No. 00-151

In The

Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

MOTION FOR LEAVE TO FILE *AMICI CURIAE* BRIEF AND BRIEF OF CALIFORNIA MEDICAL ASSOCIATION AND NATIONAL PAIN FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

May a federal court consider the needs of seriously ill patients when formulating relief in response to a request for an injunction, unless clearly denied that authority by federal statutory law?

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF OF CALIFORNIA MEDICAL ASSOCIATION AND NATIONAL PAIN FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

The California Medical Association and the National Pain Foundation hereby respectfully move for leave to file the attached brief as *amici curiae* in support of Respondents in this case. The consent of the attorneys for the petitioner and respondent has been obtained. The letters of consent have been filed separately with the court in this case.

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 National Pain Foundation ("NPF") is a nonprofit educational organization created to address the issue of chronic pain management. The NPF is establishing an extensive network of information regarding proven, integrated approaches to pain management that will draw from traditional, alternative and behavioral approaches to pain management. The Mission of The National Pain Foundation is to create a highly accessible information network that will empower individuals to make optimum use of available resources to manage chronic pain. The

NPF is committed to being an impartial resource for the pain medicine community to promote functional recovery for pain patients.

CMA and NFP move for leave to file this brief in support of Respondents. As is more fully explained in the brief itself, CMA and NFP believe that the ruling of the United States Court of Appeals on medical necessity in this case raises an issue of great importance to the medical community. CMA and NFP have 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 and NFP wish to stress that they fully support 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. *Amici* 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 Court of Appeal'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 and NFP believe that physicians and their patients must be free to explore all possible avenues of medical treatment when standard therapies have failed, and no governmental body should impede or punish that effort.

CMA and NFP have reviewed the briefs filed by the parties in this matter and is familiar with the questions involved and the scope of their presentation. CMA and

NFP believe there is a need for additional argument on the issues raised and CMA and NFP are 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 and NFP respectfully move this Court for leave to file the accompanying brief as *amici curiae* in support of Respondents.

DATE: Feb. 16, 2001 Respectfully submitted,

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BRIEF OF *AMICI CURIAE*

This brief of *amici curiae*[1] is filed in support of Respondents and is submitted on behalf of the California Medical Association and National Pain Foundation (herein referred to as *"amici"*).

INTEREST OF *AMICI CURIAE*

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."

The National Pain Foundation ("NPF") is a nonprofit educational organization created to address the issue of chronic pain management. The NPF is establishing an extensive network of information regarding proven, integrated approaches to pain management that will draw from traditional, alternative and behavioral approaches to pain management. The Mission of The National Pain

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[1] Both parties have consented to the filing of this brief. The letters of consent have been filed with the Clerk of the Court. Counsel for a party did not author this brief in whole or in part. No person or entity, other than the *amici curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

Controlled Substances Act. Accordingly, *amici* urge this Court to uphold that ruling.

B. The Court of Appeals' Ruling on Medical Necessity Supports the Effectiveness of the Physician-Patient Relationship and Promotes Good Patient Care

A patient and his or her physician often 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. 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 a treatment that has been shown to be effective in his or her case and 2) has tried all conventional 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, sound medical opinion supports the exploration of different

options.[4] 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 law must be flexible enough to permit patients and physicians to discover the option that relieves the suffering of otherwise "untreatable" patients.

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 may take, on prescription, an approved medication for an unapproved medical use, i.e., "off-label" prescription.[5] To deny physicians and their

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[4] 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.

[5] The 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

patients rights like this would seriously eviscerate the practice of medicine.[6]

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 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 alternative therapies, such as herbs, vitamins,[7] meditation, yoga, acupuncture, etc.

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

[6] Many medications, particularly pain medications, are used for "off-label," or unapproved, purposes. Such off-label use may not be supported by data from controlled clinical trials; nevertheless, it is fully within the ethical practice of medicine. Indeed, it may provide the best – or sole – source of relief for a suffering patient. Despite this fact, many carriers, including the Health Care Financing Administration, unjustifiably refuse to extend coverage to such treatments.

[7] 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

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 Court of Appeals, 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 CSA, such a basic aspect of medicine.

Amici wish to stress that they fully support the appropriate regulation of the safety and efficacy of new drugs by the Food, Drug, and Cosmetic Act (FDCA) and the appropriate control by the CSA of drugs potentially subject to abuse. *Amici* 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 did not intend to prevent the courts from recognizing and accommodating the desperate need of individual patients. The Court of Appeals' 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.

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

C. The Court of Appeals' Ruling on Medical Necessity Does Not Subvert or Contravene the Food, Drug & Cosmetic Act (FDCA) Nor the Controlled Substances Act (CSA).

