Nos. 98-16950, 98-17044, and 98-17137

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA

Appellee/Plaintiff

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,

Appellants/Defendants

Appeal from Order Modifying Injunction by the United States District Court
for the Northern District of California
Case. No. C 98-0088 CRB
entered on October 13, 1998 by Judge Charles R. Breyer.

MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF APPELLANT'S RESPONSE TO PETITION FOR REHEARING AND REHEARING EN BANC

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The California Medical Association ("CMA") respectfully moves this Court, pursuant to Federal Rule of Appellate Procedure 29, for leave to file the brief submitted herewith, as amicus curiae in support of Appellants/Defendants. Counsel for Petitioners, Mark Stern, has indicated that, while Petitioners do not consent to the filing of this amicus brief, neither will they file an opposition to such filing.

CMA is a non-profit, 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. CMA and its members share the objective of promoting high quality, cost-effective health care for the people of California. CMA has been active in proceedings before this Court in many cases of concern to the health care community.

As is more fully explained in the brief itself, CMA believes that the panel's ruling on medical necessity in this case raises an issue of great importance to the medical community. CMA has a strong interest in ensuring that patients, with the advice and approval of their physicians, are able to seek and obtain appropriate

and effective medical care. CMA wishes to stress that it fully supports the appropriate regulation of the safety and efficacy of new drugs by the Food, Drug, and Cosmetic Act and the appropriate control of drugs potentially subject to abuse by the Controlled Substances Act. CMA would not support any judicial determination that created a wholesale undermining of those Acts. However, by enacting these general laws to protect public health and safety, Congress cannot have intended to prevent the courts from recognizing and accommodating the desperate need of individual patients. The panel's ruling in this case strikes a sound balance between the basic integrity of the federal statutory scheme and the compassionate wisdom of the common law. CMA believes that physicians and their patients must explore all possible avenues of medical treatment when standard therapies have failed, and no governmental body should impede or punish that effort.

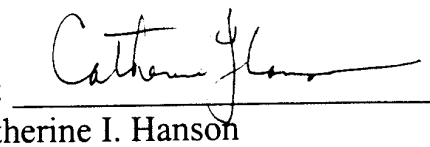
CMA has reviewed the briefs filed by the parties in this matter and is familiar with the questions involved and the scope of their presentation. CMA believes there is a need for additional argument on the issues raised and that CMA is well-placed to provide the Court with the particular perspective of the medical community concerning the impact of the medical necessity defense on the provision of good patient care.

For the foregoing reasons, CMA respectfully moves this Court for leave to file the accompanying brief as *amicus curiae* in support of Appellants.

DATE: January 11, 2000

Respectfully submitted,

California Medical Association
CATHERINE I. HANSON
ALICE P. MEAD

By: 
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PROOF OF SERVICE

I am employed in the City and County of San Francisco, California; I am over the age of 18 years and not a party to the within cause; my business address is 221 Main Street, San Francisco, California 94105.

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Parties Served: See attached list.

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I. INTRODUCTION

The California Medical Association ("CMA") is a non-profit, 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. CMA and its members share the objective of promoting high quality, cost-effective health care for the people of California.

The California Medical Association wishes to express its strong support for the panel's ruling on medical necessity in this case. CMA believes that a medical necessity defense, as narrowly defined by the panel, is wholly appropriate, and indeed essential, to protect the integrity and effectiveness of the physician-patient relationship.[1] Furthermore, the panel's ruling is entirely consistent with both the traditional common law doctrine of necessity and the federal Controlled Substances Act. Accordingly, there is no basis for the extraordinary review sought by the federal government, and CMA therefore urges this Court to deny the petition for rehearing and rehearing *en banc*.

CMA is in agreement with Attorney General Bill Lockyer that there are circumstances, such as those in this case, in which a patient should be allowed to

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[1] Under the panel's ruling, the medical necessity defense applies only to patients: 1) who have serious medical conditions for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; 2) who will suffer serious harm if they are denied cannabis; and 3) **for whom there are no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects**. U.S. v. Oakland Cannabis Buyers' Cooperative 190 F.3d 1109, 1114 (9th Cir. 1999).

