No. 03-1454

In The

Supreme Court of The United States

JOHN ASHCROFT, ATTORNEY GENERAL ET AL.,

Petitioners,

- v -

ANGEL McCLARY RAICH, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

Brief of *Amici Curiae* Robert L. DuPont, M.D., Peter B. Bensinger and Herbert Kleber, M.D. in Support of Petitioners

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BRIEF OF *AMICI CURIAE*

This brief of *amici curiae* [1] is filed in support of Petitioner and is submitted on behalf of Robert L. DuPont, M.D., Peter B. Bensinger, Herbert Kleber, M.D., (herein referred to as "*amici*").

INTEREST OF AMICI CURIAE

Robert L. DuPont, M.D., was the first Director of the National Institute on Drug Abuse (NIDA) and the second Director of the White House Special Action Office for Drug Abuse Prevention, the initial White House drug abuse prevention "Czar" position. He is the author of The Selfish Brain -- Learning From Addiction, Clinical Professor of Psychiatry at Georgetown Medical School, President of the Institute for Behavior and Health, Inc. and Vice-president of Bensinger, DuPont and Associates.

Peter B. Bensinger served as Administrator of the U.S. Drug Enforcement Administration (1976 –1981), as a Representative of the U.S. Department of Justice Delegation to the regulator meetings of the U.N. Commission on Drugs, and as a Principal Delegate of the Department of Justice to INTERPOL.

Herbert Kleber, M.D., is Professor of Psychiatry and Director of the Division on Substance Abuse at the Columbia University College of Physicians and Surgeons. He served as the Deputy for Demand Reduction at the Office of National Drug Control Policy under Director William Bennett and President George H.W. Bush. Dr. Kleber has been a pioneer in the research and treatment of narcotic and cocaine abuse for over 35 years and is the author or co-author of more than 200 papers, chapters, and books dealing with all aspects of substance abuse.

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

SUMMARY OF ARGUMENT

This case is not what it appears. The Court of Appeals' ruling below—and the parties in their written arguments—have focused only on the effect that the activities in this case do (or do not) have on illegal interstate drug trafficking. But this case implicates issues that extend far beyond that narrow question—issues of enormous national significance. This case presents the Supreme Court with the opportunity to recognize and reinforce the United States' obligation to comply with international treaties, specifically, the Single Convention on Narcotic Drugs, 1961. It also enables this Court to underscore the appropriateness of the federal government's reliance on the Food and Drug Administration as the sole agency authorized to approve medical products as safe and effective for use within the United States.

The activities in this case, if allowed to proliferate across the country, would essentially eviscerate our comprehensive federal regulatory system governing the testing and use of medical products--a system that has been carefully crafted over the last century to protect patient health and safety. Such a proliferation would also force the United States for the first time to fall out of compliance with the unmistakable and very specific mandates of the Single Convention. If the Court of Appeals' ruling is allowed to stand, it will have widespread negative consequences for the enforcement of the comprehensive provisions of the Controlled Substances Act, and therefore for the implementation of the United States' obligations under the Single Convention. For these reasons, *amici* have submitted this brief urging this Court to address these far-reaching questions.

ARGUMENT

I. The Treaty Power Provides a Separate and Independent Source of Congressional Power in This Case.

While Congress must certainly regulate in accordance with its enumerated powers, the Commerce Clause does not provide the sole source of congressional authority in this case. The United States may enter into treaties governing matters of international concern and impact. Such treaties, in conjunction with the federal Constitution and federal legislation, comprise the supreme law of the land. U.S. Const. Art. II, sec. 2. cl. 2 (power of the President to enter into treaties); U.S. Const. Art. VI, cl. 2. Congress has the power to enact all laws "necessary and proper for carrying into Execution...all...Powers granted by this Constitution." U.S. Const. Art. I, sec.8, cl.18. Accordingly, Congress has the power to enact laws implementing the United States' obligations under treaties to which the U.S. is a signatory. The Controlled Substances Act, 21 U.S.C. sec. 801 et seq. (1970), ("CSA") is such a law, and its regulation of the class of activity in this case is necessary to fulfill those obligations.

Federal laws, like the CSA, which implement U.S. treaty obligations, are unquestionably a valid exercise of congressional power, even in the face of conflicting state laws.[2] In *Missouri v. Holland,* 252 U.S. 416 (1920), this Court upheld the power of Congress to enact legislation, pursuant to a treaty, despite contrary state law. The Court stressed that such legislation--in that case the Migratory Bird Treaty Act--stands on a separate basis of congressional power, and rejected the argument that Congress must have independent constitutional authority separate from a treaty as a basis for enacting legislation. *Id.* at 432-33. The CSA's comprehensive regulatory structure, too, is supported by the Treaty Power, as well by Congress' authority under the Commerce Clause.

A. The Single Convention on Narcotic Drugs 1961 Governs the Nature and Scope of the United States' Obligations to Control Cannabis and Cannabis-Based Products.

The United States is a party to two treaties that govern the use of, and trade in, controlled substances for both medical and

[2] Of course, such laws cannot transgress upon affirmative individual rights protected under the federal Constitution. However, such issues are not before the Court in this case.

non-medical purposes: the 1961 Single Convention on Narcotic Drugs (Single Convention),18 U.S.T. 1407 (1967), 520 U.N.T.S. 151 (1964), and the 1971 Convention on Psychotropic Substances (1971 Convention), 1019 U.N.T.S. 175 (1976), Treaty No. 14,596.[3] Cannabis[4] and cannabis-derived products are exclusively regulated by the Single Convention.

Official commentaries interpreting and explaining the two treaties support this conclusion. The 1971 Convention was intended to apply only to pure, generally synthetic, substances not already under the control of the 1961 Convention. See Office of the U.N. Secretary General (1973), *Commentary on the Single Convention on Narcotic Drugs 1961* ("1961 Commentary"), pp.87-88, para.7; Office of the U.N. Secretary General (1976), *Commentary on the Convention on Psychotropic Substances 1971* ("1971 Commentary"), p.37, para.9; p.394. Hence, this discussion of the Treaty Power will focus on the requirements of the Single Convention.[5]

B. Pursuant To the Single Convention, the United States Must Ensure That the Production and Use of Narcotic Substances Accords With the Scientific Standards Established By a Country's Normal Regulatory System.

The Single Convention was intended to simplify and replace existing treaties governing the control of narcotic substances. It imposes certain restrictions and controls on domestic manufacture, distribution, import/export, and possession of controlled substances, as well as on international trade. One fundamental principle animates the entire treaty fabric: the production **and use** of narcotic substances must be limited

[3] The United States is also a party to the 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which focuses primarily on the means of addressing and controlling international drug trafficking.

[4] The proper scientific name for the marijuana plant is *Cannabis sativa*.

