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10
11 IN THE UNITED STATES DISTRICT COURT
12 FOR THE NORTHERN DISTRICT OF CALIFORNIA

13 ANGEL McCLARY RAICH, DIANE
14 MONSON, JOHN DOE NUMBER
ONE, and JOHN DOE NUMBER TWO,

15 Plaintiffs,

16 v.

17 JOHN ASHCROFT, as United States
Attorney General, and ASA
18 HUTCHINSON, as Administrator of the
Drug Enforcement Administration,

19 Defendants.
20

Case No. C 02 4872 MJJ

**PLAINTIFFS' REQUEST FOR
JUDICIAL NOTICE**

(Fed. R. Evid. 201)

Date: December 17, 2002

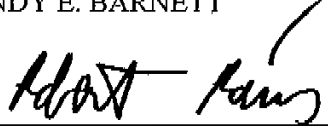
Time: 9:30 a.m.

Dept.: Courtroom 11, 19th Floor
Honorable Martin J. Jenkins

1 Plaintiffs hereby request the Court to take judicial notice pursuant to Federal Rule of
2 Evidence 201 of the following: Amicus Brief of California Medical Association In Support of
3 Defendants-Appellants Oakland Cannabis Buyers' Cooperative *et al.* filed on November 25,
4 2002, with the United States Court of Appeals for the Ninth Circuit in *United States v. Oakland*
5 *Cannabis Buyers' Coop.*, No. 02-16534, a copy of which is attached hereto. Matters of public
6 record are appropriate for judicial notice. Fed. R. Evid. 201; *MGIC Indem. Corp. v. Weisman*,
7 803 F.2d 500, 504 (9th Cir. 1986).

8
9 Dated: December 5, 2002

10 ROBERT A. RAICH
11 DAVID M. MICHAEL
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13 By: 
14 Robert A. Raich

15 Attorneys for Plaintiffs
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1 CERTIFICATE OF SERVICE

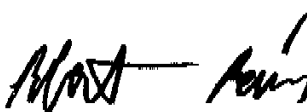
2 I am over the age of eighteen years and am not a party to the within action. My business
3 address is 1970 Broadway, Suite 1200, Oakland, California 94612. I hereby certify that on the
4 date this certificate is signed, I caused the attached:

5 **Plaintiffs' Request for Judicial Notice**

6 to be mailed by placing a true copy thereof in a sealed envelope, with postage fully prepaid, in
7 the United States mail addressed to the following counsel:

8 Mark T. Quinlivan
9 U.S. Department of Justice
10 20 Massachusetts Avenue, N.W., Room 7128
11 Washington, D.C. 20530

12 Dated: December 5, 2002



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Robert A. Raich

No. 02-16534

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
Case No. C 98-00088 CRB
entered on July 29, 2002, by Judge Charles R. Breyer

**Amicus Brief of California Medical Association
In Support of Defendants-Appellants Oakland
Cannabis Buyers' Cooperative *et al.***

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INTEREST OF *AMICUS CURIAE*¹

The California Medical Association (CMA) is a nonprofit, incorporated professional association of more than 30,000 physicians practicing in the State of California. CMA's membership includes California physicians engaged in the private practice of medicine, in all specialties. CMA's primary purposes are "... to promote the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession."

Permanently enjoining the Oakland Cannabis Buyers Cooperative's distribution of cannabis to seriously ill patients whose doctors have recommended cannabis as a last-resort medical treatment seriously infringes upon the constitutional rights of the patients whose well-being the CMA is committed to preserve. This case threatens those patients' constitutional rights to make autonomous decisions regarding their bodies, and to seek medical treatment for alleviation of pain and suffering and preservation of life. Because the CMA strongly believes that the district court's grant of injunctive relief has dire consequences for the care and well-being of patients, and the integrity of the caregiver-patient relationship, the CMA submits this brief as *amicus curiae*.