"present evidence that use of marijuana, under certain narrow conditions, may be a lawful exception to the federal drug laws." *See* Exhibit A, Letter from California Attorney General Bill Lockyer to United States Attorney General Janet Reno, dated October 6, 1999. CMA thus concurs that this matter should be allowed to proceed immediately back to the District Court for a determination of whether there are patients in this case who meet the panel's medical necessity criteria.

II. DISCUSSION

A. The Panel's Ruling on Medical Necessity Supports the Effectiveness of the Physician-Patient Relationship and Promotes Good Patient Care.

A patient and his or her physician must sometimes embark together on a difficult and frustrating process of exploration and discovery. The patient and physician must explore all therapeutic options, and the physician must be able to offer the patient his or her opinion and advice on any and all potential courses of treatment. Neither the courts, nor any other governmental entity, should punish or otherwise impede a desperate patient, acting with the advice and approval of his or her physician, who 1) seeks to relieve his or her serious suffering by using an unconventional treatment that has been shown to be effective in his or her case and 2) has tried other standard, lawful treatments without success. Furthermore, those who attempt to aid the patient in that effort should be similarly free from sanction.

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, different options must be explored[2]. Sometimes an option will involve the use of unconventional, unapproved, and, in rare instances, even unlawful substances. But the substance may offer the only hope of effective treatment for a particular patient. The practice of medicine is at its best when it discovers the one option that relieves the suffering of an otherwise "untreatable" patient. Nothing should stand in the way of the patient and physician who are genuinely seeking such a goal.

The fact that a substance or therapy has not been proven to be effective, by controlled clinical trials, for a particular condition should not invariably preclude its use by a patient. Controlled clinical trials have contributed greatly to scientific knowledge, but 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. It is well accepted that patients make take, on prescription, an approved medication for an unapproved medical use, i.e., "off-label" prescription.[3] To deny

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[2] It is incontrovertible that some patients with serious medical conditions cannot be helped by standard therapies. For example, in a recent report on medicinal marijuana, 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 (1999) at p. 151. Others will suffer from conditions for which there is no standard therapy or for whom the side effects of such therapy are intolerable.

[3] The American Medical Association (AMA) 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. The AMA Council on Scientific Affairs has reviewed the issue of off-label prescription. The Council stated 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." The California Attorney General has opined that the state and federal drug approval laws were intended to protect consumers from drug manufacturers, not to

physicians and their patients that right would seriously eviscerate the practice of medicine.

In some cases, the only alternative may involve a drug that has been approved for marketing in other countries, but has not yet received FDA approval 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 alternative therapies, such as herbs, vitamins[4], meditation, yoga, acupuncture, etc.. Physicians may assist patients in identifying whether any of such therapies are likely to be helpful. These therapies may not have been shown to be effective through controlled clinical trials. Yet they may provide a patient's sole source of relief.

The "medical necessity" defense fits well into this patient-physician dynamic. As applied by the panel, it represents, not a wholesale judicial nullification of a federal statutory scheme, but an appropriately narrow recognition that individual patients (with their physicians' advice) will sometimes seek unusual or even unlawful remedies when nothing else will alleviate their suffering. Congress would surely not have presumed to overrule, with the broad brush of the federal Controlled Substances Act (CSA), such a basic aspect of medicine.

CMA wishes to stress that it fully supports the appropriate regulation of the safety and efficacy of new drugs by the Food, Drug, and Cosmetic Act and the

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interfere with the physician's judgment regarding individual patient treatment. *See* 61 Ops.Cal.Atty.Gen. 192 (1978).

[4] 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. The Dietary Supplement Health and Education Act (DSHEA), 21 U.S.C. sec. 343(r)(6). Therefore, they have not been rigorously tested for safety and efficacy by controlled clinical trials.

appropriate control of drugs potentially subject to abuse by the Controlled Substances Act. CMA would not support any judicial determination that created a wholesale undermining of those Acts. However, by enacting these general laws to protect public health and safety, Congress cannot have intended to prevent the courts from recognizing and accommodating the desperate need of individual patients. The panel's ruling in this case strikes a sound balance between the basic integrity of the federal statutory scheme and the compassionate wisdom of the common law.