[5] However, to the extent that the Court of Appeals' ruling would be broad enough to permit the manufacture and use of other controlled substances for personal medical purposes, the U.S.'s obligations under the 1971 Convention would support the validity of the Controlled Substances Act as applied to such activity as well. In 1978, Congress enacted the Psychotropic Substances Act, Pub.L.95-633, Nov. 10, 1978, 92 Stat. 278 (which became a part of the CSA), to coincide with the 1971 Convention, which entered into force in the U.S. on July 15, 1980.

exclusively to medical and scientific purposes. 1961 Convention, preamble, Art. 4(c). See also, 1971 Convention, preamble, Art. 5.

The treaty recognizes that, while addiction to narcotic drugs is a serious evil, the proper use of legitimate medical products is essential for the relief of pain and suffering. 1961 Convention, preamble. Accordingly, its provisions were structured to ensure that each Party could make new narcotic-containing medical products available to its citizens in a timely fashion. However, it is clear that, in order to comply with those provisions, a Party must require that the development and approval processes for such medicinal products meet the exacting standards of modern medicine. The CSA was scrupulously crafted to address and implement these requirements, as well as every other aspect of the controls mandated by the treaty.

The treaty was promulgated at a time when governmental regulatory bodies, such as the United States Food and Drug Administration, were imposing strict controls on the quality and safety of medical products. The need for the practice of medicine to be "evidence-based" had become well-established, particularly in the Western world. For several decades, scientists had been conducting randomized, placebo-controlled clinical trials to investigate the safety and efficacy of investigational medical products. Chow, S. and Liu, J., *Design and Analysis of Clinical Trials*, p. 4 (1998). Then, as now, the results of such clinical trials formed the basis both of governmental regulators' marketing approvals and physicians' prescribing practices. See Guyatt, G. et al., "Evidence Based Medicine: Principles for Applying the Users' Guides to Patient Care," 284 *Journal of the American Medical Association* 1290 (Sept. 13, 2000). The Single Convention recognized that different countries may have different regulatory systems. See 1961 Commentary, Art.4, para.12, p. 111 ("legitimate" existing systems of indigenous medicine may be taken into account). However, it contemplated that each Party would employ its **conventional** regulatory standards when determining whether, and which, narcotic substances and products could be made available for medical use. Nowhere in the treaty is there any suggestion that a Party may allow a diluted or informal "medical" system solely for specific controlled substances.

Furthermore, at the time of the Single Convention, crude narcotic plant material was not considered suitable for medical use. For example, opium smoking and coca leaf chewing were not accepted methods for delivering the therapeutically useful

components contained within the herbal material. Only processed and refined botanical extracts could constitute a medicinal product.[6] Indeed, by the 1850s, the medicinal use of pure alkaloids, rather than crude opium preparations, was common in Europe. Department of Justice, Drug Enforcement Administration, "Opium Poppy Cultivation and Heroin Processing in Southeast Asia," (March 2001) at p. 2, www.usdoj.gov/dea/pubs/intel/20026/20026.html (accessed July 28, 2004) (hereafter "DEA Opium Report").

This was also true with regard to crude herbal cannabis. Cannabis had not been adequately refined into a genuine pharmaceutical product, standardized for composition and dosage, and tested in controlled clinical trials. In 1954, the World Health Organization (WHO) had determined that, on existing scientific evidence, herbal cannabis and crude cannabis preparations were obsolete and did not have current medical usefulness. Wooton, "Report On Cannabis," *Report of the Hallucinogens Subcommittee to the Advisory Committee on Drug Dependence*, appen. 2 (1967). Following the WHO determination, the Single Convention, for the first time, imposed obligations on signatories to bring **domestic cultivation and possession** of cannabis under specific controls.

The International Narcotics Control Board (INCB) has recently confirmed that a Party **may not** allow cannabis to be cultivated, manufactured, and used for medical purposes **unless** such products have satisfied the rigorous regulatory standards that apply to other medical products. Such use must be supported by objective scientific data from properly-conducted research studies and otherwise accord with principles of modern medicine:

> The Board notes that the Governments of Canada and the Netherlands have decided to authorize the medical use of cannabis, although no **conclusive results** concerning the possible therapeutic properties and medical uses of cannabis have been obtained from the research conducted in those countries or anywhere else. The Board calls on Governments to consider the scheduling status of cannabis, which is listed in Schedules I and IV of the 1961 Convention, and not to allow its medical use unless **conclusive results of research** are available indicating its medical usefulness. The Board requests Governments to then ensure that such use is in line with **general principles guiding sound medical use and practice**.

[6] The treaty defines "medicinal opium" as the "coagulated juice of the opium poppy" that "has undergone the processes necessary to adapt if for medicine use." Art. 1 (o), (p). Moreover, only licensed manufacturers were allowed to produce such a medicinal product. See discussion in text below.

INCB, *Report 2002*, at p. 21 (2003) (emphasis added).

Recent UK research demonstrates that it is possible for a country to fulfill this mandate, while still making cannabis-based medical products available to patients in a reasonably timely manner. See, Wade, D., *et al.*, "A Preliminary Controlled Study to Determine Whether Whole-Plant Cannabis Extracts Can Improve Intractable Neurogenic Symptoms," 17 *Clinical Rehabilitation* 18 (2003). The CSA, by seeking to require that cannabis and cannabis-based products can be produced and used by patients **only if** such products meet existing regulatory standards for quality, safety, and efficacy, falls squarely in line with such efforts.

C. By Prohibiting All Individual Production and Use of Cannabis Outside the Bounds of the Established Regulatory System, the Controlled Substances Act Accords With the Single Convention's System of Control.

The Single Convention categorizes controlled substances into one of four schedules. These international schedules should not be confused with the schedules that a nation, such as the U.S., may choose to incorporate into its domestic law. For example, unlike Schedule I of the CSA, Schedule I of the Single Convention is not the most restrictive. Rather, it establishes requirements and restrictions that apply to most controlled substances.[7]

Schedule IV is the "strictest" schedule under the Single Convention. Under the treaty, crude cannabis[8] and cannabis resin[9]

[7] The Convention uses the term "drugs." The term "drugs," in turn, is defined as "any of the substances in Schedules I and II, whether natural or synthetic." The controls imposed on Schedule II drugs are virtually the same as those under Schedule I, with only a few exceptions. The requirements of Schedule III are less stringent, but they apply only to specific preparations of drugs.

[8] Cannabis is defined in the Convention as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the

are contained in Schedule IV. [10] The treaty contemplated that Schedule IV drugs would not be used in medical practice unless they had therapeutic benefits not offered by other drugs. INCB, Report 2002 at p. 21 (2003). With regard to such drugs, a Party **must** take the following actions (in addition to the controls imposed by Schedule I):

- 1) adopt any special measures of control **that in its opinion** are necessary, having regard to the particularly dangerous properties of the drug; and
- 2) ***if in its opinion*** **the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare**, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drugs **except for** amounts which may be necessary to medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.

Art. 2(5). Therefore, if a Party **in good faith** believes that it must impose certain controls on a substance in Schedule IV in order to protect public health and welfare, that Party has an obligation under the treaty to implement such controls. 1961 Commentary, Art. 2, para.4, p. 65. Congress, in enacting the CSA, could rationally have concluded that its system of controls was required in the case of cannabis (and other controlled substances) to ensure that only legitimate medical products reach the hands of individual patients.

tops) from which the resin has not been extracted, by whatever name they may be designated."