¹ Pursuant to Fed. R. App. Proc. 29(a), the parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

The federal Constitution protects against governmental interference with the narrow but fundamental right to seek medical treatment. The right to seek to alleviate pain and suffering when all conventional treatments have failed is a paradigmatic example of that right. In this case, the federal government seeks to prevent seriously ill persons, who have unsuccessfully tried all other conventional treatments to alleviate their pain or symptoms, from obtaining meaningful access to the medical cannabis their competent doctors have recommended. This attempt to interfere with individual patient treatment violates those patients' fundamental rights, and the Court should therefore reverse the district court's grant of the government's requested injunction.

ARGUMENT

THE GOVERNMENT'S REQUEST FOR A PERMANENT INJUNCTION PREVENTING MEDICAL CANNABIS DISTRIBUTION MUST BE CLOSELY SCRUTINIZED BECAUSE IT INFRINGES UPON PATIENTS' FUNDAMENTAL RIGHTS.

"[T]he Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, 521

U.S. 703, 720-21 (1997) (internal citations and quotation marks omitted); *see also Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934) (describing rights “so rooted in the traditions and conscience of our people as to be ranked as fundamental”).

Such rights are identified by reference to “[o]ur Nation’s history, legal traditions, and practices.” *Glucksberg*, 521 U.S. at 721. If a plaintiff articulates such a right with specificity, and demonstrates historical recognition and protection of that right, government action that infringes upon the right will be deemed unlawful unless it is narrowly tailored to serve a compelling state interest. *Id.*

This case implicates a narrow, yet fundamental, right—the right, upon a physician’s advice, to seek medical treatment to treat medical conditions, to alleviate pain and suffering, and to preserve one’s life, when conventional treatments have failed. That right originates in our Nation’s long history of protecting an individual’s right to bodily integrity, and the longstanding sovereignty accorded to decisions regarding what will be done with one’s body—rights that are at the core of the liberty interests that the Constitution protects. Indeed, when the Constitution was written, there were no federal restrictions on medications or patient care.²

² The passage of the Pure Food & Drug Act of 1906 marked the first direct federal regulation of drugs. *See United States v. Articles of Drug*, 585 F.2d 575,

Neither the courts, nor any other governmental entity, should impede a desperate patient who has tried all conventional treatments without success and, acting with the advice and approval of his or her physician, seeks to alleviate his or her serious suffering by using a non-conventional treatment that has been reasonably shown to be effective in his or her case. Enjoining distribution of medical cannabis to seriously ill patients whose physicians have informed them that cannabis is the only available last-resort treatment to alleviate their pain and suffering impedes patients' rights in precisely that manner, and presents grave constitutional concerns. Accordingly, the government's action here must be carefully scrutinized by this Court.

577 (3d Cir. 1978); Pub L. No. 59-384, § 8 (1906). Although that Act required the producers of foods and over-the counter medicines to provide labels clearly indicating the content and amount of substances such as cannabis that appeared in the products, *see Articles of Drug*, 585 F.2d at 577, it did not prohibit the medical use of cannabis. *See* Lauryn P. Gouldin, *Cannabis, Compassionate Use and the Commerce Clause: Why Developments in California May Limit the Constitutional Reach of the Federal Drug Laws*, 1999 Annual Survey of Am. Law 471, 475 & nn.18-19 (describing history of regulation of drugs and cannabis). The United States did not make the medical use of cannabis unlawful as a matter of federal law until 1970, when it passed the Controlled Substances Act. *See* Note, *Urgent Compassion: Medical Marijuana, Prosecutorial Discretion, and the Medical Necessity Defense*, 41 Boston Coll. L. Rev. 699, 701-05 (2000) (discussing history of medical use of cannabis and laws regulating that use).

A. Individuals Have A Fundamental Right To Seek Medical Treatment To Alleviate Pain And Suffering And Prolong Life.

1. The Right To Seek Medical Treatment Is A Core Liberty Interest Recognized In This Nation's History And Legal Traditions.

