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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO HEADQUARTERS

ANGEL McCLARY RAICH; DIANE MONSON; JOHN DOE NUMBER ONE; and JOHN DOE NUMBER TWO, Plaintiffs, v. JOHN ASHCROFT, *et al.,* Defendants.	No. C 02-4872 MMJ DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION Date: December 10, 2002 Time: 9:30 a.m. Courtroom 11, 19th Floor The Hon. Martin J. Jenkins

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PRELIMINARY STATEMENT

Plaintiffs Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two, seek a preliminary injunction barring defendants from enforcing the provisions of the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, against them, contending that Congress' prohibition on the distribution, cultivation, or possession of marijuana exceeds its authority under the Commerce Clause, infringes upon state sovereignty in violation of the Tenth Amendment, infringes upon plaintiffs' fundamental rights protected by the Fifth and Ninth Amendments, and threatens plaintiffs' rights under the "medical necessity" doctrine. See Plaintiffs' Memorandum of Law in Support of Motion for Preliminary Injunction ("Pl. Mem.") at 4-27.

None of the arguments raised by the plaintiffs has merit. Governing Supreme Court and Ninth Circuit authority forecloses each of plaintiffs' contentions. The Ninth Circuit has squarely held that the Controlled Substances Act's prohibition on the distribution, manufacture, or possession of marijuana and other controlled substances "is constitutional under the Commerce Clause," United States v. Bramble, 103 F.3d 1475, 1479 (9th Cir. 1996), and this conclusion necessarily disposes of the plaintiffs' Tenth Amendment challenge, for "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." New York v. United States, 505 U.S. 144, 156 (1992). The Ninth Circuit also has rejected the contention that there is a fundamental right to unproven medical treatments, holding that "[c]onstitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of the government's police

power." Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980). Finally, the Supreme Court has held that "there is no medical necessity exception to the prohibitions at issue [in the Controlled Substances Act], even when the patient is "seriously ill" and lacks alternative avenues for relief." United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483, 494 n.7 (2001). These authorities, which are entirely and inexplicably absent from plaintiffs' memorandum, compel the conclusion that plaintiffs' motion for a preliminary injunction must be denied.

STATUTORY AND REGULATORY BACKGROUND

In 1970, Congress passed the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236. While recognizing that many controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people," 21 U.S.C. § 801(1), Congress found that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect of the health and general welfare of the American people." 21 U.S.C. § 801(2).[1] In particular, Congress made the following express findings:

> (3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because--
>
> (A) after manufacture, many controlled substances are transported in interstate commerce,
>
> (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and
>
> (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

[1] Congress defined a controlled substance as "a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter." 21 U.S.C. § 802(6).

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

21 U.S.C. § 801(3)-(6).

The Controlled Substances Act establishes "a 'closed' system of drug distribution" for all controlled substances. See H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 6 (1970). See also United States v. Moore, 423 U.S. 122, 141 (1975) (Controlled Substances Act "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal." (quoting H.R. Rep. No. 1444, *supra*, at 3)). Congress therefore made it unlawful, except as otherwise authorized by the Act, to manufacture, distribute, or possess with the intent to manufacture or distribute, a controlled substance. See 21 U.S.C. § 841(a)(1). Congress also made it unlawful to possess a controlled substance. See 21 U.S.C. § 844(a). Congress imposed criminal and civil penalties for violations of the Act. See 21 U.S.C. §§ 841-863.

Congress also established a comprehensive regulatory scheme in which controlled substances are placed in one of five "Schedules" depending on their potential for abuse, the extent to which
they may lead to psychological or physical dependence, and whether they have a currently accepted medical use in treatment in the United States. See 21 U.S.C. § 812(b). Controlled substances in "schedule I" have been determined to have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and a "lack of accepted safety for use under medical supervision." 21 U.S.C. § 812(b)(1). Given these characteristics, Congress has mandated that substances in Schedule I be subject to the most stringent regulation.

In particular, as compared with controlled substances in schedules II-V,[2] no physician may dispense a Schedule I controlled substance to any patient outside of a strictly controlled research project registered with the DEA, and approved by the Secretary of Health and Human Services, acting through the Food and Drug Administration ("FDA"). See 21 U.S.C. § 823(f). When it passed the Act in 1970, Congress placed marijuana in Schedule I, where it remains today. See 21 U.S.C. § 812 Schedule I(c)(10).

