma.

C. OBJECTIVE 3—PRESERVE FEDERAL DRUG-FREE WORKPLACE AND SAFETY PROGRAMS

Transportation Workers: Department of Transportation has issued a formal advisory to the transportation industry that safety-sensitive transportation workers who test positive under the Federally-required drug testing program may not under any circumstances use state law as a legitimate medical explanation for the presence of prohibited drugs. DOT is encouraging private employers to follow its example.

Federal Contractors and Grantees: Under the Drug-Free Workplace Act, the recipients of Federal grants or contracts must have policies that prohibit the use of illegal drugs. Each Federal agency will issue a notice to its grantees and contractors to remind them: (a) of their responsibilities; (b) that any use of marijuana or other Schedule I controlled substances remains a prohibited activity; and (c) that the failure to comply with this prohibition will make the grantee or contractor subject to the loss of eligibility to Federal grants and contracts. Further, Federal agencies will increase their efforts to monitor compliance with the provisions of the Act, and to institute suspension or debarment actions against violators—with special priority given to states enacting drug medicalization measures.

Federal Civilian Employees: HHS will issue policy guidance to all 130 Federal Agency Drug-Free Workplace program coordinators, the 72 laboratories certified by HHS to conduct drug tests, and trade publications that reach medical review offi-

cers. This policy guidance states that the Propositions do not change the requirements of the Federal Drug-Free Workplace Program, which will continue to be fully enforced for federal civilian employees nationwide. Medical Review Officers will not accept physician recommendations for Schedule I substances as a legitimate explanation for a positive drug test.

DoD and the Military Services: The Department of Defense will instruct civilian employees and military personnel in the active, reserve and National Guard components, that DoD is a drug-free organization, a fact that is not changed by the Propositions. The requirement that all DoD contractors maintain drug-free workplaces will continue to be enforced.

Nuclear Industry Workers: The Nuclear Regulatory Commission will continue to demand drug-free employees in the nuclear power industry, and will develop a formal advisory to emphasize that its drug free workplace regulations continue to apply.

Public Housing: The Propositions will not affect the Department of Housing and Urban Development's continued aggressive execution of the "One Strike and You're Out" policy to improve the safety and security of our nation's public housing developments. HUD's principal tool for implementing "One Strike" will be the systematic evaluation of public housing agencies screening and evictions efforts through the Public Housing Management Assessment Program. This program will give HUD a standard measurement of the progress of all public housing authorities in developing effective law enforcement, screening, and occupancy policies to

reduce the level of drug use, crime, and drug distribution and sales in their communities.

Safe Work Places: Department of Labor will continue to implement its Working Partners Initiative, providing information to small businesses about workplace substance abuse prevention programs, focusing specific attention on trade and business organizations located in California and Arizona. DOL will accelerate its effort to post its updated *Substance Abuse Information Database* (SAID) on the Internet. SAID will provide information to businesses about workplace substance abuse and how to establish workplace substance abuse prevention programs. DOL will give priority to its efforts in California and Arizona.

DOL's Occupational Safety and Health Administration will send letters to the California and Arizona Occupational Safety and Health Administrations reiterating the dangers of drugs in the workplace and providing information on programs to help employers address these problems.

DOL's Mine Safety and Health Administration will continue to strictly enforce the prohibition on the use of alcohol and illegal drugs notwithstanding these Propositions.

D. OBJECTIVE 4—PROTECT CHILDREN FROM INCREASED MARIJUANA AVAILABILITY AND USE

HHS and the Department of Education will educate the public in both Arizona and California about the real and proven dangers of smoking marijuana. A message will be tailored for preteens, teens, parents, educators, and medical professionals. Research demonstrates that marijuana: (a) harms the brain, heart, lungs, and immune system; and (b) limits learning, memory, perception, judgment, and the ability to drive a motor vehicle. In addition, research shows that marijuana smoke typically contains over 400 carcinogenic compounds and may be addictive. The message will remind the public there is no medical use for smoked marijuana and will educate the public about strategies to prevent marijuana use. The message will also remind the public that the production, sale, and distribution of marijuana for medical uses not approved by DEA violates the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act.

HHS will analyze all available data on marijuana use, expand ongoing surveys to determine current levels of marijuana use in California and Arizona, and track changes in marijuana use in those states.

HHS will develop the survey capacity to assess trends in drug use in all states on a state-by-state basis.