At bottom, the uniquely American right of self-determination is at issue here. “[T]he right of every individual to the possession and control of his own person, free from all restraint or interference of others, is so rooted in the traditions and conscience of our people, as to be ranked as one of the fundamental liberties protected by the substantive component of the Due Process Clause.” *Newman v. Sathyavaglswaran*, 287 F.3d 786, 789 (9th Cir. 2002) (internal citations and quotation marks omitted), *cert. denied*, 71 U.S.L.W. 3191 (U.S. Nov. 18, 2002) (No. 02-423). The protection of this interest predates the establishment of this Nation’s laws, and is a touchstone of the Anglo-American legal tradition. *See, e.g.*, 1 William Blackstone, *Commentaries* *129 (1765) (discussing right to personal security “which consists in a person’s legal and uninterrupted enjoyment of his life, his limbs, his body, his health, and his reputation.”). Indeed, over a century ago, the Supreme Court recognized that, “[n]o right is held more sacred, or is more carefully guarded by the common law,

than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.” *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

The courts have reaffirmed this principle, and have repeatedly protected individuals against government interference with the “right to determine what shall be done with [one’s] own body.” *Schloendorff v. Society of New York Hosp.*, 105 N.E. 92, 93 (N.Y. 1914). For example, in *Rochin v. California*, the Supreme Court ruled that the police unconstitutionally violated a defendant’s bodily integrity by administering an emetic to recover a pill swallowed upon arrest. 342 U.S. 165, 172 (1952). In *Cruzan*, the Court recognized that its precedent supported the inference that competent individuals possess a constitutionally protected liberty interest in refusing life-sustaining medical treatment. *See Cruzan v. Director, Mo. Dep’t of Health*, 497 U.S. 261, 278-79 (1990); *see also id.* at 287-88 (O’Connor, J., concurring) (explaining that liberty interest in refusing medical treatment “flows from decisions involving the State’s invasion into the body” and noting that “our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination”). The overwhelming majority of states, in turn, have protected that right by allowing individuals to sign “living wills” or similar documents to direct the course of their medical treatment in the event that

they become incapacitated, and to formally establish their desire to receive or refuse life-sustaining procedures. See Note, *The Right to Choose How to Die: A Constitutional Assessment of State Laws Prohibiting Physician-Assisted Suicide*, 48 Stan. L. Rev. 937, 945-46 & nn. 49-50 (1996) (citing state laws). Similarly, courts have recognized a mentally ill prisoner's "significant liberty interest in avoiding the unwanted administration of antipsychotic drugs." *Washington v. Harper*, 494 U.S. 210, 221-22 (1990). And in the Fourth Amendment context of search and seizure, the Court has also protected a person's bodily integrity. See, e.g., *Winston v. Lee*, 470 U.S. 753, 766 (1985) (involuntary surgery was an unreasonable invasion of a defendant's body); *Schmerber v. California*, 384 U.S. 757, 773 (1966) (subjecting involuntary blood test administered upon drunken driving suspect to exacting constitutional scrutiny because "[t]he integrity of an individual's person is a cherished value of our society"). See generally *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting) (describing "right to be let alone").

"Avoiding intolerable pain and the indignity of living one's final days incapacitated and in agony" is an equally fundamental liberty interest that is derivative of the right to bodily integrity and sovereignty. *Glucksberg*, 521 U.S. at 745 (Stevens, J., concurring). State action that prevents a person from taking

measures to ameliorate such suffering is therefore as offensive to principles of liberty and personal sovereignty as the government infliction of severe pain and suffering.³ *See, e.g., Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 852 (1992) (noting that laws prohibiting abortion force women to endure anxiety and pain and thereby infringe upon women’s liberty interests); *see also Glucksberg*, 502 U.S. at 790 (Breyer, J., concurring) (describing “right to death with dignity” as combination of “personal control over the manner of death, professional medical assistance, and the avoidance of unnecessary and severe physical suffering”). Indeed, it is difficult to conceive of a right more “central to personal dignity and autonomy.” *Casey*, 505 U.S. at 851.