Congress recognized, however, that the schedules may sometimes need to be modified to reflect changes in scientific knowledge and patterns of abuse of particular drugs. Congress

therefore established an exclusive set of statutory procedures under which controlled substances that have been placed in schedule I (or any other schedule) may be transferred to another schedule or be entirely removed from the schedules. See 21 U.S.C. 811(a).[3] Pursuant to that process, "any interested party" who believes that medical, scientific, or other relevant data warrant transferring marijuana to a less restrictive schedule may petition the Attorney General to initiate a rulemaking proceeding to reschedule marijuana. See 21 U.S.C. 811(a). The Administrator of the DEA, to whom the Attorney General has delegated his authority under the CSA, see 28 C.F.R. § 0.100(b), must refer any such rescheduling petition to the Secretary of Health and Human Services ("HHS") for a scientific and medical evaluation and a

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[2] Controlled substances in Schedules II through V may be prescribed by a physician, and are subject to decreasing levels of controls, because they have been determined to have some currently accepted medical uses in treatment in the United States. See 21 U.S.C. §§ 812(b)(2)-(5).

[3] For example, in 1986, the DEA Administrator rescheduled "Marinol," or synthetic dronabinol
in sesame oil and encapsulated in soft gelatin capsules, a substance which is the synthetic equivalent of the isomer of delta-9-tetrahydrocannabinol ("THC"), the principal psychoactive substance in marijuana, from Schedule I to Schedule II. See 51 Fed. Reg. 17,476 (May 13, 1986). Marinol currently is approved in treatment for nausea and anorexia associated with cancer and AIDS patients.

recommendation as to whether the substance should be reclassified or decontrolled. The recommendations of the Secretary are binding on the Administrator with respect to scientific and medical matters. See 21 U.S.C. 811(b). Any party aggrieved by a final decision of the Administrator may seek review in the courts of appeals. See 21 U.S.C. 877.

Several groups and individuals who believe that marijuana should be permissible for therapeutic purposes have petitioned the Administrator to move marijuana from Schedule I (where Congress placed it) to Schedule II or other schedules. In 1992, the Administrator declined to reschedule marijuana, finding that the record demonstrated that marijuana had "no currently accepted medical use in treatment in the United States," and thus had to remain in Schedule I. See 57 Fed. Reg. 10,499 (Mar. 26, 1992). This decision was upheld by a unanimous panel of the D.C. Circuit, which held that the Administrator's findings were "consistent with the view that only rigorous scientific proof can satisfy the [Controlled Substances Act's] 'currently accepted medical use requirement.'" Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131,

1137 (D.C. Cir. 1994). The petitioners did not seek Supreme Court review.

More recently, on March 20, 2001, the DEA Administrator once again denied a petition to reschedule marijuana, based, in part, on HHS's scientific and medical analysis recommending that marijuana remain in schedule I. See 66 Fed. Reg. 20038 (April 18, 2001). In particular, General David Satcher, the then-Assistant Secretary for Health and Surgeon General of the United States, concluded that, based on a comprehensive review by the FDA's Controlled Substance Staff, it remained the case that "marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of accepted safety

for use under medical supervision." Id. at 20039. Assistant Secretary and Surgeon General Satcher therefore recommended, on behalf of HHS, that marijuana "continue to be subject to control under Schedule I of the CSA." Id. The D.C. Circuit unanimously dismissed for lack of standing a petition challenging the DEA Administrator's determination. See Gettman v. DEA,

290 F.3d 430, 432-35 (D.C. Cir. 2002).

In addition to the restrictions under the Controlled Substances Act, marijuana is subject to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*. The FDCA prohibits the "introduc[tion] or deliver[y] for introduction into interstate commerce" of any new drug,[4] absent the submission of a new drug application ("NDA") and a finding by the FDA that the drug is both safe and effective for each of its intended uses. See 21 U.S.C. §§ 355(a), (b). The drug must be proven safe through "adequate tests by all methods reasonably applicable," and it must be proven effective by "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." 21 U.S.C. § 355(d). See generally Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629-632 (1973) (holding that the FDA's "strict and demanding standards," which "bar[] anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug, are amply justified by the legislative history" of the FDCA, which reflects "a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous").

Congress has revisited the question of whether marijuana may be authorized for medicinal uses since the passage of various initiatives regarding this subject in several states. In a statutory provision enacted in 1998 and entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress declared that:

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[4] A "new" drug includes any drug that "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p).

(1) certain drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision;

* * * * *

(3) pursuant to section 401 of the Controlled Substances Act, it is illegal to manufacture, distribute, or dispense marijuana * * *;

(4) pursuant to section 505 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 355], before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective;

(5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;

(6) the Federal Food, Drug and Cosmetic Act already prohibits the sale of any unapproved drug, including marijuana, that has not been proven safe and effective for medical purposes and grants the Food and Drug Administration the authority to enforce this prohibition through seizure and other civil action, as well as through criminal penalties;

* * * * *

(11) Congress continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration.

Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761.

ARGUMENT

I. STANDARDS

In determining whether to grant a preliminary injunction, courts in the Ninth Circuit traditionally consider "(1) the likelihood of the moving party's success on the merits; (2) the possibility of irreparable injury to the moving party if the relief is not granted; (3) the extent to which the balance of hardships favors the respective parties; and (4) in certain cases, whether the public interest will be advanced by granting the preliminary relief." Miller v. California Pacific Medical Center, 19 F.3d 449, 456 (9th Cir. 1994) (en banc). The moving party must demonstrate either "(1) a combination of probable success on the merits and the possibility of irreparable harm, or (2) the existence of serious questions going to the merits, the balance of hardships tipping sharply in its favor, and at least a fair chance of success on the merits." Id. (internal quotation omitted).