The Department of Education (ED) will use provisions of the Safe and Drug Free Schools Act to reinforce the message to all local education agencies receiving Federal Safe and Drug Free School funds

that any drug possession or use will not be tolerated in schools. This affects approximately 95% of school districts. Notwithstanding the passage of the two Propositions, local education agencies must continue to: (a) develop programs which prevent the use, possession, and distribution of tobacco, alcohol, and illegal drugs by students; (b) develop programs which prevent the illegal use, possession, and distribution of such substances by school employees; and (c) ensure that programs supported by and with Federal Safe and Drug Free Schools funds convey the message that the illegal use of alcohol and other drugs, including marijuana, is wrong and harmful. ED will review with educators in Arizona and California the effect Propositions 200 and 215 will have on drug use by students. They will also communicate nationally with school superintendents, administrators, principals, boards of education, and PTAs about the Arizona and California Propositions and the implications for their states.

ED will develop a model policy to confront "medical marijuana" use in schools and outline actions educators can take to prevent illicit drugs from coming into schools.

ED will develop model drug prevention programs to discourage marijuana use. These models will be disseminated to the states at a Spring 1997 conference.

ONDCP and DOT will provide recommendations pursuant to the October 19, 1996 Presidential directive to deter teen drug use and drugged driving through pre-license drug testing, strengthened law enforcement and other means. The recommendations will underscore the point that the use of mari-

juana for *any* reason endangers the health and safety of the public.

5. **Legislative Enactments**: ONDCP, HHS and DOJ will work with Congress to consider changes to the Federal Food, Drug and Cosmetic Act and the Controlled Substances Act, as appropriate, to limit the states' ability to rely on these similar medical use provisions. The Administration believes that working with Congress is the course of action that will affirm the national policy to control substances that have a high potential for abuse and no accepted medical use. The objective is to provide a uniform policy which preserves the integrity of the medical-scientific process by which substances are approved as safe and effective medicines. We will also consider additional steps, including conditioning Federal funds on compliance with the Controlled Substances Act and the National Drug Control Strategy.

APPENDIX F

DEPARTMENT OF HEALTH & HUMAN SERVICES
Washington, D.C. 20201

DEPARTMENT OF JUSTICE
Washington, D.C. 20530

February 27, 1997

John C. Lewin MD
Executive Vice President
California Medical Association
P.O. Box 7690
San Francisco, CA 94120

Dear Medical Leader:

On December 30, 1996, Barry R. McCaffrey, Director of the Office of National Drug Control Policy, Attorney General Janet Reno, and Donna E. Shalala, Secretary of the Department of Health and Human Services (HHS), announced the Administration's position regarding the recent passage of California Proposition 215 and Arizona Proposition 200. Among other things, they stated that the Department of Justice and HHS would follow up with a letter to national, state, and local medical organizations such as yours with respect to the Administration's position.

We are concerned that several misperceptions have developed concerning the federal government's response to the two Propositions. Before their enactment, nothing in federal law prevented a physician, in the context of a legitimate physician-patient relationship, from merely discussing with a patient the risks

and alleged benefits of the use of marijuana to relieve pain or alleviate symptoms. This continues to be true.

The federal government recognizes that patients look to their physicians as their primary source of knowledge about a wide variety of potential health hazards and treatments. Thus, physicians are encouraged to talk with patients about their concerns and answer inquiries about any procedure, treatment, substance, or device that may affect a patient's health. Physicians are also encouraged to share their knowledge and their professional expertise regarding the risks, benefits, and legality of any potential medical treatment or modality. No "gag rule" stops physicians from engaging in these discussions.

Such discussions, however, have their limits. Physicians may not intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law. Physicians who do so risk revocation of their DEA prescription authority, criminal prosecution, and exclusion from participation in the Medicare and Medicaid programs. Federal law establishes specific criteria that every potential medication must meet before it can be sold to the public or prescribed by doctors. For decades, this process of federal drug approval has protected the American public from dangerous drugs and ineffective treatments, and has helped provide the public with a medical care system that is the envy of the world. This process must be preserved. What is, and what is not, a drug with an accepted medical use should continue to be determined through rigorous scientific testing.

To date, the scientific testing of marijuana has not demonstrated that marijuana is a safe and effective drug with an accepted medical use. We remain concerned that the weight of current scientific evidence shows that marijuana can significantly harm the central nervous, cardiovascular, respiratory, and immune systems, and can limit memory, perception, judgment, and the ability to drive a motor vehicle. In addition, marijuana smoke contains over 400 compounds, some of which are carcinogens and may be addictive.