Underscoring the depth of this fundamental right to seek and obtain medical treatment is the long-settled law recognizing the special nature of the physician-patient relationship. Because that relationship furthers these important rights, the courts have even allowed doctors to raise the privacy and liberty rights of their patients in court. *E.g., Roe v. Wade*, 410 U.S. 113, 153, 156 (1973); *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965). Similarly, because courts have recognized the critical nature of communication between doctor and patient, and that to

³ The Supreme Court has recognized that the Constitution prevents the government from inflicting pain and suffering. *See, e.g., Ingraham v. Wright*, 430 U.S. 651, 674 (1977); *Hudson v. McMillian*, 503 U.S. 1, 9-10 (1992).

pursue one's best health interests, any communication with a physician must be unfettered, such communications are, and have long been as a matter of common law, privileged communications. *See Conant v. Walters*, 309 F.3d 629, 636 (9th Cir. 2002). Finally, as noted recently by this Court, patients have the right to their physicians' full and frank discussion of all possible treatments, even those that may be proscribed by federal law, such as the use of medical cannabis. *See id.* at 636-37. Because the patients' rights are so significant, the government cannot punish or threaten doctors for discussing possible treatments, including even those that federal law prohibits. *See id.*

But these rights would be virtually meaningless in modern society if all assistance in exercising such a right is forbidden. Most women could not protect their right to choose to terminate a pregnancy if physicians were forbidden to provide abortions. *See, e.g., Glucksberg*, 521 U.S. at 778 ("Without physician assistance in abortion, the woman's right would have too often amounted to nothing more than a right to self-mutilation."). Terminally ill patients who do not wish to receive artificial life support could not exercise their rights to refuse medical treatment if physicians or caregivers were not empowered to turn off life support systems after the patient's wishes are made known. In this case, the plight of the suffering patient is serious if he or she cannot exercise this fundamental

right with assistance. A patient may lack the strength to cultivate his or her own medicine. If that ill patient cannot use the assistance of a dispensary that screens its medical cannabis for safety and quality, then he or she may be forced to seek medicine from street dealers with a significant risk of contamination and the risk of violence. As a matter of policy, this seems unwise—as a matter of constitutional right, it is effectively a denial.

2. The Ninth And Tenth Circuit Cases Rejecting Efforts To Change The Laetrile Laws Do Not Undermine The Right Asserted Here.

The government has previously argued that *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980) (per curiam), and *Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980), preclude judicial recognition of the liberty interest articulated here. That argument is incorrect.

In *Carnohan*, the plaintiff affirmatively sought a declaratory ruling that he had a right to use and procure laetrile in connection with a nutritional program for the prevention of cancer, without following the procedures that would ordinarily govern efforts to obtain FDA approval of a “new drug.” 616 F.2d at 1121-22. This Court concluded he could not seek judicial review without first exhausting his administrative remedies by filing a new drug application with the FDA.

Rejecting Carnohan’s assertion that the regulatory procedures were so burdensome as to infringe upon his constitutional rights of privacy and personal liberty, the Court determined that it “need not decide whether Carnohan has a constitutional right to treat himself with home remedies of his own confection.” *Id.*

Carnohan differs from this case in two critical respects. First, the liberty interest here is far narrower. Unlike the seriously ill patients here, who have no other alternatives to treat or alleviate current conditions, Carnohan sought to access laetrile as a potential *preventive* measure. He did not allege that his physician had advised that laetrile was the only remaining option for alleviation of extreme pain and suffering or the preservation of his life, or even the only useful drug for a nutritional program for cancer prevention. Thus, his case simply did not implicate the narrow right asserted here.

Second, Carnohan sought to *compel* government action—reclassifying laetrile—that would apply generally to the public. In contrast, the parties here have not requested that the government reclassify marijuana for medical use, or otherwise alter the federal laws regulating drugs. Instead, they are defending against federal government interference with their state right to use and obtain marijuana as a last-resort medical treatment, consistent with their physician’s advice and California law. The difference between requiring the government to

enable a person's exercise of a fundamental right, and preventing the government from affirmatively proscribing the exercise of that right, is more than semantic. *See, e.g., Harris v. McRae*, 448 U.S. 297, 313-16 (1980) (Congress may decline to fund medically necessary abortions even though the government cannot deprive a woman of her constitutional right to obtain an abortion). The latter is a direct attack upon the sovereignty and freedom to make decisions concerning one's body and a classic example of government interference with the right to be let alone.