In this case, because an Act of Congress is being challenged, plaintiff must satisfy the more rigorous "likelihood of success" standard. See Able v. United States, 44 F.3d 128, 131-32 (2d Cir. 1995) (per curiam). As the Second Circuit has explained, the requirement that the more rigorous "likelihood of success" standard be applied when a Congressional enactment is being challenged "reflects the idea that governmental policies implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly." Id. at 131. Under any of these governing standards, plaintiff's motion for a preliminary injunction must be denied.

II. PLAINTIFFS HAVE FAILED TO DEMONSTRATE THAT THEY ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS

A. The Controlled Substances Act is a Valid Exercise of Congress' Authority Under the Commerce Clause

Relying in large part upon the Supreme Court's decisions in United States v. Lopez, 514 U.S. 549 (1995), and United States v. Morrison, 529 U.S. 598 (2000), plaintiffs allege that the activities for which they seek protection "are purely intrastate actions pursuant to valid California

State law – the personal cultivation and personal use of cannabis for medical purposes by California citizens as recommended by the patients' physicians," and contend that "[t]his wholly intrastate activity is beyond the power of Congress 'to regulate Commerce * * * among the several States." Pl. Mem. at 6-7.

There is no merit to this contention; indeed, it has been foreclosed by circuit precedent. It has long been established in the Ninth Circuit that the Controlled Substances Act's prohibition on the distribution, manufacture, or possession of marijuana and other controlled substances "is constitutional under the Commerce Clause." Bramble, 103 F.3d at 1479. Accord United States v. Tisor, 96 F.3d 370, 373-75 (9th Cir. 1996), *cert. denied*, 519 U.S. 1140 (1997); United States v. Kim, 94 F.3d 1247, 1249-50 (9th Cir. 1996); United States v. Visman, 919 F.2d 1390, 1393 (9th Cir. 1990), *cert. denied*, 502 U.S. 969 (1991); United States v. Montes-Zarate, 552 F.2d 1330, 1331-32 (9th Cir. 1977), *cert. denied*, 435 U.S. 947 (1978); United States v. Rodriquez-Camacho, 468 F.2d 1220, 1221-22 (9th Cir. 1972), *cert. denied*, 410 U.S. 985 (1973). The Ninth Circuit is not alone in reaching this conclusion; ***all*** eleven other regional courts of appeals -- with nary a single dissenting vote -- have likewise upheld the constitutionality of the Controlled Substances Act against Commerce Clause challenges.[5] The plaintiffs reliance on Lopez and its progeny, therefore, is misplaced.

Lopez involved a challenge to a statute which proscribed the knowing possession of a firearm

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[5] See United States v. Edwards, 98 F.3d 1364, 1369 (D.C. Cir. 1996), *cert. denied*, 520 U.S. 1170 (1997); United States v. Lerebours, 87 F.3d 582, 584-85 (1st Cir. 1996), *cert. denied*, 519 U.S. 1060 (1997); Proyect v. United States, 101 F.3d 11, 13-14 (2d Cir. 1996) (per curiam); United States v. Orozco, 98 F.3d 105, 107 (3d Cir. 1996); United States v. Leshuk, 65 F.3d 1105, 1111-12 (4th Cir. 1995); United States v. Lopez, 459 F.2d 949, 953 (5th Cir.), *cert. denied*, 409 U.S. 878 (1972); United States v. Brown, 276 F.3d 211, 214-15 (6th Cir. 2002); United States v. Westbrook, 125 F.3d 996, 1009-10 (7th Cir.), *cert. denied*, 522 U.S. 1036 (1997); United States v. Patterson, 140 F.3d 767, 772 (8th Cir.), *cert. denied*, 525 U.S. 907 (1998); United States v. Price, 265 F.3d 1097, 1106-07 (10th Cir. 2001), *cert. denied*, 122 S. Ct. 2299 (2002); United States v. Jackson, 111 F.3d 101, 102 (11th Cir.) (per curiam), *cert. denied*, 522 U.S. 878 (1997).

in a school zone. As the Supreme Court found, the statute challenged in Lopez "by its terms has nothing to do with 'commerce' or any sort of economic enterprise, however broadly one might

define those terms." 514 U.S. at 561. Similarly, Morrison involved a challenge to a statute that created a federal civil remedy for victims of "[g]ender-motivated crimes of violence [that] are not, in any sense of the phrase, economic activity." 529 U.S. at 613. The Supreme Court warned against any attempt to "downplay the role that the economic nature of the regulated activity plays in our Commerce Clause analysis" in Morrison, emphasizing that "a fair reading of Lopez shows that the noneconomic, criminal nature of the conduct at issue was *central* to our decision in that case," and that "Lopez's review of Commerce Clause case law demonstrates that in those cases where we have sustained federal regulation of intrastate activity based upon the activity's substantial effects on interstate commerce, the activity in question has been some sort of economic endeavor." Id. at 610 (emphasis supplied). The Supreme Court therefore held that, "[w]hile we need not adopt a categorical rule against aggregating the effects of noneconomic activity in order to decide these cases, 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."
Id. at 613.