B. The Panel's Ruling on Medical Necessity Does Not Contravene the Controlled Substances Act.

The federal government contends that the panel's ruling on medical necessity is inconsistent with the Controlled Substances Act and re-balances the factors already weighed by Congress when it placed marijuana in Schedule I of the CSA. However, the concept of medical necessity, as set forth by the panel, can quite logically coexist with that congressional determination.

By placing a substance in Schedule I, Congress has **not** thereby decided that the substance can provide **no** medical benefit to **any** individual under **any** circumstances. The following factors determine a substance's categorization as Schedule I:

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

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

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

The finding that a substance lacks "currently accepted medical use" within the meaning of the **statutory term** does not suggest that there is **no** evidence of

the substance's medical effectiveness, and, indeed, **the federal government has never before made such a claim.** The requirements for a finding of "currently accepted medical use" are both stringent and complex. In a proceeding seeking to move a substance from Schedule I to Schedule II, the Drug Enforcement Administration (DEA) has stated that it will examine the following factors in determining whether the drug has a "currently accepted medical use":

1. The drug's chemistry must be known and reproducible;
2. There must be adequate safety studies;
3. There must be adequate and well-controlled studies proving efficacy;
4. The drug must be accepted by qualified experts; and
5. The scientific evidence must be widely available.

See Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C.Cir. 1994).[5]

During litigation involving a petition to reschedule marijuana, the DEA explained the meaning of each of these factors. *See* 57 Fed.Reg. 10499,10506 (March 26, 1992). According to the DEA, a failure to meet **any** of the factors precludes a drug from having a "currently accepted medical use." 57 Fed.Reg. at 10507.

1. Known and Reproducible Chemistry

To satisfy this criterion, the substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by the Food, Drug & Cosmetic Act, 21 U.S.C. sec. 321(j), is sufficient

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[5]These factors were created by the Final Order of the DEA Administrator in the course of rescheduling litigation, *see* 57 Fed.Reg. 10499 (March 26, 1992) and subsequently approved by the Court of Appeals.

generally to meet this requirement.[6]

2. Adequate Safety Studies

To satisfy this criterion, there must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly by concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder.

3. Adequate and Well-Controlled Studies Proving Efficacy

Under this criterion, there must be adequate, well-controlled, well-designed, well-conducted, and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of which it could fairly and reasonably be concluded by such experts, that the substance will have its intended effect in treating a specific, recognized disorder.

4. Drug Accepted by Qualified Experts

Under this requirement, the drug must have a New Drug Application (NDA) approved by the FDA, or a consensus of the national community of experts,

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[6]In 1992, at the end of the NORML rescheduling litigation, see text *infra*, the DEA Administrator found that marijuana does not meet this standard:

> [M]arijuana's chemistry is neither fully known, nor reproducible. Thus far, over 400 different chemicals have been identified in the plant. The proportions and concentrations differ from plant to plant, depending on growing conditions, age of the plant, harvesting and storage factors. THC levels can vary from less than 0.2% to over 10%. It is not known how smoking or burning the plant material affects the composition of all these chemicals. It is not possible to reproduce the drug in dosages which can be considered standardized by any currently accepted scientific criteria. Marijuana is not recognized in any current edition of the official compendia, 21 U.S.C. sec. 321(j).

57 Fed.Reg. 10499, 10507.

qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, must accept the safety and effectiveness of the substance of use in treating a specific, recognized disorder. A "material" conflict of opinion among experts precludes a finding of "consensus."

5. Scientific Evidence Must Be Widely Available

This element requires that, in the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder. 57 Fed.Reg. at 10506.

The DEA Administrator has made it clear that, in determining whether the above five standards have been met, the DEA will **not** consider as proof either "isolated case reports" or the "clinical impressions of practitioners."[7] 57 Fed.Reg. at 10506-07. In other words, in refusing to remove marijuana from Schedule I, the

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[7] The Administrator also will not consider:

- Opinions of person not qualified by scientific training and experience to evaluate the safety and effectiveness of the substance at issue;
- Studies or reports so lacking in detail as to preclude responsible scientific evaluation;
- Studies or reports involving drug substances other than the precise substance at issue;
- Studies or reports involving the substance at issue combined with other drug substances;
- Studies conducted by persons not qualified by scientific training and experience to evaluate the safety and effectiveness of the substance at issue;
- Opinions of experts based entirely on unrevealed or unspecified information; or
- Opinion of experts based entirely on theoretical evaluations of safety or effectiveness.