Nor does *Rutherford* determine this case. There, the Tenth Circuit rejected cancer patients' challenge to the FDA's decision to not approve lactrile. *See* 616 F.2d at 456-57. The court concluded that "[i]t is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health." 616 F.2d at 457.

Unlike *Rutherford*, this case turns on the fundamental right whose existence the Tenth Circuit deemed "apparent"—"the decision *whether to have a treatment or not.*" *Id.* (emphasis added). The *Rutherford* plaintiffs never alleged that the drug was the only effective treatment available to them. But several patients have done so here. For example, Lucy Vier has terminal squamous cell cancer, and as a

result of chemotherapy treatments has experienced nausea so severe that it impedes her ability to consume sufficient food to support her body; her physician recommended cannabis as an appetite stimulant so that she could eat enough food to maintain her health, and deemed its use a medical necessity because no known traditional medicines effectively stimulate her appetite. *See Declaration of Edward Neil Brundridge, Ima Carter, Rebecca Nikkel and Lucia Y. Vier as Amicus Curiae In Support of Respondents, United States v. Oakland Cannabis Buyers' Cooperative*, No. 00-151, at 6 (U.S. filed Feb. 20, 2001). Becky Nikkel's physician recommended cannabis as the *only* medicine that effectively and safely alleviates the pain caused by the muscle spasms she experiences as a result of fibromyalgia and multiple sclerosis. *See id.* at 6-7. Ed Brundridge has severe arthritis and loss of appetite due to anxiety and depression; his physician recommended cannabis to relieve his pain and to stimulate his appetite, after unsuccessfully trying traditional medications. *See id.* at 7. Ima Carter has congenital scoliosis, fibromyalgia and cervical nerve damage, and suffers severe back and head pain; cannabis is the only drug that has effectively treated her disabling pain, and her physician deems it medically necessary. *See id.* at 7-8.

In sum, neither *Carnohan* nor *Rutherford* prevent this Court from recognizing the narrow fundamental right that has been claimed here. Whether or

not an individual can require the government regulators to reclassify cannabis, the Constitution *does* protect seriously ill individuals from the government's use of its prosecutorial powers to foreclose their ability to obtain the only treatment their physicians deem effective for the treatment of their pain or the preservation of their life.

B. The Practice Of Medicine Has Long Recognized And Protected The Fundamental Right Of Patients To Seek Relief From Pain And Suffering.

Protecting a patient's right to take measures to treat a medical condition, or to relieve or alleviate pain implicates one of the most historically profound functions of physicians, nurses, and other medical professionals. A patient should not endure unnecessary pain and suffering of any form, regardless of the nature of the patient's condition or the goals of medical intervention. *See, e.g., Ben A. Rich, A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 Wm. Mitchell L. Rev. 1, 4 (2000). Thus, physicians must be free to try to provide relief from pain and suffering: "One caregiver mandate remains as constant and compelling as it was for the earliest shaman—the relief of pain. Even when cure is impossible, the physician seeks to provide effective palliation. Moreover, the centrality of this role is both unquestioned and universal,

transcending time and cultural boundaries.” Post et al., *Pain: Ethics, Culture, and Informed Consent to Relief*, 24 J. Law, Med. & Ethics 348 (1996).

Because a patient does have the right to seek treatment for medical conditions or therapies that will alleviate pain, physicians and nurses must be able to address patients’ particular needs as they arise. And because individual response to various treatments may vary dramatically, treating severe or chronic pain often requires a patient and his or her physician to embark together on a difficult and frustrating process of exploration and discovery. When medical problems remain intractable, the patient and physician must be free to explore all therapeutic options, and the physician needs the latitude to offer the patient his or her opinion and advice on any and all potential courses of treatment. The collective effort to pursue and provide these remedies is a fundamental aspect of good patient care.