In contrast to the "noneconomic" conduct at issue in Lopez and Morrison, the Ninth Circuit
has expressly held that the "[i]ntrastate distribution and sale of [controlled substances] are commercial activities," Tisor, 96 F.3d at 375, and that, "'[u]nlike education, drug trafficking is a commercial activity which substantially affects interstate commerce.'" Kim, 94 F.3d at 1250 (quoting United States v. Staples, 85 F.3d 461, 463 (9th Cir.), *cert. denied*, 519 U.S. 938 (1996)). Other circuits have reached the same conclusion. See, e.g., United States v. Goodwin, 141 F.3d 394, 399 (2d Cir. 1997) ("We have repeatedly held that the Controlled Substances Act concerns an obviously economic activity substantially affecting interstate commerce, namely narcotics

trafficking, and have sustained the Act against criminal defendants' Lopez challenges." (internal quotation omitted)), *cert. denied*, 523 U.S. 1086, 525 U.S. 881 (1998); United States v. Zorrilla, 93 F.3d 7, 8 (1st Cir. 1997) ("Here, unlike in Lopez * * * the underlying conduct possesses a significant economic dimension. Many courts, including this court, have held that drug trafficking is precisely the kind of economic enterprise that substantially affects interstate commerce and that, therefore, comes within Congress's regulatory power under the Commerce Clause.").

The Ninth Circuit therefore has rejected as "misplaced" the contention that Lopez supports a Commerce Clause challenge to the Controlled Substances Act because, as compared to section 841(a)(1), "[t]he activity condemned in Lopez did not involve a commercial transaction." Tisor, 96 F.3d at 373. Similarly, in rejecting an Commerce Clause challenge to section 841(a)(1) identical to that advanced by the plaintiffs here, Judge Breyer of this Court ruled that, "[u]nlike violence, the manufacture and distribution of marijuana is economic activity; indeed, the Ninth Circuit has specifically held that 'drug trafficking is a commercial activity which substantially affects interstate commerce.'" United States v. Cannabis Cultivators Club, No. C 98-0085 CRB and related cases, slip op. at 11 (N.D. Cal. May 3, 2002) (attached hereto as Exhibit 1) (quoting Staples, 85 F.3d at 463).

Likewise, following the Supreme Court's decision in Morrison, *every* court to have considered the question has rejected the argument that that case calls into question the constitutionality of the Controlled Substances Act. See United States v. Davis, 288 F.3d 359, 361-62 (8th Cir. 2002) (rejecting argument that Controlled Substances Act is unconstitutional in light of Lopez and Morrison, insofar as "[t]he activities which were targeted in those cases were unlike drug manufacture and distribution, however, because they were not economic endeavors"); Price, 265 F.3d at 1107 ("Because Morrison involved the regulation of non-economic activities, while § 841(a)(1) deals with the regulation of economic activities * * * §

841(a)(1) and § 846 are within Congress' power to regulate interstate commerce."), *cert. denied*, 123 S. Ct. 107 (2002); United States v. Pompey, 264 F.3d 1176, 1180 (10th Cir. 2001) (holding that defendant's reliance on Morrison was "unavailing" because "[w]e think any party would be hard-pressed to prove that trafficking in controlled substances is not an economic activity and not an issue of national concern"), *cert. denied*, 122 S. Ct. 929 (2002); Bertoldo v. United States, 145 F. Supp.2d 111, 118-19 (D. Mass. 2001) ("Unlike gender-motivated crimes, narcotics activity regulated under the CSA is obvious economic activity. * * * Although local distribution and

possession may, strictly speaking, be considered intrastate activity, this activity is still directly connected with interstate commerce.").

In Tisor, the Ninth Circuit distinguished the Controlled Substances Act from the statute at issue in Lopez in another key respect. In enacting the Controlled Substances Act, Congress made detailed findings that the intrastate manufacture, distribution, and possession of controlled substances, as a class of activities, "'have a substantial and direct effect upon interstate commerce.'" 96 F.3d at 374 (quoting 21 U.S.C. § 801(3)). In particular, Congress found that, "after manufacture, many controlled substances are transported in interstate commerce, 21 U.S.C.