[9] Cannabis resin is defined in the Convention as "the separated resin, whether crude or purified, obtained from the cannabis plant."

[10] All drugs listed in Schedule IV must also be listed in, and subject to the controls attendant upon, Schedule I. Hence, it is this **joint placement** in Schedules IV and I that imposes the greatest degree of control under the Convention. Cannabis extracts and tinctures, which have undergone some degree of processing and refining, are listed only in Schedule I.

1. The Treaty Specifically Requires Parties to Impose Strict and Very Specific Domestic Controls on Crude Herbal Cannabis.

In addition to the Schedule IV admonitions, the treaty specifically imposes severe and very specific restrictions on the cultivation of cannabis, opium, and coca. Indeed, Article 22 **requires** a Party **to prohibit cultivation**, ***if*** the Party concludes in good faith that the "prevailing conditions" in the country make such prohibition the most suitable measure of protecting the public health and safety. Furthermore, a Party that prohibits such cultivation must "take appropriate measures" to seize **and destroy** any plants that are illegally cultivated, except for small quantities that **the Party** itself may need for scientific or research purposes.[11]

If a Party does choose to **permit** cultivation of the cannabis plant, opium poppy, or coca bush, the Party must, under Article 23, establish and maintain a national Agency to carry out the Party's obligations. See also Art. 26 (coca bush), 28 (cannabis plant). Article 23 requires that **only** nationally-licensed cultivators, whose license specifically identifies the precise extent and location of the land that they are authorized to cultivate, may grow such narcotic plants, and they must deliver their total crops to the Agency.[12]

Only the Agency may deal with such crops. The Agency must have the **exclusive right** of importing, exporting, wholesale trading, and maintaining stocks.[13] **However**, in recognition of the importance of facilitating legitimate pharmaceutical development, the treaty does make a clear exception for those stocks held by manufacturers of extracts, alkaloids, or preparations that the manufacturer will use to produce a pharmaceutical product. Indeed, the Parties are not required to extend the agency's exclusive rights either to such raw materials or to partially processed materials that will be used in the manufacture of a finished pharmaceutical product.

[11] This section conspicuously fails to include "medical use."

[12] The Agency must purchase and take physical possession of such crops as soon as possible, but, in the case of opium and cannabis, not later than four months after the end of the harvest.

[13] The United States has established such an Agency in the National Institute on Drug Abuse, which has contracted with the University of Mississippi to cultivate herbal cannabis for research purposes.

There is no doubt, in light of the other control provisions of the treaty generally applying to Schedule I (of the treaty) substances, that this last exception for "manufacturers" was **not** intended to apply to, or authorize, individuals to cultivate cannabis (or opium or coca) in their backyards and transform it into baked goods, teas, or other homemade concoctions. The specific controls imposed on cultivation, coupled with the treaty's overarching controls on all narcotic substances, demonstrate that **all** manufacture[14] and distribution must be conducted by licensed and regulated entities that are producing standardized products for medical or research purposes.[15] Therefore, were the U.S. to permit individuals, in various States across the country, to cultivate cannabis or other narcotics for personal medical use, the U.S. would be in violation of these unmistakably clear treaty obligations.

In addition to these controls, the Single Convention, in an effort to prevent legitimate medical products from being diverted to illicit use, imposes strict requirements on Parties to provide annual estimates regarding quantities of drugs utilized or held for specific purposes, Art. 19, as well as statistical returns concerning, among other things, production, manufacture, consumption, imports/exports, seizures/disposals, and year end stocks. Art. 20. These requirements apply even to substances used in research. INCB, *Narcotic Drugs* 2002 at p. 97 (2003) (recognizing appropriateness of UK reporting of amounts of cannabis extracts

[14] "Production" means the separation of opium, coca leaves, cannabis and cannabis resin from the plant. "Manufacture" means all processes by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs. Art. 1(n), (t).

[15] The treaty obligates the US and other parties to **license and control *all*** persons and entities engaged in the manufacture of narcotic substances and products, as well as to control under license the premises where such manufacture takes place. In addition, those manufacturers must obtain "periodical permits" indicating the kinds and amounts of drugs they are authorized to manufacture. Art. 29. The Party must also control **all** persons and entities distributing such substances and license the premises in which such distribution takes place. Art. 30. Finally, the Parties must require all licensees to have adequate **qualifications**. Art. 34(a). They must also require all manufacturers, traders, scientists, scientific institutions and hospitals to keep records for two years showing 1) the quantities of each drug manufactured and 2) each individual acquisition and disposal of drugs. Art. 34(b). The Parties are also obligated to impose specific requirements and restrictions on the labeling and import/export of a medication. See Art. 30-31. The provisions of the CSA, in conjunction with those of the Food, Drug & Cosmetic Act, satisfy these obligations.

used for medical research). Even if an individual practitioner or scientist wishes to conduct a small study using cannabis or some other narcotic substance, the Party must ensure that those small amounts are accounted for through the estimate and statistical return system. If individuals (in any State authorizing it) could cultivate and possess cannabis (or some other narcotic) on a physician's advice, this entire system would rapidly become disrupted and meaningless.

The Single Convention also controls the means by which **individual patients** may obtain and possess narcotic substances for medical use. The treaty dictates that narcotic substances may only be supplied or dispensed to individuals on prescription, except to the extent that physicians may lawfully obtain, use, dispense or administer such substances in connection with their "duly authorized" therapeutic functions. Art. 30(2)(b). Furthermore, a Party may permit the **possession** of such substances **only "under legal authority**." Art. 33. The mere fact that a State may authorize a physician to "recommend" the use of a crude cannabis product—one that he/she can neither prescribe nor dispense under either state or federal law—would not be sufficient to meet the United States' treaty obligations.[16]

Thus, it is apparent that the Single Convention imposes obligations on the United States comprehensively to control cannabis, from the point of its cultivation through its ultimate possession and use by individuals for medical purposes. The CSA, by requiring that cannabis and cannabis-based products meet rigorous scientific criteria for quality, safety, and efficacy, satisfies these obligations.

2. The Overarching Purpose of the CSA is Much Broader Than the Prohibition and Control of Illegal "Drug Trafficking."

The CSA establishes a comprehensive scheme that 1) provides a mechanism (the scheduling process) by which the results of scientific research may be used to support the approval and availability of new pharmaceutical products containing controlled substances; and 2) reduces the likelihood that controlled substances or products will be diverted to nonmedical use. As a

[16] Under the Controlled Substances Act, a prescription is only valid if the **issuing physician has authority to dispense** the drug. 21 U.S.C. sec. 353(b).

necessary part of that scheme, the CSA places controlled substances in one of five schedules, depending on the substance's recognized therapeutic usefulness, safety for use under medical supervision, and abuse liability. Other provisions of the CSA regulate and control the manufacture, import/export, distribution, research, and possession of controlled substances which will generally form a part of pharmaceutical products approved by the Food and Drug Administration.