Id.

DEA Administrator did not reject evidence that in individual instances, marijuana may have provided great benefit, but rather ruled that such "anecdotal cases" could not satisfy the **demanding statutory criterion** of "currently accepted medical use."

The panel's ruling on medical necessity therefore does not "set aside" the congressional judgment concerning placement of a substance in Schedule I. Instead, its ruling recognizes that the CSA humanely leaves room for the reality of "anecdotal cases," i.e., individual patients who, in consultation with their physicians, have discovered relief from their tormenting medical condition only by using a particular substance.

Despite the federal government's argument to the contrary, the panel's ruling in this case is quite unlike that of the Court of Appeals reviewed in U.S. v. Rutherford, 442 U.S. 544 (1979), which involved an improper judicial interference with congressional intent. In Rutherford, the Court of Appeals had ruled that the "safety" and "effectiveness" requirements of the federal Food, Drug and Cosmetic Act could have "no reasonable application" to terminally ill patients, thereby creating a wholesale exception to the requirements of the Act for all such persons. The panel's ruling does not involve such a broad rewriting of a federal law. Rather, it applies only to a limited number of patients who, **in the face of an enforcement action brought by the federal government[8], merely desire to be left alone —to be allowed to obtain and use a medication that has been shown**

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[8] Rutherford involved a class action composed of "terminally ill cancer patients" seeking to enjoin the government from enforcing a provision of the Food, Drug and Cosmetic Act that prohibits the interstate shipment of any substance which has not been proved safe and effective for a particular medical use. *See* 21 U.S.C. sec. 355.

to the satisfaction of their physician be the only source of relief for their torments.

In Rutherford, the Supreme Court stressed that the ruling of the Court of Appeals would effectively have "den[ied] the [FDA] Commissioner's authority over all drugs, however toxic or ineffectual," for terminal cancer patients. 442 U.S. 557-58, citing U.S. v. Rutherford, 582 F.2d 1234, 1236 (10th Cir. 1978).[9] This would clearly have contravened the intent of Congress, which "could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise." Id. The panel's limited ruling on medical necessity in this case cannot be compared to such a far-reaching judicial fiat.

C. The Availability of Complex and Prolonged Legislative, Political and Judicial Processes Does Not Offer A Reasonable "Lawful" Alternative Where Seriously Ill and Dying Patients Are Involved.

The federal government further argues that the medical necessity defense "has no application when a defendant can seek relief through the political, administrative process." While this contention may hold true for the defense of necessity in certain other contexts, it certainly cannot apply in cases involving patients with an urgent need for medical treatment.

A patient with a life-threatening or otherwise serious medical condition, who has not been able to obtain medical relief from standard therapies, cannot be expected to suffer until the completion of complex, expensive and time-consuming political, legislative, and judicial processes. Any effort to seek the rescheduling of

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[9] The Court of Appeals further directed the FDA to promulgate regulations "as if" the substance in question (Laetrile) had been found "safe" and "effective" for terminally ill cancer patients. Id.

marijuana, even if ultimately successful, would necessitate many years of waiting. In 1972, the National Organization for the Reform of Marijuana Laws (NORML) filed a petition to reschedule marijuana under the CSA. After prolonged litigation and 14 days of hearings, an administrative law judge recommended that marijuana be rescheduled to Schedule II. In so doing, Judge Francis Young made extensive findings of fact on the issue of marijuana's currently accepted medical use." He found that a "significant minority" of physicians accepted marijuana as medically useful and concluded:

> The evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision.

In The Matter of Marijuana Rescheduling Petition, Docket No. 86-22 (Sept. 6, 1988). However, the DEA Administrator rejected Judge Young's recommendation and findings:

> [T]he effectiveness of marijuana has not been documented in humans with scientifically-designed clinical trials. While many individuals have used marijuana and claim that it is effective in treating their ailments, these testimonials do not rise to the level of scientific evidence.