§ 801(3)(A); that "controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution," 21 U.S.C. § 801(3)(B); and that "controlled substances possessed commonly flow through interstate commerce immediately prior to such possession." 21 U.S.C. § 801(3)(C). Congress further found that the intrastate traffic in controlled substances: "contribute[s] to swelling the interstate traffic in such substances," 21 U.S.C. § 801(4); "cannot be differentiated from controlled substances manufactured and distributed interstate," 21 U.S.C. § 801(5); and that "[f]ederal control of the intrastate incidents of

the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic." 21 U.S.C. § 801(6). "These declarations provide a specific, reasonable finding

by Congress that local narcotics activity substantially affects interstate commerce." United States

v. Walker, 142 F.3d 103, 111 (2d Cir.), *cert. denied*, 525 U.S. 896, 525 U.S. 988 (1998).

Accordingly, as the Ninth Circuit has noted that, "[b]ased on [Congress'] findings and the ample judicial recognition that an interstate market for illegal drugs exists, every circuit that has considered a Commerce Clause challenge to § 841 [of the Controlled Substances Act] after Lopez has upheld the provision's constitutionality." Kim, 94 F.3d at 1250.

2. Notwithstanding this unbroken line of authority which, with the exception of Kim and Visman, plaintiffs do not bother to discuss, let alone even cite, plaintiffs emphasize that their case is different because the activities for which they seek protection are allegedly purely intrastate in character, are done for medicinal purposes, and are authorized by California law.

See Pl. Mem. at 6-7. These arguments betray a fundamental misunderstanding of basic tenets of Commerce Clause jurisprudence.

In Lopez, the Supreme Court reaffirmed the cardinal rule that, "'where *a general regulatory statute bears a substantial relation to commerce*, the *de minimis* character of individual instances arising under that statute is of no consequence.'" 514 U.S. at 558 (emphasis in original) (quoting Maryland v. Wirtz, 392 U.S. 183, 197 n.27 (1968) (emphasis by Court)). In other words,

"[w]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class." Perez v. United States, 402 U.S. 146, 154 (1971). Rather, in such circumstances, the only function of a court "is to determine whether the particular activity regulated or prohibited is within the reach of federal power." United States v. Darby, 312 U.S. 100, 120-21 (1941).

Here, as set forth above, Congress has made express findings that, as a class of activities, the intrastate distribution, cultivation, and possession of marijuana and other controlled

substances substantially affects interstate commerce. See 21 U.S.C. §§ 801(3)-(6). Based on these findings,

the Ninth Circuit has expressly rejected contentions that individualized proof of an interstate nexus is required in cases alleging violations of the Controlled Substances Act. In Visman, for example, the Ninth Circuit turned away a contention that federal jurisdiction was lacking in that case because there was no reasonable basis to assume that "marijuana plants found rooted in the soil" affect interstate commerce. Noting that the "local criminal cultivation of marijuana is within a class of activities that adversely affects interstate commerce," the Ninth Circuit ruled that:

> We hold that Congress may constitutionally regulate intrastate criminal cultivation of marijuana plants found rooted in the soil. We defer to Congress' findings that controlled substances have a detrimental impact on the health and general welfare of the American people and that intrastate drug activity affects interstate commerce. We further hold that local criminal cultivation of marijuana is within a class of activities that adversely affects interstate commerce.

Id. at 1393 (internal citation omitted). The Second Circuit has similarly ruled that, "[b]ecause narcotics trafficking represents a type of activity that Congress reasonably found substantially affected interstate commerce, the actual effect that each drug conspiracy has on interstate commerce is *constitutionally irrelevant*." United States v. Genao, 79 F.3d 1333, 1336 (2d Cir. 1996) (emphasis supplied)).

Judge Breyer faithfully applied these principles in granting the motions by the United States

for preliminary injunctions against six "cannabis buyers clubs," and rejecting the identical argument advanced by the plaintiffs here. In pertinent part, Judge Breyer held that, even if the defendants in those cases could prove "that all marijuana was cultivated locally, distributed locally, and consumed locally by California residents," it did not follow "that the class of activities within which defendants' conduct falls--non-profit distribution of medical marijuana--necessarily does not affect interstate commerce." United States v. Cannabis Cultivators Club, 5

F. Supp.2d 1086, 1098 (N.D. Cal. 1998). Noting that Congress "has the power 'to declare an entire class of activities affects interstate commerce'" (id. at 1097 (quoting Maryland v. Wirtz, 392 U.S. at 192)), Judge Breyer reasoned that:

> Medical marijuana may be grown locally, or out of state or country, and *there is nothing about medical marijuana that limits it to intrastate cultivation*. Similarly, it may be transported across state lines and consumed across state lines.
>
> * * *
>
> To hold that the Controlled Substances Act is unconstitutional as applied here would mean that in every action in which a plaintiff seeks to prove a defendant violated federal law, an element of every case-in-chief would be that the defendant's specific conduct at issue, based on the facts proved at an evidentiary hearing or trial, substantially affected interstate commerce. No case so holds and the Court declines to do so for the first time here.