The Court of Appeals in this case found that, by enacting the Controlled Substances Act, Congress was "primarily concerned with the trafficking or distribution of controlled substances." *Raich v. Ashcroft*, 352 F3d. 1222, 1232 (9th Cir. 2003). Repeatedly, the Court stressed that the intrastate, noncommercial use of cannabis for personal medical use on the advice of a physician and in accordance with state law would not have a substantial effect on interstate "drug trafficking." With all due respect, the Court of Appeals' view of the CSA is far too narrow. As indicated above, the purposes of the CSA go far beyond the prohibition, prevention, and punishment of the illegal trade in drugs.

The CSA was enacted shortly after, and in response to, the United States' 1967 ratification of the Single Convention. The congressional findings unquestionably reflect that fact.[17] Congress found, among other things, that: "The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances." 21 U.S.C. sec. 801(7) (findings).[18]

The structure of the CSA demonstrates that Congress was seeking, in accordance with the Single Convention, to ensure that narcotic and other psychoactive substances are manufactured, traded, **and used** only for medical and scientific purposes. The

[17] See also, congressional findings establishing the role of the CSA in satisfying the United States' obligations under the 1971 Convention. 21 U.S.C. sec. 801a.

[18] In light of the comprehensive domestic controls required by the Single Convention, the term "traffic" can be interpreted to include all cultivation, manufacture, delivery or distribution (constructive or actual), and ultimate possession of a "medical" product containing a narcotic substance, even where such activities are conducted within a State. In 1969, in *U.S. v. Leary*, 395 U.S. 6 (1969), this Court invalidated an aspect of the Marijuana Tax Act, 26 U.S.C. sec. 4741 *et seq.*, as violative of the constitutional privilege against self-incrimination. Hence, the United States had an additional need to enact federal legislation regulating individual possession of cannabis, in order to meet its treaty obligations.

CSA is keyed to comport with the requirements of the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. sec 301 *et seq.*, that objective scientific data must determine which products should be considered appropriate and available for medical use. Congress could certainly have rationally determined that the CSA's (and FDCA's) standards and criteria, as well as its prohibitions, were necessary to fulfill the United States' obligations under the Single Convention.

This is further demonstrated by the role that the Single Convention plays in the rescheduling of substances under the CSA. The CSA establishes a rulemaking procedure by which the Attorney General may schedule a substance or transfer ("reschedule") a substance between schedules. 21 U.S.C. sec.811. The Attorney General must make specific findings relating to the relevant schedule. Before doing so, the Attorney General must request, from the Secretary of Health and Human Services, a medical and scientific evaluation of, and recommendations upon, certain statutory criteria relating to scientific knowledge, pharmacological effect, and abuse potential. These recommendations are binding on the Attorney General as to scientific and medical matters. **However**, if control is required by the United States' obligations under international treaties, the Attorney General must issue an order controlling the drug under the schedule he/she deems most appropriate to carry out such obligations, without regard to any of the findings described above. 21 U.S.C. sec.811.[19] This section demonstrates Congress' clear awareness that the availability of a medical product containing a controlled substance must be governed by the U.S.'s obligations under international treaties.

II. The Commerce Clause Provides a Firm Basis for the Application of the CSA to the Activities at Issue in This Case.

Over the last century, the United States has developed one of the most stringent pharmaceutical regulatory systems in the world. That system governs all aspects of the pharmaceutical development process, including products containing controlled substances. The Food, Drug, and Cosmetic Act (FDCA) utilizes exacting scientific criteria and standards to ensure that patients

[19] See *NORML v. DEA*, 559 F.2d 735 (D.C.Cir.1977) for a description of the rulemaking procedure that this section permits.

receive medications that are safe and efficacious for their intended use. The standards and criteria of the CSA, which coordinate with those of the FDCA, determine the circumstances under which a controlled substance with abuse potential may, when properly formulated, tested, and delivered as a pharmaceutical product, be made available as a prescription medicine. The Court of Appeals' ruling will subvert this integrated system, thereby adversely affecting interstate commerce in legitimate medical products and threatening harm to public health and safety.

A. The Court of Appeals' Ruling is Not Consistent with This Court's Recent Commerce Clause Jurisprudence.

The CSA's prohibition against unauthorized manufacture, distribution, and possession of controlled substances differs significantly from those federal laws at issue in recent Commerce Clause cases decided by this Court. In those cases, Congress had attempted to enact narrow, targeted legislation to punish, and thereby deter, the commission of specific types of crimes of violence. See *U.S. v. Lopez*, 514 U.S. 549 (1995) (federal criminal prosecution under Gun-Free School Zones Act, prohibiting the possession of a firearm in a school zone); *U.S. v. Morrison*, 529 U.S. 598 (2000) (federal civil remedy under Violence Against Women Act). Such legislation, this Court determined, directly infringed on the States' police power--an area in which States have been traditionally sovereign.

By contrast, the CSA is not such targeted legislation, nor is punishment of local intrastate crime its primary focus. Rather, the CSA, in conjunction with the FDCA, comprises a comprehensive federal system that regulates all aspects of pharmaceutical products containing controlled substances, as well as illegal trafficking in licit and illicit substances. In *Lopez*, this Court emphasized that the criminal statute in that case was "not an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." 514 U.S. at 561. The CSA's and FDCA's comprehensive regulation of pharmaceutical products, from initial manufacture (including cultivation) to individual use by patients, is essential to ensure that only safe and effective, i.e., standardized and tested, products are made available to patients and their physicians. The Court of Appeals' ruling in this case will unquestionably undercut that regulatory system.

1. The Determination of W*hich* Medical Products Can be Made Available for Medical Use is Not an Area Traditionally Reserved to the States, Particularly if Those Products Contain Controlled Substances.

The "practice of medicine," i.e., a physician's methods of diagnosis, assessment, documentation, monitoring, and follow-up, have traditionally fallen within the purview of State regulation. However, since the beginning of the 20th century, the federal government has had the primary responsibility for the **regulation of medical products, particularly those containing controlled substances.**[20] Often the states have acted to create parallel systems—sometimes only in the wake of federal legislation. Often that federal legislation has directly affected the practice of medicine, and in some areas, has been the exclusive source of the parameters of professional practice.[21]

Our federal regulatory system has developed in response to serious threats to patient health and safety. In 1900, medical products were essentially unregulated. Many "patent" medicines contained significant amounts of opium, cocaine, alcohol, and cannabis. "Accidental" addiction became a serious problem. See Whitebread, C., "The History of the Non-Medical Use of Drugs in the United States," (speech to the California Judges Association

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[20] The Court of Appeals has itself recognized that the federal government can lawfully impose constraints on a physician's practice in cases involving the use of cannabis for alleged medical purposes. While the First Amendment protects a physician's right to provide medical information and advice about cannabis for a number of legitimate purposes, a physician can be subject to federal sanction if he/she provides such advice deliberately to enable the patient to obtain cannabis. See *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002), *cert. denied*, 124 S.Ct. 387 (2003). This Court need not decide whether a State may determine that an FDA-approved medical product may be prescribed by physicians for a specific "off-label" use. See *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004) (CSA does not apply to prescription issued by physician to enable competent, terminally ill patient to end his/her life, as authorized by State law).