1. The Stringent Statutory Criteria for Placement of a Substance in Schedule I of the CSA Are Qualitatively Different From the Criteria That Establish Medical Necessity.

The federal government contends that the Court of Appeals' ruling on medical necessity is inconsistent with the CSA and re-balances the factors already weighed by Congress when it placed marijuana in Schedule I of that Act. However, the concept of medical necessity, as set forth by the Court of Appeals, 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).[8]

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. 10507.

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[8] 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.

a. 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. §321(j), is sufficient generally to meet this requirement.

b. 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 be 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.

c. 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.

d. 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, 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."

e. 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."[9] 57 Fed.Reg. at 10506-07. In other words, in refusing to remove marijuana from Schedule I, the 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 Court of Appeals' 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.,

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[9] 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.

individual patients who, in consultation with their physicians, have discovered relief from their tormenting medical condition only by using a particular substance.

2. When Enacting the CSA, Congress Demonstrated a Concern for the Public Interest That is Perfectly Consistent With the Concept of Medical Necessity.

The federal government asserts that the CSA contains an "absolute ban" on the distribution of cannabis and other Schedule I substances outside the "strict confines" of the CSA. Brief for the Petitioner at p. 29. However, the clear statutory language of the CSA demonstrates that Congress anticipated instances in which the public interest would require a relaxation of such "confines." There is no indication that Congress intended to limit the equitable power of a district court to fashion appropriate injunctive relief, including relief that incorporates the concept of medical necessity, when it is asked to enforce the Act's provisions. Indeed, rather than undermining the administration and effectiveness of the CSA, the concept of medical necessity is perfectly consistent with the structure of that Act.

When it enacted the CSA, Congress repeatedly recognized that the stringent requirements and prohibitions of the Act must often be tempered by a compassionate consideration of the public interest. Furthermore, contrary to the federal government's contention, when considering this public interest, Congress explicitly contemplated that a controlled substance, including one on Schedule I, ***may*** under some circumstances be manufactured, distributed,

or dispensed outside of a research program approved by the FDA and conducted by a practitioner registered with the DEA. For example, the CSA generally states that anyone who manufactures, distributes, or dispenses a controlled substance must obtain a registration from the Attorney General (delegated to the DEA). 21 U.S.C. §822(a), (b). However, **this requirement may be completely waived for a manufacturer, distributor, or dispenser if such a waiver is consistent with the public health and safety. 21 U.S.C. §822(d).**

Furthermore, Congress has deliberately **constrained** the DEA's power to **refuse** to register a manufacturer or distributor. The DEA **must** register an applicant to distribute a Schedule I or II substance **unless** it determines that the issuance of such registration is **inconsistent with the public interest.**[10] 21 U.S.C. §823(b). Similarly, the DEA **must** register an applicant to manufacture a Schedule I or II substance **if** it determines that such registration is consistent with the public interest and with U.S. international obligations.[11]

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[10] In determining the public interest, the DEA must consider, among other things, whether there will be effective control against diversion of the substance into other than legitimate medical, scientific, and industrial channels. 21 U.S.C. §823(b)(1). This clear distinction between legitimate "medical" and "scientific" suggests that there can be lawful medical uses of a Schedule I substance outside of a research ("scientific") program.

[11] When imposing these limits on the DEA's discretion, Congress made no distinction in the type of controlled substance at issue. That is, the standards for issuance of a registration are consistent, even if the controlled substance at issue falls within Schedules III, IV or V. *See* 21 U.S.C. §§823(d),

By enacting such provisions, Congress deliberately built a substantial degree of flexibility into the CSA, in order to take into account the needs of a specific situation.[12] Congress has already contemplated that the many

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(e). The only difference is that, under a registration granted for a Schedule I or II substance, a registrant cannot manufacture or distribute a Schedule I or II substance other than those specified in the registration, nor manufacture any quantity in excess of its assigned quota. 21 U.S.C. §823(c). Thus, under the CSA, Schedule I is not a *sui generis* category, subject to unique and inflexible requirements. Indeed, the standards for issuance of a registration for distribution and/or manufacture are absolutely the same for a Schedule I and a Schedule II substance, even though Schedule II substances can be prescribed by physicians and dispensed by pharmacies.