Id. (emphasis supplied).

These authorities foreclose plaintiffs' contention that they may cabin the Court's consideration of the Commerce Clause question based on their assertion that their conduct occurs wholly intrastate. In the words of the Second Circuit, such assertions are "constitutionally irrelevant." Genao, 79 F.3d at 1336.

Nor do plaintiffs' assertions that their conduct occurs pursuant to the auspices of California law, and for alleged medicinal purposes, in any way alter this analysis. The Ninth Circuit has squarely rejected the argument that section 841(a)(1) "intrudes into an area traditionally regulated by the states," as "lack[ing] merit." Kim, 94 F.3d at 1250 n.4. And, in Oakland Cannabis, the Supreme Court unanimously held that, "for purposes of the Controlled Substances Act, marijuana

has 'no currently accepted medical use' at all," id. at 491 (quoting 21 U.S.C. § 811), and that, "[b]ecause the statutory prohibitions cover even those who have what could be termed a medical necessity, the [Controlled Substances] Act *precludes consideration of this evidence*." 532 U.S. at 499 (emphasis supplied). Hence, because a court sitting in equity cannot "override Congress' policy choice, articulated in a statute, as to what behavior should be prohibited," id. at 497, this Court may not take into account the alleged medicinal purposes for plaintiffs' actions.

In sum, these authorities foreclose the contention that this Court should limit its inquiry to whether Congress may regulate what the plaintiffs characterize to be the wholly intrastate commerce in medical marijuana.

B. The Controlled Substances Act Does Not Run Afoul of the Tenth Amendment

Plaintiffs next contend that, even if Congress' prohibition on the distribution, cultivation, and possession of marijuana satisfies the Commerce Clause, it nonetheless intrudes into the sovereignty of the State of California, thereby violating the Tenth Amendment. See Pl. Mem. at 15-17. This contention is easily disposed of. The Supreme Court "long ago rejected the suggestion that Congress invades areas reserved to the States by the Tenth Amendment simply because it exercises its authority under the Commerce Clause in a manner that displaces the States' exercise of their police powers" or that "curtail[s] or prohibit[s] the States' prerogatives to make legislative choices respecting subjects the States may consider important." Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc., 452 U.S. 264, 290, 291 (1981). Rather, in the absence of federal "commandeer[ing] [of] the state legislative process by requiring state legislature to enact a particular kind of law," Reno v. Condon, 528 U.S. 141, 149 (2000), the Tenth Amendment "states but a truism that all is retained which has not been surrendered." Darby, 312 U.S. at 124.

Hence, "[a]s long as it is acting within the powers granted it under the Constitution, Congress

may impose its will on the States [and] Congress may legislate in areas traditionally regulated by

the States." Gregory v. Ashcroft, 501 U.S. 452, 460 (1991). Here, the conclusion that the federal prohibition on the distribution, cultivation, and possession of marijuana is a valid exercise of

Congress' Commerce Clause authority necessarily disposes of the plaintiffs' Tenth Amendment challenge. As the Supreme Court has stated, "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." New York, 505 U.S. at 156.

Indeed, the Ninth Circuit has specifically rejected a claim closely analogous to that advanced

by the plaintiffs here -- that a federal grand jury inquiry into the alleged dispensation of anabolic steroids, of which a physician was a target, violated the Tenth Amendment because control of medical practice was asserted to be beyond the power of the federal government. In pertinent part, the Ninth Circuit held that "the Commerce Clause empowers the federal government to regulate prescription drugs," and that, therefore, "a physician may not defend a federal prosecution for improper drug prescription practices on Tenth Amendment grounds." In re Grand Jury Proceedings, 801 F.2d 1164, 1169-70 (9th Cir. 1986).

Likewise, in United States v. Rosenberg, 515 F.2d 190 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975), the Ninth Circuit rejected as "singularly unpersuasive" the contention that the Tenth Amendment requires that "the determination of whether or not [a physician] was acting in the course of his professional practice must be determined by the state," and that "Congress intended that the federal government rely on such a state determination." Id. at 198. To the contrary, the Ninth Circuit held that, "[i]f the Constitution allows the federal government to regulate the dispensation of drugs, it allows it to do so *in every case,* and not just where more than a certain quantity of drugs are involved. * * * The question of whether federal criminal laws have been violated is a *federal* issue to be determined in *federal* courts." Id. at 198 n.14 (emphasis supplied).

Accordingly, because Congress had authority under the Commerce Clause to prohibit the distribution, cultivation, and possession of marijuana, the argument that the statute "intrudes into an area traditionally regulated by states lacks merit." Kim, 94 F.3d at 1250 n.4.

C. The Controlled Substances Act Does Not Infringe Upon Fundamental Rights

Plaintiffs next contend that, "in the absence of a compelling interest that would be furthered by such a proscription, the federal government cannot, consistent with the Due Process Clause, abridge the rights of seriously ill patients by preventing or deterring them from using medicine in a kind and quantity sufficient to relieve their pain or prolong their lives." Pl. Mem. at 21.