[21] For example, in order to dispense narcotics to addicted patients for purposes of maintenance or detoxification, a physician must be specially licensed as an opiate treatment program. See 21 U.S.C. sec. 823(g). Under the recent Drug Abuse Treatment Act, 21 U.S.C. sec. 823(g), physicians who do not obtain such a registration may, subject to a number of requirements, prescribe to patients narcotic products in Schedules III-V, if such products have been approved by the FDA for treatment of addiction. See 21 U.S.C. sec. 823(g)(2).

1995). When the States failed adequately to address the problem, Congress acted by passing the Food and Drug Act, Act June 30, 1906, c.3915, 34 Stat.768, which required, among other things, that medications indicate on the label the quantity of alcohol, morphine, opium, cocaine, heroin, or cannabis that they contained.[22]

Over the following decades, federal legislation was gradually expanded to address various abusive practices or, unfortunately, events involving significant suffering and harm. For example, the Elixir Sulfanilamide disaster led to the enactment of the 1938 Food, Drug & Cosmetic Act (FDCA), Act June 25, 1938, c.675, 52 Stat. 1040, which required, among other things, that new drugs be tested for safety before marketing. The thalidomide tragedy in Europe led to the passage of the Drug Amendments of 1962, Pub.L.87-781, sec. 1, Oct. 10, 1962, 76 Stat. 780 (also known as the Kefauver-Harris Amendments), which required that products be proved to be both safe and effective before marketing. Since that time, Congress has enacted numerous additional federal laws governing multiple aspects of medical products and controlled substances, among them the CSA.[23]

Across the United States, the FDCA's criteria became the "gold standard" for the quality, safety, and efficacy of medical

[22] While new cases of accidental addiction waned following the Act, many physicians felt obligated, as a part of their medical practice, to prescribe controlled substances to those unfortunate individuals who had become addicted. Congress rejected the concept that such prescribing constituted the legitimate practice of medicine and, in 1914, enacted the Harrison Narcotics Act, 38 Stat. 785, Comp. St. sec 6287g-6287q (1914), *as amended* 26 U.S.C. 4701-36. The Harrison Act, although ostensibly a revenue measure founded on the Taxing Power, essentially precluded the prescription of opiates to addicts for maintenance purposes. In 1937, the Marihuana Tax Act, 26 U.S.C. sec. 4741-76, created strong disincentives for physicians prescribing cannabis, thereby effectively making it unavailable for medical use. These acts were replaced by the CSA.

[23] The FDCA maintained significant control over controlled substances until 1968, when all federal drug control was consolidated under the Department of Justice. The Drug Abuse Control Amendments of 1965 (DACA), Pub.L.89-74, July 15, 1965, 79 Stat. 226 , 21 U.S.C. sec. 360a, which were founded on the Commerce Clause, imposed restrictions and prohibitions on the **intra- or interstate** manufacture, sale, delivery, disposal, or possession of depressants, stimulants, and hallucinogens. *White v. U.S.*, 399 F.2d 813, 822 (8th Cir. 1968). Although DACA contained an exception for personal use, by the time of the CSA's enactment, the United States was obliged by the Single Convention to extend its system of controls to local/individual manufacture, possession and use of controlled substances.

products. Recognizing the importance of such stringent standards and procedures, States established similar regulatory systems to govern **those few products** that were manufactured, distributed, and sold only within a single state. For example, California enacted the Sherman Food, Drug, & Cosmetic Law ("Sherman Law"), Calif. Health & Safety Code sec. 109875 *et seq.* The Sherman Law requires that, in order to be approved as a medical product, a "new drug" must meet exacting scientific standards parallel to those established under the FDCA. See Kizer, K., "New State Program Puts Experimental Drugs on Fast Track," *California Physician* (Dec. 1988) (describing procedures and standards).

An intrastate investigational product may satisfy **either** the FDCA or state law. The Sherman Law prohibits **any person** from selling, delivering, or giving away any new drug unless either the FDA **or** the California Department of Health Services ("Department") has approved the drug for marketing. Calif. Health & Safety Code sec.111550. Physicians wishing to conduct clinical research with such drugs may do so only under an investigational new drug application filed with the FDA **or** with the Department. Calif. Health & Safety Code sec. 111590-95. Similarly, following the enactment of the CSA, many states adopted the Uniform Controlled Substances Act, which was directly modeled upon the CSA's provisions. California was among those states. See Calif. Health & Safety Code sec. 11000 *et seq.* The California Uniform Controlled Substances Act, like the CSA, placed cannabis in Schedule I. Calif. Health & Safety Code sec. 11054(d)(13).

When these systems work together in concert, patient protection is maximized. Because of their smaller size and greater flexibility, States may be able to sponsor research and move forward with the development of important pharmaceutical products more quickly than the FDA. See Kizer, *supra.* By contrast, a State may wish to maintain greater restrictions on pharmaceutical products containing controlled substances than those imposed under federal law.[24] However, if States permit unstructured and ungovernable systems to flourish within their borders, this synergy will quickly collapse, and the federal regulatory structure will be irreparably harmed.

[24] For example, while the branded product Marinol, which contains synthetic tetrahydrocannabinol (THC),[24] was rescheduled in 1999 to Schedule III of the CSA, see 64 Fed. Reg. 35928 (July 2, 1999), it was not rescheduled under California law until 2000 and in other states even later.

2. Instead of Providing Useful and Objective Scientific Data, California's Approach Will Undermine the Protections of the Food, Drug, and Cosmetic Act.

Our federal system is designed such that, in many areas, individual states "may serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Lieberman*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). However, the State of California has **not** attempted to establish a system designed to generate new and usable scientific data that could lead to a meaningful assessment of the future of cannabis or cannabis-based medical products.[25] It did not amend the Sherman Law. Indeed, the State did not remove cannabis from Schedule I of its own controlled substances law. Rather, by enacting Proposition 215, the California Compassionate Use Act of 1996 (CCUA), Calif. Health & Safety Code sec. 11362.5, the State merely abrogated certain of its own criminal laws as they applied to seriously ill patients who cultivate and/or possess cannabis for personal medical use on the advice of their physicians.[26] The CCUA authorizes patients to use any type of cannabis or cannabis products they wish, including hashish. Ops.Cal.Atty.Gen. No.03-411 (2003).

[25] The State of California did for three years make $3 million/year (which has now lapsed) available to researchers wishing to investigate the safety and efficacy of cannabis and cannabis-based products. See "The Marijuana Research Act of 1999," Calif. Health & Safety Code sec. 11362.9. This research has been conducted under the auspices of the Center for Medicinal Cannabis Research (CMCR) at the University of California San Diego. After funding 13 clinical trials using crude herbal cannabis obtained from the University of Mississippi, CMCR has apparently determined that future research, if it is to lead to a prescribable medical product, must involve purified cannabis administered through alternative, nonsmoked delivery systems, as well as synthetic cannabinoids. See CMCR, "Future Directions in Cannabinoid Therapeutics II: From the Bench to the Clinic" (workshop description) (June 27, 2004, Paestum, Italy), www.cmcr.ucsd.edu (accessed July 28, 2004). Advocates for herbal cannabis have criticized the CMCR for deviating from research involving "the crude plant that grows in the crude soil." Gardner, F., "The Politics of Marijuana: Cannabinoid Therapeutics," *CounterPunch* (July 17/18, 2004).