Marijuana Scheduling Petition, 54 Fed. Reg. 53767, 53784. The Administrator did not deny that a "significant minority" of physicians accepted the medical efficacy of marijuana, nor that patients had benefitted from its use; but rather ruled, among other things, that this was not sufficient to meet the "currently accepted medical use" statutory standard. Id. at p.53783-4. The Administrator's findings were upheld in 1994 by a federal Court of Appeals under a "substantial evidence" standard. *See* Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C.Cir. 1994). *See also* Alliance for Cannabis Therapeutics v. DEA, 930 F.2d

936 (D.C.Cir. 1994); NORML v. DEA, 559 F.2d 735 (D.C.Cir. 1977); NORML v. Ingersoll, 497 F.2d 654 (D.C.Cir. 1977). This litigation dragged on for 22 years.

Another marijuana rescheduling petition was filed on July 10, 1995.[10] That petition has been forwarded by the DEA to the Department of Health and Human Services (HHS) for a scientific and medical review and scheduling recommendation. The petitioner is still awaiting a response from HHS. After almost five years, he has still not received even this initial determination, much less a final disposition after the culmination of any ensuing litigation. Surely desperately sick and dying patients and their physicians should not be required to await the completion of such an onerous route. Indeed, the federal government's suggestion that dying patients, and those attempting to assist them, should petition the government to reschedule marijuana ignores this Court's own clear statement that "[T]he law implies a reasonableness requirement in judging whether legal alternatives exist." U.S. v. Schoon, 971 F.2d 193, 198 (9th Cir. 1992), cert. denied, 504 U.S. 990 (1992).

This is not a case like U.S. v. Schoon , supra, or U.S. v. Dorrell, 758 F.2d 427 (9th Cir. 1985), in which political protesters, frustrated with the political process, took matters into their own hands to try to change congressional policy or decisions. The political protesters in Schoon and Dorrell were not themselves sick and suffering; they did not have a special relationship with those whom they were purportedly trying to protect; nor could their actions be expected to achieve the goal sought. Their "impatience" therefore did not constitute a true emergency.

By sharp contrast to the protesters in those cases, a patient who satisfies the panel's medical necessity criteria is more like a prisoner "fleeing a burning jail"

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[10] *See* Exhibit B, Letter from Jon Gettman to Sandra Bressler, dated July 9, 1998.

described by this Court in Schoon, who, without the medical necessity defense, must either "perish or wait in his cell" in the hope that he or she might be saved (in this case, that marijuana will be rescheduled or a treatment or cure miraculously found). U.S. v. Schoon, supra, 971 F.2d at 198. Such a patient has no "legal alternative to the illegal conduct contemplated that would abate the evil." Id. The patient will suffer unspeakably and perhaps die before the "legal alternative," i.e., a petition seeking the rescheduling of marijuana, will even be reviewed, much less finally resolved. Under no stretch of the imagination can such a "legal alternative" be considered reasonable.

The "alternatives" described in U.S. v. Richardson, 588 F.2d 1235 (9th Cir. 1978) are also not available in this case. In Richardson, the defendants were criminally prosecuted for conspiring to smuggle a substance (Laetrile) into the U.S., in violation of 18 U.S.C. sec. 545, which makes it a crime knowingly and willfully, with intent to defraud the U.S., to smuggle into the U.S. any merchandise (legal or illegal) that should have been invoiced. The Court, in declining to apply the necessity defense, stressed that several lawful alternatives had been available to the defendants: 1) bringing an action to reclassify Laetrile or have it approved by the FDA; ***or*** 2) declaring the substance at the border and challenging its inevitable seizure by the government ***or*** 3) producing the substance in the U.S. 588 F.2d at 1239.

In this case, none of those alternatives is viable. As demonstrated above, the reclassification route is not a reasonable alternative for suffering patients. Furthermore, the choice of producing the substance in the U.S. is not a "lawful alternative" available to these defendants. While the provisions of the Food, Drug, and Cosmetic Act, applicable to the substance in question in Richardson, apply only to new drugs that are shipped and marketed interstate (or imported), the

provisions and prohibitions of the Controlled Substances Act apply **both** to interstate and intrastate activity. Compare 21 U.S.C. sec. 321(b), 355(a) with 21 U.S.C. sec. 801(5). Indeed, manufacturing and distributing marijuana are precisely the activities that precipitated the federal government's enforcement action. Finally, the federal government's decision to proceed with a civil action deprived the defendants of the opportunity to "challenge the seizure of the medicinal marijuana.