This contention, too, is foreclosed by binding Ninth Circuit authority. In Carnohan, yet another decision which the plaintiffs entirely fail to discuss or cite, the Ninth Circuit affirmed the dismissal of a declaratory judgment action in which the plaintiff, a terminally ill cancer patient,[6] had sought to secure the right to obtain and use laetrile for the prevention of cancer. Among other claims, the patient argued that the regulatory scheme established by the Food and Drug Administration was so burdensome as applied to individuals that it infringed upon his fundamental right to privacy. The Ninth Circuit squarely rejected this contention, holding that "[c]onstitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of the government's police power." 616 F.2d at 1122. In so ruling, the Ninth Circuit cited with approval the Tenth Circuit's decision in Rutherford v. United States, 616 F.2d 455 (10th Cir.), *cert. denied*, 449 U.S. 937 (1980), where that court reversed an injunction entered on behalf of a class of terminally ill cancer patients who sought to obtain laetrile. In pertinent part, the Tenth Circuit held that "the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health." Id. at 457.[7]

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6 See People v. Privitera, 23 Cal.3d 697, 734, 591 P.2d 919, 942, 153 Cal.Rptr. 431, 454 (1979) (recounting district court proceedings in Carnohan), *cert. denied*, 444 U.S. 949 (1979).

7 Every other court of appeals to consider the question has likewise held that individuals do

The Ninth Circuit's decision in Carnohan is dispositive of the plaintiffs' claim in this case. Indeed, every court to have considered a like contention, including Judge Breyer, has held that there is no fundamental right to obtain, cultivate, or treat oneself with marijuana, including for alleged medicinal purposes. See United States v. Cannabis Cultivators Club, No. C 98-0085 CRB and related cases, slip op. at 8 (N.D. Cal. May 3, 2002) (rejecting contention that "the persons to whom [the defendants] distribute marijuana have a fundamental right to treat themselves with medical marijuana"); Pearson v. McCaffrey, 139 F. Supp.2d 113, 123 (D.D.C. 2001) ("[N]o court has recognized a fundamental right to sell, distribute, or use marijuana. Prescription, recommendation (in states that recognize recommendation as a quasi-prescription), and use of marijuana is illegal under the [Controlled Substances Act]. The Court declines to find that the federal policy, in upholding federal law, violates the Ninth Amendment."); Kuromiya v. United States, 37 F. Supp.2d 717, 725 (E.D. Pa. 1999) ("[A]s there is no constitutional provision by which one can discern a fundamental right to possess, use, grow, or sell marijuana, it is equally untenable to claim that there is a Ninth Amendment right violated by its criminalization" (internal quotations omitted)).

Plaintiffs make no attempt to distinguish these authorities as, here again, they are entirely absent from their memorandum. Nonetheless, Judge Breyer's reasoning remains sound today. Just as the plaintiffs in Carnohan had no fundamental right to obtain laetrile free from the government's police power, the plaintiffs in this case have no fundamental right to obtain marijuana free from the government's police power. As Judge Breyer has noted, "[t]o hold

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not have a fundamental right to obtain particular medical treatments. See, e.g., Sammon v. New Jersey Bd. of Med. Examiners, 66 F.3d 639, 645 n.10 (3d Cir. 1995) ("In the absence of extraordinary circumstances, state restrictions on a patient's choice of a particular treatment also have been found to warrant only rational basis review"); Mitchell v. Clayton, 995 F.2d 772, 775-76 (7th Cir. 1993) ("A patient does not have a constitutional right to obtain a particular type of treatment or to obtain treatment from a particular provider if the government has reasonably prohibited that type of treatment or provider"); United States v. Burzynski, 819 F.2d 1301, 1313-14 (5th Cir. 1987) (rejecting cancer patients' claim of constitutional right to obtain antineoplastin drugs), *cert. denied*, 484 U.S. 1065 (1988).

otherwise would directly contradict the Carnohan holding." United States v. Cannabis Cultivators Club, 1999 WL 111893, slip op. at 3 (N.D. Cal. Feb. 25, 1999), *vacated and remanded,* 221 F.3d 1349 (9th Cir. 2000) (Mem.).

That the State of California has decriminalized the possession and cultivation of marijuana for certain medical conditions does not in any way alter this analysis. As Judge Breyer explained, "[t]he fact that California law does not prohibit the distribution of medical marijuana under certain circumstances is not relevant as to whether the Intervenors have a fundamental right. If that were the case, whether one had a fundamental right to treat oneself with marijuana would depend on whether the state in which one lived prohibited such conduct." Id. 1999 WL 111893, slip op. at 3-4. Nor does the plaintiffs' reference to the fact that marijuana may have been recommended to them by their physicians have any bearing on this question, for "[i]f one does not have a right to obtain medication free from government regulation, there is no reason one would have that right upon a physician's recommendation." Id. 1999 WL 111893, slip op. at 4 (citing Kulsar v. Ambach, 598 F. Supp. 1124, 1126 (W.D.N.Y. 1984)). See also Warner-Lambert Co. v. Heckler, 787 F.2d 147, 156 (3d Cir. 1986) (Congress rejected the notion that "individual physicians should be left to decide whether particular drugs are safe and effective").