[12] Canada allows patients to obtain access to unapproved/controlled substances, **including cannabis**, through Canada's "Section 56 exemption" to its controlled substances act. Under section 56, the Minister of Health has the discretionary power to grant exemptions from all of any of the provisions of the act or its regulations in exceptional circumstances. Section 56 states that the Minister may, on such terms and conditions as the Minister deems necessary, exempt any person or class of persons from the application of all or any of the provisions of the CDSA if, in the Minister's opinion, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest. *See* also, Health Canada, Interim Guidance Document, Exemption Under Section 56 For Medical Purposes, *http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/cds/guides/interim___e.html.*

This is precisely what is permitted under our CSA. As indicated above, the CSA is replete with references to the Administrator's right to waive the provisions of the CSA if that would serve the public interest or otherwise be appropriate. Congress thus intended that the CSA would be sufficiently flexible and capacious to be able to tolerate such exceptions to its provisions. Surely, in light of this flexibility, it cannot be

requirements and prohibitions can be modified on a case-by-case basis. There is, therefore, no reason to conclude that Congress intended to deprive the federal courts of a similar power, particularly when that power is so well-established in the common law.[13]

That the CSA should have such flexibility is not surprising. The CSA, like the FDCA, is largely directed toward the regulation of commercial, and the prohibition

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concluded, merely from the CSA's structure and penumbras, that Congress intended to prohibit a federal court also from recognizing the public interest when it is asked to apply that law.

[13] This Court should consider the laws of sister sovereigns when determining the compatibility of the common law concept of medical necessity with the FDCA and CSA. For example, Canada has a regulatory system that parallels our own. It has statutory schemes and regulatory bodies that protect the public from ineffective and unsafe medicines (The Food and Drug Act and Regulations) and control the manufacture and distribution of drugs that may be subject to abuse (the Controlled Drugs and Substances Act (CDSA)). However, even if a drug has not been approved for any medical condition, and even if it is a controlled substance, patients in Canada, with the approval of their physicians, can obtain access to it for medical treatment through Canada's Special Access Programme (SAP).

The SAP has a mandate to provide access to non-marketed drugs to practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, are unavailable, or offer limited options. It provides the authority for a manufacturer to sell a specific quantity of a drug and therefore to grant access to a drug which cannot be otherwise sold or distributed in Canada. Health Canada, Special Access Programme, *http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/edrg.html*. Such an exemption procedure has not eviscerated the effectiveness of Canada's regulatory scheme.

of "black market," manufacturing and distributing/dealing. Under its primary offense provision, it is unlawful for a person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance. The penalties for a violation of this provision are substantial, but the quantities of controlled substances required to trigger such penalties are also substantial. *See* 21 U.S.C. §841 (Prohibited Acts A).

By contrast, the offense and penalty provisions that relate to individual use and possession are far less severe. 21 U.S.C. §§844, 844a. Indeed, the possession of a controlled substance in a personal use amount is subject only to civil penalty, which can be compromised, modified or entirely remitted by the DEA. 21 U.S.C. §844a(a), (f). Such a penalty can be assessed only after the individual has been given an opportunity for a hearing. Section 844a(e). If, after such a hearing, the Attorney General issues a penalty order, the individual may challenge that order in federal court. The facts of the violation must be proved beyond a reasonable doubt. Section 844a(g). Thus, the recognition of a common law defense such as the defense of necessity, that protects individual personal use in very special circumstances, is not inconsistent with the predominant purpose of the CSA and, indeed, would seem to be invited by provisions such as these.[14]

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[14] At the very least, we urge the Court to recognize that the defense can be raised by **an individual patient** who meets the criteria established by the Court of Appeals and who seeks to **possess and use cannabis on the advice of his or her physician.**

3. Allowing Patients to Raise the Medical Necessity Defense Will Not Impede The Government's Ability to Enforce the CSA.

The medical necessity defense will not interfere with the government's ability to enforce the CSA. In their enforcement activities, the DEA and the Department of Justice must regularly determine, on a case-by-case basis, whether a situation involves legitimate medical use or unlawful recreational/street use. Many street drugs, such as cocaine and methamphetamine, have lawful medical applications.[15] Furthermore, approved Schedule II products, such as methadone or oxycontin, are not uncommonly diverted to non-medical uses.[16] Indeed, if a substance is listed in **either** Schedule I or Schedule II (the latter being available for general prescription by physicians), it is deemed to have a "high potential for abuse." 21 U.S.C. §812. A potentially addictive substance remains in Schedule I only if it has not been approved for any medical indication by the FDA. R. Cooper, "Therapeutic Use of Marijuana and Heroin: The Legal Framework," 35 *Food Drug Cosmetic Law Journal* 68 (1980); IOM Report at p. 210 n.++. Once the FDA approves a substance for at least one medical indication in at least one patient population, the Drug Enforcement Administration (DEA) does not have the power to retain the substance's placement in Schedule I.