[26] California recently enacted legislation to clarify the provisions of the CCUA, make its application uniform across the state, and authorize a voluntary identification card system. Calif. Health & Safety Code sec. 11362.7 *et seq.*

Herbal cannabis (like herbal opium) is not a homogeneous substance. There are multiple strains of cannabis of varying cannabinoid composition that can be cultivated; different dosage forms --inhaled (smoked or vaporized), orally consumed (baked goods, candies, teas, or tinctures), transdermal (pastes or salves)-- that a patient may choose; and various amounts of active components that those dosage forms may deliver. Consequently, there is no possible way that the use of such unregulated products by patients throughout California will result in meaningful data that could answer the question: can cannabis or cannabis-based products satisfy modern scientific standards of quality, safety, and efficacy, and, if so, which specific product would be appropriate for which medical conditions?[27] For these reasons, major medical and healthcare organizations have not supported such state laws and initiatives. See, e.g., American Medical Association, Council on Scientific Affairs, Report A-01, "Medical Marijuana" (2001), www.ama-assn.org/ama/pub/article/print/2036-6124.html (calling for further adequate and well-controlled studies) (accessed July 28, 2004).

This action by the state of California did not create a "novel social and economic experiment," but rather chaos in the scientific and medical communities. Furthermore, under Court of Appeals ruling, such informal State systems could be replicated, and even expanded, in a manner that puts at risk the critical protections so carefully crafted under the national food and drug legislation of the 20th century.

3. The Controlled Substances Act, in Conjunction with the Food, Drug, and Cosmetic Act, Establishes a Comprehensive System of Regulation That Must, If Its

[27] There is, for that reason, complete uncertainty regarding how much cannabis a patient should be allowed to cultivate or possess for personal use. Compare Calif. Health & Safety Code sec. 11362.77 (allowing possession of eight ounces per patient) with Whitten, L., "Medical Marijuana Limits OK'd," *The Eureka Reporter* (July 15, 2004)(county ordinance allowing a patient to cultivate, possess, and consume three pounds of dried cannabis per year). Thus, in many cases the question arises as to whether an individual is cultivating cannabis for non-medical, as well as medical, purposes. The Court of Appeals' ruling would therefore mean that often the enforceability of the CSA would have to be litigated on a case-by-case basis.

Integrity is to be Maintained, Regulate the Activity at Issue in This Case.

The Food, Drug, and Cosmetic Act has established rigorous criteria to determine when a substance or product has been sufficiently studied and tested to justify its use by individual patients. The Controlled Substances Act employs similar standards to ensure that a product containing a controlled substance will be used by patients only when that use is supported by good scientific evidence. Accordingly, the Drug Enforcement Administration (DEA) looks to objective evidence when determining whether or not to move a substance from Schedule I to Schedule II. In an administrative rulemaking proceeding involving cannabis, the DEA Administrator has stated that he/she will examine the following factors in determining whether Schedule I substances such as cannabis, or a specific product[28] containing such substances, has a "currently accepted medical use":

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

See 57 Fed.Reg. 10499,10506 (March 26, 1992). The DEA's use of these factors was upheld by the federal courts. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C.Cir. 1994).

The Drug Enforcement Administration and the Food and Drug Administration, in a recent rejection of another herbal cannabis rescheduling petition, stressed that the different strains of the cannabis plant can vary in composition and that such strains will have different effects on the human body. Different delivery forms will also have different effects. The FDA specifically stated that "there are many variables that can influence the strength,

[28] As indicated above, a bulk substance can remain in Schedule I, while a specific product (containing such a substance), that has been formulated and tested, can be placed in a lower schedule.

quality, and purity of marijuana as a botanical substance." Therefore, the agency stressed:

> The agency cannot conclude that marijuana has an acceptable level of safety without assurance of a consistent and predictable potency and without proof that the substance is free of contamination. If marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing and specifications of marijuana must be developed.

DEA, Notice of Denial of Petition, 66 Fed. Reg. 20038, 20045 (April 18, 2001).

Recent research in the United Kingdom has demonstrated that it is possible to develop a cannabis-based medical product that satisfies such stringent regulatory standards. However, that process is very challenging. The UK pharmaceutical development program cultivates specific cannabis strains in computer controlled greenhouses. Those strains are propagated by clones to maintain the plants' unique cannabinoid ratios. All aspects of the cultivation and harvesting process are standardized and strictly controlled. The pharmacologically active components of the plants are extracted by means of a proprietary and quality-controlled process. The extracts are carefully formulated with standard excipients into a conventional nonsmoked pharmaceutical dosage form (an oromucosal spray), which delivers a precise dose in each dosing increment. See Russo, E., *Cannabis: From Pariah to Prescription* (2003); Guy, G., and Whittle, B., "Prospects for New Cannabis-Based Prescription Medicines," 1 *Journal of Cannabis Therapeutics* 183 (2001); Notcutt, W., "Initial Experiments With Medicinal Extracts of Cannabis for Chronic Pain: Results From 34 'N of 1' Studies," 59 *Anaesthesia* 440 (2004).

The UK clinical research has involved over 1400 patients and has shown promising results in spasticity in multiple sclerosis and in certain types of neuropathic pain. The product's marketing application has been under consideration by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for 16 months, as each aspect of the product dossier is carefully examined and assessed.

The U.S. government has apparently expressed interest in such a program. See Johnson-Skinner, D., "New Drug Could

Affect Debate on Medical Pot," *The Hill* (Feb. 24, 2004). So, too, have leading physicians. See DuPont, R., Testimony Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, "Marijuana and Medicine: The Need for a Science-Based Approach," (April 1, 2004).[29] Surely the United States, through the CSA and the FDCA, must have the power to conclude that, if a cannabis-based botanical product is to be used for medical purposes, it must be similarly standardized for quality, safety and efficacy.[30] However, the Court of Appeals' ruling would effectively disable the federal government from being able to enforce such a requirement.

B. The Court of Appeals' Ruling Will Authorize an Underground "Medical" System That Will Adversely Affect Federal Regulation of Pharmaceutical Products, and Thereby, Interstate Commerce.

The Court of Appeals stated that its holding was "sufficiently narrow" to avoid concerns that it would "significantly undermine the FDA drug approval process." However, the Court's ruling, rather than being narrow, has the potential to authorize a vast, underground "medical" system that will substantially and adversely affect the protections afforded by that process.

1. Under the Court of Appeals' Ruling, Congress Would be Disabled From Acting Even in States That Have Not Authorized the Use of Cannabis for Medical Purposes.