Good medicine does not involve just the application of cold data to “a case.” Rather, it requires the application of intuition, sensitivity, and creativity to the circumstances of a specific patient. If the patient has an intractable problem, various measures may be tried and abandoned; consultation may be sought; research may be undertaken. To be sure, standard therapies, if available, will certainly be tried first, but if those fail, sound medical opinion supports the

exploration of different options.⁴ Sometimes an option will involve the use of unconventional or unapproved substances. In rare instances, treatment options may require the use of a substance, like cannabis, whose medical purpose the federal government does recognize (although many doctors and the state of California disagree).⁵ But the substance may offer the only hope of effective treatment for a particular patient. The government should not and cannot deprive patients and physicians of the opportunity to discover the option that relieves the suffering of otherwise “untreatable” patients. In some cases, the only alternative may involve a drug that has been approved for marketing in other countries, but has not yet received approval for any indication by the Food and Drug Administration (FDA) in the U.S. For example, there are patients who suffer from debilitating seizures who can obtain relief only from drugs available in Europe, but not the U.S. In other cases, patients may seek relief from various types of

⁴ It is incontrovertible that some patients with serious medical conditions *cannot be helped by standard therapies*. For example, in a recent report on medical cannabis, the prestigious Institute of Medicine noted that, despite new advances in antiemetic (anti-vomiting) medications, 20-30% of cancer patients who receive highly emetogenic chemotherapy will still experience acute emesis. Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, 151-52 (1999). Others will suffer from conditions for which there is no standard therapy or for whom the side effects of such therapy are intolerable.

⁵ For a discussion of the research indicating that cannabis may have medical uses for certain patients who do not respond to conventional treatment, *see Conant v. Walters*, 309 F.3d at 640-43 (Kozinski, J., concurring).

alternative therapies, such as herbs, vitamins,⁶ meditation, yoga, and acupuncture. Physicians may assist patients in identifying whether any of such therapies are likely to be helpful. Although these therapies may not have been shown to be effective for a large percentage of people through controlled clinical trial, they may provide a patient's sole source of relief.

In sum, the exhaustion of treatment options, including those that are unconventional, is an accepted aspect of medicine. Indeed, the ability to pursue such options motivates and informs many patients' decision to seek the care of a physician and selection of a particular caregiver. Judicial recognition of the right of the desperately ill to seek unusual or even unapproved remedies, based on their physicians' advice, is consistent with these longstanding medical practices.

C. The Federal Government's Regulation Of Drugs Generally Cannot Justify Interfering With A Patient's Right To Seek And Obtain Specific Competent Medical Treatment.

Although the federal government has a significant role to play in ensuring that manufacturers who claim that their products will accomplish particular medical results are held to a high level of accountability of efficacy and safety,

⁶ Herbs, vitamins, minerals, botanicals, and similar substances are regulated as "dietary supplements," rather than "new drugs," by the FDA, so long as they are not accompanied by claims of specific medical or health benefits. 21 U.S.C. § 343(r)(6). Therefore, they have not been rigorously tested for safety and efficacy by controlled clinical trials.

that consumer protection role has never justified interfering with a specific doctor's recommendation to a specific patient about how best to treat or help alleviate a particular condition. Indeed, if anything is clear in the area of federal government interest in health care, it is that the "direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925); *see also Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) (noting that "health care" is a "subject of traditional state regulation").

For this reason, federal law regulating drug labelling and testing does *not* limit the manner in which physicians can use prescription drugs. Although controlled clinical trials have contributed greatly to scientific knowledge, they are not the only means of obtaining useful information about a potential treatment modality. Anecdotal cases, particularly if they are meaningful in number, may offer critically important guidance to physicians and patients.

Consequently, it is well-accepted that patients may take, on prescription, an approved medication for an unapproved medical use, i.e. "off-label" prescriptions. The American Medical Association takes the position that "a physician may lawfully use an FDA approved drug product for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion."