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[15] Cocaine and methamphetamine are among the substances listed in Schedule II. 21 U.S.C. §812.

[16] *See* T. Roche, "The Potent Perils of a Miracle Drug," Time Magazine (Jan. 8, 2001).

Therefore, if the FDA were to approve another Schedule I substance, such as 3,4-methylenedioxymethamphetamine (MDMA or "ecstasy"),[17] for some medical indication, physicians would be allowed to prescribe it (including perhaps off-label) for a variety of indications, and the DEA would be forced to distinguish between legitimate and illegitimate uses. As with cocaine, methamphetamine, and other drugs, the facts and circumstances surrounding the case, including the existence and validity of a physician's written approval or prescription, will establish the nature of the person's use. The DEA commonly deals with this issue, and the CSA has not thereby been subverted or eviscerated.[18]

The above discussion amply demonstrates that the government's reliance on the "closed" structure of the CSA does not support its contention that the Act inherently precludes a court from applying the concept of medical necessity.

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[17] A Phase 1 safety study was approved by the FDA in 1992 and completed in 1995 by Dr. Charles Grob at Harbor-UCLA Medical Center. *See* C. Grob et al., "Psychobiologic Effects of 3,4-methylenedioxymethamphetamine (MDMA) in Humans: Methodological Considerations and Preliminary Observations," 73 *Behav. Brain Res.* 103 (1996).

[18] To be sure, the FDA has not yet approved cannabis for a particular medical condition. However, the government's arguments do not apply only to cannabis; they would encompass **any** unapproved drug or medicine, whether or not that substance is listed in Schedule I.

4. The Food, Drug & Cosmetic Act (FDCA) Does Not Displace the Concept of Medical Necessity.

The federal government contends that the FDCA has "rejected reliance on the subjective views of individual physicians and patients" to support the use of a new medicine. However, the FDCA was enacted primarily to regulate **commercial transactions** involving medical drugs, as well as food, cosmetics, and medical devices. Its purpose was to protect unwitting consumers from unsafe or ineffective medications. It prohibits, among other things, acts which involve the **interstate** movement of misbranded or adulterated drugs, including those that have not been approved by the FDA for any medical use (and are therefore misbranded). 21 U.S.C. §331(a)-(d).[19]

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[19] Despite the federal government's argument to the contrary, the Court of Appeals' 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 Court of Appeals' 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,** merely desire to be left alone: to be allowed to obtain and use a medication that has been **shown to the satisfaction of their physician to 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

The Act **was never intended to regulate individual consumption of medical drugs, nor does it directly govern the practice of medicine**:

> The FD&CA does not reference the practice of medicine and FDA does not view its mission to include regulation of the practice of medicine. FDA's responsibility is the market introduction of new medical products for particular uses. . . .

Attachment to letter from FDA to Hon. Joseph Barton, Chairman, Subcommittee on Oversight and Investigation, House Committee on Commerce (Apr. 14, 1995). For example, physicians may prescribe, and pharmacists may thereby dispense, drugs "off label," i.e., for "unapproved" or "unlabeled" indications.[20] To be sure, such a

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or ineffectual" for terminal cancer patients. 442 U.S. 557-58, citing *U.S. v. Rutherford*, 582 F.2d 1234, 1236 (10th Cir. 1978). This would clearly have contravened the intent of Congress, which "would 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.* By contrast, the concept of medical necessity, as defined by the Court of Appeals, requires a patient to demonstrate that cannabis is necessary to prevent imminent harm. Therefore, the concept incorporates a definitional protection against ineffective "panaceas." Accordingly, the Court of Appeals' limited ruling on medical necessity in this case cannot be compared to the far-reaching judicial fiat that this Court rightly rejected in *Rutherford*.

[20] 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

drug has received approval from the FDA for some indication. Therefore, the manufacturer has established that the drug is reasonably safe and effective for that indication. However, the fact that the FDA has approved a medication for a particular use does not necessarily mean that the medication is safe for an off-label use or population. An investigational drug is tested within a particular patient population and its benefits and risks are assessed within that population. Its safety profile, and the balance of risks and benefits, may be quite different in another patient group, with different medical problems, different concomitant medications, and different vulnerabilities. Thus, a physician who prescribes a medication off-label often is forced to do so with much more limited information about the safety risks of that medication.

Furthermore, although the FDCA prohibits manufacturers from promoting a drug for an unapproved use,[21] it does not restrict other persons – if they derive no direct commercial interest from the sale or distribution of the product – from making such claims. Indeed, such persons may make claims about a drug or dietary supplement, even if the FDA has never evaluated the drug or dietary supplement for **any** medical indication. The FDA does not question the right of physicians to describe, in a

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marketed device to a patient for any condition or disease within a legitimate health-care-practitioner-patient relationship.