The Court of Appeals ruled that intrastate cultivation and possession of cannabis for personal medical use on the advice of a physician did not affect interstate commerce **if** those activities were authorized by State law. However, if Congress is disabled from regulating an activity because it falls within an area of state sovereign power—an area "traditionally left to the states to

[29] Dr. DuPont is a former Director of the National Institute on Drug Abuse.

[30] The FDA does not foreclose the possibility that an approvable pharmaceutical product can be botanically-derived if properly manufactured, tested, formulated, and delivered. U.S. Department of Health & Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, "Guidance for Industry: Botanical Drug Products," (June 2004), www.fda.gov/cder/guidance/index.htm (accessed July 28, 2004).

regulate"--then in principle each State would be free to determine **how** it wishes to exercise that power to regulate. For example, in *Lopez*, this Court emphasized that, while over 40 states had enacted criminal laws outlawing the possession of firearms on or near school grounds, some states might choose other means of addressing the issue: "Other, more practical means to rid the schools of guns may be thought by the citizens of some State to be preferable for the safety and welfare of the schools those States are charged with maintaining." 514 U.S. at 581. Thus, in areas of truly local concern, States have discretion to decide how they will govern. Compare *Oregon v. Ashcroft*, *supra*, fn.20, with *Washington v. Glucksberg*, 521 U.S. 702 (1997) (upholding state's prohibition against assisted suicide).

The same is true in this case. If intrastate cultivation and possession of cannabis for personal medical use on the advice of a physician truly does not affect interstate commerce, then the question of how a State has chosen to regulate the issue should add little to the analysis. A State would be free to decide whether or not it wishes to permit the use of cannabis for medicinal purposes. If it wishes to address the issue in a different way, or indeed, does not recognize such use as legitimate, the State is quite capable of limiting or prohibiting such use and maintaining criminal and/or civil sanctions to enforce that limit or prohibition.[31] Accordingly, under the Court of Appeals' ruling, Congress would be unable to regulate the intrastate activity in question, **even** in States that have not approved the medicinal use of cannabis.

2. The Court of Appeals' Ruling Would Not be Limited to the Use of Cannabis.

The Court of Appeals ostensibly ruled only on the intrastate cultivation and possession of cannabis for personal medical use. However, the ruling would in theory apply to a wide variety of controlled substances. It would encompass any narcotic that could be cultivated locally, such as opium, ibogaine, or peyote. Indeed, it would apply to **any** controlled substance that could be produced with local materials, such as methamphetamine,

[31] In Maryland, for example, recent legislation merely requires a court to consider a defendant's use of cannabis for medical purposes as a mitigating factor in a criminal prosecution. If convicted, a defendant must pay a $100 fine.

heroin, and MDMA (ecstasy).[32] See Proposition 200, "The Drug Medicalization, Prevention, and Control Act of 1996," Title 13, ch.34, Ariz. Rev. Stat. sec.13-3412.01 (physician may prescribe any Schedule I substance). All these substances can be argued to have "medical" uses. Indeed, methamphetamine, cocaine (and coca), and opium are located in Schedule II of the CSA. Heroin is used medically in the UK.[33]

Furthermore, under the Court of Appeals' analysis, the use of such substances, or products made from them, would be exempt from federal regulation, even if the seeds or certain other components had traveled in interstate commerce. See *Raich v. Ashcroft*, 352 F.3d 1222, 1233 fn. 8 (9th Cir. 2003). See also, *U.S. v. McCoy*, 323 F.3d 1114,1125 (film and camera used to take pornographic photograph were manufactured out of state); *U.S. v. Stewart*, 348 F.3d 1132, 1135 (9th Cir. 2003)(parts for homemade machine gun had moved in interstate commerce).

Hence, the reach of the appellate court's ruling would permit the establishment of a wholly separate, quasi-medical system of "homemade" controlled substances. Surely this would subvert the FDA's and DEA's ability to regulate such products and thereby adversely affect interstate commerce in approved medical products.

In addition, it would wholly undermine the careful state and federal protections that have been enacted to protect patients who are the subjects of research involving investigational products, i.e., new drugs. Under the FDCA and CSA, physicians are permitted to conduct research with investigational products only if they have submitted adequate evidence of safety, obtained Institutional Review Board approval, and otherwise satisfied the requirements of the IND process. If the product contains a controlled substance, the physician must obtain a research registration (license) from the DEA; that registration is limited to the specific substance to be used, and the specific protocol to be followed, in the study. However, under the Court of Appeals' ruling, a physician could endlessly "research" unapproved products containing controlled substances without satisfying these

[32] Morphine can be easily produced from the opium poppy using chemicals lawfully available on the open market. Similarly, the conversion of morphine to heroin base is a relatively simple and inexpensive procedure. DEA Opium Report, *supra*, at 9-10.

[33] Indeed, heroin was originally manufactured for medical use, as a cough suppressant for patients with tuberculosis. DEA Opium Report, *supra*, at 2.

requirements. Patients might be used as unwitting guinea pigs—exactly the situation that the federal and state research regulations seek to avoid.

3. The Concept of "Noncommercial" Cultivation and Possession Would Allow Widespread Use Across a State.

The Court of Appeals attempted to limit its ruling to "noncommercial" cultivation and possession of cannabis for personal medical use. However, the ruling cannot be so easily contained. Indeed, the Court of Appeals' ruling avowedly encompassed the cultivation and distribution or delivery (albeit perhaps constructive in this case) of cannabis to a patient by third parties. Depending on the state law, a "caregiver" may be authorized to cultivate cannabis (or manufacture other controlled substances) for more than one patient. See Calif. Health & Safety Code sec. 11362.7(d). Furthermore, such cultivation/manufacture could arguably remain "noncommercial" even if the caregivers are compensated for their out-of-pocket expenses, or even for their services, **so long as they do not receive compensation for the cannabis itself**. See Calif. Health & Safety Code sec. 11362.765(c).

Furthermore, it is a small step from the situation presented here to one in which a "non-profit" dispensary provides cannabis (or some other controlled substance) to individuals for medical use. See *County of Santa Cruz v. Ashcroft*, 314 F.Supp. 1000 (N.D. Cal. 2004)(non-profit collective allowed under *Raich* to distribute cannabis). The Oakland Cannabis Buyers' Cooperative, whose distribution of cannabis was the subject of this Court's opinion in *U.S. v. OCBC*, 532 U.S. 483 (2001), has also argued that its distribution falls squarely within the Court of Appeals' ruling in this case. See *U.S. v. OCBC*, Nos. 02-16334, 02-16534, 02-16715, Appellants' Supplemental Brief (April 29, 2004).[34] Depending on the altruism of donors, such nonprofit collectives or cooperatives may be able to provide cannabis to members without charge. Thus, the court's ruling may have the effect of authorizing

[34] OCBC is organized as a Consumer Cooperative Corporation under Calif. Corp. Code sec. 12700 *et seq. Id.* Recent California legislation authorizes collective or cooperative cultivation of cannabis under the CCUA. Calif. Health & Safety Code sec. 11362.775.

numerous collectives or cooperatives to cultivate cannabis (and/or manufacture other controlled substances) within a State's borders.[35] Again, this would seriously disrupt the current federal regulatory system for medical products containing controlled substances.[36]

4. The Court of Appeals' Ruling Will Negatively Impact on the Development and Availability of Approved Medical Products.

As recognized by the dissent in the ruling below, the proliferation of such an underground system would negatively affect the incentives of pharmaceutical companies to expend resources on research and development programs involving cannabis or other controlled substances. For example, the Institute of Medicine (IOM), in its 1999 report *Marijuana as Medicine: Assessing the Science Base*, described the many financial and other obstacles that would impede the development of cannabis-based pharmaceutical products, even if a parallel, "informal" system did not exist. The Court of Appeals' ruling would increase these disincentives and potentially prevent the United States from responding to the IOM's call for the development of rapid-onset, alternative delivery systems for cannabis- or cannabinoid-based products.