Policy 120.988, AMA Policy Compendium 1996.⁷ The AMA Council on Scientific Affairs has reviewed the issue of off-label prescription and concluded that the prevalence and clinical importance of unapproved indications are substantial, especially in the areas of oncology, rare diseases, and pediatrics. Report of the Council on Scientific Affairs 3-A-97, *Unlabeled Indications of Food and Drug Administration-Approved Drugs*. Similarly, the California Attorney General has opined that the state and federal drug approval laws were intended to protect consumers from drug manufacturers, not to interfere with the physician's judgment regarding individual patient treatment. *See* 61 Ops. Cal. Atty. Gen. 192 (1978).

Further, although the Food, Drug, and Cosmetic Act prohibits *manufacturers* from promoting a drug for an unapproved use, it does not restrict other persons—if they derive no direct commercial interest from the sale or

⁷ This is also true of medical devices. In fact, the FDA Modernization Act (FDAMA) explicitly prohibits FDA intrusion into medical practice with regard to the off-label use of devices:

Nothing in this [Act] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

21 U.S.C. § 396.

distribution of the product—from making such claims. The FDCA also does not prohibit a physician from prescribing or dispensing an unapproved drug outside the bounds of an approved investigational drug study. To the contrary, it explicitly permits a physician, or a pharmacist upon a physician’s order, to compound—mix up on its own—a drug product for an identified patient, without obtaining the approval the FDCA would otherwise require for a “new drug.” 21 U.S.C. § 353a.

Finally, as this Court has recently made clear, the federal government lacks authority under the Controlled Substances Act to interfere with the patient’s right to obtain information about possible treatment modalities from his or her doctor, even if the doctor advises the patient that some illegal substance might be helpful in treatment. In *Conant v. Walters*, this Court held that the CSA did *not* justify a federal government directive that physicians who “recommended” the use of medical cannabis could lose their DEA licenses to prescribe controlled substances, or be subjected to investigations that might lead to revocation of those licenses, *see* 309 F.3d at 632, because physician-patient communication regarding treatment options is “an integral component of the practice of medicine.” *Id.* at 636. Indeed, as Judge Kozinski noted, the policy invalidated there was particularly offensive

because it deprived patients of “information critical to their well-being.” *Id.* at 640.

Thus, the federal government’s role as market regulator has never been, and cannot now be, transmuted into medical expertise that overrides a particular physician’s judgment as to a particular patient’s needs.

D. Because Access To Medicine Is Essential To Exercising The Fundamental Right To Seek And Obtain Medically Necessary Treatment, The Injunction Against Distribution Must Fail.

Because patients have a fundamental right to seek medical treatment, the Constitution also prevents the government from cutting off access to those treatments. This notion of necessary access justified the court’s decision in *Carey v. Population Services, International*, 431 U.S. 678, 688 (1977). There, the Court invalidated a law prohibiting distribution of contraceptives which interfered with the fundamental right to decide whether or not to bear a child. The Court rejected the government’s efforts to defend the challenged statute on the ground that there was no fundamental “right of access to contraceptives,” because the court found that “such access is essential to exercise of the constitutionally protected right. . . .” *Id.* Accordingly, the Court ruled that government laws or regulations that “burden an individual’s right to decide to prevent conception or terminate

pregnancy by substantially limiting access to the means of effectuating that decision” must be subjected to the same scrutiny as those that expressly prohibit the decision. *Id.*

The principle articulated in *Carey* applies with equal force here. The cooperatives provide an essential source of cannabis for the narrow class of seriously ill patients whose rights are implicated in this case. While some individuals may be able to grow their own cannabis, others will not, due to the locations of their homes or the physical constraints and complications that accompany their debilitating illnesses. Patients who cannot furnish their own have turned to the dispensaries like the ones at issue here: nonprofit, purely intrastate groups that are set up for the sole purpose of providing medical cannabis to those who need it, according to their doctors. Without such dispensaries who can insure that the cannabis is not contaminated, patients are left to suffer or to brave the vagaries and violence of black market cannabis.⁸ For these reasons, the cooperatives’ ability to distribute cannabis is essential to those patients’ exercise of the right to seek medically necessary treatment. The government’s efforts to