Had the federal government initiated a criminal action to prosecute the defendants (and concomitantly to seize the medicinal marijuana), rather than a civil action to enjoin their conduct, the defendants could have directly availed themselves of this "lawful alternative" recommended by Richardson. The government should not be allowed both to deny the defendants this alternative by its choice of enforcement methods and then to claim that defendants have not exercised any of the lawful options described in Richardson.

III. CONCLUSION

The panel's ruling on medical necessity comports fully with the practice of medicine and good patient care, with the common law, and with the CSA. Accordingly, for the foregoing reasons, the petition for rehearing and rehearing *en banc* should be denied.

DATE: January 11, 2000

Respectfully submitted,

California Medical Association
CATHERINE I. HANSON
ALICE P. MEAD

By: 
Catherine I. Hanson
Alice P. Mead
Attorneys for Amicus Curiae
CALIFORNIA MEDICAL
ASSOCIATION

EXHIBIT A

STATE OF CALIFORNIA

OFFICE OF THE ATTORNEY GENERAL

BILL LOCKYER
ATTORNEY GENERAL

October 6, 1999

The Honorable Janet Reno
Attorney General
United States Department of Justice
Constitution Avenue & 10th Street, NW
Washington, DC 20530

Dear Attorney General Reno:

On September 13, 1999, a panel of the Ninth Circuit Court of Appeals decided a case raising issues related to the medicinal use of marijuana. The court's final decision potentially has a substantial impact on the implementation of Proposition 215, the Compassionate Use Act of 1996, in the State of California. In a matter entitled *United States of America* v. *Oakland Cannabis Buyers' Cooperative*, No. 98-16950, the appellate court concluded that the United States District Court could properly consider the needs of seriously ill patients in a proposed order modifying a previously issued injunction enjoining the Oakland Cannabis Buyers' Cooperative from furnishing marijuana to patients. The court directed the District Court upon remand to determine whether there exists "...a class of people with serious medical conditions for whom the use of cannabis is necessary..." and who would suffer serious harm if they are denied the use of cannabis.

I understand your office has not yet made a decision whether to request a rehearing in the case. I write to ask that you consider foregoing the filing of a petition for rehearing and allow the matter to proceed back to the District Court for further proceedings. As you know, the voters in my state have endorsed the medicinal use of marijuana and the court's decision holding that a citizen may present evidence that use of marijuana, under certain narrow conditions, may be a lawful exception to the federal drug laws is consistent with that expression of their will.

Sincerely,

Bill Lockyer

BILL LOCKYER
Attorney General

1300 I STREET • SUITE 1740 • SACRAMENTO, CALIFORNIA • 95814 • 916-324-5437

EXHIBIT B

July 9, 1998

Sandra Bressler
Director of Professional and Scientific Policy
California Medical Association
221 Main Street
P.O. Box 7690
San Francisco, CA 94120-7690

Dear Ms Bressler:

The federal government is currently reviewing the scheduling of marijuana under the Controlled Substances Act (CSA). I filed the 1995 petition responsible for this review. I am writing to request that the petition and two related articles be reviewed by the California Medical Association.

I realize that formal review by expert panels is a complicated exercise even for federal government agencies, and that such an independent review is not practical. I believe that information about the petition will be of interest to the CMA given your recent recommendations on marijuana's re-scheduling. Any review of the petition that you can bring before your members and the public will be in the public interest.

The issue of medical access to marijuana has heightened public and professional interest in the federal process for regulating controlled substances. As I will explain further below, I believe the public interest would be served by additional scrutiny of the case I have made for marijuana's rescheduling. I don't know what the appropriate form of such scrutiny should be, and I make this request for review without condition. I have enclosed a description and electronic copies of the relevant documents. Some background information follows below.

In December, 1997 the Drug Enforcement Administration (DEA) determined that my petition provided "sufficient grounds" for the removal of marijuana and all cannabinoid drugs from schedules 1 and 2 of the CSA. The petition was forwarded to the Department of Health and Human Services (HHS) for a scientific and medical review and a binding scheduling recommendation. The HHS review is currently underway.