21 U.S.C. §396.

[21] But *see Washington Legal Foundation v. Henney*, No. 99-5304, 2000 WL 122099 (D.C.Cir. Feb. 11, 2000) described in 65 Fed.Reg. 14286 (Mar. 16, 2000) (discussing the extent to which manufacturers may engage in certain promotional activities).

formal educational conference or in a peer-reviewed journal, the case of a patient who obtained benefit from an unapproved use of a drug or from an unapproved drug, and to suggest that the drug may have broader usefulness for that medical condition. As indicated above, the FDA has repeatedly stressed that it does not have jurisdiction over the practice of medicine.

Importantly, the FDCA does not flatly prohibit a physician from prescribing or dispensing an unapproved drug outside of the bounds of an approved investigational drug study. To the contrary, the FDCA explicitly permits a physician, or a pharmacist upon a physician's order, to compound a drug product for an identified patient. Such compounded drug product **is exempt** from the requirements that the FDCA would otherwise impose on a "new drug," i.e., only after FDA approval of an investigational new drug (IND) for a particular research project or of a new drug application (NDA) for commercial marketing. 21 U.S.C. §353a.

In short, such provisions indicate that Congress recognized that there will be instances wherein a particular patient's needs can and must be addressed outside of the confines of the new drug approval process. Therefore, contrary to the federal government's contention, the FDCA has "windows" that are wide enough to accommodate the concept of medical necessity.

D. The Court of Appeals' Ruling Does Not Conflict With the Recent Congressional Declaration Opposing State Medicinal Cannabis Legislation.

The federal government contends that a medical necessity exception to the CSA conflicts with the recent congressional legislation opposing the legalization of medicinal cannabis outside the procedures established by the FDCA. Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761. However, there is nothing in that legislation that reflects a congressional intent to abrogate the well-established common law doctrine of necessity. Similarly, there is no evidence that, in enacting that statement, Congress sought to place narrow limits on a court's equitable power to formulate appropriate injunctive relief in a particular case.

As the federal government correctly states, that declaration was prompted by state initiatives around the country to decriminalize cannabis for medicinal uses. Many of these initiatives have an extremely broad reach and authorize the use of medical marijuana for a wide variety of medical conditions. For example, Proposition 215, the California initiative, authorizes a patient, with the approval or recommendation of his or her physician, to possess and cultivate cannabis for medical use if the patient has any of the following conditions: "cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or ***any other illness for which marijuana provides relief.***" Cal. Health & Safety Code §11362.5(b)(1)(A) (emphasis added).

The scope of such an initiative bears no resemblance to the doctrine of necessity. There is no requirement that the patient has failed on, or even tried, other standard therapies. There is no requirement that the patient's condition be serious or debilitating. There is no requirement that cannabis must be necessary for the effective treatment of that condition. In short, such initiatives do potentially impinge upon federal regulatory concerns.[22] The congressional concern articulated in the declaration targets that situation.

However, by contrast, the medical necessity doctrine is sharply confined. Only those patients who have tried all other standard therapies, who have a serious medical condition, and who will suffer imminent harm if they are not able to use cannabis, will fall within it. The congressional legislation did not address this narrow category of desperate patients, nor did it seek to prevent a court, acting in equity, from considering the plight of such patients when assessing the public interest.

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[22] For this reason, CMA opposed Proposition 215.

E. 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 or 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 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 many 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 cannabis, nor that patients had benefited 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.***

Based on new scientific evidence, Mr. Jon Gettman filed a cannabis rescheduling petition on July 10, 1995. In 1997, his petition was forwarded by the DEA to the Department of Health and Human Services (HHS) for a scientific and medical review and scheduling recommendation. Brief for the Petitioner at p. 24 n.12. Mr. Gettman is still awaiting a response from HHS. After **almost six**

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 a prolonged and onerous process. Indeed, the federal government's suggestion that dying patients, and those attempting to assist them, should petition the government to reschedule marijuana ignores the fact 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).

Patients will suffer unspeakably and perhaps die before the "legal alternative," i.e., a petition seeking the rescheduling of cannabis, will be finally resolved. Under no stretch of the imagination can such a "legal alternative" be considered reasonable.

CONCLUSION

The Court of Appeals' ruling on medical necessity comports fully with the practice of medicine and good patient care, is well-established in the common law, and is consistent with federal statutory law. Accordingly, for the foregoing reasons, *amici* urge this Court to uphold that ruling.

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Respectfully submitted,

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