⁸ For a discussion of the violence and risks inherent in purchasing cannabis on the black market, see Randy E. Bennett, Book Review, *Bad Trip: Drug Prohibition and the Weakness of Public Policy*, 103 Yale L.J. 2593, 2593-98 (1994).

prohibit that distribution must therefore be analyzed with the heightened scrutiny that applies to direct infringements of fundamental rights. *See, e.g., Nyberg v. City of Virginia*, 667 F.2d 754, 757-58 (8th Cir. 1982) (applying *Carey* to invalidate state hospital rule prohibiting physicians from performing abortions on hospital grounds); *Postscript Enters., Inc. v. Whaley*, 658 F.2d 1249, 1252-53 (8th Cir. 1981) (applying *Carey* to invalidate ordinance allowing only physicians, pharmacists, wholesale druggists and manufacturers to distribute contraceptives and prophylactics).

E. This Case Should Be Resolved Narrowly.

This case raises complex issues regarding individuals' ability to make intimate decisions regarding their physical health, and to access unconventional medical treatments when all others have failed. The constitutional protection accorded to those sensitive and innately personal decisions prevents the permanent injunction sought here, because the articulated governmental interests in applying the Controlled Substances Act do not survive the heightened scrutiny applicable to actions that infringe upon fundamental rights. *See* Appellants' Br. at 58-59 (explaining why the government's interests do not meet those heightened standards). The CMA therefore urges this Court to hold that the permanent injunction is unconstitutional, and reverse the district

court's decision. Because *amicus* writes primarily to underscore the significance of the rights at issue here, and to avoid repetition, we will rely on Appellant's brief, and not argue that point further here.

But there is a final point. The questions raised by this case are large and complex and involve the intersection of state and federal law in a relatively new way. “[I]n deciding a question of such magnitude and importance . . . it is the [better] part of wisdom not to attempt, by any general statement, to cover every possible phase of the subject.” *Cruzan*, 497 U.S. at 277-78 (internal quotation marks and citation omitted). Accordingly, even if the Court affirms the judgment below, it should resolve this dispute on narrow grounds. A broad ruling could inadvertently prejudice other pending and future litigation in cases that involve medical cannabis but present factual scenarios, and consequently liberty interests, quite different from those at issue here. For example, an individual who grows his or her own medical cannabis may seek to assert a constitutional challenge to the application of the Controlled Substances Act to his or her actions, and may rest that challenge on a right to use home-grown remedies. A caregiver might raise the claim in connection with providing medical cannabis to a patient too sick to grow his own. Or, a cooperative whose members collectively grow cannabis for medicinal purposes could present a different factual situation from any of those.

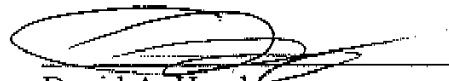
The legitimacy of those actions is not at issue here, and plaintiffs in such cases should have an opportunity to fully litigate their constitutional claims, and to articulate the liberty and privacy interests that may arise from their unique situations. Accordingly, even if the Court should conclude that the Constitution does not protect the particular distribution at issue here, the CMA respectfully requests that the Court issue an opinion that does not essentially preclude or decide those other issues without the benefit of full factual development.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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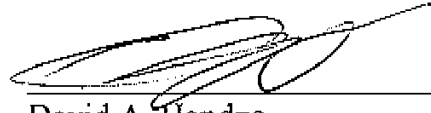


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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that the foregoing Amicus Brief of the California Medical Association, in Support of Defendants-Appellants complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B), Fed. R. App. P. 29(d), and Ninth Circuit Rule 32-1. The text of the brief is proportionally spaced, has a typeface of 14 points, and contains 5527 words as counted by Word Perfect 9.



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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of November, 2002, I caused true and accurate copies of the foregoing Amicus Brief of California Medical Association In Support of Defendants-Appellants Oakland Cannabis Buyers' Cooperative *et al.* to be served via first-class mail, postage prepaid, on the parties indicated below.

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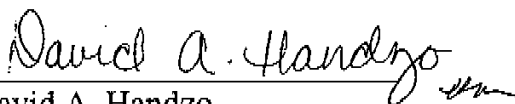
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