The organization and composition of the petition was specified by law. The petition is a 70,000 word non-exhaustive review of the scientific literature in each of 8 areas designated by the CSA. For legal reasons the scope of this review and the presentation of material was heavily influenced by the last proceedings of record concerning the scheduling of marijuana. The petition focuses on literature published between 1988, when the record of the prior proceedings closed, and 1994, the most recent published material available at the time the petition was filed. The Trans-High Corporation joined me as co-petitioners in 1995 and helped to secure pro bono legal representation from the law offices of Michael Kennedy.

A drug must have a high potential for abuse to be subject to either the absolute prohibition of schedule 1 or the tightest possible regulations for controlled substances provided by schedule 2 controls. The petition argues that marijuana does not have the abuse potential necessary for schedule 1 status. Furthermore, the petition argues that neither marijuana, Marinol, or Nabilone has sufficient abuse potential for schedule 2 status. The petition proposes rules removing all of these substances from their current schedules and asks that they be rescheduled as required by the CSA, beginning with a review and recommendation from HHS.

I am a former National Director of the National Organization for the Reform of Marijuana Laws (NORML). I have degrees in anthropology and justice, and am now working on my doctorate at The Institute of Public Policy of George Mason University. The petition has already passed review and inspection by the professional staff at the DEA. I would hope that this provides the scientific and legal argument of the petition with some credibility. The public policy process and public discussion would benefit from independent review of the scientific and legal issues discussed in the petition.

Independent review of this material will also greatly contribute to the public's understanding of the HHS review and subsequent national debate and discussion on the appropriate regulation of marijuana.

There are several reasons why independent review is important to me as petitioner in this administrative rule making proceeding. The most important reason is that I want to make these proceedings as transparent and as public as possible. This is the public's business. The public should understand the issues, the law, and the relevant scientific findings. I remain confident in obtaining an objective and constructive review from HHS, however I'd also like to get at least one second opinion before the public as well. I am also sending this request to the New England Journal of Medicine, the Journal of the American Medical Association, and the American Journal of Public Health.

I would also greatly appreciate any advice you may have on other ways I can bring these issues before the public. Thank you for your time and consideration of this request.

Sincerely,

Jon Gettman
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enclosures

Certification Pursuant to Circuit Rule 32(e)(4), Form of Brief

Pursuant to Ninth Circuit Rule 32(e)(4), I certify that the attached brief

- ■ Uses proportionately spaced, has a typeface of 14 points or more and contains 4,157 words, or
- □ Uses monospaced, has 10.5 or less characters per inch and
  - □ Does not exceed 40 pages (opening and answering briefs) or 20 pages (reply briefs), or
  - □ Contains _____ words.

1/10/2001 ~~97~~ — Alice P. Mead

Date — Signature of Attorney or Unrepresented Party

PROOF OF SERVICE

I am employed in the City and County of San Francisco, California; I am over the age of 18 years and not a party to the within cause; my business address is 221 Main Street, San Francisco, California 94105.

I served the document(s) listed below by placing a true copy thereof in a sealed envelope with postage thereon fully prepaid, addressed as follows:

Date Served: January 11, 2000

Document Served: **Amicus Curiae Brief of California Medical Association in Support of Appellant's Response to Petition for Rehearing and Rehearing En Banc.**

Parties Served: See attached list.

■ **(BY MAIL)** I caused such envelope to be placed for collection and mailing on that date in accordance with ordinary business practice for deposit in the United States at San Francisco, California. I am readily familiar with the practice of this office of the California Medical Association for collection and processing of correspondence for mailing with the United States Postal Service and that this correspondence will be deposited with the United States Postal Service on the same day as I deposit it in the office mail system in the ordinary course of business.

☐ **(BY PERSONAL SERVICE)** I caused such envelope to be delivered by hand to the offices of the addressee.

☐ **(BY FEDERAL EXPRESS)** I caused such envelope to be placed for collection and delivery on this date in accordance with standard Federal Express Overnight delivery procedures.

☐ (State) I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct.

■ (Federal) I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

The original of any document filed with the court was printed on recycled paper.

Executed on January 11, 2000, at San Francisco, California.

Ernesto B. Tanjuan

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