The federal government is undertaking additional steps to analyze carefully the state of all available scientific knowledge about the risks and alleged benefits of marijuana for medicinal purposes. In January, the Office of National Drug Control Policy committed nearly $1 million to fund a comprehensive review by the Institute of Medicine of the National Academy of Sciences of the existing clinical, medical, and scientific knowledge of the health effects and potential medical use of smoked marijuana. Moreover, on February 19 and 20, 1997, the National Institute of Health held a two-day workshop at which non-government experts in fields such as cancer treatment, infectious diseases, neurology, and ophthalmology reviewed existing research about marijuana, assessed what is known about its possible therapeutic potential, and discussed the factors to be taken into account in undertaking clinical research of marijuana. If and when there is adequate scientific evidence to support a reclassification of marijuana under the Controlled Substances Act, rulemaking

proceedings could be used to change marijuana's current classification as a Schedule I controlled substance. However, unless and until that occurs, current federal law remains in effect.

Sincerely yours,

/s/ JO IVEY BOUFFORD
JO IVEY BOUFFORD, MD
Acting Assistant Secretary for Health
Department of Health and Human Services

/s/ MARK M. RICHARD
MARK M. RICHARD, ESQ.
Acting Assistant Attorney General
Criminal Division
Department of Justice

APPENDIX G

STATUTORY PROVISIONS

1. Section 811 of Title 21 of the United States Code states in relevant part as follows:

§ 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a

hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not contol the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence

of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

* * * * *

2. Section 812 of Title 21 of the United States Code states in relevant part as follows:

§ 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

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

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

* * * * *

3. Section 823(f) of Title 21 of the United States Code states in relevant part as follows:

§ 823. Registration Requirements

* * * * *

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

4. Section 824 of Title 21 of the United States Code states in relevant part as follows:

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

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—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(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; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

* * * * *

5. Pub. L. 105-277, Div. F, 112 Stat. 2681, 2760-2761, 105th Cong., 2d Sess. (1998) states in relevant part as follows:

DIVISION F—NOT LEGALIZING MARIJUANA FOR MEDICINAL USE

It is the sense of the Congess that–

(1) certain drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision;

(2) the consequences of illegal use of Schedule I drugs are well documented, particularly with regard to physical health, highway safety, and criminal activity;

(3) pursuant to section 401 of the Controlled Substances Act, it is illegal to manufacture, distribute, or dispense marijuana, heroin, LSD, and more than 100 other Schedule I drugs;

(4) pursuant to section 505 of the Federal Food, Drug and Cosmetic Act, before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective;

(5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;

(6) the Federal Food, Drug and Cosmetic Act already prohibits the sale of any unapproved drug, including marijuana, that has not been proved safe and effective for medical purposes and grants the Food and Drug Administation the authority to enforce this prohibition through seizure and other civil action, as well as through criminal penalties;

(7) marijuana use by children in grades 8 through 12 declined steadily from 1980 to 1992, but, from 1992 to 1996, has dramatically increased by 253 percent among 8th graders, 151 percent amont 10th graders, and 84 percent among 12th graders, and the average age of first-time use of marijuana is now younger than it has ever been;

(8) according to the 1997 survey by the Center on Addiction and Substance Abuse at Columbia University, 500,000 8th graders began using marijuana in the 6th and 7th grades;

(9) according to that same 1997 survey, youths between the ages of 12 and 17 who use marijuana are 85

times more likely to use cocaine than those who abstain from marijuana, and 60 percent of adolescents who use marijuana before the age of 15 will later use cocaine; and

(10) the rate of illegal drug use among youth is linked to their perceptions of the health and safety risks of those drugs, and the ambiguous cultural messages about marijuana use are contributing to a growing acceptance of marijuana use among children and teenagers;

(11) Congress continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration; and

(12) not later than 90 days after the date of the enactment of this Act–

(A) the Attorney General shall submit to the Committees on the Judiciary of the House of Representatives and the Senate a report on–

(i) the total quantity of marijuana eradicated in the United states during the period from 1992 through 1997; and

(ii) the annual number of arrests and prosecutions for Federal marijuana offenses during the period described in clause (i); and

(B) the Commissioner of Foods and Drugs shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a re-

port on the specific efforts underway to enforce sections 304 and 505 of the Federal Food, Drug and Cosmetic Act with respect to marijuana and other Schedule I drugs.

6. California Health & Safety Code § 11362.5 provides in relevant part as follows:

§ 11362.5. Medical use

(a) This section shall be known and may be cited as the Compassionate Use Act of 1996.

(b)(1) The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:

(A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

(B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.

(C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana.

(2) Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for nonmedical purposes.

(c) Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes.

(d) Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.

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