The experiences of other countries clearly demonstrate that chaos erupts when a national regulatory system must compete with an informal system of local cannabis cultivation and use. In the Netherlands, cannabis is grown for medical use by two cultivators who are licensed by the government's Office of Medicinal Cannabis and whose cultivation practices must be standardized in conformity with Good Agricultural Practices. Even so, the cannabis has such high microbial content that it must be irradiated before it can be distributed to patients. Scholten, W., "Therapeutic Cannabis in the Netherlands," Drug Information Association Annual Meeting (June 17, 2004) (presentation). Furthermore, the government's efforts to produce high quality herbal cannabis have caused the price of that cannabis to exceed that of crude cannabis

[35] In Oregon, an initiative has qualified for the November ballot that would allow non-profit dispensaries to distribute cannabis for medical use.

[36] This Court has **not** adopted a categorical rule against aggregating the effect of intrastate non-economic activity. *U.S. v. Morrison*, *supra*, at 613.

available in "coffee houses." Despite the uncertain quality of such unstandardized cannabis, patients are choosing to purchase it over the government's product, and the government's program is now in jeopardy. Scrip, *World Pharmaceutical News* (July 13, 2004). The impact of an informal cultivation system would be even greater on true pharmaceutical products that have been fully tested, standardized, refined, and are administered through medically-appropriate, nonsmoked delivery systems.

Canada, too, is facing the same dilemma. Forced by its courts to allow patients to use cannabis for medical purposes, Canada has funded and licensed a single cultivator to produce "medical quality" cannabis for direct distribution to patients (or through their physicians). However, patients dislike the governmental product and are urging the government to license the many small dispensaries that provide cannabis to patients outside the law. Beeby, D., "Canadian Pot Smokers Spurning New Batch of 'Stronger' Health Canada Marijuana," *The Canadian Press* (July 12, 2004).

5. California's "Medical Marijuana" System Has Placed Physicians in an Untenable Position and Could Ultimately Threaten to Obliterate the Distinction Between Medical and Non-Medical Use.

The Court of Appeals stressed that the patients' possession and use of cannabis did not affect interstate commerce, in part because they were acting on the advice of their physicians. However, it is difficult to understand why the mandated involvement of a physician should attenuate, rather than strengthen, the nexus between the activity in this case and interstate commerce. California--like other states--has authorized the use of cannabis for medical purposes, not simply by revoking its criminal laws as to patients diagnosed with certain medical conditions. Rather, it has utilized a "prescription medicine" model to identify when a patient's use of cannabis is "medical." That is, a patient can lawfully cultivate (or otherwise obtain), possess and use cannabis **only if** approved or recommended **by a physician.**

The State of California has placed physicians in an impossible position. On the one hand, the State has forced physicians into the role of legal gatekeepers of patients' lawful use and possession of cannabis. On the other, it has failed to provide them with objective scientific standards and data to use in

exercising that authority. In fact, the State has endowed physicians with tremendous, indeed, almost unfettered, power to undermine the effectiveness of the federal regulatory system--ironically, a system fervently supported by all major medical associations.

As indicated above, the standards of the medical profession are no longer local or provincial, but rather are evidence-based. While a physician must always use professional judgment, this judgment must be informed by the "best evidence" available, typically the results of controlled clinical trials conducted in the United States or elsewhere around the world. For example, in determining appropriate uses (on- or off-label) of an *approved* pharmaceutical product, physicians look to articles in national specialty peer-reviewed journals describing such trials and case studies presented at national conferences. Lyman, G., and Kuderer, N., "A Primer for Evaluating Clinical Trials," Moffitt Cancer Center, *Cancer Control* (Sept.-Oct. 1997).

California has given its physicians no assistance in this effort, and the Court of Appeals' decision will exacerbate this conundrum. The Court of Appeals appears to contemplate that the physician will somehow divine what type of use by patients qualifies as "medical." However, the CCUA does not provide guidance. While enumerating a number of specific conditions that are covered by the act, the Act also authorizes patients to use cannabis for "any other illness for which marijuana provides relief," as determined by their physicians. Calif. Health & Safety Code sec. 11362.5(b)(1)(A).

Although the patients in this case alleged that they had failed on all conventional medications, neither the Court of Appeals' ruling, nor state law (the CCUA), limits its reach to such patients. Indeed, under the Court of Appeals' ruling, patients could completely reject conventional medicine, in favor of "homegrown" concoctions containing controlled substances, and, if a physician were to approve it, would be beyond the reach of the FDCA and CSA. Again, this would permit a wholly separate underground "medical" system to exist for controlled substances and other pharmaceutical products.

The significance of this step cannot be underestimated. It would take us back to the days when the practice of medicine was based on intuitive judgment, rather than objective data, and patients could easily obtain medical products that were unstandardized, unproved and often unsafe. A State could even authorize a physician to conclude that, since opiate addiction is a

brain disease, opiate addicts should be allowed to "self-treat" with heroin or opium, and state law could permit such a "medical" use. However, Congress long ago determined that the federal government, rather than the medical profession or the States, would determine how, and under what circumstances, narcotics could be used to treat opiate addiction.

The mere fact that a physician has recommended to a patient that he/she use a controlled substance, and the fact that such substance can easily be manufactured or prepared locally by the patient or others, does not deprive Congress of its power to control the use of that substance. The federal government should not, of course, heartlessly institute a criminal prosecution against a suffering patient, but rather should seek to ensure that the patient can obtain proper medical care and treatment. However, this is a policy matter that can be dealt with through the political process. Congressional **power** to regulate such conduct does not disappear in the face of a physician's advice--whether or not State law has given that physician gatekeeping power.

CONCLUSION

The Treaty Power provides an independent source of congressional authority upon which the Controlled Substances Act should be upheld in this case. By enacting and enforcing the CSA, the United States has thus far served as an exemplar to the international community regarding compliance with the obligations of the Single Convention. The Court of Appeals' ruling, if allowed to stand, will subvert those efforts. In addition, the activities at issue here, if aggregated with similar activities around the country, will eviscerate the federal regulatory system governing medical products—a system resulting from a century of difficult choices and hard-won lessons. Congress can without question conclude that such an evisceration would substantially and adversely affect interstate commerce. For the foregoing reasons, *amici* urge this Court to reverse the Court of Appeals' ruling.

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