No. 00-16411
(Related Case Nos. 98-16950, 98-17044, 98-17137, 99-15838, 99-15844, and 99-15879)

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,

Defendants-Appellees.

Appeal from Order Modifying Injunction by the United States District Court for the Northern District of California
Case No. C 98-00088 CRB
entered on July 17, 2000, by Judge Charles R. Breyer.

APPELLEES' ANSWERING BRIEF ON THE MERITS

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CORPORATE DISCLOSURE STATEMENT

Oakland Cannabis Buyers' Cooperative ("OCBC") submits the following Corporate Disclosure Statement as required by Federal Rule of Appellate Procedure 26.1.

OCBC, a California corporation, has no parent companies, subsidiaries, or affiliates.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed.R.App.P. 32(a)(5)(B), Respondents hereby certify that this Brief is prepared in proportionately spaced 14-point Times New Roman typeface.

The Brief, excluding this certificate of compliance, the cover page, the table of contents, the table of authorities, the statement of related cases, the corporate disclosure statement, and the proof of service, contains 14,824 words, which exceeds the 14,000-word limit of Fed.R.App.P. 32(a)(7)(B). Concurrently with this brief, Respondents have filed a motion for leave to file a brief exceeding the applicable type volume limitation pursuant to Ninth Circuit Rule 32-2.

STATEMENT OF RELATED CASES

Pursuant to Circuit Rule 28-2.6 ("The appellee need not include any case identified as related in the appellant's brief."), Appellees state that there are no related cases other than those identified in the Statement of Related Cases contained in the Appellant's brief.

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INTRODUCTION

Appellees Oakland Cannabis Buyers' Cooperative ("OCBC") and Jeffrey Jones (collectively "Appellees") submit this brief in response to the government's Opening Brief on appeal. For many months Appellees have been unable to provide medicine to sick and dying patients. During that time, these patients were deprived of the only safe means, authorized by state and local law, of obtaining medicine that their physicians have deemed necessary to their very survival. During that time, some patients died and others lived in severe pain with chronic, debilitating, and life-threatening illnesses. In a previous appeal in this matter ("*OCBC I*"), this Court directed that the district court consider and protect the rights and interests of these patients. The district court issued an order that faithfully adheres to that directive. Justice and fairness now require that this Court continue to protect the rights of these fragile individuals.

The government's appeal is without merit. The government does not dispute that there are seriously ill patients for whom cannabis provides the only effective relief. Nor does the government challenge the evidence establishing that cannabis is a safe and effective medicine. The government also fails to present any legal argument that would justify a reversal of the district court's order. Instead, the government merely rehashes legal arguments that this Court previously and properly rejected. Because *OCBC I* correctly applied controlling authority and because, consistent with that ruling, the district court properly exercised its equitable discretion to modify the injunction, the district court's order should be affirmed.

STATEMENT OF ISSUES

Whether the district court abused its discretion in amending the preliminary injunction order to permit distribution of cannabis for medical purposes to

seriously ill patients who meet the legal criteria for medical necessity derived from *United States v. Aguilar*, 883 F.2d 662, 692-694 (9th Cir. 1989), when:

(1) The Controlled Substances Act (the "CSA") does not abrogate a defense of medical necessity;

(2) The CSA does not divest the district court of equitable jurisdiction to fashion an injunction to protect the rights of seriously ill patients; and

(3) Appellees met the legal standard for modification of the injunction.

STANDARD OF REVIEW

The *only* issue before this Court is whether the district court erred when it modified the preliminary injunction. "A district court's order regarding preliminary injunctive relief is subject to limited review." *United States v. Nutri-Cology, Inc.*, 982 F.2d 394, 397 (9th Cir. 1992); *see also California Prolife Council Political Action Comm. v. Scully*, 164 F.3d 1189, 1190 (9th Cir. 1999) ("When reviewing the grant of a preliminary injunction, our inquiry is narrow."). An order granting, denying, or modifying a preliminary injunction will be set aside only if the appellant proves that the district court abused its discretion. *Roe v. Anderson*, 134 F.3d 1400, 1402 (9th Cir. 1998). To establish an abuse of discretion, the appellant must show that the district court "based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence," *Roe*, 134 F.3d at 1402 (quoting *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990)) or that its findings of fact were clearly erroneous. *Senate of Cal. v. Mosbacher*, 968 F.2d 974, 975 (9th Cir. 1992).

The government does not challenge the district court's express or implied findings of fact. Nor does the government challenge this Court's finding in *United States v. Oakland Cannabis Buyers' Coop.*, 190 F.3d 1109 (9th Cir. 1999) ("*OCBC I*") that Appellees have introduced sufficient evidence of irreparable injury "to justify the requested modification." (Gov't. Br. at 10, n.4.) To the

contrary, the government admits that it "did not introduce any evidence" to rebut Appellees' showing of irreparable injury upon remand. (*Id.*) Finally, the government concedes that the district court correctly applied the law that directly controlled its analysis: this Court's decision in *OCBC I.* (Gov't. Br. at 12.)

The government's *only* contention in this appeal is that this Court wrongly decided *OCBC I* because this Court held that medical necessity is a defense in a civil injunctive action under 21 U.S.C. § 882(a). The government candidly states that "[i]f the panel does not choose to reconsider" this aspect of *OCBC I*, the government "agree[s] that this Court's [*OCBC I*] decision supports affirmance." (Gov't. Br. at 13.)

The government also concedes that this Court's decision in *OCBC I* is the law of the case. (*Id.* at 12.) A three-judge panel may depart from the law of the case established in a prior three-judge panel's decision only if the party urging the departure shows that "[1] there has been an intervening change of controlling authority, [2] new evidence has surfaced, or [3] the previous disposition was clearly erroneous and would work a manifest injustice." *Leslie Salt Co. v. United States*, 55 F.3d 1388, 1393 (9th Cir.), *cert. denied sub nom., Cargill, Inc. v. United States*, 516 U.S. 955 (1995).

The government does not contend that new evidence or an intervening change in the law justify a departure from the law of this case. Nor could the government seriously make such an argument: it offered no evidence *at all* in the district court, much less "new evidence," and *all* of the authority it cites in its Opening Brief in this Court existed and was or could have been cited in its brief in *OCBC I.*

Accordingly, the government must show that *OCBC I* was "clearly erroneous and would work a manifest injustice." *Leslie Salt Co.*, 55 F.3d at 1393. The government has not and cannot make either showing. To the contrary, there

would be a "manifest injustice" only if this Court were to depart from *OCBC I* and order reinstatement of the broad preliminary injunction in this case. Such a result would be manifestly unjust because it would deny seriously ill and dying patients access to treatment they so desperately need.

FACTUAL AND PROCEDURAL BACKGROUND

I. THE GOVERNMENT'S EFFORTS TO BLOCK PROPOSITION 215

In November 1996, the voters of California passed Proposition 215, the Compassionate Use Act of 1996 ("The Act"). Cal. Health & Safety Code § 11362.5. "The Act makes it legal under California law for seriously ill patients and their primary caregivers to possess and cultivate marijuana for use by the seriously ill patient if the patient's physician recommends such treatment. In particular, it exempts a seriously ill patient, or the patient's primary caregiver, from prosecution . . . relating to the possession of marijuana and . . . the cultivation of marijuana." *United States v. Cannabis Cultivators' Club*, 5 F. Supp. 2d 1086, 1091 (N.D. Cal. 1998); *Speeches From the 1999 HWLJ Symposium: The Criminalization of Medicinal Marijuana*, 11 Hastings Women's L.J. 75 (2000). Pursuant to California law, OCBC, a not-for-profit organization, was established to meet the needs of seriously ill patients. The OCBC's goal is to provide seriously ill patients with safe access to necessary medicine so that these individuals do not have to resort to the streets, thereby exposing themselves to criminal elements and products of dubious quality. (SER 88-89, 222-263.)[1] Pursuant to state law, the City of Oakland also established a medical cannabis distribution program and designated OCBC as the City's agent to administer the program. (SER 25-72.) OCBC is a well run, professional organization that has served the medical needs of

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[1] As used in this Brief, "ER" refers to the government's excerpts of record, and "SER" refers to OCBC's supplemental excerpts of record.

seriously ill patients and has worked with law enforcement to ensure that those with legitimate medical needs may obtain cannabis safely, and without fear of criminal prosecution.

Despite the fact that the voters of California have spoken, the federal government moved to block Appellees' distribution of medicinal cannabis to those suffering from severe illnesses. In January 1998, it filed six civil suits for injunctive relief under 21 U.S.C. § 882(a), a rarely used statute that, according to the district court (Hon. Charles R. Breyer), has been used in only five published decisions since Congress enacted it in 1970. *Cannabis Cultivators' Club*, 5 F. Supp. 2d at 1104. However, the government has never attempted to prosecute Appellees criminally under the federal drug laws.

In May 1998, the district court granted the government's request for a preliminary injunction. *Id.* at 1106. On October 15, 1998, Appellees requested that the district court modify the injunction to allow distribution of cannabis to patients who meet the legal test of medical necessity derived from *United States v. Aguilar*, 883 F.2d 662 (9th Cir. 1989). Apparently relying on the government's position that necessity is not a legal defense under the CSA, the district court summarily denied the requested modification on October 16, 1998. The district court thus authorized the closure of OCBC as of October 19, 1998.

Recognizing the danger to public health and safety posed by the closure of OCBC, on October 27, 1998, the Oakland City Council issued Resolution No. 74618 declaring a Local Public Health Emergency with Respect to Safe, Affordable Access to Medical Cannabis in the City of Oakland. (SER 25-72.) The Resolution found that closure of OCBC "impairs public safety. . . ." and that "[OCBC's] . . . closure . . . will cause pain and suffering to seriously ill Oakland residents. . . ." (SER 71.) The Resolution declares a public health emergency and urges the federal government to cease actions "that pose obstacles to access to

cannabis for Oakland residents. . . ." *Id.* The City of Oakland has since renewed this resolution every two weeks. *Id.*

II. THIS COURT'S DECISION IN *OCBC I*

On September 13, 1999, this Court issued an opinion in this case explicitly recognizing that seriously ill patients who meet the legal definition of medical necessity legally could obtain medical cannabis for their illnesses in these injunctive proceedings. *OCBC I,* 190 F.3d 1109 (9th Cir. 1999). In so doing, this Court expressly confirmed that the sweeping prohibition against any distribution of cannabis sought by the government must be rejected and instead that any injunction in this case must safeguard the medical needs of seriously ill people who require cannabis to survive. *Id.* at 1113-1114. This Court reversed the district court's order summarily denying Appellees' request to modify the injunction to permit distribution to patient-members with a medical necessity, and directed that the district court reconsider its decision. *Id.* at 1115.

Specifically, this Court observed:

> The district court summarily denied OCBC's motion, saying that it lacked the power to make the requested modification because "its equitable powers do not permit it to ignore federal law." In doing so, the district court misapprehended the issue. The court was not being asked to ignore the law. It was being asked to take into account a legally cognizable defense that likely would pertain in the circumstances.

190 F.3d at 1114-1115.

This Court also held that the district court erroneously failed to weigh the public interest when it summarily denied the requested modification:

> The district court erred in another respect as well. In deciding whether to issue an injunction in which the public interest would be affected, or whether to modify such an injunction once issued, a district court *must* expressly consider the public interest on the record. The failure to do so constitutes an abuse of discretion . . . .

Id. at 1114 (*emphasis added*).

Finally, this Court expressly determined that Appellees had presented sufficient evidence to justify the requested modification:

> OCBC has identified a strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses. Indeed, the City of Oakland has declared a public health emergency in response to the district court's refusal to grant the modification under appeal here . . . .
>
> We have no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion. *The evidence in the record is sufficient to justify the requested modification.*

Id. at 1114-1115 (*emphasis added*).

This Court has since rejected the government's petition for rehearing and rehearing en banc, and the mandate issued in March 2000. The government has sought review of *OCBC I* in the United States Supreme Court.

III. THE DISTRICT COURT PROCEEDINGS ON REMAND

On remand, Appellees renewed their motion to modify, and submitted additional evidence establishing that the preliminary injunction should be modified to allow patients who satisfy the legal criteria for necessity to obtain medical cannabis. Appellees submitted declarations from OCBC's patient-members, all of which satisfy the criteria for medical necessity. (*See* SER 92-189, 208-220, 476-477, 485-494, 499-587.) Appellees also submitted the declarations of Dr. Michael Alcalay, OCBC's Medical Director, Lauri Galli, an OCBC Staff Nurse, and James McClelland, OCBC's Chief Financial Officer, which confirmed the medical necessity of certain patient-members. (SER 193-207, 222-263, 383-470.)

Appellees' evidence satisfied each criterion for medical necessity. First, the evidence established that these patient-members are faced with a choice of evils. Certain patient-members suffer from debilitating and deadly diseases such as cancer. (SER 96-106, 118-120, 132-134, 151-155, 175-176, 508-509, 568-569.)

Others suffer from HIV/AIDS. (SER 108-110, 125-127, 144-146, 168-169, 568-569, 586-589.) Still others suffer from devastating chronic conditions that cause paralysis, severe physical impairments, and unbearable pain. (SER 92-94, 112-116, 148-149, 157-158, 178-179.)

Second, Appellees' evidence established that these patient-members need cannabis to avert severe pain, blindness and life-threatening harm. (E.g., SER 132-134, 216-220.) As one patient-member, Willie Beal, a 71-year old cancer patient, put it: "I would die, I would simply die . . . I'm trying to live from day to day. [Cannabis] is helping me make it." (SER 101.) Mr. Beal has since died. (SER 89.)

Finally, Appellees' evidence established that for certain patient-members there are no legal or safe alternatives to medical cannabis. Other medications are ineffective or cause intolerable side effects. (*See, e.g.*, SER 103, 112-113, 115-116, 129-134.)

During the course of these proceedings, many patients died. (SER 89.) For these people, even if cannabis could not have prevented their deaths, having safe, legal access to cannabis may have ameliorated their suffering in their final days. *Id.*

The government submitted no evidence in opposition, nor did it challenge Appellees' evidentiary showing. Instead, the government chose to rely upon the arguments previously rejected by this Court. Accordingly, the district court rejected the government's arguments and modified the injunction. (ER 41-45.)

The government then moved the district court for a stay, which the district court denied, concluding that the government had shown neither a likelihood of success on the merits, nor irreparable harm. (ER 46-47.) Specifically, the district court found that "the record in this case indicates that a stay would impose more

significant hardship on [Appellees] and their clients than it would on the government itself." (SER 47.)[2]

ARGUMENT

I. THE CSA DOES NOT FORECLOSE THE DEFENSE OF MEDICAL NECESSITY

A. The Necessity Defense Is Well-Established In Anglo-American Jurisprudence And Cannot Be Abrogated Absent A Clear Intention By Congress to Do So.

The government points to no explicit expression of an intent by Congress to eliminate a well-recognized defense — necessity — from the CSA. Necessity is one of the oldest and most well-entrenched common law defenses in Anglo-American jurisprudence whose roots can be traced to the mid-Thirteenth Century in England, and earlier on the Continent. *See* Reeve, *Necessity: The Right To Present a Recognized Defense*, 21 New Eng. L. Rev. 779, 781-784 (1985-86); Conde, *Necessity Defined: A New Role in the Criminal Defense System*, 29 U.C.L.A. L. Rev. 409 (1981); Arnolds & Garland, *The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil*, 65 J. Crim. L. & Criminology 289 (1974). "The defense, which we have inherited from early English common law, posits that '[a] man may break the words of the law, and yet not break the law itself ... where the words of [the law] are broken ... through necessity." *United States v. Dorell*, 758 F.2d 427, 436 (9th Cir. 1985) (Fergusen, J., concurring) (quoting *Reninger v. Fagossa*, 1 Plowd. 1, 75 Eng. Rep. 1 (1551)).

Contrary to the government's contention, recognition of a necessity defense does not undermine the rule of law. "[T]he necessity defense proclaims legal some

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[2] Despite this Court's subsequent decision to deny the government's stay request, on August 29, 2000 the Supreme Court agreed to stay the district court's modification of the preliminary injunction pending disposition of this appeal. *United States v. Oakland Cannabis Buyers' Cooperative*, 69 U.S.L.W. 3165, 2000 U.S. LEXIS 4832 (No. 00-A151, Aug. 29, 2000).

conduct which, in other contexts, would plainly be illegal.... *The defense is not aimed at subverting existing laws or at hastening their demise. Rather, the defense simply recognizes that, in certain circumstances, the choice made by the defendant is a choice that society would also have made and now is given the opportunity to ratify.*" *United States v. Dorell*, 758 F.2d at 436 (Fergusen, J., concurring) (emphasis added).

The common law justification of necessity also implicates a significant moral judgment about criminal culpability. An accused who faces a dilemma of either obeying the law and enduring an evil consequence that is even greater than the violation of the law, or violating the law and avoiding the evil consequence, is not morally culpable when he chooses to violate the law. He has done what any rational, ethical human being would do under the circumstances, and no rational purpose of the criminal law is served by punishing him.

While the justification of necessity is frequently analyzed in consequentialist terms, calling for a utilitarian "balancing" of the "harms," there is an underlying equation of moral culpability that must be assessed. In the seminal case of *The Queen v. Dudley and Stephens,* 14 Q.B.D. 273 (1884), for example, the court explicitly upheld a moral conception of necessity that would forbid taking a life to save one's own, warning that "the absolute divorce of law from morality would be of fatal consequence." *Id.* at 297. The court considered the fact that the defendants, trapped in a life-boat, took one life to save three. But its conception of the greater good for society was based on more than just balancing the number of lives at issue; it rested (at least in part) on a moral judgment of appropriate conduct.

This insight also emerged in the concurring opinion of Judge Fernandez in *United States v. Schoon,* 971 F.2d 193, 200 (9th Cir. 1992): "I am not so sure that this defense of justification should be grounded on utilitarian theory alone rather

than on a concept of what is right and proper conduct under the circumstances." Many eminent legal scholars and commentators have voiced the same concern.[3]

This conception of necessity suggests that a jury has a crucial role to play, as the conscience of the community, in assessing a defendant's claim of justification. The crucial role of the jury, in turn, suggests that courts should approach with grave caution the argument that a legislature has foreclosed a necessity justification by making its own balance of competing values. The legislative judgment cannot accommodate all of the factual variables that might affect a moral judgment of "what is right and proper conduct under the circumstances." Sir James Fitzjames Stephens tellingly makes the point:

> "[I]t is just possible to imagine cases in which the expediency of breaking the law is so overwhelmingly great that people may be justified in breaking it, but these cases cannot be defined beforehand, and must be adjudicated upon by a jury afterwards . . . . I see no good in trying to make the law more definite than this, and there would I think be danger in attempting to do so."

2 Sir James Fitzjames Stephen, *A History of the Criminal Law of England*, pp. 109-110 (1883).

The Model Penal Code, in its formulation of the necessity justification, suggests caution in concluding the defense is legislatively foreclosed in its requirement that a legislative purpose to exclude the justification "plainly appear." Model Penal Code, §3.02(1)(c). Even Professor LaFave, a leading proponent of the utilitarian approach, emphasizes that courts must be free to consider the relative merits of a necessity claim when a statute is silent upon the matter. LaFave, *Criminal Law*, § 5.4 at 478 (3rd Ed. 2000).

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[3] George P. Fletcher, *Rethinking Criminal Law*, § 10.2. at 792-93 (1978); Jerome Hall, *General Principles of Criminal Law*, p. 419 & n.16 (2d Ed. 1960); John T. Parry, "*The Virtue of Necessity: Reshaping Culpability and the Rule of Law*," 36 Houston L. Rev. 397 (1999).

Courts should be particularly reluctant to assume the legislature has foreclosed the justification of necessity when, as in this case, the justification arises in the context of an individual's assertion of a constitutionally protected right.[4] In *Cross v. State,* 370 P.2d 371 (Wyo. 1962), for example, the Wyoming legislature had enacted a comprehensive game law for the protection of wild animals, enumerating those circumstances in which animals could be killed. It omitted the right to kill animals in the protection of one's property. The state argued that no further exceptions could be permitted under the guise of the necessity justification. The court, in upholding the claim of necessity, responded, "[i]f it is true that the legislature intended that the constitutional rights of persons could not be asserted in this connection, then it clearly exceeded its authority." *Id.* at 374.

Where the constitutional right at stake is the individual's constitutionally protected autonomy with regard to his own health decisions, a claim of necessity must rank especially high. In this respect, "medical necessity" is not a hybrid off-shoot of the necessity doctrine, but a manifestation of the core values of the necessity doctrine in its most exalted form.

Indeed, in the context of medical cannabis, the District of Columbia court carefully noted the constitutional protection given to an individual's personal health decisions in upholding Robert Randall's claim of necessity to justify the use of cannabis to save his sight from the ravages of glaucoma:

> "[A] law which apparently requires an individual to submit to deteriorating health without proof of a significant public interest to be protected raises questions of constitutional dimension."

United States v. Randall, 104 Daily Wash. L. Rep. 2249, 2253 n.29 (D.C. Super. 1976).

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[4] As discussed in Section III, *infra*, Appellees have asserted, among other things, a fundamental right to be free from pain, to control the medical treatment they receive in consultation with their physicians, and to save their lives.

Which of us, with a mother or sister confronting the ravages of cancer, experiencing gut-wrenching nausea while undergoing chemotherapy, would hesitate to find a friend who could supply some cannabis so she could eat again? In a 1991 survey of oncologists, nearly half indicated they would prescribe cannabis to relieve chemotherapy side effects if the drug were legal. *Annals of Internal Medicine*, May 1, 1991. Would we reject this alternative, because cannabis remains on Schedule I of the CSA? The government cannot seriously argue that Congress *thought* about our dilemma in 1970 when it placed cannabis on Schedule I, and made a deliberate value choice that the majesty of the federal law outweighs the pain and suffering of our mother or sister. The common law defense of medical necessity allows the assessment of the moral culpability of these choices to rest in the hands and hearts of an American jury. That is where it belongs, and nothing Congress has said or done remotely suggests that Congress would have it any other way.

B. The CSA Does Not Evidence Any Intent To Abrogate A Necessity Defense.

Nothing in the text or legislative history of the CSA evidences any intent to abrogate a medical necessity defense. Congress had no information upon which to make any judgment about the medical necessity of cannabis when it enacted the CSA in 1970. Act of Oct. 14, 1970, Pub. L. No. 91-513, 84 Stat. 1236, codified as amended at 21 U.S.C. §§ 801 *et seq.* Congress itself admitted that it did not have a firm understanding of cannabis. Months before it enacted the CSA, Congress enacted the Marihuana and Health Reporting Act, Pub. L. No. 91-296, §§ 501-503, 1970 U.S.C.C.A.N. 418, which directed the Secretary of the Department of Health, Education, and Welfare ("HEW") to prepare a report within 90 days and annually thereafter, "containing current information on the health consequences of using marihuana" and "containing such recommendations for legislative and

administrative action as he may deem appropriate." *Id.* Congress ordered this report because it had found that "notwithstanding the various studies carried out, and research engaged in, with respect to the use of marihuana, there is a lack of an authoritative source for obtaining information involving the health consequences of using marihuana." *Id.*

On August 14, 1970, during the debates on the CSA but before the report was to be completed, HEW advised Congress as follows:

> Some question has been raised whether the use of the plant itself produces "severe psychological or physical dependence" as required by a schedule I or even a schedule II criterion. Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marihuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue.

H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. at 4579 & 4629. Congress also received a list of "facts" and "fables" about cannabis from the Director of the National Institute of Mental Health, which included the fact that cannabis is not physically addictive, and that cannabis does not necessarily lead to violence or the use of other drugs. *Id.* at 4577-78.

Congress acknowledged this debate and its own uncertainty, stating: "The extent to which marihuana should be controlled is a subject upon which opinions diverge widely." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4577. On the one hand, Congress tentatively placed marihuana on Schedule I, which includes substances that have "a high potential for abuse," "no currently accepted medical use in treatment in the United States, and for which "[t]here is a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b)(1) & (c), Schedule 1(c). But, to resolve the uncertainty about whether cannabis belongs on Schedule I, Congress created the bipartisan Commission on Marihuana and Drug Abuse (the "Shafer Commission"),

and directed it to prepare a report to guide Congress. *Id.*; *see* Act of Oct. 14, 1970, Pub. L. No. 91-513, § 601, 1970 U.S.C.C.A.N. (84 Stat.) 1489-90. The Shafer Commission included two members of the House, two members of the Senate, and nine presidential appointees. *Id.* The report was to include, among other things, a study of "the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological" as part of a "comprehensive report" that included "proposals for legislation and administrative action as may be necessary to carry out its recommendations." Act of Oct. 14, 1970, Pub. L. No. 91-513, § 601(d)(1)(C) & (2), 1970 U.S.C.C.A.N. (84 Stat.) 1490; see H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4579 & 4588 (recommendation of the Katzenbach Commission that the National Institute of Mental Health "devise and execute a plan of research, to be carried on both on an intramural and extramural basis, covering all aspects of marihuana use") & 4626 (stating the purpose of § 601). The corresponding Senate Bill (S. 3246) also proposed to create a "Committee of Marihuana" to "identif[y] existing gaps in our knowledge of marihuana," "examin[e] the important medical and social aspects of marihuana use," and "stud[y] the pharmacological effects of marihuana." S. Rep. No. 91-613, at 10 & 34 (1969).

The Shafer Commission recommended that Congress amend the CSA, and that the states amend their laws, so that possession of cannabis for personal use would not subject the possessor to punishment, even as a misdemeanor, and "casual distribution of small amounts of marihuana for no remuneration, or insignificant remuneration not involving profit would no longer be an offense." *Marihuana: A Signal of Misunderstanding; First Report of the National Commission on Marihuana and Drug Abuse*, 152-153 (1972) (*OCBC I* ER at

475.)[5] The Report also stated that not enough was known about the medical benefits of cannabis and recommended further study:

> Historical references have been noted throughout the literature referring to the use of cannabis products as therapeutically useful agents. Of particular significance for current research with controlled quality, quantity and therapeutic settings, would be investigations into the treatment of glaucoma, migraine, alcoholism and terminal cancer. The NIMH-FDA Psychotomimetic Advisory Committee's authorization of studies designed to explore the therapeutic uses of marihuana is commended.

Id. at 176; *OCBC I* ER at 583.

Absent some unambiguous statement by Congress that it intended to eliminate medical necessity as a defense, the CSA, a criminal statute, cannot be read to preclude that defense in *all* circumstances. *See United States v. Granderson*, 511 U.S. 39, 49 (1994) (the Government cannot rely on general statements that Congress intended to "get tough on drug offenders"; instead, the Government must point to specific evidence that Congress expressed intent on the narrow issue in question); *United States v. Lewis*, 67 F.3d 225, 232, n.11 (9th Cir. 1995) ("Faced with a statute susceptible to two rational interpretations, the rule of lenity requires that we choose the harsher interpretation 'only when Congress has spoken in clear and definite language.'"), quoting *McNally v. United States*, 483 U.S. 350, 359-60 (1987). The CSA is, at best, silent regarding application of the medical necessity defense in cases involving the medical use of cannabis.

The CSA must be interpreted using the "ancient rule of statutory construction that penal statutes should be strictly construed against the government ... and in favor of the persons on whom the penalties are sought to be imposed." 3 Sutherland Stat. Const. § 59.03, p. 102 (5th ed.). A corollary to this "ancient

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[5] "*OCBC I* ER" refers to OCBC's excerpts of record filed in *OCBC I*. *See* Request for Judicial Notice, filed herewith.

rule" is that when, as in this case, the "text, structure, and history fail to establish that the Government's position is unambiguously correct--[courts] apply the rule of lenity and resolve the ambiguity in [the defendant's] favor." *Granderson*, 511 U.S. at 54; *see also People v. Materne*, 72 F.3d 103, 106 (9th Cir. 1995) ("[T]he rule of lenity applies where a criminal statute is vague enough to deem both the defendant's and the government's interpretations of it as reasonable. Only where the defendant's interpretation is unreasonable does the rule of lenity not apply.")

By arguing that the otherwise universally applicable common law defense of necessity is unavailable in criminal prosecutions under the CSA, the government argues, in effect, that the scope of proscribed conduct under the CSA is broader than under all other criminal statutes. *See, e.g., People v. Tippett*, 56 Cal.App.4th 1532, 1538 (1997) ("The [necessity] defense may be available where a defendant is charged with committing any criminal act except the taking of an innocent human life."); *People v. Pena*, 149 Cal.App.3d Supp. 14, 17, n. 2 & 22 (1983). If a specific criminal statute proscribes more conduct than the criminal laws generally proscribe, however, citizens are entitled to clear notice of that fact. *See, e.g., Crandon v. United States*, 494 U.S. 152, 158 (1990) (The rule of lenity is a "'time-honored interpretive guideline' [that] serves to ensure both that there is fair warning of the boundaries of criminal conduct and that legislatures, not courts, define criminal liability."); *United States v. Apex Oil Co.*, 132 F.3d 1287, 1291 (9th Cir. 1997) (applying the rule of lenity and dismissing a criminal charge "[i]n the face of uncertainty as to the meaning of what is forbidden" by the regulation allegedly violated); *United States v. Nguyen*, 73 F.3d 887, 891 (9th Cir. 1995) ("Application of the rule of lenity ensures that criminal statutes will provide fair warning concerning conduct rendered illegal and strikes the appropriate balance between the legislature, the prosecutor, and the court in defining criminal liability."), quoting *Liparota v. United States*, 471 U.S. 419, 427 (1985).

The notice that a criminal statute is broader than others generally must appear in the text of the statute. If the text is silent or ambiguous, a finding of Congressional intent to abrogate a universally applicable defense should not be based solely on the statute's legislative history. "Because construction of a criminal statute must be guided by the need for fair warning, it is rare that legislative history or statutory policies will support a construction of a statute broader than that clearly warranted by the text." *Crandon*, 494 U.S. at 160; *see also American Rivers v. Federal Energy Regulatory Comm'n*, 201 F.3d 1186, 1204 (9th Cir. 2000) ("[T]his Court steadfastly abides by the principle that 'legislative history-no matter how clear-can't override statutory text.'").

In this case, there is nothing in the text of the CSA that places average citizens on notice that Congress supposedly intended to abrogate the ancient, universally applicable common law defense of necessity. Accordingly, neither the recognition of the defense in *OCBC I* nor the district court's modification of the injunction to exempt those with a medical necessity was erroneous.

C. The "Sense of Congress" Does Not Abrogate the Medical Necessity Defense.

Having failed to credibly argue that either the text or legislative history of the CSA foreclose a medical necessity defense, the government next relies on a "Sense of Congress" provision buried in the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. 105-277, 112 Stat. 2681-760 to 2681-761, enacted almost 30 years *after* the CSA to support its interpretation of what Congress intended when it enacted the original CSA in 1970.

For several reasons the government's reliance on this "Sense of Congress" is misplaced. First, in *Yang v. California Dept. of Soc. Servs.*, 183 F.3d 953, 961-962 (9th Cir. 1999), this Court held that a similar "sense of Congress" provision buried in a budget act was merely "non-binding, legislative dicta." *See also id.* at 958,

citing *Monahan v. Dorchester Counseling Ctr., Inc.*, 961 F.2d 987, 994-95 (1st Cir. 1992) ("sense of Congress" provision was "merely precatory" and "create[d] no enforceable federal rights"); *Trojan Technologies, Inc. v. Pennsylvania*, 916 F.2d 903, 909 (3rd Cir. 1990) ("sense of Congress" provision was only "persuasive," not "mandatory"); *Carriage of Agric. Prod. in U.S. Vessels*, 37 U.S. Op. Atty. Gen. 546, 548 (1934) ("sense of Congress" provision provided "guidance" but was not "mandatory"). This Court also noted that "[s]everal Supreme Court cases indirectly support the principle that sense of Congress resolutions do not have the force of law," citing *Boos v. Barry*, 485 U.S. 312, 327-28 (1988) and *Lyng v. Northwest Indian Cemetery Protective Ass'n*, 485 U.S. 439, 455 (1988) as examples. *Yang*, 183 F.3d at 958, n.3. There is no reason for this Court to give the "Sense of Congress" that the government now cites any more weight than the "Sense of Congress" at issue in *Yang*.

Moreover, the "Sense of Congress" does not purport to amend the CSA, expressly or by implication. The plain language of the "Sense of Congress" merely reaffirms that cannabis can be moved from Schedule I and thus legalized for medicinal use by the general public *only* through the administrative process set out in the CSA. Because neither this Court nor the district court purported to move cannabis from Schedule I of the CSA to some other schedule or generally to legalize medicinal cannabis *across the board* for *all* people under *all* circumstances, the "Sense of Congress" has no bearing on the issues before this Court. Finally, the "Sense of Congress" does not specifically mention the common law defense of medical necessity. In the absence of an unambiguous statement of an intent to foreclose that defense under the CSA, it must be presumed that the defense remains available. The "Sense of Congress" clearly does not provide any notice to the average citizen that such a defense is now unavailable under the CSA. *See Crandon*, 494 U.S. at 160.

D. Recognition of a Defense of Medical Necessity for Cannabis Use Is Not Inconsistent with the Classification of Marijuana on Schedule I of the CSA.

Under Section 812(b)(1) of the CSA, substances may be classified on Schedule I for the following reasons: (1) the substance has a high potential for abuse; (2) the substance has no accepted medical use in treatment in the United States; and (3) there is a lack of accepted safety for use in treatment of the substance under medical supervision. The government argues that because a Schedule I drug by definition has "no currently accepted medical use," any justification for use asserted on the basis of "medical necessity" could not have been within legislative contemplation. This argument necessarily presumes that the terms "accepted medical use in treatment" and "medical necessity" are equivalent expressions and have exactly the same meaning. These concepts plainly serve different purposes, however. While "medical necessity" focuses on the urgent needs of a specific patient, the term "accepted medical use in treatment" clearly is intended to apply to use by the general public as a whole. Accordingly, there is no reason to conclude that the Schedule I classification has any bearing on the availability of a medical necessity exception.

The validity of the government's position turns on what Congress meant by the phrase "accepted medical use in treatment" in defining Schedule I controlled substances. In construing the term, first resort should be to the plain meaning of the words used. *Caminetti v. United States*, 242 U.S. 470, 485 (1917). The words used suggest that a medical use is one that is generally accepted by the medical community. Initially, the Drug Enforcement Administration required that a drug with "currently accepted medical use in treatment in the United States" must have first received NDA-approval from the Food and Drug Administration. 51 Fed. Reg. 36,552 (1986). This standard was rejected as "disingenuous" by a unanimous

panel of the U.S. Court of Appeals for the First Circuit. *Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881, 888 (1st Cir. 1987).

In *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration*, 15 F.3d 1131 (D.C. Cir. 1994), the court upheld a new five-part test formulated by the DEA to determine whether a drug is in "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;

(5) The scientific evidence must be widely available.

Id. at 1135, citing 57 Fed. Reg. at 10,506. These guidelines are intended to scrutinize a drug for use by the *general public*. The legal standard for medical necessity is quite different, however.[6] *OCBC I*, 190 F.3d at 1115. The medical necessity test applies to a *particular patient*, and provides a safety valve for a person who must act to prevent a greater harm. Thus, the two standards have no impact on each other.

The legislative history of the CSA confirms the importance to be attached to the opinions of qualified medical experts. During hearings before the House Subcommittee on Foreign and Interstate Commerce, representatives of

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[6] It requires a showing by:

> [1] people with serious medical conditions [2] for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; [3] who will suffer serious harm if they are denied cannabis; and [4] for whom there is 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.

OCBC I, 190 F.3d at 115.

pharmaceutical companies and medical researchers voiced concern that the Federal Bureau of Narcotics and Dangerous Drugs would have total authority to determine whether drugs have accepted medical uses in treatment. Addressing this concern, Deputy Chief Counsel for the BNDD Michael Sonnenreich testified that the determination of accepted medical use "will be made by the medical community."

> "Mainly our feeling is that the trigger on your Schedule I drugs which are really different from your II, III and IV drugs. It is this basic determination that is not made by any part of the Federal Government. It is made by the medical community as to whether or not the drug has medical use or doesn't."

Drug Abuse Control Amendments—1970: Hearings Before the Subcommittee on Public Health and Welfare of the Committee on Interstate and Foreign Commerce, House of Representatives, 91st Cong., 2d Sess. (1970) at 698. Sonnenreich also observed, "You don't have to be a doctor to find out whether or not [a drug] has an accepted medical use in the United States or not . . . a lawyer can find out as well as a doctor." *Id.* at 165. Obviously, he alluded to the numerous occasions upon which lawyers are required to ascertain "accepted medical use" to determine issues such as medical malpractice or the admissibility of expert testimony. Indeed, the standard of "currently accepted medical use" is often used to determine whether a physician's use of a particular drug was medical malpractice. See *Chumbler v. McClure*, 505 F.2d 489 (6th Cir. 1974); *Furey v. Thomas Jefferson Univ. Hospital*, 472 A.2d 1083 (Pa. Super. Ct. 1984). There is also a parallel between the phrase "accepted medical use" and the standard widely used to determine the competency and admissibility of scientific evidence, *i.e.*, whether there is general acceptance of a technique in the relevant scientific community. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).[7] Reliability of

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[7] In *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court held that Federal Rule of Evidence 702 replaced the *Frye* test, but that

(Footnote continues on following page.)

evidence does not depend upon unanimous belief or universal agreement, however. The admissibility standard implicitly recognizes that even a technique that is not generally accepted could nevertheless be effective in an individual situation. Similarly, a patient could consent to a unique form of medical treatment that is not generally accepted, as long as the risks were fully explained. A physician administering such treatment would not be engaged in malpractice.

So understood, an "accepted medical use" is one that would be generally recognized by medical experts as being reliable and effective for general medical purposes based upon widely available safety and efficacy studies. Consequently, a medical use that is efficacious only in a unique, special, or isolated individual case would, for that reason alone, not constitute an "accepted medical use." Thus, a Schedule I drug is one that does not have a recognized or generally accepted medical use, even though it might have an effective individualized or idiosyncratic use.

Viewed from this perspective, the concept of "medical necessity" reflects the reality of medical practice. A physician can freely resort to the generally accepted pharmacopoeia in the general treatment of patients. But when generally accepted treatments are ineffective, the physician and the patient may jointly agree that medical necessity requires treatment that is not generally accepted. The medical necessity test applies to a particular patient or class of patients, and provides a safety valve for the individual patient who has exhausted other treatments.

The CSA's criteria are not at war with good medical practice, and good medical practice requires that physicians keep searching, even when conventional, "generally accepted" remedies do not work. That conclusion was eloquently stated

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(Footnote continued from previous page)

"general acceptance" is still a relevant consideration in determining admissibility of scientific evidence.

by George J. Annas, the Editor of the prestigious New England Journal of Medicine:

> Doctors are not the enemy in the "war" on drugs; ignorance and hypocrisy are. Research should go on, and while it does, marijuana should be available to all patients who need it to help them undergo treatment for life-threatening illnesses. There is certainly sufficient evidence to reclassify marijuana as a Schedule II drug. Unlike quack remedies such as laetrile, marijuana is not claimed to be a treatment in itself; instead it is used to help patients withstand the effect of accepted treatment that can lead to a cure or amelioration of their condition. As long as the therapy is safe and has not been proved ineffective, seriously ill patients (and their physicians) should have access to whatever they need to fight for their lives.

George J. Annas, "*Reefer Madness—The Federal Response to California's Medical-Marijuana Law*," *337 New Eng. J. of Medicine* 435-439, No. 6 (Aug. 7, 1997).

E. Interpretation of Parallel Provisions in the Uniform Controlled Substances Act Demonstrate That Recognition of Medical Necessity Is Not Inconsistent with Marijuana's Classification on Schedule I.

The CSA served as the model for the Uniform Controlled Substances Act, subsequently adopted by forty-five states.[8] The Uniform Controlled Substances Act ("the Uniform Act") establishes the same five schedules as the federal act, with the same criteria to determine which drugs are placed on which schedule. Just as under the CSA, cannabis was placed on Schedule I of the Uniform Act.[9] Of the

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[8] Only the states of Alaska, Colorado, Maine, New Hampshire, and Vermont, and the District of Columbia failed to enact the Uniform Controlled Substances Act. Uelmen & Haddox, *Drug Abuse and the Law Sourcebook*, § 3.2, p. 3-4 (Rev. 1999).

[9] All of the states adopting the Uniform Controlled Substances Act have retained its classification of marijuana on Schedule I except for Arkansas, Tennessee and North Carolina. These three states have created a separate "Schedule VI" for drugs that are inappropriately classified by placing them on Schedules I through v. Only marijuana and THC are listed on Schedule VI. *Id.*, at p. 3-18.

forty-two states that maintain the classification of cannabis on Schedule I, twenty-six subsequently enacted the "Controlled Substances Therapeutic Research Act," (the "Therapeutic Research Act") recognizing the therapeutic value of cannabis and permitting its use for medical purposes in circumstances remarkably similar to the circumstances presented in the case of "medical necessity": patients suffering from life-threatening or sight-threatening illnesses for whom the alternatives offered by conventional medicine do not work.[10]

The Therapeutic Research Act included a legislative finding "that recent research has shown that the use of cannabis may alleviate nausea and ill-effects of cancer chemotherapy, and may alleviate the ill-effects of cancer chemotherapy, and may alleviate the ill-effects of glaucoma." *See, e.g.*, N.M. Stat. Ann. § 26-2A-2(2000). The Therapeutic Research Act limited the distribution of cannabis to cancer chemotherapy patients and glaucoma patients "involved in a life-threatening or sense-threatening situation and who are not responding to conventional controlled substances or where the conventional controlled substances administered have proven to be effective but where the patient has incurred severe side effects." N.M. Stat. Ann. § 26-2A-4 (2000).[11]

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[10] These states are listed, with statutory citations, in *Marijuana, Medicine & The Law*, (Randall, Ed.), at p. 279 (1987).

[11] Many states could not implement the Therapeutic Research Act because they could not obtain a dependable supply of cannabis from federal authorities, or they found it unnecessary because the patients who qualified were accepted in to the federally operated I.N.D. program. The Act later was repealed in many of these states, but remains in effect in a substantial number of jurisdictions. Ala. Code Ann. § 20-2-110 *et seq.* (2000); Ga. Code Ann. § 43-34-120 *et seq.* (2000); N.J. Stat. Ann. § 26:2L-1 *et seq.* (2000); N.M. Stat. Ann. § 26-2A-1 *et seq.* (2000); N.Y. Public Health Law, § 3397-a *et seq.* (2000); R.I. Gen. Laws § 21-28.4-1 *et seq.* (2000); S.C. Code Ann. § 44-53-610 *et seq.* (1999); Rev. Code Wash. § 69.51.010 *et seq.* (2000).

The most important aspect of this history is the fact that so many states were willing to accommodate the urgent medical needs of patients for cannabis, even though it was classified on Schedule I of their Controlled Substances Act, and required a finding that there was "no currently accepted medical use" for the drug. They saw no inconsistency between a finding of no *currently accepted* medical use, and a finding that access to the drug was necessary for patients facing potential loss of life or sight.

In some states, the legislature even added cannabis used in compliance with the Therapeutic Research Act to Schedule II of their Controlled Substances Act, while cannabis for all other purposes remained on Schedule I. N.M. Stat. Ann. §§ 30-31-6(E); 30-31-7(e) (2000); Rev. Code Wash. § 69.51.080 (2000). Nothing could demonstrate more clearly that the finding of no "currently accepted medical use" required for Schedule I does *not* preclude the possibility of medical use in unusual circumstances than the placement of the same drug on both Schedule I and II. For the general practice of medicine, Schedule I applies: there is no "currently accepted medical use." But for unusual cases of medical necessity covered by the Therapeutic Research Act, Schedule II applies, which permits the drug to be prescribed.

In the State of Washington, the courts rejected the argument that the subsequent enactment of the Therapeutic Research Act undercut the classification of cannabis as a Schedule I drug, recognizing that there may be medical uses of cannabis falling outside "currently accepted" medical use:

> "The 1979 act sets up a program to research the effects of marijuana on cancer and glaucoma patients, and authorizes the use by such patients of the drug under controlled circumstances. This provision does not manifest a legislative finding that there is an accepted medical use for the drug, but rather a finding that there may be such a use. *State v. Palmer*, 96 Wn.2d 573, 637 P.2d 239 (1981). The act removes marijuana from schedule I and places it in schedule II only for purposes of the research program.

RCW 69.51.080 . . . The retention of the drug in schedule I for purposes other than the research program cannot reasonably be said to bear no rational relation to a legitimate legislative purpose."

State v. Whitney, 637 P.2d 956, 960 (1981).

In subsequently recognizing the defense of medical necessity in the State of Washington, the court noted that the enactment of the Therapeutic Research Act was itself a recognition of the validity of the medical necessity defense, and concluded that the defense should be extended to permit the use of cannabis by patients not included in the Therapeutic Research Act, such as victims of multiple sclerosis. *State v. Diana,* 604 P.2d 1312 (Wash. App. 1979).[12]

Thus, there is widespread concurrence among the States that adopted the Uniform Act that its classification of cannabis on Schedule I was not inconsistent with permitting the medical use of cannabis under circumstances closely analogous to the medical necessity defense, or even with the explicit recognition of a defense of medical necessity. This strongly supports the conclusion that parallel provisions in the CSA are no barrier to recognition of the defense in federal cases.

F. The Federal Government's Continued Administration of the Compassionate I.N.D. Program Confirms That Recognition of Medical Necessity Is Not Inconsistent with Marijuana's Classification on Schedule I.

For twenty-two years after adoption of the CSA by Congress in 1970, federal authorities saw no inconsistency between the classification of marijuana on Schedule I, and a compassionate program of therapeutic use for patients whose

[12] *State v. Diana* was subsequently followed in *State v. Cole,* 874 P.2d 878 (Wash. App. 1994) (held error not to submit medical necessity defense to jury) and *State v. Pittman,* 943 P.2d 713 (Wash.App. 1997) (held necessity defense properly submitted to jury with regard to supplying marijuana to glaucoma patient, but expert evidence insufficient with regard to use by cancer patient). It was rejected, however, by *State v. Williams,* 968 P.2d 26 (Wash. App. 1998). In November, 1998, however, the State of Washington adopted a popular initiative which permits medical use of marijuana with the approval of a physician. Washington Initiative No. 692 (November, 1998). Rev. Code Wash. 69.15A.005 *et seq.* (2000).

serious medical conditions were alleviated by the use of cannabis. Federal authorities actually supplied these patients with government-grown cannabis, and to this day, there are still eight patients enrolled in this program who receive a regular supply of medical cannabis from the United States government.

The consistent interpretation of the CSA by those charged with its administration to permit medical use by some patients is persuasive evidence that the Schedule I classification was never intended to preclude any use for medical purposes. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (The rulings, practices and opinions of Administrators "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.")

The initiation of the Compassionate Investigative New Drug ("I.N.D.") program corresponded with the acquittal of glaucoma patient Robert Randall in the District of Columbia, based upon a showing of medical necessity. *United States v. Randall,* 104 Wash. D.C. Rep. 2249 (D.C. Super. 1976); *see* Isenberg, *Medical Necessity As a Defense to Criminal Liability: United States v. Randall,* 46 Geo. Wash. L. Rev. 273 (1978); s*ee generally*, Robert C. Randall & Alice M. O'Leary, *Marijuana RX: The Patient's Fight for Medicinal Pot* (1988) (Randall's personal account of his courageous twenty-five year struggle to overcome federal political resistance to medical use of cannabis and preserve his eyesight).

Randall presented inconvertible evidence that use of cannabis dramatically reduced the intraocular eye pressure caused by his glaucoma with greater success than conventional medical treatment. Sustained high intraocular pressure causes permanent nerve damage and eventual blindness. The court ruled, "The evil he sought to prevent, blindness, is greater than that he performed to accomplish it, growing marijuana in his residence in violation of the D.C. Code." *Id.* at 2252-53. The court did not reach the constitutional issues raised by Randall, but noted that

"a law which apparently requires a person to submit to deteriorating health without proof of a significant public interest to be protected raises questions of constitutional dimensions." *Id.* at 2253 n.29.

In direct response to Randall's dilemma, that preservation of his eyesight required access to cannabis, the federal government created a Compassionate Investigative New Drug protocol to make government-grown cannabis available for medical treatment. By 1983, the federal Food and Drug Administration (FDA) had approved seventy-nine I.N.D. plans to permit therapeutic use of THC and cannabis. Of these plans, fifty-three dealt with nausea and vomiting from cancer chemotherapy, thirteen were for glaucoma patients, eight were for patients with spasticity, three with anorexia and weight loss, and two with miscellaneous syndromes. H.C. Jones & D.W. Lovinger, *The Marijuana Question* p. 136 (1985).

In *United States v. Burton,* 894 F.2d 188 (6th Cir. 1990), when a glaucoma patient asserted a medical necessity defense in federal court, the defense was *not* rejected because it was inconsistent with the classification of marijuana on Schedule I; it was rejected *because the availability of the Compassionate I.N.D. program provided, at that time, a reasonable legal alternative other than violating the law:*

> We expressly decline to hold that such a defense was available here. Following *United States v. Randall, supra,* a government program was established to study the effects of marijuana on glaucoma sufferers, as Burton admitted at trial. Thus, a reasonable legal alternative existed for Burton which he failed to utilize.

894 F.2d at 191. The Sixth Circuit further noted, "Notably, after this proceeding was begun, Burton became a part of this program and *now receives marijuana for his glaucoma under a physician's supervision."* *Id.*, n. 2 (emphasis supplied).

The subsequent history of the Compassionate I.N.D. program is one of the saddest and cruelest chapters in the history of federal government's "War on

Drugs." It has a great deal to do with the onset of the AIDS epidemic in America. Reports that cannabis helped AIDS patients avoid the "wasting syndrome," maintaining their weight so they could benefit from other new medications, led to the inclusion of several AIDS patients in the Compassionate I.N.D. program in 1989 and 1990. Application forms were then made widely available to the growing legions of those afflicted with AIDS, and the FDA was literally flooded with new applications. In June, 1991, James O. Mason, chief of the U.S. Public Health Service, announced that the federal government was planning to close the Compassionate I.N.D. program. The official explanation offered by Dr. Mason was as follows:

> Mason said yesterday he was concerned about a surge in new applications in recent months, especially from AIDS patients, and the message it would send if HHS were to approve them. "If it's perceived that the Public Health Service is going around giving marijuana to folks, there would be a perception that this stuff can't be so bad," said Mason. "It gives a bad signal. I don't mind doing that if there's no other way of helping these people . . . But there's not a shred of evidence that smoking marijuana assists a person with AIDS."

Michael Isikoff, "HHS to Phase Out Marijuana Program; Officials Fear Sending 'Bad Signal' by Giving Drug to Seriously Ill," *The Washington Post*, June 22, 1991, p. A14. While more than a "shred" of evidence existed in 1991 that AIDS patients benefit a great deal from cannabis use, that fact has since been publicly acknowledged by the authoritative report prepared for the National Institute of Medicine. Janet E. Joy, *et al.*, *Marijuana and Health: Assessing the Science Base* (National Academy Press, 1999). The Report includes among its recommendations that a program similar to the Compassionate I.N.D. program be re-established to accommodate the needs of AIDS patients:

> Until a non-smoked, rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from *chronic* conditions that might

> be relieved by smoking marijuana, such as pain or AIDS wasting. One possible approach is to treat patients as n-of-1 clinical trials, in which patients are fully informed of their status as experimental subjects using a harmful drug delivery system [smoking], and in which their condition is closely monitored and documented under medical supervision, thereby increasing the knowledge base of the risks and benefits of marijuana use under such circumstances.

Id. at 8. Dr. Mason offered the same "sending a bad signal" rationale to journalist Brian Hecht to justify the closing of the Compassionate I.N.D. program, confirming that its demise had nothing to do with any inconsistency with marijuana's placement on Schedule I, but everything to do with the politics of the "War on Drugs."

> In justifying the new decision, PHS chief James O. Mason told me, "it puts the government in sort of a tenuous situation to be passing out marijuana cigarettes that can be used by a person that can cloud their judgment if they choose to use an automobile or get out in the street or in the context of sexual behavior. I think it sends a signal that's not the best signal." Mason's rationale was uncannily prophesied by Judge Young in his 1998 decision: "There are those who, in all sincerity, argue that the transfer of marijuana to Schedule II will 'send a signal' that marijuana is 'OK' generally for recreational use. This argument is specious. . . ."[13] Marijuana, it seems, does indeed cloud the mind. But in this instance, the clouded minds are in government buildings, not in doctors' offices or patients' sick rooms.

Hecht, "Out of Joint," The New Republic, July 15 & 22, 1991, p. 10.

The establishment and administration of the federal government's Compassionate I.N.D. program to make government-grown cannabis available to seriously ill patients cannot be reconciled with its argument in this case that the

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[13] *See In the Matter of Marijuana Rescheduling Petition,* Exh. E of S. Ct. Exhibit 13, Docket No. 86-22, U.S. Dept. of Justice, Drug Enforcement Administration, Sept. 6, 1988. The decision of Administrative Law Judge Francis L. Young, recommending that cannabis be rescheduled, concluded: "The fear of sending such a signal cannot be permitted to override the legitimate need, amply demonstrated in this record, of countless sufferers for the relief marijuana can provide when prescribed by a physician in a legitimate case."

operation of a local government's compassionate program to make cannabis available to AIDS and cancer patients with the approval of their physicians under circumstances demonstrating "medical necessity" violates federal law. The placement of marijuana on Schedule I of the CSA is not inconsistent with either program. Both are fully justified by medical necessity. The public explanation for closure of the federal program to new patients demonstrated that compassion was overcome by cynical political expediency, rather than concern for consistency or for public health.

G. The Administrative Rescheduling Scheme of the CSA Does Not Defeat the Availability of the Medical Necessity Defense.

The government also suggests that the very existence of the administrative procedures for rescheduling cannabis makes the medical necessity defense legally unavailable. (Gov't. Br. at 22-23; see 21 U.S.C. § 811.) The government is mixing apples and oranges, however. When the Attorney General reclassifies a drug in a rulemaking proceeding under the CSA or the FDA approves a drug under the Federal Food Drug and Cosmetic Act ("FFDCA"), the legal treatment of the drug profoundly and universally changes. The approval or rescheduling governs its use in *all* cases for *all* purposes and for *all* individuals. Neither this Court nor the district court purported to make such a sweeping change in how cannabis is treated under the law. Instead, the district court merely refused the government's request to enjoin use by an extremely narrow group of seriously ill patients who meet the legal standard of medical necessity.[14] Accordingly, the government's citation of cases holding that courts lack the power to reschedule cannabis is irrelevant.

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[14] The district court's order does not, as the government contends, allow distribution to those merely "claiming" a medical necessity. The district court's order plainly applies only to those who satisfy the legal test for medical necessity.

Nothing in *United States v. Rutherford*, 442 U.S. 544 (1979) requires a contrary result. In *Rutherford*, plaintiffs brought an *affirmative* case to exempt laetrile, an unproven drug, from the requirements of the FFDCA. Appellees do not seek that relief here. There also was no claim in *Rutherford* that laetrile was the *only* effective treatment for the patients, and indeed there was a significant concern that these patients would forego conventional treatment in favor of laetrile. In contrast, OCBC's patient-members with a medical necessity are the target of a civil injunction action brought by the government to preclude their use of the *only* medicine that has proven effective in relieving their conditions or symptoms. As this Court recognized, if the government had sought to prosecute Appellees individually, they would have been able to litigate the issue of necessity in due course. *OCBC I*, 190 F.2d at 1114. Appellees should not be penalized because the government sought to proceed by injunction.

Moreover, *United States v. Richardson*, 588 F.2d 1235 (9th Cir. 1978), relied on by the government, supports Appellees' position. In *Richardson*, four individuals conspired to smuggle laetrile from Mexico to the United States to treat cancer patients. The defendants asserted the defense of necessity. This Court did not foreclose the possibility that necessity can be a defense to a drug charge. Instead, it held only that the defense "is hedged about with many conditions," and that one of those conditions defeated application of the defense under the particular facts of the case. *Id.* at 1239. That condition was that there was no alternative course of action reasonably available. *Id.* This Court concluded that there were three alternatives to smuggling laetrile from Mexico: (1) "as the government suggest[ed] ... production of Laetrile in the United States"; (2) attempting to secure FDA approval under the FFDCA; and (3) declaring the laetrile at customs and challenging the seizure in court. *Id.* Thus, even if Congress has established an administrative mechanism for challenging the scheduling of a drug under the CSA

or the approval of a drug under the FFDCA, a criminal defendant may assert the necessity defense if pursuing that administrative remedy is not a reasonable alternative.

In this case, the administrative and political process has been exhausted over the course of two decades of litigation and administrative wrangling. Further administrative proceedings are not a reasonable alternative for the seriously ill patients protected by the district court's amended injunction. As recognized by the district court, "it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to alleviate a current medical problem." *Cannabis Cultivators' Club*, 5 F.Supp.2d at 1102. The dismal results of those two decades of proceedings also distinguish this case from *Aguilar*, 883 F.2d at 693-694, in which this Court held that a civil suit against the INS was a reasonable alternative remedy because provisional relief was available and similar suits had improved the INS asylum and detention procedures involving Salvadorans in California.

II. THE CSA DOES NOT DIVEST THE DISTRICT COURT OF ITS EQUITABLE AUTHORITY TO ISSUE AN INJUNCTION WITH AN EXEMPTION FOR MEDICAL NECESSITY

When the government first decided to challenge Appellees' conduct, it made a conscious strategic decision not to assemble a grand jury, secure an indictment, and initiate a criminal prosecution. The government apparently recognized that, if it chose the criminal route, it would be forced to prove its case beyond a reasonable doubt, the defendants would be entitled to various constitutional protections, the government could not seek summary judgment or a preliminary injunction, the government's ability to appeal a judgment in the defendants' favor would be limited, there would be a twelve-member jury that could convict only upon a unanimous verdict, and a jury might take a dim view of the government's decision

to prosecute and attempt to imprison grievously ill men and women during the last days of their lives.

To avoid these strategic disadvantages, the government chose to file a civil injunctive action under 21 U.S.C. § 882(a). When the government bargained for the advantages of filing this suit as a civil injunctive proceeding rather than a criminal prosecution, however, it also agreed to be bound by the centuries-old rule that courts sitting in equity have broad discretion to fashion injunctions.

The government now claims, however, that Congress somehow intended to restrict the district court's traditional broad equitable discretion to fashion injunctions when it enacted the CSA, and particularly 21 U.S.C. § 882(a). This congressional limitation on the district court's equitable discretion, the government argues, somehow deprived the district court of discretion to incorporate the medical necessity exception into the preliminary injunction. As explained below, however, controlling Supreme Court and Ninth Circuit precedent require that "such an abrupt departure from traditional equity practice" plainly appear in the legislation. *The Hecht Co.* v. *Bowles*, 321 U.S. 321, 330 (1944); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 329-330 (1982); *see Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531 (1987); *Northern Cheyenne Tribe v. Hodel*, 851 F.2d 1152 (9th Cir. 1988). There is no evidence in this case that Congress ever intended such a drastic departure from well-established traditions of equity.

The Supreme Court has established that when Congress authorizes a district court to issue injunctions to enforce federal statutes, Congress also must plainly state its intention to deprive the district court of its traditional equitable discretion to fashion appropriate relief. In *Hecht*, the Administrator of the Emergency Price Control Act ("the Act") sought an injunction barring a store from selling goods for more than the maximum price allowed under the Act and related regulations. It was undisputed that the store violated the Act and the regulations on many

occasions. *Hecht*, 321 U.S. at 324. The district court refused to issue an injunction against future violations on the equitable grounds that the violations were inadvertent and that the store had acted in good faith. Like the government in this case, the Administrator argued that, by making a legislative decision that the store's conduct was unlawful and by giving the district court jurisdiction to issue injunctions to aid the Administrator in enforcing the Act and regulations, Congress restricted the district court's traditional equitable discretion, and imposed a mandate to issue an injunction upon request.

The Supreme Court held that the issue was whether, under the general law governing civil injunctive relief, the district court had discretion to consider *equitable factors* in deciding whether to issue an injunction. The Supreme Court unequivocally re-confirmed that district courts have broad discretion to consider equitable grounds in deciding whether and how to enjoin particular conduct, even when that conduct indisputably violates an Act of Congress:

> We are dealing here with the requirements of equity practice with a background of several hundred years of history. . . . The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mold each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims. We do not believe that such a major departure from that long tradition as is here proposed should be lightly implied. . . . [I]f Congress desired to make such an abrupt departure from traditional equity practice as is suggested, it would have made its desire plain. Hence we resolve the ambiguities of [the Act] in favor of that interpretation which affords a full opportunity for equity courts to treat enforcement proceedings . . . in accordance with their traditional practices, as conditioned by the necessities of the public interest which Congress has sought to protect.

Hecht Co., 321 U.S. at 329-330. Moreover, in reaching its conclusion, the Supreme Court did not consider whether "good faith" and "inadvertence" were

defenses to a charge of violating the Act, and instead focused solely on whether there was an equitable basis for the district court's decision. Thus, unless Congress makes an "unequivocal statement of its purpose" to "make such a drastic departure from the traditions of equity practice" by making issuance of an injunction mandatory, a district court retains the full panoply of equitable discretion in cases where Congress has given the district court jurisdiction to issue an injunction to enforce a statute. *Id.* at 329.

The Supreme Court reached the same conclusion in *Romero-Barcelo*, 456 U.S. 305. In *Romero-Barcelo*, the Governor and residents of Puerto Rico sued to enjoin the Navy from discharging into navigable waters in violation of the Federal Water Pollution Control Act ("FWPCA"). The district court found that the Navy had violated the FWPCA, but denied the injunction because the Navy's violations were "technical," there was no "appreciable harm" to the environment, and the Navy would be irreparably harmed if denied the opportunity to use the area as a training ground. The First Circuit reversed, holding that Congress intended to override the district court's equitable discretion and imposed a mandatory duty to issue an injunction.

The Supreme Court reversed, relying primarily on *Hecht*. First, as in *Hecht*, there was no discussion of whether "technicality," lack of appreciable harm to the environment, or irreparable harm to the violator are valid defenses to a prosecution under the FWCPA. Second, as in *Hecht*, the Supreme Court reiterated: "The grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation." *Romero-Barcelo*, 456 U.S. at 313.

The Supreme Court reaffirmed *Hecht* and *Romero-Barcelo* in *Village of Gambell*, 480 U.S. 531. In that case, the district court refused to enjoin certain oil

exploration activities in Alaska. The Ninth Circuit reversed, believing that the district court had a mandatory duty to issue the injunction. The Supreme Court reversed, holding that there was "nothing which distinguishes *Romero-Barcelo* from the instant case." *Amoco Prod. Co.*, 480 U.S. at 544. The Supreme Court found "no clear indication [in the applicable statute] that Congress intended to deny federal district courts their traditional equitable discretion ... nor are we compelled to infer such a limitation." *Id.* Instead, as in *Romero-Barcelo*, the legislative purpose of the federal statute — protecting native people who hunt and fish for their subsistence — could be fulfilled without the injunction. *Id.* at 545.[15]

TVA v. Hill, 437 U.S. 153 (1978), on which the government relies, establishes that where the government's own tactical choices deprive it of the means to fulfill Congress's purposes, it cannot argue that a district court lacks discretion to fashion appropriate relief. In *Hill*, the issue was whether, by enacting the Endangered Species Act, Congress intended to deprive the district court of its traditional equitable discretion to issue an injunction barring completion of a dam that, if it became operational, would inevitably cause the extinction of an endangered species, the snail darter. The Supreme Court held in *Hill* that Congress had deprived the district court of its discretion and had mandated that an injunction issue.

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[15] Many other cases have reached the same conclusion under various Acts of Congress. *See, e.g., Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946) ("the comprehensiveness of [the district court's] equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command"); *Brown v. Swann*, 35 U.S. (10 Pet.) 497, 503 (1836) ("Unless a statute then, in so many words, or by an inference which does not admit of a doubt, commands the courts of equity ... to give relief ... the law should not be so construed. The great principles of equity, securing complete justice, should not be yielded to light inferences, or doubtful construction."); *United States v. Marine Shale Processors*, 81 F.3d 1329, 1358-1361 (5th Cir. 1996) (district court has discretion to issue or refuse the United States' request for an injunction under The Resource Conservation and Recovery Act, even if it proves a violation).

The Supreme Court explained in *Romero-Barcelo*, however, that the injunction in *Hill* was mandatory because the *only* way to fulfill the objective of the Endangered Species Act was to issue the injunction. *Id.* at 314. In contrast, in *Romero-Barcelo*, "[a]n injunction [was] not the *only means* of insuring compliance" with federal law. *Id.* (emphasis added.)

Unlike in *Hill*, Congress did not intend that an injunction be the only remedy available to fulfill the purposes of the CSA. The CSA carries heavy criminal penalties. Congress's intent to prosecute illicit drug use can be fulfilled regardless of whether an injunction issues or is crafted to exclude those who fall within the "medical necessity" exception carved out by the district court. The government merely abandoned the other remedies available to it. Absent unmistakable evidence of Congressional intent to override the district court's discretion in *all* cases, the government cannot ask this Court to override the district court's discretion in an individual case merely to relieve the government of what has turned out to be a poor litigation strategy.[16]

There is no evidence in the text of the CSA that Congress intended to deprive the district court of its traditional equitable powers. Indeed, Section 882(a) provides broad authority to the district court to issue injunctions: "The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in

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[16] *See also Northern Cheyenne Tribe*, 851 F.2d at 1156 (cited in *OCBC I*, 190 F.3d at 1114) (holding that the district court was not under a mandatory duty to issue an injunction because the district court had a mandatory duty to issue an injunction voiding the leases under the Federal Coal Leasing Amendments Act ("FCLAA"). This Court distinguished *Hill* because "[n]othing in the [FCLAA] indicates that Congress intended to restrict the court's jurisdiction in equity," the underlying purpose of the Act could be fulfilled without issuing an injunction, and the district court retained its equitable discretion.

proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of [the Controlled Substances Act]."

Nor is there anything in the legislative history of section 882(a) suggesting that Congress intended to strip the district courts of their traditional equitable discretion. *See* H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4624; S. Rep. No. 91-613, at 33 (1969). As discussed in Section I.B., *supra*, Congress only tentatively placed cannabis in Schedule I. There is no basis for concluding that Congress made any determination that a district court in an injunctive proceeding, faced with uncontroverted evidence that cannabis was necessary to save a person's life, was prohibited from fashioning equitable relief to protect the rights of that individual.

Nor can the government rely on the "Sense of Congress" proclamation. Even if it had the full force of a statute, which it does not (*see* Section I.C. *supra*) the "Sense of Congress" does not mention section 882(a), much less purport to limit the district courts' equitable discretion under section 882(a) or under any other statute. Accordingly, the "Sense of Congress" proclamation falls far short of being the "unequivocal statement of [Congressional] purpose" to "make such a drastic departure from the traditions of equity practice," that must exist before an Act of Congress can override a district court's equitable discretion. *See Hecht Co.*, 321 U.S. at 329.

Before the district court could foreclose application of the medical necessity defense to *any* member of the enjoined group by refusing to incorporate that defense into the injunction, the district court would be required to conclude that Congress intended that *no person* could *ever* rely on the defense under *any set of facts* that could be proven by any member of the group to be enjoined. Otherwise, seriously ill men and women would be deprived of their fundamental rights. The

government has fallen far short of demonstrating any such direct, unequivocal, compelling, expression of Congressional intent.

III. THE GOVERNMENT'S PROHIBITION AGAINST USE OF CANNABIS BY PERSONS WITH A MEDICAL NECESSITY VIOLATES THE CONSTITUTION

A. The Prohibition Violates Patients' Substantive Due Process Rights.

A faithful application of the Due Process analysis required by the federal Constitution compels the conclusion that depriving seriously ill patients of the one medicine that alleviates their symptoms and in many cases saves their lives, violates their fundamental rights. These patients have a liberty interest in being free from pain and in preserving their lives. *See Washington v. Glucksberg,* 521 U.S. 702, 737, 745, 117 S. Ct. 2258 (1997) (O'Conner J. concurring), (Stevens, J., concurring) ("Avoiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly '[a]t the heart of [the] liberty . . . to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life."') That interest cannot be infringed absent a compelling state interest. *Id. See Washington v. Glucksberg*, 521 U.S. at 721. Moreover, an examination of our "nation's history, legal traditions and practices" (*Washington v. Glucksberg*, 521 U.S. at 710) reveals the long accepted use of cannabis as a medicine (SER 268-270), and current legislation in several states allowing the medical use of cannabis.[17] *See Conant v. McCaffrey*, No. C97-00139 WHA, 2000 U.S. Dist. LEXIS 13024 (N.D. Cal. Sept. 7, 2000) at *40, n.5; Dixon,

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[17] At least six other states (Alaska (Alaska Stat. § 17.37.010 *et. seq.*) Arizona (A.R.S. § 13-3412.01 *et. seq.*), Maine (22 M.R.S. § 2383-B), Oregon (1999 Ore. ALS 825, 1999 Ore. Laws 825, 1999 Ore. HB 3052), Washington (ARCW § 69.51A *et. seq.*) and most recently Hawaii), now have laws similar to that of California's Compassionate Use Act.

Conant v. McCaffrey: Physicians, Marijuana, and the First Amendment, 70 U. Colo. L. Rev. 975 (1999).

The government has previously attempted to trivialize these claims by relying on *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980), and *Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980), for the proposition that there is no fundamental, constitutional right to obtain a particular medical treatment.[18] This case does not, however, involve (a) an attempted reclassification of any drug, (b) a suit by persons who have found no medically effective treatment to relieve their pain and suffering (compare *Rutherford*) or (c) an attempt to obtain access to a wholly experimental drug that has not been shown to be effective in relieving patient-members' pain and suffering. (Compare *United States v. Rutherford,* 442 U.S. 544 (1979). To permit the government to interfere with the right of seriously ill patient-members to use of medical cannabis is to deny them the right recognized by *Rutherford:* the right to decide whether or not to have effective medical treatment at all. Cannabis is not simply the "medication of choice." It is the *only* effective medication for these patient-members and, therefore, enjoys constitutional protection.

B. The Government's Prohibition Against Medical Use of Cannabis Violates The First, Ninth and Tenth Amendments.

Even if seriously ill patients have no Fifth Amendment due process right to select specific medical treatment, they nevertheless have such a fundamental right based on the Ninth Amendment. The Ninth Amendment recognizes that the people have fundamental rights beyond those listed elsewhere in the Constitution. *See*

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[18] Even if the government were correct, the government has failed to show that a prohibition against *all* medical use of cannabis, particularly by those with a medical necessity is neither irrational nor arbitrary, and that it serves a legitimate government interest. *See Carnohan*, 616 F.2d at 1122.

Planned Parenthood v. Casey, 505 U.S. 833, 848 (1992) (Plurality opinion of O'Connor, Kennedy, and Souter) ("Neither the Bill of Rights nor the specific practices of the States at the time of the adoption of the Fourteenth Amendment marks the outer limits of the substantive sphere of liberty which the Fourteenth Amendment protects." *See* U.S. Const. Amend. 9."); *United States v. Choate*, 576 F.2d 165, 182 (9th Cir. 1978) (Ninth Amendment recognizes rights "'so basic and fundamental and so deep-rooted in our society' to be truly 'essential rights,' [but] which nevertheless, cannot find direct support elsewhere in the Constitution."), citing *Griswold v. Connecticut*, 381 U.S. 479, 488-489, 491 (1965) (Goldberg, J., concurring); Axler, *The Power of the Preamble and the Ninth Amendment: The Restoration of the People's Enumerated Rights*, 24 Seton Hall Legis. J. 431 (2000).

Moreover, OCBC's activity is purely local. Accordingly, there is a serious question whether Congress has authority to regulate it under the Commerce Clause, (*see United States v. Lopez*, 514 U.S. 549 (1995)), and whether the Tenth Amendment reserves the power to regulate OCBC to the People and the State of California, who expressed their will when they enacted Proposition 215. *See United States v. Mussari*, 95 F.3d 787, 791 (9th Cir. 1996) (if Congress prevents purely local activity permitted by state law but lacks power to do so under the Commerce Clause, Congress violates the Tenth Amendment by attempting to regulate it, because the Commerce Clause and the Tenth Amendment "complement each other, fitting together like two concave surfaces to make a constitutional whole."), citing *New York v. United States*, 505 U.S. 144, 156 (1992).

Finally, to the extent that a broader injunction would infringe on the doctor-patient relationship, it would violate the First Amendment rights of the physicians caring for the seriously ill patients exempted by the current amended injunction. *See Conant v. McCaffrey*, 172 F.R.D. 681, 694-698 (N.D. Cal. 1997); *Conant*, 2000 U.S. Dist. LEXIS 13024, at *34-48; *See also,* J. Wells Dixon, *Conant v.*

McCaffrey: Physicians, Marijuana, and the First Amendment, 70 U. Colo. L. Rev. 975 (1999).

The potential infringement of physicians' and seriously ill patients' constitutional rights is significant, with respect both to the availability of the medical necessity defense generally and whether the district court acted within its discretion when it incorporated that exception into the preliminary injunction. It is well established that all statutes, including the CSA, must be interpreted to avoid constitutional questions. *See, e.g., Ma v. Reno*, 208 F.3d 815, 827 (9th Cir. 2000) ("a statute should be construed to avoid constitutional problems so long as the saving construction is not 'plainly contrary to the intent of Congress.') (quoting *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 78 (1994).) If the Court were to accept the government's argument that the CSA and "Sense of Congress" abrogated the medical necessity defense even for the seriously ill patients to whom it applies under the district court's amended injunction, the Court would be required to decide whether Congress infringed the constitutional rights of those physicians and seriously ill patients by blocking access to the treatment recommended by their physicians as authorized under California law. The Court also would be required to decide whether Congress's decision to override the rights expressly retained by the People of California and the powers reserved by the People and the State of California, and to place federal interests over states' rights violated the Ninth or Tenth Amendments. In view of these potential constitutional issues, the rules of statutory interpretation, combined with the fact that there is nothing in the text, the legislative history of the CSA, or the "Sense of Congress" to support the government's position, strongly support a holding that Congress did not intend to abrogate the medical necessity defense in civil injunctive proceedings under Section 882(a). Also, by incorporating the exception into the injunction, the district court acted well within its discretion to avoid constitutional conflicts by

minimizing any potential adverse impact on the enjoined parties' constitutional rights. *See Conant*, 2000 U.S. Dist. LEXIS 13024, at *34-48.

IV. A DECISION ALLOWING A LIMITED GROUP OF SERIOUSLY ILL PATIENTS TO RECEIVE MEDICAL CANNABIS UNDER THE LEGAL CRITERIA FOR NECESSITY IS NOT MANIFESTLY UNJUST

There is no basis for the Government's assertion that the Court's decision in *OCBC I*, or the district court's order modifying the injunction constitute "manifest injustice." The record establishes that the modification ordered by the district court is consistent with controlling authority and clearly in the public interest. The record includes uncontradicted evidence establishing the safety of cannabis as a medicine, uncontradicted declarations from sick and dying patients establishing that cannabis is the only medicine that can ease their pain and suffering, a determination of a public health emergency by the City of Oakland, and the support of prestigious medical organizations for Appellees' position.

The City of Oakland has determined that the inability of these seriously ill patients to receive medical cannabis constitutes a public health emergency. (SER 70-72.) Medical groups, such as the prestigious California Medical Association ("CMA"), also support Appellees' arguments regarding the necessity of cannabis to treat seriously ill patients. (SER 738-757.) Although the CMA supports the process for approving drugs for medical use, it simultaneously recognizes that the immediate needs of seriously ill patients, in consultation with their physicians, may require pursuit of other treatments while that process is underway. This position was joined by the California Nurses Association, the City of Oakland, the County of Alameda, and the City and County of San Francisco, all of whom plainly have a stake in identifying and protecting "the public interest." (SER 766-772.) Finally, the Attorney General of California repeatedly has

requested that the federal government allow the Court of Appeals' September 13, 1999, opinion (*OCBC I*) to take effect. (SER 759.)

The government has provided no evidence that states with a recognized medical necessity exception, or that have passed medical cannabis laws, have any difficulty prosecuting violations of their drug statutes. Indeed, California statistics plainly demonstrate that since passage of the Compassionate Use Act of 1996. California has arrested more persons for recreational marijuana violations than before passage of the Act. California cannabis arrests have consistently increased every year since 1992 unabated during the period from 1996 (56,996 arrests) through 1999 (62,844 arrests). (California Marijuana Arrests, California Department of Justice, Criminal Justice Statistics Center "Adult and Juvenile Arrests Reported" various years, Req. for Jud. Notice Ex. B) Plainly, law enforcement authorities and the judicial system in California have no trouble differentiating between medical cannabis patients and recreational marijuana violators.

Moreover, as previously discussed, neither *OCBC I* nor the district court's order authorizes the removal of cannabis from Schedule I, or nullifies any act of Congress. Rather, the amended injunction promotes the public interest by protecting the health and safety of seriously ill patients. The amended injunction allows these patients to obtain medicine in an irrefutably controlled, well-regulated, and safe environment. Illicit drug traffickers will no longer prey on these patients, nor will these patients be forced to forego life saving treatment to avoid breaking federal law. Thus, far from promoting "disrespect and disregard" for law, the amended injunction furthers the rule of law by compassionately protecting the legal rights of those who most need the Court's protection.

V. CONCLUSION

For all of the foregoing reasons, this Court should affirm the district court's amended injunction and should also specifically reaffirm its analysis and holding in *OCBC I.*

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