IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

DR. MARCUS CONANT, et al.,

Plaintiffs,

v.

BARRY R. MCCAFFREY, et al.,

Defendants.

/

No. C 97-00139 WHA

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

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 controlled 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 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

[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.

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]

[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).

Drs. Estes, Follansbee, Scott, O'Brien, Maccabee, Tripathy, Conant, and Flynn subjectively fear that they will be prosecuted or lose their DEA registrations to 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 government'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 movi 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 de-registration policy is justiciable but their challenges to the government's policies on criminal prosecutions and Medicare/Medicaid participation are not**.** The DEA de-registration 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 conspirac 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 fo 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 prosecution 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 *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

[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.

above, however, 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 th 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 Fir 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 tha 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, mig 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 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 the best medical judgment. Like *Gentile*, this case involves punishment of affirmative professional speech

[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. 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.

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 substance 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 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 patient 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

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

medical information. Without open communication with their physicians, patients would fall silent an appear uninformed. The ability of patients to participate meaningfully in the public discourse would b 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] 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 believ 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,

---

[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 *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.

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 i 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 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 Substances 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.

Dated: September 7, 2000.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE