No. 00-151

IN THE SUPREME COURT OF THE UNITED STATES

UNITED STATES OF AMERICA

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE

BRIEF FOR THE RESPONDENT'S

Filed February 20th, 2001

This is a replacement cover page for the above referenced brief filed at the U.S. Supreme Court. Original cover could not be legibly photocopied

RESTATED QUESTIONS PRESENTED

1. Did Congress limit the traditional equitable powers of the federal courts to consider the public interest in shaping injunctive relief under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*?

2. Did Congress abrogate the traditional common law defense of necessity under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*?

3. Does Congress have the power to foreclose wholly intrastate access to the only medication that will avoid death, intractable pain, starvation or blindness of seriously ill patients participating in a state-sponsored emergency medical program?

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STATUTES AND CONSTITUTIONAL PROVISIONS

Sections 811, 812(b), and 882(a) of Title 21 of the United States Code are reprinted at App. 83a-89a.[1] Sections 801 and 903 of Title 21 of the United States Code and the Fifth, Ninth, and Tenth Amendments to the United States Constitution are reprinted in an appendix attached hereto.

STATEMENT OF FACTS

In November 1996, California voters enacted an initiative measure entitled the Compassionate Use Act of 1996 (Proposition 215), to permit seriously ill patients and their primary caregivers to possess and cultivate cannabis with the approval or recommendation of a physician. Cal. Health and Safety Code § 11362.5. The physician must determine "that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief." *Id.* § 11362.5(b)(1)(A).[2]

To implement the will of California voters, Respondents organized a Cooperative to provide seriously ill patients with a safe and reliable source of medical cannabis. A physician serves as Medical Director, and registered nurses staff the Cooperative during business hours.

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[1] "App." refers to the Appendix filed by Petitioner with the Petition for a Writ of Certiorari.

[2] Although the district court assumed that Respondents' conduct complied with state law (App. 47a), Petitioner wrongly asserts that Proposition 215 does not authorize distribution of cannabis. Pet.Br. 8 n.6. The City of Oakland established its Distribution Program with the Cooperative to fulfill the initiative's mandate to governments to "implement a plan to provide for safe and affordable distribution of marijuana to all patients in need of marijuana." Cal. Health & Safety Code § 11362.5(b)(1)(C).

J.A. 24-25.[3] The Cooperative's Protocols, revised March 30, 1998, require prospective members to provide a written statement from a treating physician assenting to cannabis therapy, and submit to a screening interview by staff and verification of the physician's approval. Patients accepted as members receive identification cards.

The Cooperative, a not-for-profit organization, operates in downtown Oakland, in cooperation with the City of Oakland and its police department. No smoking is permitted on the premises. J.A. 2-3, 9-10, 23-24, 148, 150-151, 153. On July 28, 1998, the City of Oakland adopted, by ordinance, a Medical Cannabis Distribution Program, and on August 11, 1998, officially designated the Cooperative to administer the City's program. J.A. 138-46.[4]

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[3] "J.A." refers to the Joint Appendix filed in this Court.

[4] The government quotes from the 1997 declarations of DEA agents to suggest that the distribution of cannabis to patients demonstrating necessity under the amended injunction would not be subject to "strict controls" by the City of Oakland. Pet.Br. 22-23 n.11, 30-31 n.16. Respondents categorically deny numerous assertions in the agents' declarations. The agents presented phony physician's statements to gain admission in May and October, 1997. J.A. 46-51, 68-73. The agents also misrepresented themselves as primary caregivers for members who were too sick to come in (J.A. 65) and set up phone lines where agents posed as physicians' staff to provide telephone verification of the phony physician's statements. J.A. 78-79. This activity *predated* the establishment of the City of Oakland's Medical Cannabis Distribution Program by more than one year, and predated by three years the amended injunction, which itself establishes strict controls over which patients may establish legal necessity. Implementation of the amended injunction would remain under the continuing jurisdiction of the district court, which retains the authority to punish any violations as contempt. The threat of immediate contempt sanctions, of course, vastly exceeds the normal control mechanisms of the CSA.

On January 9, 1998, the United States sued in the United States District Court for the Northern District of California, seeking to enjoin Respondents from distributing cannabis to patient-members. On May 19, 1998, the district court issued a preliminary injunction enjoining Respondents from "engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana, in violation of 21 U.S.C. § 841(a)(1)." App. 39a-40a. In so doing, the district court rejected a "blanket" assertion of medical necessity, but specifically left this justification open for later consideration on an individual basis. App. 70a-71a.

On October 13, 1998, the district court held Respondents in contempt of the preliminary injunction. The district court rejected a necessity defense, finding that only four patients to whom cannabis was allegedly distributed on the day covered by the Order to Show Cause submitted evidence sufficient to determine legal necessity under *United States v. Aguilar*.[5] App. 29a-32a. The district court then modified the injunction to permit the U.S. Marshal to seize Respondents' offices. App. 37a. Respondents thereafter informed the district court that they would comply with the injunction. Order re Ex Parte Motion at p.2 filed Oct. 30, 1998. Respondents moved for a modification of the injunction to permit distribution of cannabis to the limited number of patients who could demonstrate necessity under the *Aguilar* standard and

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[5] In *United States v. Aguilar*, 883 F.2d 662, 693 (9th Cir. 1989), the court reaffirmed the following elements of a necessity defense:

> (1) that he was faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent harm; (3) that he reasonably anticipated a causal relationship between his conduct and the harm to be avoided; and (4) that there were no other legal alternatives to violating the law.

submitted numerous declarations in support of their motion. The district court denied that motion. App. 7a.

On October 27, 1998, the Oakland City Council adopted a resolution declaring a public health emergency, finding that the closure of the Cooperative "impairs public safety by encouraging a market for street narcotic peddlers to prey upon Oakland's ill residents" and that the closure will cause pain and suffering to thousands of seriously ill persons. The resolution urged the federal government to desist from any and all actions that pose obstacles to access to cannabis for Oakland residents whose physicians have determined that their health will benefit from the use of cannabis. J.A. 149-50. The City Council renews that resolution every two weeks. *E.g.*, J.A. 152-57.

On September 13, 1999, the Court of Appeals reversed the district court's denial of the motion to modify and remanded the case to the district court, holding that (1) the court could take into account a legally cognizable defense of necessity in considering the proposed modification (App. 8a), (2) in exercising its equitable discretion, the court must expressly consider the public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of persons with serious or fatal illnesses, and (3) the record before the district court justified the proposed modification. App. 9a-10a.[6] The government's petition for rehearing and rehearing en banc was denied on February 29, 2000, without a single judge even requesting to vote for rehearing. App. 82a.

On remand, Respondents renewed their motion to modify the preliminary injunction, submitting more declarations to establish that patient-members could meet all

[6] The Court of Appeals dismissed Respondents' appeal of the contempt order as moot, on the grounds the contempt was purged. App. 5a.

of the *Aguilar* requirements for a claim of necessity. The evidence established that:

(1) Some patient-members face a choice of evils, requiring them to violate the law to gain relief from debilitating pain, life-threatening illness, or loss of sight. Patients described the agony of suffering from HIV/AIDS and its "wasting syndrome" (Decls. of Alcalay, J.A. 20; Dunham, J.A. 86; Stogdell, J.A. 89), nausea, loss of appetite, and dramatic weight loss accompanying cancer treatment (Decls. of Bonardi, J.A. 80; Beal, J.A. 84; Frost, J.A. 91), and pain and deteriorating field of vision from glaucoma (Sweet Decl., J.A. 93.)

(2) Those patient-members will suffer imminent harm if deprived of cannabis, including loss of life (Decls. of Alcalay, J.A. 22; Beal, J.A. 84), starvation (Decls. of Bonardi, J.A. 82; Stogdell, J.A. 89), and blindness (Sweet Decl., J.A. 94.)

(3) There is a direct, causal relationship between patient-members' use of cannabis and averting imminent harm. For example, Dr. Marcus Conant, M.D., who has treated 5,000 HIV-infected men and women, states:

> In my practice, marijuana has been of greatest benefit to patients with wasting syndrome. I do not routinely recommend marijuana to my patients, nor do I consider it the first line of defense against AIDS-related symptoms. However, for some patients, marijuana proves to be the *only* effective medicine for stimulating appetite and suppressing nausea, thus allowing the AIDS patient to recover lost body mass and become healthier.

J.A. 101.[7] Dr. Howard MacCabee, M.D., who directs the Radiation Oncology Center, and treats 2,000 patients in various stages of radiation therapy for cancer, states:

[7] The Joint Appendix erroneously states that the district court never acted upon Respondents' request for judicial notice

> Because of the nature of some cancers, I must sometimes irradiate large portions of my patient's abdomens. Such patients often experience nausea, vomiting, and other side effects. Because of the severity of these side effects, some of my patients choose to discontinue treatment altogether, even when they know that ceasing treatment could lead to death. . . . I have witnessed cases where patients suffered from nausea or vomiting that could not be controlled by prescription anti-emetics. . . . As a practical matter, some patients are unable to swallow pills because of the side effects of radiation therapy or chemotherapy, or because of the nature of the cancer (for instance, throat cancer). For these patients, medical marijuana can be [an] effective form of treatment.

J.A. 110-11. Additionally, Dr. Lester Grinspoon, M.D., a leading researcher on the use of cannabis for medical purposes, and author of 154 scholarly articles and 13 books on related subjects, summarized the published scientific evidence establishing the efficacy of cannabis as an anti-emetic for cancer chemotherapy, as a retardant to reduce intraocular pressure experienced by glaucoma sufferers, as an anticonvulsant to control seizures, as an analgesic to control pain, and as an appetite stimulant to combat the AIDS wasting syndrome. J.A. 118-37; *see also* Decl. of Dr. Morgan, J.A. 113-115.

(4) There are no legal alternatives to cannabis for these patients. They described how they had tried alternative medications available by prescription, including the synthetic THC pill known as "Marinol," and found them ineffective. J.A. 22, 90, 92. Dr. Conant, who served as one of the principal investigators when Marinol was approved by the FDA, testified:

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of the declarations of Doctors Conant and MacCabee. J.A. II n.**. The motion was granted on October 13, 1998. App. 24a.

> . . . Marinol (like any medication) is not effective in treating all patients. In some cases, the reason is simple: Marinol is taken orally, in pill form. Patients suffering from severe nausea and retching cannot tolerate the pills and thus do not benefit from the drug. There are likely other reasons why smoked marijuana is sometimes more effective that Marinol. The body's absorption of the chemical may be faster or more complete when inhaled.

J.A. 104-05. *See also* J.A. 113-15 and 132-33.

The government submitted no evidence in opposition, nor did it challenge Respondents' evidentiary showing. Instead the government relied upon its legal argument that a necessity defense was not available under the Controlled Substances Act (the "CSA"). On July 17, 2000, the district court modified the preliminary injunction to exempt the distribution of cannabis to patient-members who (1) suffer from a serious medical condition, (2) will suffer imminent harm if denied access to cannabis, (3) need cannabis to treat or alleviate the medical condition or its associated symptoms, and (4) have no reasonable legal alternative to cannabis for effective treatment or alleviation of symptoms, because all other legal alternatives have been tried and were ineffective or intolerable. App. 16a-17a.

On July 25, 2000, the government noticed an appeal from the district court's order modifying the injunction. That appeal has been fully briefed and awaits argument before the Court of Appeals, which suspended proceedings to await this Court's ruling. On August 29, 2000, this Court granted the government's request for a stay of the July 17 order, "pending final disposition of the appeal by the United States Court of Appeals for the Ninth Circuit and further order of this Court." *United States v. Oakland Cannabis Buyers' Cooperative*, 121 S. Ct. 21 (2000). On November 27, 2000, this Court granted the government's

petition for writ of certiorari to review the Court of Appeal's September 13, 1999 decision.

SUMMARY OF ARGUMENT

With heated rhetoric, the government urges that the Court of Appeals' ruling in this case will significantly impair its enforcement of the CSA "against drug traffickers who are acting under the guise of 'medical necessity,' " and an *amicus* characterizes Respondents as stealthy subversives whose real agenda is back-door legalization of recreational drug use. Cert. Reply Br. 4-5; *Amicus* Br. of Family Research Council 4-5, 26-28. The Court should note, however, that the government declined to present any evidence of any potential threat that modification of the injunction might allegedly pose to the public interest when invited to do so by the district court in these proceedings. App. 13a. In other proceedings, the district court found government fears that the medical use of cannabis would create a significant drug enforcement problem were "exaggerated and without evidentiary support." *Conant v. McCaffrey*, 172 F.R.D. 681, 694 n.5 (N.D. Cal. 1997).

The citizens of every state in which this issue has appeared on the ballot, and the thousands of physicians who have concluded that scientific evidence supports the conclusion that cannabis has legitimate therapeutic value, are not "drug traffickers" or renegades. They now include the National Institute of Medicine,[8] as well as the

[8] *Marijuana and Health: Assessing the Science Base*, A Report Prepared for the National Institute of Medicine at the request of the White House Office of National Drug Control Policy (1999). The report concludes that despite the risks associated with smoking, smoked cannabis may be the best alternative available for some patients. *Id.* at 177. Many of Respondents' patients ingest cannabis by means other than smoking, e.g., vaporization, tincture, compress, and salve.

New England Journal of Medicine, which states "that a federal policy that prohibits physicians from alleviating suffering by prescribing marijuana for seriously ill patients is misguided, heavy-handed, and inhumane." Jerome Kassirer, *Federal Foolishness and Marijuana*, New Eng. J. of Medicine (Jan. 30, 1997) at 366. The nine states that have rejected this policy are not defying the federal government. In enacting the CSA, Congress clearly expressed its intention to leave the states free to exercise their independent authority over public health:

> No provision of this subchapter shall be construed as indicating an intention on the part of Congress to occupy the field . . . unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. California's Compassionate Use Act and the CSA *can* consistently stand together, at least in the narrow canyons created by the equitable discretion of federal courts and the common law doctrine of necessity. The limited exception crafted by the district court would allow a small group of patients who need medical cannabis to avert imminent harm such as death, starvation, or blindness.[9]

The resolution of this case does not require a broad ruling by this Court that medical necessity may be asserted as a defense in any prosecution for violation of the CSA. To affirm the court below, this Court need only hold that where the government invokes the equity jurisdiction of the federal courts by seeking injunctive relief, the federal courts have discretion to limit that relief by balancing the government's need against the hardships

[9] Although two-thirds of Respondents patient-members suffer from AIDS or related disorders, and many are undergoing treatment for cancer, only 14 members (fewer than 2/10 of one percent) qualify under the rigorous standards established by this exception. App. 16a-17a.

imposed upon the Respondents. This Court can leave the amended injunction in place, and let the resolution of the availability of a defense of medical necessity await the government's criminal prosecution of a defendant who offers evidence to support the defense.

Should this Court choose to address the availability of a medical necessity defense, Respondents contend that the CSA does not foreclose this defense. As with other common law defenses such as duress and entrapment, the necessity defense is implicit in a sensible construction of the CSA to avoid injustice, oppression, or absurd consequences. *United States v. Kirby*, 7 Wall. 482, 486-87 (1869); *Sorrells v. United States*, 287 U.S. 435, 451 (1932). The placement of marijuana on Schedule I of the CSA reflects no Congressional finding that cannabis has no medical use, or that it can never serve any legitimate medical purpose. Government acquiescence in medical use by selected patients who have demonstrated medical necessity confirms that such use is not inconsistent with the CSA, and parallel provisions of the Uniform Controlled Substances Act also have been widely applied to permit compassionate use by patients demonstrating medical necessity.

Finally, to interpret the CSA as foreclosing a claim of medical necessity would raise substantial doubts as to its constitutionality. Such an interpretation exceeds the limited power of Congress to regulate interstate commerce. Respondents' activities involving the private possession and use of cannabis for medicinal purposes are solely intrastate, and do not fall within Congress's power to regulate commerce or under its power to pass laws that are "necessary and proper" for such regulation.

Moreover, if the Court were to adopt the government's position, such an interpretation would deprive patients of their fundamental liberties. These fundamental liberties are secured both by the Due Process Clause of the Fifth Amendment and rights reserved to the people

and protected by the Ninth and Tenth Amendments. In this case, exercising powers reserved to them under the Tenth Amendment, the people have recognized a fundamental liberty interest in allowing access to cannabis to alleviate illness. The Court in this case can affirm and deepen its commitment to federalism, fundamental liberties, and the powers reserved to the States and the people, and by doing so enable seriously ill patients to alleviate their suffering. Or the Court can relegate these patients to the unfettered discretion of Congress without any Congressional showing that the prohibition or conduct in question is within its powers.

ARGUMENT

I. THE CSA DOES NOT DIVEST FEDERAL COURTS OF THEIR AUTHORITY TO CONSIDER EQUITABLE FACTORS, SUCH AS HARDSHIP TO SERIOUSLY ILL PATIENTS, IN FASHIONING INJUNCTIVE RELIEF.

The Court of Appeals based its ruling upon two separate and independent grounds. The court ruled that, even if the proposed injunction were coextensive with the criminal provisions of the CSA, medical necessity was a "legally cognizable defense," and the district court could modify the injunction to exempt those who qualify for this defense. Alternatively, the court concluded that in exercising its equitable discretion, the district court must balance the strong public interest in the availability of treatment that would relieve the pain and suffering of persons with serious or fatal illnesses, against the government's asserted interests. App. 8a-9a. Thus, affirmance of the ruling of the Court of Appeals does not require this Court to decide whether medical necessity is a cognizable defense in criminal prosecutions under the CSA. This Court need only reaffirm that federal courts, in the exercise of their equity jurisdiction, have discretion to modify

an injunction based upon an equitable weighing of the public interest.

When the government decided to challenge Respondents' activities, it made a conscious, tactical decision not to initiate a criminal prosecution. The government recognized that, if it initiated criminal prosecution, it would have to prove its case beyond a reasonable doubt to a twelve-member jury that could only convict upon a unanimous verdict, and it could not seek summary judgment or appeal a verdict in the defendants' favor. The government was also aware of the risk that a jury of California citizens, who overwhelmingly approve of the medicinal use of cannabis, might take a dim view of the governmental attempt to deprive grievously ill citizens of medication essential for relief during the last days of their lives. In avoiding the judgment of a jury, however, the government must submit to the discretion of a court of equity.

Any restriction of the federal courts' broad equitable discretion must plainly appear in the legislation authorizing the injunction. *Hecht Co. v. Bowles*, 321 U.S. 321, 329-30 (1944); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 329-30 (1982); *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542-44 (1987). In conferring jurisdiction to issue injunctions against CSA violations under 21 U.S.C. § 882(a), Congress expressed no intention to limit the traditional equitable discretion of federal courts to weigh the public interest, and to consider the hardship that an injunction would impose before granting relief.

In *Hecht*, the Administrator of the Emergency Price Control Act sought an injunction barring a store from selling goods for more than the maximum price allowed under the Act. The district court refused to issue an injunction against future violations on the equitable grounds that past violations were inadvertent and the defendant had acted in good faith. As in this case, the

government argued that by giving the district court jurisdiction to issue injunctions to aid in enforcement of the Act, Congress restricted the court's traditional equitable discretion, imposing a mandatory duty to issue an injunction.

This Court ruled that district courts have broad discretion to consider equitable factors 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.

Hecht, 321 U.S. at 329-30 n.9. Believing that an abrupt departure from this long historical tradition could not be lightly implied, this Court concluded that Congress must make its desire for such a departure plain. *Id.* at 330.

In reaching its conclusion, this Court did not consider whether "good faith" or "inadvertence" were defenses to a charge of violating the Act, focusing instead on whether there was an equitable basis for the court's decision. Similarly, the issue here is *not* whether "necessity" is a defense to violations of the CSA, but whether the district court in the exercise of its equitable discretion can appropriately consider the hardship to seriously ill individuals who have no alternative to cannabis for relief of their pain and suffering.

There is no evidence in the text of the CSA that when Congress enacted the statute in 1970, Congress intended to deprive the district courts of their traditional equitable

discretion. Indeed, Section 882(a) simply confers jurisdiction to issue injunctions.[10] Nor is there anything in the legislative history of Section 882(a) remotely suggesting that Congress intended to strip 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).

Respondents do not dispute the government's assertion that a district court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation," (Pet.Br. 37, 40), nor any of the cases cited to support this proposition.[11] The cases demonstrate that Congress can clearly express its intent to limit the equitable jurisdiction of the federal courts, when it wishes to do so. Congress did *not* do so in the CSA. Instead, Congress simply acknowledged the jurisdiction of the courts to issue injunctions. As recognized by this Court, however, "[a] grant of *jurisdiction* to issue compliance orders hardly suggests an absolute duty to do so under any and all circumstances." *Hecht*, 321 U.S. at 329 (emphasis added).

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[10] Section 882(a) provides:

> 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 proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of [the CSA].

[11] *E.g., Virginian Ry. v. System Fed'n No. 40, et al.*, 300 U.S. 515, 552 (1937) (injunction mandating negotiation appropriate where Congress indicated purpose to make negotiations "obligatory"); *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 421 (1975) (inclusion of a backpay remedy in the Equal Employment Opportunity Act of 1972 was "to make possible the 'fashion[ing] [of] the most complete relief possible"); *Miller v. French*, 120 S. Ct. 2246, 2252-53 (2000) (Prison Litigation Reform Act included unambiguous limitation on equitable powers of courts to enjoin automatic stay).

This Court has not retreated from *Hecht's* insistence upon a clear expression of Congressional intent to limit equitable discretion. In *Romero-Barcelo, supra*, residents of Puerto Rico sued to enjoin the Navy from discharging waste in violation of the Federal Water Pollution Control Act (FWPCA). The district court concluded the Navy violated the FWPCA, but denied injunctive relief because the 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. The First Circuit reversed, holding that Congress intended to impose a mandatory duty on courts to issue injunctions under the FWPCA. Reversing the First Circuit, this Court reiterated the holding of *Hecht*. 456 U.S. at 313. Moreover, 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 FWPCA. *See also Village of Gambell*, 480 U.S. at 544. ("no clear indication . . . that Congress intended to deny federal district courts their traditional equitable discretion . . . nor [is this Court] compelled to infer such a limitation.")

The government relies upon *TVA v. Hill*, 437 U.S. 153 (1978), in which this Court held that in enacting the Endangered Species Act (ESA), Congress deprived district courts of discretion and mandated that injunctions issue to prevent the eradication of endangered species. Thus, the Court enjoined construction of a dam that would cause the extinction of an endangered species. *Hill* preceded *Romero-Barcelo*, which explained the *Hill* ruling in terms of the unique configuration of the ESA. The injunction in *Hill* was mandatory because it was the *only* way to fulfill the purpose of the statute. *Romero-Barcelo* 456 U.S. at 314. In contrast, in *Romero-Barcelo*, "[a]n injunction [was] not the *only means* of ensuring compliance with federal law." *Id.* (emphasis added).

Unlike the ESA considered in *Hill*, the CSA relies principally upon criminal prosecution to fulfill its prohibition of unlawful distribution of controlled substances. An injunction is *not* the *only* remedy available to fulfill its purposes. In fact, the injunction is rarely used at all. Throughout the entire thirty year history of the CSA, only two reported cases can be found in which Section 882(a) was ever employed by the government to enjoin CSA violations.[12]

The government's attempt to distinguish injunctions that "countenance" or "allow" continuing violations from those in which a court is deciding "how best to assure *compliance* with a congressional act" is disingenuous. Pet.Br. 40-42. First, the refusal to enjoin seriously ill patients from resort to the only medication that relieves their suffering is *not* to "countenance" or "allow" an alleged violation, but simply to require that the government use the alternative most commonly and routinely pursued to enforce the CSA: criminal prosecution. Second, the alleged violations that the court below held need not be enjoined did not threaten "the large objectives of the Act." *Hecht*, 321 U.S. at 331. Pet.Br. 42. The "large objective" of the CSA is to promote "the health and general welfare of the American people." 21 U.S.C. § 801(1),(2). That purpose is advanced by refusing to enjoin seriously ill Americans who have no other alternative available to stay alive, retain their sight, or stop vomiting and start eating. Third, the government overlooks the important fact that it is seeking to restrain state officers in the administration of state law, and the scope

[12] *United States v. Leasehold Interest in 121 Nostrand Ave.*, 760 F. Supp. 1015, 1035 (E.D.N.Y. 1991) (enjoining use of public housing to facilitate narcotics offenses); *United States v. Williams*, 416 F. Supp. 611, 614 (D.D.C. 1976) (enjoining defendant from filling prescriptions).

of relief is constrained by principles of comity and federalism.[13]

Thus, the government's decision to forego criminal prosecution in this case, and seek injunctive relief for tactical reasons, does not impose a mandatory duty upon the district court and eliminate its traditional equitable discretion. The ruling of the court below recognizes the existence of that discretion, and calls upon the district court to exercise it in considering a modification of the injunction to exempt a miniscule number of seriously ill patients who face dire health consequences and have exhausted all other alternatives for relief of their suffering.

II. THE CSA DOES NOT FORECLOSE THE DEFENSE OF NECESSITY.

A. Courts Cannot Abrogate The Necessity Defense Absent a Clearly Expressed Intention by Congress to Do So.

The government argues that the CSA creates a "closed system" that forecloses any common law defense of necessity, because possession or distribution of a controlled substance in response to such necessity would not conform to the strict regulatory controls of the CSA. Pet.Br. 20-23. This extravagant claim proves too much. If the government's argument succeeded, it would foreclose not only claims of necessity, but also claims of duress and entrapment. If a defendant proved that he distributed a Schedule I substance only because someone put a gun to his head and threatened to pull the trigger, would this

[13] "Where, as here, the exercise of authority by state officials is attacked, federal courts must be constantly mindful of the 'special delicacy of the adjustment to be preserved between federal equitable power and State administration of its own law.' [citation omitted]." *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 104 n.13 (1984).

Court declare he still committed a crime, because his act of distribution was "outside" the "closed system" of the CSA? If a defendant established that, without predisposition, he supplied a Schedule I substance to an undercover government agent who repeatedly entreated him with false claims of dire medical need, would this Court respond that a claim of entrapment was foreclosed, because the CSA does not spell out an entrapment exception to its "closed system"?

This Court has already declared that a defendant with no predisposition who is enticed into violating the CSA by a government agent *can* assert a defense of entrapment. *Hampton v. United States*, 425 U.S. 484, 490 (1976). Lower federal courts have consistently recognized that a defendant can raise a duress defense to defeat a prosecution for violating the CSA.[14] Obviously, transactions that are excused on a showing of entrapment or duress do not conform with any of the regulatory controls the CSA imposes on drug distribution, such as registration and record-keeping. Yet these defenses do not render the regulatory scheme "wholly nugatory." Pet.Br. 20, citing *United States v. Bailey*, 444 U.S. 394, 416 n.11 (1980). Rather, they make the regulatory scheme consistent with our broader notions of justice and common sense. The underlying purpose of the CSA is not the bureaucratic compilation of a paper trail for every transfer of a pill but rather to promote "the health and general welfare of the American people." 21 U.S.C. § 801(1),(2). The minuscule number of transactions that would be excused by a necessity defense, where the necessity is to avoid greater

[14] *See, e.g., United States v. Contento-Pachon*, 723 F.2d 691 (9th Cir. 1984). The duress defense sometimes has been rejected under the CSA not because the CSA does not allow the defense, but because the defendant did not present credible evidence that other alternatives were not available. *See, e.g., United States v. Posada-Rios*, 158 F.3d 832 (5th Cir. 1998), *cert. denied*, 526 U.S. 1031 (1999).

harms such as death, blindness, or starvation, would not render the registration or record-keeping regulations of the CSA "wholly nugatory."

In terms of the underlying common law policies that justify them, the defenses of duress and entrapment are indistinguishable from the necessity defense. In *Sorrells v. United States*, 287 U.S. 435 (1932), this Court addressed the availability of the entrapment defense to a charge of distributing whiskey in violation of the "closed system" created by the National Prohibition Act. The government made essentially the same argument it makes here: "the legislature, acting within its constitutional authority, is the arbiter of public policy and that, where conduct is expressly forbidden and penalized by a valid statute, the courts are not at liberty to disregard the law and to bar a prosecution for its violation because they are of the opinion that the crime has been instigated by government officials." *Id.* at 445-46. In rejecting this argument, Chief Justice Hughes turned to the venerable precedent of *Kirby*, where the Court declared:

> All laws should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence. It will always, therefore, be presumed that the legislature intended exceptions to its language, which would avoid results of this character.

7 Wall. at 486-87. Among its "common sense" illustrations of this principle, the Court cited the common law ruling that a statutory prohibition of prison escape "does not extend to a prisoner who breaks out when the prison is on fire – 'for he is not to be hanged because he would not stay to be burnt.' " *Id.* at 487.

In similar terms, and again citing *Kirby*, this Court recognized that a defense of duress or necessity could be asserted to a violation of the Congressional prohibition of prison escape, 18 U.S.C. § 751(a):

> The statute itself, as we have noted, requires no heightened *mens rea* that might be negated by any defense of duress or coercion. We nonetheless recognize that Congress in enacting criminal statutes legislates against a background of Anglo-Saxon common law, see *Morissette v. United States*, 342 U.S. 246 (1952), and that therefore a defense of duress or coercion may well have been contemplated by Congress when it enacted § 751(a).

Bailey, 444 U.S. at 415-16 n.11.

Necessity is among the oldest and most deeply entrenched defenses in Anglo-Saxon common law, whose roots can be traced to the mid-thirteenth century in England, and earlier on the Continent.[15] Although the necessity defense is frequently analyzed in consequentialist terms, calling for a utilitarian "balancing" of the "harms," it also implicates a moral judgment by a jury regarding the defendant's conduct.[16] The crucial role of the jury, in turn, suggests that courts should approach with caution the argument that a legislature has foreclosed a necessity defense by making its own balance of competing values. A legislative judgment cannot accommodate all of the factual variables that might affect a moral judgment of what is right and proper under the circumstances.

Similarly, the Model Penal Code, in its formulation of the necessity defense, suggests caution in concluding the

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[15] *See* Reeve, *Necessity: The Right to Present a Recognized Defense*, 21 New Eng. L. Rev. 779, 781-84 (1986); 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).

[16] *See* Fletcher, *Rethinking Criminal Law*, § 0.2 at 792-93 (1978); Hall, *General Principles of Criminal Law*, p. 419 & n.16 (2d Ed. 1960); Parry, *The Virtue of Necessity: Reshaping Culpability and the Rule of Law*, 36 Houston L. Rev. 397 (1999).

defense is legislatively foreclosed in its requirement that a legislative purpose to exclude the justification "plainly appear." Model Penal Code, § 3.02(1)(c) (1962).[17] Congress has never enacted a statute that explicitly foreclosed the common law defenses of necessity, duress, or entrapment, and this Court has never found that abrogation of any of these defenses could be implied from the language of any Congressional enactment.

The record in this case offers some dramatic examples of the compelling dimensions of necessity claims. Consider, for example, the plight of Robert Bonardi, the 74-year-old owner of a vacuum cleaner store who is now deceased. J.A. 80. Mr. Bonardi survived a bout of cancer of the larynx with a permanent tracheotomy, and lived through prostrate cancer. With the discovery of numerous new tumors in his neck and chest, he underwent an aggressive regimen of radiation and chemotherapy. He experienced serious nausea as a side effect of the chemotherapy:

> I would retch whenever I thought about food or whenever anyone tried to put food in front of me. The nausea made me particularly afraid to eat because my throat condition makes it especially unpleasant if I vomit. Not only would vomit come out of my mouth, but it would also come out of my nose.

J.A. 81. After losing forty pounds in six weeks, and finding none of the prescribed medications helped, Mr. Bonardi's daughter brought him to the Cooperative. "At first I did not want to go," he said. "It took my daughter a long time to convince me to go. I am 74 years old, and

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[17] Even Professor LaFave, a leading proponent of the utilitarian approach, emphasizes that courts must be free to consider the merits of a necessity claim when a statute is silent upon the matter. Wayne LaFave, *Criminal Law*, § 5.4 at p. 478 (3d Ed. 2000).

had never used marijuana before in my life." After struggling to consume a cannabis brownie (he could not smoke), he reported:

> [F]or the first time in several weeks, I felt like eating. The brownie caused my nausea to go away. I asked my wife to cook me eggs and sausage. She was so happy because it had been so long since I had asked for food. I have since regained some of the weight I lost.

J.A. 82. If Mr. Bonardi were our own father or brother, which of us would hesitate for a moment before supplying him with cannabis? Would any civilized society *punish* Mr. Bonardi or his daughter? Under circumstances such as these, implicating the very instinct for survival, the necessity defense simply reflects the law of nature:

> This law of nature, being coeval with mankind and dictated by God himself, is of course superior in obligation to any other. It is binding over all the globe in all countries, and at all times; no human laws are of any validity, if contrary to this; and such of them as are valid derive all their force, and all their authority, mediately or immediately, from this original.

1 William Blackstone, *Commentaries* *39.

The government cannot seriously suggest that Congress intended to foreclose all claims of necessity when it enacted the CSA, and made a conscious value choice that the majesty of the federal law outweighed the retching discomfort of patients such as Robert Bonardi. The common law defense of necessity wisely allows the assessment of the moral culpability of Mr. Bonardi and his daughter to rest in the hands and hearts of an American jury.[18]

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[18] A common law necessity defense may be asserted by both the patient and the person who provides the medication needed to avoid imminent harm. *United States v. Newcomb*, 6 F.3d 1129 (6th Cir. 1993) ("it is fundamental that the defense must apply equally to a choice-of-evils case when the evil is to a third party as to the case where the evil is to one's self").

B. Recognition of a Defense of Necessity Is Not Inconsistent with the Congressional Classification of Marijuana on Schedule I of the CSA.

Unable to point to any explicit rejection of any common law defenses in the text of the CSA, the government erroneously asserts that Congress "has declared" and "found" that marijuana has no "currently accepted medical use in treatment in the United States," and has no "accepted safety for use * * * under medical supervision," citing the criteria contained in 21 U.S.C. § 812(b)(1)(B) and (C). Pet.Br. 13, 20. Section 812(b), however, implies no Congressional finding or declaration about cannabis whatsoever. Section 812(b) merely establishes the criteria for *administrative* classification or reclassification of drugs pursuant to 21 U.S.C. § 811. When *Congress* directly classifies a drug, as it did cannabis in 1970, it is not bound by the criteria in section 812(b). In fact, Congress has directly classified drugs on Schedule I precisely because they *did* have an accepted medical use, and for that very reason they could not be *administratively* placed on Schedule I.[19]

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[19] In 1984, Congress by statute ordered the transfer of methaqualone from Schedule II to Schedule I of the CSA, even though it was universally acknowledged to have an accepted medical use and had been approved for marketing by the FDA. Pub. L. 98-329, 98 Stat. 280 (1984). The House Committee Report noted:

> [T]he [DEA] does not have authority to impose Schedule I controls on a drug which has been approved by the [FDA] for medical use. The statutory findings required for agency scheduling decisions clearly state that the agency may not, *in the absence of Congressional action*, subject drugs with a currently

Thus, mere placement of a substance on Schedule I *by Congress* implicates no declaration, finding, or any determination whatsoever as to its currently accepted medical use. It only indicates Congress wishes to assert the most restrictive level of controls created by the CSA over its use. The assertion of the most restrictive level of controls over a substance, in turn, implies no judgment regarding the availability of a defense of necessity to justify use in exceptional, urgent circumstances.

Alternatively, the government suggests that a court cannot reconcile the common law doctrine of necessity with the statutory procedures for administrative reclassification of drugs. Respondents do not challenge the current classification of cannabis in these proceedings.[20] Administrative reclassification is a process that addresses the availability of drugs for general medical use, not the appropriateness of its use by an individual patient who has no other alternative to avoid imminent harm. In the context of administrative reclassification, the statutory criteria of "currently accepted medical use" serves a completely different purpose than the necessity defense. In *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994), the court upheld a 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;

> accepted medical use in the United States to Schedule I controls.

H.R. Rep. No. 98-534, 98th Congress, 2d Sess. 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 540, 543-44 (emphasis added).

[20] Nor do Respondents seek permission to market cannabis as a "new" drug in interstate commerce. Thus, the restrictions of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, (*see* Pet.Br. 6) are irrelevant.

> (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. If cannabis meets these criteria, the DEA can administratively reclassify it to another schedule of the CSA and it will then be generally available by prescription from any physician. The physician will not then be required to treat a patient who must meet the stringent criteria for medical necessity. *See* App. 16a-17a. But it is unreasonable to expect a patient who demonstrates true legal necessity to await the drug's administrative reclassification. As the district court noted, the last challenge to the Schedule I classification of cannabis took over twenty years to resolve. "Needless to say, it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to relieve a current medical problem." App. 70a. The necessity defense exists to accommodate the urgent needs of a particular patient who will suffer a greater harm if denied access to the drug. The necessity doctrine functions as a safety valve, to prevent rigid application of the law despite unusual circumstances the legislature did not contemplate.

Viewed from this perspective, the concept of 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 all generally accepted treatments prove ineffective or intolerable, the physician and the patient may jointly agree that necessity requires treatment that has not yet achieved general acceptance. The necessity doctrine applies to a particular patient or class of patients who have exhausted all generally accepted treatments. The CSA is 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.

C. Nothing in the Legislative History of the CSA Suggests Any Intent to Abrogate the Common Law Necessity Defense.

Congress conceded that it lacked information to make any judgment about medical necessity for cannabis when it enacted the CSA in 1970. Months before it enacted the CSA, Congress enacted the Marijuana and Health Reporting Act, Pub. L. No. 91-296, § 501-03, 1970 U.S.C.C.A.N. 418, which directed the Secretary of 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 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 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 marijuana 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 tentatively placed marijuana on Schedule I, but to resolve uncertainty, 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. 27, 1970, Pub. L. No. 91-513, § 601, 1970 U.S.C.C.A.N. (84 Stat.) 1489-90. The report was to

include 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. 27, 1970, Pub. L. 91-513, § 601(d)(1)(C) & (2), 1970 U.S.C.C.A.N. (84 Stat.) 1490.

The Shafer Commission recommended that Congress amend the CSA, and that the States amend their laws, so that all possession of marijuana 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." *Marijuana: A Signal of Misunderstanding; First Report of the National Commission on Marihuana and Drug Abuse*, 152-53 (1972). Thus, the legislative history of the treatment of cannabis yields neither an explicit rejection of a necessity defense, nor any implicit criticism of such a defense.

Because the CSA is a criminal statute, which imposes severe penalties for its violation, courts must interpret it 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. 1992). A corollary to this ancient 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." *United States v. Granderson*, 511 U.S. 39, 54 (1994). Drug laws are no exception to this rule, as this Court warned in *Granderson*. The government cannot rely on general statements that Congress intended to "get tough on drug offenders," but must point to specific evidence that Congress expressed intent on the narrow issue in question. *Id.* at 49.

Acceptance of the government's argument in this case would make the CSA the only federal criminal prohibition to which a citizen could not assert a necessity defense. However, citizens are entitled to clear notice if a particular criminal statute proscribes more conduct than the criminal laws generally proscribe. *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.").

If a court were to construe the CSA to impose broader criminal liability than any other statute enacted by Congress, the government must point to its text to support such a construction. If the text is silent or ambiguous, a finding of Congressional intent to abrogate a universally available defense should not be based on the statute's legislative history.[21] In this case, nothing in the CSA's legislative history evidences any intent to abrogate the necessity defense.

D. Government Acquiescence in the Continued Governmental Distribution of Cannabis to Patients Demonstrating Necessity Confirms that a Necessity Defense Is Not Inconsistent With the CSA.

Throughout the thirty years that federal authorities have administered the CSA, they have perceived no inconsistency between the classification of marijuana on Schedule I, and the federal program for therapeutic use by patients whose serious medical conditions could be alleviated only by the use of cannabis. Federal authorities continue to supply these patients with government-grown cannabis to this very day. At last report, there are eight patients still enrolled in this

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[21] "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.

program who receive a regular supply of medical cannabis from the United States government. *Despite Marijuana Furor, 8 Users Get Drug From The Government*, The N.Y. Times, Dec. 1, 1996, p. 33.

The government initiated the Compassionate Investigative New Drug ("I.N.D.") program to settle a lawsuit filed by glaucoma patient Robert Randall after he was acquitted of unlawful cannabis cultivation in the District of Columbia, based upon a showing of necessity. *United States v. Randall*, 104 Wash. D. Rep. 2249 (D.C. Super., 1976).[22]

Randall presented incontrovertible 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.

In response to Randall's dilemma, the federal government created an I.N.D. protocol to make government-grown cannabis available for medical treatment.[23] By 1983,

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[22] *See also* Robin Isenberg, *Medical Necessity As a Defense to Criminal Liability: United States v. Randall*, 46 Geo. Wash. L. Rev. 273 (1978).

[23] In testimony before the House Select Committee on Narcotics Abuse and Control in 1980, Randall congratulated the National Institute on Drug Abuse, the Federal Drug Administration, and the Drug Enforcement Administration for devising a plan to meet his medical necessity:

> My private physician writes prescriptions, and I take these prescriptions to a pharmacy near my home here in Washington, D.C. On the basis of such a prescription, the pharmacy provides me with seventy NIDA prepared and pre-rolled marijuana cigarettes

the FDA had approved seventy-nine I.N.D. plans to permit therapeutic use of THC and cannabis. These plans dealt with nausea and vomiting from cancer chemotherapy, glaucoma, spasticity, and weight loss.[24] Jones & Lovinger, *The Marijuana Question*, 136 (1985). These were *not* clinical trials to test the drug for eventual approval, however. Rather, they were a convenient umbrella for the government to administer a program of medical use by patients demonstrating necessity:

> The very existence of the compassionate-care program contradicts federal policy and puts the Food and Drug Administration in an "awkward position," said Don McLearn, a spokesman for the Agency. Despite its name, the Compassionate Investigative New Drug program, known as a compassionate I.N.D., is not a research study intended to evaluate the medicinal value of marijuana. "It is not a clinical trial," Mr. McLearn said, "There was never any intent of using reports from the compassionate I.N.D.'s to reach approval for the drug."

> of a known potency. Dismissing all past complaints, NIDA, FDA, and DEA have been, are now, and will continue to provide me with marijuana within a system of care which respects my personal needs and reflects the medical demands of my condition, not the preordained assumptions of a federal bureaucrat.

Therapeutic Uses of Marijuana and Schedule I Drugs, Hearing Before the Select Committee on Narcotics Abuse and Control, House of Representatives, 96th Cong., 2d Sess., May 20, 1980, at p. 8.

[24] In *United States v. Burton*, 894 F.2d 188 (6th Cir. 1990), when a glaucoma patient asserted a necessity defense in federal court, the defense was rejected *not* because it was inconsistent with the classification of marijuana on Schedule I; but because the Compassionate I.N.D. program at that time provided a reasonable legal alternative to violating the law. 894 F.2d at 191.

Despite Marijuana Furor, 8 Users Get Drug From the Government, The N.Y. Times, Dec. 1, 1996, p. 33.

The consistent interpretation of the CSA by those charged with its administration to permit medical use by some patients with necessity is persuasive evidence that the Schedule I classification was *never* intended to preclude any use for medical purposes.[25] It should be presumed that legislative intent has been correctly discerned when an agency's interpretation has been fully brought to the attention of the public and Congress, and the latter has not sought to alter that interpretation. *United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979).[26]

The government still operates the Compassionate I.N.D. Program for eight patients. The government cannot reconcile its establishment and continued administration of the Compassionate I.N.D. program providing cannabis to seriously ill patients with its argument in this case that the operation of a local government's compassionate program providing cannabis to seriously ill patients under circumstances demonstrating necessity violates federal law. The placement of cannabis on Schedule I of the CSA is not inconsistent with either program. Both are fully justified by necessity.

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[25] *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.").

[26] Congress was made fully aware of the operation of the Compassionate I.N.D. Program to meet the medical needs of select patients. *See* Therapeutic Uses of Marijuana and Schedule I Drugs, Hearing Before the Select Committee on Narcotics Abuse and Control, *supra* n.23. Testimony of Dr. Marvin Snyder, National Institute on Drug Abuse. *Id.* at 821. The program was also widely publicized in press and television reports. Randall & O'Leary, *Marijuana Rx: The Patient's Fight for Medicinal Pot* (1998).

E. The Widespread Creation of "Therapeutic Research Programs" by States That Have Adopted the Uniform Controlled Substances Act Demonstrates that Accommodation of Necessity Is Not Inconsistent With the CSA.

The CSA served as the model for the Uniform Controlled Substances Act (the "Uniform Act"), subsequently adopted by forty-eight states.[27] 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, the Uniform Act places marijuana on Schedule I.[28] Of the forty-five states that maintain the classification of marijuana on Schedule I, twenty-six subsequently enacted the "Controlled Substances Therapeutic Research Act," (TRA) recognizing the therapeutic value of cannabis and permitting its use for medical purposes in circumstances virtually identical to the circumstances presented in cases of necessity: patients suffering from life-threatening or sight-threatening illnesses for whom the alternatives offered by conventional medicine do not work. *See Marijuana, Medicine & The Law* (Randall, Ed.) at 279 (1987).

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

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[27] Only New Hampshire and Vermont failed to enact the Uniform Controlled Substances Act. *See* Table, Uniform Controlled Substances Act, 21 U.S.C.A. § 357 to 840, pp. 539-40 (West 1999); Unif. Controlled Substances Act, 9 U.L.A., Part II, pp. 1-2 (1997).

[28] Most states adopting the Uniform Act retained its classification of marijuana on Schedule I. *But see* Alaska Statutes, § 11.71.160 (Michie 2000) (Schedule IIIA); Ark. Code Ann. § 5-64-215 (Schedule VI) (Michie 1999); D.C. Code Ann. § 33-516 (Schedule II) (1981); 17-A Maine R.S. § 1102 (1999) (Schedule Z); N.C. Gen. Stat. § 90-94 (2000) (Schedule 6); Tenn. Code Ann. § 39-17-408, 415 (2000) (Schedules 2, 4).

though they classified it on Schedule I of their Controlled Substances Act. They saw no inconsistency between a Schedule I classification and a finding that access to the drug was necessary for patients facing potential loss of life or sight.

Although interpretations of state statutes do not control construction of federal law, they can indicate general understanding of terms such as "no currently accepted medical use." *Cf. Espinoza v. Farah Mfg. Co., Inc.*, 414 U.S. 86, 88 n.2 (1973). This is especially true where the state and federal statutes employ precisely the same language.

The government cites the rejection of a necessity defense by the Supreme Court of New Jersey as a purported example of the principle that the necessity defense is unavailable when the legislature has foreseen the circumstances faced by the defendant and rejected them. *State v. Tate*, 505 A.2d 941, 946 (1986); Pet.Br. 18 n.9. This ignores the fact, however, that New Jersey is among the states that adopted the TRA. The *Tate* court rejected a statutory defense of necessity based upon its satisfaction "that our legislature has contemplated the defense urged by Michael Tate, has provided a specific exception dealing with it (citing the TRA) and has made plain its intent to exclude the defense as specifically provided." 505 A.2d at 945. Thus, the legislative "rejection" suggested by the government was actually the adoption of the necessity exception in the TRA, which Michael Tate did not utilize. The New Jersey Court concluded that even if cannabis were not available for medical purposes through the state's TRA, "marijuana is and was legally available through the FDA," noting that eight of the 79 patients then enrolled in the federal Compassionate I.N.D. program were also afflicted with spasticity. *Id.* at 946 n.1.

Thus, there is widespread concurrence among the states adopting the Uniform Act that the classification of cannabis on Schedule I is not inconsistent with permitting the medical use of cannabis under circumstances closely

analogous to the necessity defense, or even with the explicit recognition of a necessity defense. This strongly supports the conclusion that parallel provisions in the CSA do not prohibit recognition of the necessity defense in federal cases.

F. The 1998 "Sense of Congress" Resolution Does Not Restrict the Availability of a Necessity Defense Under the CSA.

Lacking any credible support in the text or legislative history of the CSA to suggest foreclosure of a necessity defense, the government seizes upon a "Sense of Congress" resolution that Schedule I drugs "are unsafe, even under medical supervision." Pet.Br. 7-8, quoting Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760. This is not a finding of fact based upon any hearings or empirical investigation meriting judicial deference. In truth, it is not a finding of fact at all. It is buried in the massive *Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999*.[29]

Though captioned, "Not Legalizing Marijuana for Medical Use," the resolution contains no findings concerning the medical use of cannabis or anything else. It merely reiterates provisions of the CSA and Federal Food, Drug, and Cosmetic Act, and expresses opposition to efforts to "legalize" marijuana for medical use. Neither the court below nor the district court purported to "legalize" marijuana, however. They merely declined to enjoin its use under limited circumstances where the patient will suffer

[29] The Sense of Congress resolution did not purport to amend the CSA, nor could it do so by implication. Repeals by implication are especially disfavored in the appropriations context. *Hill*, 437 U.S. at 190-191. Congress may amend substantive law in an appropriations statute, but only if it clearly expresses its intent to do so. *Robertson v. Seattle Audubon Soc'y*, 503 U.S. 429, 440 (1992).

imminent harm and all available alternatives are ineffective or intolerable.

The "Sense of Congress" resolution makes no mention of necessity. The statements of the sponsor quoted in the government's brief (Pet.Br. 26) confirm that his purpose was to express opposition to the enactment of initiative measures by the States, which permit much broader use of cannabis for medical purposes than does the doctrine of medical necessity. A Congressional resolution expressing political opposition to state initiatives does not have the force of law. *Boos v. Barry*, 485 U.S. 312, 327-28 (1988).

Characterizing the resolution as reinforcement of a previous prohibition of unauthorized distribution of marijuana (Pet.Br. 26 n.15) simply engages us in tautology. While the classification of marijuana on Schedule I precludes the issuance of ordinary medical prescriptions, it does not purport to preclude its use under circumstances of necessity. The CSA is silent as to the defense of necessity – and the "Sense of Congress" resolution adds nothing to that silence.

G. *United States v. Rutherford* Does Not Support the Government's Contention that Necessity Is Not Available As a Defense Under the CSA.

Citing this Court's holding in *United States v. Rutherford*, 442 U.S. 544 (1979), the government argues that a claim of "medical need" cannot override a Congressional judgment. Pet.Br. 27. Here, of course, Respondents do not contend that their medical need "overrides" Congressional intent, but that Congress has expressed no intent to limit the availability of common law defenses such as necessity under the CSA. The claim made in *Rutherford* was very different: that drugs used by the terminally ill were an implied exception to the safety and effectiveness standards imposed by the FDA upon the interstate marketing of new drugs.

Here, the government seeks to enjoin seriously ill patients from individually obtaining a therapy of proven

effectiveness and which is their only available alternative. In *Rutherford,* a group of patients sought to enjoin the government from interfering with the interstate shipment and sale of Laetrile. No claim of "necessity" was asserted, nor could one be asserted.[30] There was no credible evidence to support the claim that Laetrile was a cancer cure. The *Rutherford* plaintiffs asserted a right to use it *regardless* of its efficacy, simply because they were terminally ill. The Court responded that Congress clearly intended the protections of the Food, Drug, and Cosmetic Act to apply to the terminally ill, to protect them from fraudulent cures whose false claims might induce them to forego conventional treatment.[31] 442 U.S. at 552-53.

The Court also noted that the FDA itself had never made exception for drugs used by the terminally ill. *Id.* at 553. The FDA has, on the other hand, made exceptions for the medical use of cannabis through the Compassionate I.N.D. Program.

Rutherford does not support the government's position in this case. The ruling this Court reversed in that case would have "den[ied] the Commissioner's authority over all drugs, however toxic or ineffectual, for [terminal patients]." *Id.* at 557-58. In contrast, the Court of Appeals' decision here does not challenge to the authority of Congress or the DEA to classify or reclassify substances under

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[30] The only case in which a claim of "medical necessity" for Laetrile was ever asserted is *United States v. Richardson,* 588 F.2d 1235 (9th Cir. 1978). Defendants were convicted of illegally smuggling Laetrile from Mexico. The defense was rejected, not because the statute precluded it, but because the defendants could not establish that no reasonable alternatives to violation of the law were available. *Id.* at 1239.

[31] There is no risk that patients who use cannabis as a medicine will forego conventional treatment. Cannabis is used to alleviate symptoms, or side-effects of conventional treatments. In this respect, it actually *promotes* the conventional treatment. J.A. 127-129.

the CSA, nor does it limit the government's power to enforce the CSA. Rather, the decision merely protects individual patients' access to a medication that has been shown to offer the only source of relief for their torment.

III. IF THE CSA IS INTERPRETED TO FORECLOSE A NECESSITY DEFENSE, IT IS UNCONSTITUTIONAL.

Courts must interpret all statutes, including the CSA, to avoid constitutional problems, so long as the saving construction is not "plainly contrary to the intent of Congress." *United States v. X-Citement Video, Inc.,* 513 U.S. 64, 78 (1994), *Solid Waste v. United States,* 2001 WL 15333 (U.S. Jan. 7, 2001) (interpreting Clean Water Act narrowly to avoid "significant constitutional and federalism questions" under *United States v. Lopez,* 514 U.S. 549 (1995) and *United States v. Morrison,* 120 S. Ct. 1740 (2000)). If the Court accepts the government's argument that the CSA abrogated the discretion of federal courts to balance the potential harm to patients in issuing injunctions, and eliminated the medical necessity defense even for seriously ill patients with no other alternative, the Court must decide whether Congress exceeded the powers granted to it by the Constitution to regulate interstate commerce, violated the substantive due process rights of patients to be free from pain and preserve their lives and infringed upon rights expressly retained by the people of California and powers reserved by the people and State of California in violation of the Ninth and Tenth Amendments.

A. It Is Beyond The Powers of Congress Under Either the Commerce Clause or The Necessary and Proper Clause to Prohibit the Use of Cannabis In Cases of Medical Necessity.

The government seeks to prohibit the medical use of cannabis by seriously ill persons upon recommendation of their physicians, and the cultivation and distribution of

cannabis for this limited purpose by an organization authorized and regulated by a local municipality in accordance with state law. If this prohibition exceeds the enumerated powers of Congress, there is no need to consider whether the prohibition violates a fundamental right.

Congress has no general police powers. *Lopez*, 514 U.S. at 566 ("The Constitution . . . withhold[s] from Congress a plenary police power that would authorize enactment of every type of legislation."); *McCulloch v. Maryland*, 17 U.S. (4 Wheat) 316, 405 (1819); *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 176 (1803) ("The powers of the legislature are defined, and limited; and that those limits may not be mistaken or forgotten, the constitution is written."). The Constitution confines Congress to enumerated powers and execution of those powers through laws that are necessary and proper.

The activities involved in this case fall within neither the power of Congress "to regulate Commerce . . . among the several states," nor its power to pass laws that "shall be necessary and proper" to execute its power to regulate commerce. U.S. Const., Art. I, § 8. The private possession, use, and cultivation of cannabis for medicinal purposes is not commerce at all. While the buying or selling of cannabis may be commerce, the prohibition asserted by the government here extends to *any* distribution, even the delivery from a primary caregiver to the patient for no charge.

As recently noted by this Court, "thus far in our Nation's history our cases have upheld Commerce Clause regulation of intrastate activity only where that activity is economic in nature." *Morrison*, 120 S. Ct. at 1751; *see also id.* at 1750 ("[W]here we have sustained federal regulation of intrastate activity based upon the activity's substantial effect on interstate commerce, the activity in question has been some sort of economic endeavor."). Supplying cannabis to another for medical purposes without charge is not an economic endeavor. Nor is growing a cannabis

plant for one's own medical use. Therefore, like the crime of rape in *Morrison*, the regulation and prohibition of these activities lie solely within the police power of the state. The fact that the possession, use and cultivation of cannabis for medical purposes is a nonviolent activity related to health only bolsters this conclusion. *See GMC v. Tracy*, 519 U.S. 278, 306 (1997) (reaffirming the paramount interest of the states in regulating health matters.)[32]

Only the cultivation and distribution of cannabis in exchange for money or barter can be considered commerce, but even such commerce here is exclusively intrastate and therefore not within the power of Congress to regulate commerce "among the states." The government does not dispute that Respondents provided cannabis grown entirely in California, by California cultivators, and distributed wholly within California, by only California residents, exclusively to California patients, who had recommendations or approvals issued solely by California-licensed physicians, for use only within California.[33]

If Congress is to reach the solely intrastate distribution of cannabis for medical use, it must do so under its power to pass laws that are "necessary and proper" to put

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[32] Nor can the noncommercial possession, use or cultivation of cannabis for medicinal purposes be reached under the "aggregation principle" of *Wickard v. Filburn*, 317 U.S. 111 (1942). As was explained in *Morrison*, "in every case where we have sustained federal regulation under *Wickard's* aggregation principle, the regulated activity was of an apparent commercial character." *Morrison*, 120 S. Ct. at 1750 n.4. These activities are neither economic nor commercial and are therefore outside the power of Congress either under the Commerce Clause or the expansive reading of the Necessary and Proper Clause adopted in *Wickard*.

[33] Should there be any doubt about the reach of the medical necessity exception to the injunction below, this Court can remand the case to clarify that it applies only to exclusively intrastate cultivation and distribution.

into execution its enumerated powers. *See New York v. United States*, 505 U.S. 144, 158 (1992) ("The Court's broad construction of Congress' power under the Commerce and Spending Clauses has of course been guided, as it has with respect to Congress' power generally, by the Constitution's Necessary and Proper Clause. . . . ").

In *Morrison* and *United States v. Lopez*, 514 U.S. 549 (1995), this Court recognized previous rulings that Congress may reach wholly intrastate *economic* activity under the Necessary and Proper Clause if that activity was shown to "substantially affect interstate commerce." *Lopez*, 514 U.S. at 560 (emphasis added). Here, however, as in *Lopez*, the government has not shown that the wholly intrastate distribution of cannabis solely for medical use would have a "substantial effect" on interstate commerce.[34] As with the statute at issue in *Lopez*, neither the CSA "nor its legislative history contain express Congressional findings regarding the effects upon interstate commerce" (*id.* at 562) of the wholly intrastate use and distribution of cannabis for medical use. The findings in the CSA regarding jurisdiction over intrastate activity are general, and do not address in any manner the effect of recognizing a defense of medical necessity upon interstate commerce. *See, e.g.*, 21 U.S.C. § 801(4) ("Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances."); 21 U.S.C. § 801(5) ("Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate.").

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[34] This case is thus distinguishable from lower court cases generally upholding the constitutionality of the CSA as applied to illicit intrastate drug trafficking. *See, e.g., United States v. Tisor*, 96 F.3d 370 (9th Cir. 1996).

Neither of these findings addresses the standard articulated in *Lopez* and *Morrison:* whether the intrastate production or distribution of cannabis for medical purposes has a *substantial effect* upon interstate commerce. Interpreting the Necessary and Proper Clause to allow Congress to prohibit the wholly intrastate commerce of a particular good on the unsupported speculation that such goods might "contribute to swelling" interstate commerce, or because the goods produced within a state "cannot be differentiated" from those imported from other states, would give Congress the plenary power over all commerce that the Constitutional text explicitly denies it. If this satisfies the standard of *Lopez* and *Morrison*, then Congress could render these two decisions inoperative simply by accompanying every prohibition of intrastate economic activity with a blanket assertion that the activity "substantially affects interstate commerce."[35]

Moreover, under the medical necessity standard articulated by the courts below, a qualified patient must, by definition, meet an extremely strict four-prong test. App. 16a-17a. To meet the requirement of *Lopez* (and *Wickard*), the government must show that permitting *this* very limited activity would, in the aggregate, have a substantial effect on commerce between the states, something it has not even attempted to do.

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[35] In *Wickard v. Filburn, supra*, the Court found that Congress could regulate the intrastate production and consumption of wheat because such production and consumption was in competition with wheat sold interstate, and therefore only by reaching these intrastate activities could it successfully increase the market price of wheat in interstate commerce. *See Lopez*, 514 U.S. at 560, quoting *Wickard*. Here, there is no federal scheme of price maintenance with which the intrastate production of medical cannabis could possibly interfere. Rather, the CSA is a scheme to prohibit completely all commerce in cannabis.

B. The Government's Interpretation Violates the Substantive Due Process Rights of Patients.

Even if the Court finds the CSA as applied to medical necessity patients is within the power of Congress, such an application would violate the patients' fundamental rights. This Court has established that the Due Process Clause "provides heightened protection against government interference with certain fundamental rights and liberty interests". *Washington v. Glucksberg*, 521 U.S. 702, 719 (1997) (citations omitted).[36] Declarations from many of the patients served by Respondents establish that access to medical cannabis is the reason they are alive today. J.A. 42, 44-45, 82, 84-85, 89. These patients have a liberty interest in being free from pain and in preserving their lives with assistance of a physician.[37] *See Glucksberg*, 521 U.S. at 737, 745 (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.' "). More precisely, these

[36] In *Queen v. Parker*, No. C28732L (Ont. App. July 31, 2000) the Ontario Court of Appeal upheld a constitutional challenge by an epileptic to the prohibition against the medical use of cannabis. The court concluded that the prohibition infringed impermissibly upon the patient's constitutional rights to life, liberty and personal autonomy. While not binding precedent, it is instructive in its analysis of the constitutional rights at stake. The decision is available at http://www.ontariocourts.on.ca/decisions/2000//july/parker.pdf.

[37] The Cooperative has standing to assert the constitutional rights of patient-members. *NAACP v. Alabama*, 357 U.S. 449, 459 (1958). The patient-members have standing to assert these rights on their own behalf, the interests protected are germane to the purpose of the Cooperative, and the direct participation of patient-members is not required to decide these issues. *Warth v. Seldin*, 422 U.S. 490, 511 (1975).

patients have a fundamental right to be free from government interdiction of their personal self-funded medical decision, in consultation with their physician, to alleviate their suffering through the only alternative available to them. Under traditional Due Process analysis, that interest cannot be infringed absent government action that is narrowly tailored to serve a compelling state interest. *See Glucksberg*, 521 U.S. at 721.[38]

Due Process analysis begins with an examination of our "Nation's history, legal traditions and practices." *Id.* at 710. The uncontradicted record in this case establishes the ancient and long accepted use of cannabis as a medicine. J.A. 122-126. The common law contained no proscription against medical cannabis, and when the original 13 States ratified the Bill of Rights, cannabis was in use as a medicine. J.A. 123-124. Until 1941, cannabis was indicated for numerous medical conditions in the pharmacopoeia of the United States. While the liberty to use cannabis for medical purposes has a long tradition in America, the same cannot be said for the claim of federal power to control it. J.A. 124-125. Indeed, the first federal restriction on its sale was the Marihuana Tax Act of 1937.

Moreover, the liberty to use cannabis under conditions of medical necessity meets the requirements for a protected right identified by Justice Souter. First, the right is among "those truly deserving constitutional stature, either

[38] The government mischaracterizes these claims by relying on cases such as *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 constitutional right to obtain a particular medical treatment. Pet.Br. 25 n.14. Unlike those cases, however, this case does not involve (a) an attempted governmental reclassification or approval of any drug, (b) a suit by persons for whom *no* medically effective treatment to save their lives is available, or (c) an attempt to gain access to a wholly experimental drug not shown to be effective.

to those expressed in constitutional text, or those exemplified by 'the traditions from which [the Nation] developed,' or revealed by contrast with 'the traditions from which it broke.' " *Glucksberg*, 521 U.S. at 767 (Souter, J., concurring). The right of privacy for personal and intimate decisions, the right of bodily integrity to be free of unnecessary pain, and the physician-patient relationship are each aspects of the inalienable right to life that is identified in the Declaration of Independence and explicitly protected by the text of the Fifth and Fourteenth Amendments. *Id.* at 777-779. Respondents' patients need cannabis to combat serious illness (such as cancer), to prolong their lives or to enable them to withstand the rigors of other treatments that are essential to prolonging their lives. It is difficult to imagine a right more fundamental or textually supported than the right to life.

Second, here "the legislation's justifying principle," such as it is, "critically valued, is so far from being commensurate with the individual interest as to be arbitrary or pointlessly applied that the statute must give way." *Id.* U.S. at 768 (Souter, J., concurring). There is simply no principled reason to deprive the class of seriously ill patients of the therapeutic benefits of cannabis. In the face of an interest as powerful as the avoidance of physical suffering, the restoration of health, and the preservation of life, "a State may not rest on threshold rationality or a presumption of constitutionality, but may prevail only on the ground of an interest sufficiently compelling to place within the realm of the reasonable a refusal to recognize the individual right asserted." *Id.* at 766. If any right is implicit in the concept of "ordered liberty," *Poe v. Ullman*, 367 U.S. 497, 549 (1961) (Harlan, J., dissenting), it is the right to seek medical assistance and to protect one's health and life by reasonable means that do not harm others.

Nor is the prohibition at issue here merely a "law that incidentally makes it somewhat harder to exercise a fundamental liberty." *Glucksburg*, 521 U.S. at 767 n.8 (Souter, J.,

concurring). Rather it is "law that creates a 'substantial obstacle,' for the exercise of a fundamental liberty interest." *Id.* at 767 (quoting *Planned Parenthood v. Casey*, 505 U.S. 833, 877 (1992)) and consequently "requires a commensurably substantial justification in order to place the legislation within the realm of the reasonable." *Id.* Under the terms of the amended injunction, cannabis is the *only* effective therapy available to a small number of patients facing dire health consequences. The government has offered no evidence to justify this significant interference with these patients' fundamental rights.

C. Prohibiting the Use of Cannabis in Cases of Medical Necessity Violates The Fundamental Liberties of the People Under the Fifth Amendment Due Process Clause or the Ninth Amendment and the Powers Reserved Under the Tenth Amendment.

Assuming *arguendo* that the prohibition of purely intrastate distribution of cannabis for medical purposes is necessary to effectuate Congress's power over interstate commerce, this prohibition must also be "proper," insofar as it does not intrude upon either the fundamental liberties of the people or on their sovereign reserved powers. This Court has recently noted one aspect of the "propriety" of means in *Printz v. United States*, 521 U.S. 898, 923-24 (1997): "When a 'Law for carrying into Execution' the Commerce Clause violates the principle of state sovereignty . . . it is not a 'Law . . . proper for carrying into Execution the Commerce Clause,' and is thus, in the words of The Federalist, 'merely [an] act of usurpation' which 'deserves to be treated as such.' The Federalist No. 33, at 204 (A. Hamilton)." Citing also Gary Lawson & Patricia Granger, *The 'Proper' Scope of Federal Power: A Jurisdictional Interpretation of the Sweeping Clause*, 43 Duke L.J. 267, 297-326, 330-333 (1993). As Lawson & Granger have

shown, the historical meaning of "proper" had other dimensions as well:

> In view of the limited character of the national government under the Constitution, Congress's choice of means to execute federal powers would be constrained in at least three ways: . . . [E]xecutory laws must be consistent with principles of separation of powers, principles of federalism, and *individual rights*.

Id. at 297 (emphasis added).

The effect of fundamental liberties on the propriety of means by which Congress exercises its enumerated powers was also recognized in *United States v. Carolene Products*, 304 U.S. 144 (1938), which famously states that "there may be a narrower scope for operation of the presumption of constitutionality when legislation appears on its face to be within a specific prohibition of the Constitution, such as those of the first ten amendments. . . . " *Id.* at 152 n.4. Moreover, this Court has long recognized unenumerated liberties can be as fundamental as those that are enumerated. *See, e.g., Meyer v. Nebraska*, 262 U.S. 390 (1923) (right of parents to educate their children in the German language); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (right of parents to send their children to private Catholic school).

Although the protection of unenumerated liberties traditionally has been afforded under the Due Process Clause of the Fifth Amendment (*see* § III. B., *supra*), it would also be both textually and historically warranted under the Necessary and Proper Clause and under the Ninth Amendment's express injunction that "The enumeration in the Constitution of certain rights shall not be construed to deny or disparage others retained by the people." U.S. Const. Amend. IX. As Madison explained in his speech to the House on the Bill of Rights, the provision that became the Ninth Amendment was intended to negate any inference that "those rights which were not singled out, were

intended to be assigned into the hands of the General Government, and were consequently insecure." 1 Annals of Cong. 456 (1789). And in his speech to the Congress concerning the constitutionality of the national bank he explained that, while the Tenth Amendment "exclude[s] every source of power not within the Constitution itself," the Ninth Amendment "guard[s] against a latitude of interpretation" of the enumerated powers. 2 Annals. of Cong. 1951 (1791) (referring to the 11th and 12th article proposed to the states for ratification).

Members of this Court have strongly affirmed its power to identify and protect unenumerated liberties that are deemed "fundamental" in the same manner as those that are enumerated. *See, e.g., Planned Parenthood*, 505 U.S. at 848 (opinion of the Court relying in part on Ninth Amendment). Others have expressed doubts that judges should be entrusted with the task of identifying whether a particular liberty interest is or is not fundamental. *See, e.g., Troxel v. Granville*, 120 S. Ct. 2054, 2074 (2000) (Scalia, J., dissenting). This case, however, is both unusual and distinguishable from other unenumerated rights cases because here it is *the people themselves*, using powers reserved under the Tenth Amendment, who have recognized the fundamentality of the liberty interest in using cannabis to alleviate pain and preserve life. In nine states, voters have protected this liberty directly by popular referenda or ballot initiative. *See, e.g.*, Cal. Health and Safety Code § 11362.5(b)(1). In his *Troxel* dissent, Justice Scalia observed that it is "entirely compatible with the commitment to representative democracy set forth in the founding documents to argue, in legislative chambers or in electoral campaigns, that the state has no power to interfere with parents' authority over the rearing of their children. . . . " *Troxel*, 120 S. Ct. at 2074. (Scalia, J., dissenting). For the same reason, it is entirely compatible with the commitment to representative democracy for the people of a State,

acting through the initiative process, to declare that a particular liberty is fundamental, and for this Court to acknowledge and defer to their judgment. Indeed, four members of this Court concluded that the people of a State, amending their State Constitution by popular vote, could impose additional qualifications on their Representatives to Congress. *See U.S. Term Limits v. Thornton*, 514 U.S. 779, 845 (1995) (Thomas, J., dissenting).

Respondents agree that "[t]he States have no power, reserved or otherwise, over the exercise of federal authority within its proper sphere." *Id.* at 841 (Kennedy, J., concurring). Respondents do not contend that the people of a State can override a federal law any more than can their legislature. Rather, the people of California and their State using powers reserved under the Tenth Amendment, recognized a liberty to be worthy of legal protection. This justifies a federal court to subject a federal exercise of an implied power to meaningful scrutiny to determine whether it is indeed "within its proper sphere" to restrict such a liberty. In so doing, the court should give great deference to the people's judgment that a liberty interest is fundamental.[39]

This case represents an intersection of the Tenth and Ninth Amendments. The people have used the initiative power reserved to themselves under the Tenth Amendment to recognize a fundmental liberty interest they have retained under the Ninth Amendment. By an unwarranted

[39] In affirming that the people may exercise their reserved powers to declare a liberty interest to be fundamental, Respondents do not suggest that this Court has no power to protect the rights of individuals and minorities from popular referenda and initiatives. To the contrary, this slippery slope has already been avoided by the limiting principle supplied in *Romer v. Evans*, 517 U.S. 620 (1996), invalidating an initiative amending the Colorado constitution on the ground it violated the Equal Protection Clause.

extension of its powers under the Necessary and Proper Clause, the federal government now seeks to interfere with both the exercise of the "power reserved" by the people and the States and the "rights retained" by the people.

Finding a liberty interest to be "fundamental" does not end the inquiry. It merely shifts the presumption to one favoring the individual, which the government may then overcome with an adequate showing. *See Carolene Products*, 304 U.S. at 152 n.4. Respondents agree with Justice Thomas' opinion that interferences with an unenumerated fundamental right should be subjected to strict scrutiny. *Troxel*, 120 S. Ct. at 2068 (Thomas, J., concurring).

In this case, the government has offered no evidence showing why a complete prohibition against the medical use of cannabis rather than appropriate regulation is necessary to further whatever governmental interest allegedly may exist. Nor has the government shown why the complete prohibition of cannabis for medical use is warranted in light of the availability of other substances for medical use such as morphine or cocaine.[40] For these reasons, the Court must conclude that the government's complete prohibition of all medical use of cannabis is unconstitutional.

CONCLUSION

Because federal courts retain their traditional equitable discretion to consider the hardship to seriously ill patients in fashioning injunctive relief under the CSA, the judgment of the Court of Appeals should be affirmed.

[40] For these reasons, the application of the CSA to prohibit the medical use of cannabis would also fail intermediate scrutiny, an "undue burden" standard, and even the rational basis test employed by the Court in *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432 (1985) or in *Romer v. Evans*, 517 U.S. 620 (1996).

Alternatively, because the CSA does not foreclose the defense of medical necessity, the judgment of the Court of Appeals should be affirmed. Any other interpretation of the CSA would render the statute unconstitutional, exceed Congress's powers under the Commerce Clause, violate the Ninth and Tenth Amendments, and deny the fundamental rights of seriously ill patients.

Respectfully submitted,

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APPENDIX TO BRIEF FOR RESPONDENTS

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1. Section 801 of Title 21 of the United State Code states in relevant part as follows:

Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

2. Section 903 of Title 21 of the United State Code states in relevant part as follows:

Application of State law

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

3. The Fifth Amendment to the Constitution states as follows:

AMENDMENT V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

4. The Ninth Amendment to the Constitution states as follows:

AMENDMENT IX

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

5. The Tenth Amendment to the Constitution states as follows:

AMENDMENT X

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.