Finally, plaintiffs' suggestion that this Court may discover unenumerated rights protected by

the Ninth Amendment in state law, even when state law is in conflict with federal law, see Pl. Mem. at 24, cannot be squared with first principles of constitutional law. Under the Supremacy Clause, "'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield,'" Felder v. Casey, 487 U.S. 131, 138 (1988) (quoting Free v. Bland, 369 U.S. 663, 666 (1962)), and "even state regulation designed to protect ital state interests must give way to paramount federal legislation." De Canas v. Bica, 424 U.S. 351, 357 (1976). See also Cannabis Cultivators Club, 5 F. Supp.2d at 1094 ("The Supremacy Clause of Article VI of the United States Constitution mandates that federal law supersede state

law where there is an outright conflict between such laws.").[8] Thus, as the Supreme Court has explained:

> The powers granted by the Constitution to the Federal Government are subtracted from the totality of sovereignty in the states and the people. Therefore, when objection is made that the exercise of a federal power infringes upon rights reserved by the Ninth and Tenth Amendments, the inquiry must be directed toward the granted power under which the action of the Union was taken. *If granted power is found, the objection of invasion of those rights, reserved by the Ninth and Tenth Amendments, must fail*.

United Public Workers v. Mitchell, 330 U.S. 75, 95-96 (1947) (emphasis supplied), *overruled in part on other grounds by* Adler v. Board of Education, 342 U.S. 485 (1952). Here, because, as we have shown, the Controlled Substances Act is a proper exercise of Congress' authority under Article I, see Bramble, 103 F.3d at 1479; Tisor, 96 F.3d at 375; Kim, 94 F.3d 1247, 1249-50, any challenge to that authority on the ground that it infringes on rights founded in state law and r eserved by the Ninth Amendment (or Tenth Amendment) necessarily "must fail." United Public Workers, 330 U.S. at 96.

Indeed, by positing that state law could trump conflicting federal law by virtue of the Ninth Amendment, the plaintiffs would turn the Supremacy Clause on its head. But, as the Seventh Circuit stated in rejecting a like argument, "[t]he Ninth Amendment does not invert the supremacy clause and allow state constitutional provisions to override otherwise lawful federal statutes." United States v. Spencer, 160 F.3d 413, 414 (7th Cir. 1998), *cert. denied*, 526 U.S. 1078 (1999). In that case, a defendant, who had been convicted of possession of crack cocaine with the intent to distribute, in violation of section 841(a)(1), argued that the disproportionate punishment of crimes involving crack cocaine relative to crimes involving powdered cocaine violated a provision of the Illinois Constitution which had been interpreted to require that

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[8] In order to avoid any possible confusion on this point, we wish to emphasize that we are not contending here that the Controlled Substances Act necessarily preempts the Compassionate Use Act. We are instead responding to the plaintiffs' suggestion that, by virtue of the Ninth Amendment, the passage of the Compassionate Use Act by California voters serves to preempt the prohibitions enacted by Congress in the Controlled Substances Act.

punishment be proportional to the gravity of the offense, and that the Ninth Amendment prevented Congress from overriding the state constitutional provision. Writing for a unanimous panel, then-Chief Judge Posner found no merit to this argument, holding that " the Ninth Amendment does not empower the states, by creating new state constitutional rights, to truncate the power of Congress under Article I by preempting federal legislation." Id. at 414-15 (internal citations omitted). Judge Posner further commented on the folly of this argument, noting that

"Illinois could not by creating a state constitutional right to possess child pornography preempt the federal laws that prohibit such possession." Id. at 414.[9] Judge Posner's persuasive analysis is equally applicable to these cases.

Finally, for all the *sturm und drung* raised regarding state sovereignty, plaintiffs are remarkably unfamiliar with the fact that the California courts likewise have rejected the notion that an individual has a fundamental right to use unproven medical treatments, including marijuana. In Privitera, the California Supreme Court rejected the contention that a terminally ill cancer patient had a fundamental right to use laetrile, holding that "the asserted right to obtain drugs of unproven efficacy is not encompassed by the right of privacy embodied in either the federal or state Constitutions." 23 Cal. 3d at 702, 591 P.2d at 921. More recently, the California Court of Appeal, in a case involving the alleged medicinal use of marijuana, reaffirmed that, "[t]here is *no fundamental state or federal* constitutional right to use drugs of unproven efficacy." People v. Bianco, 93 Cal.App.4th 748, 754, 113 Cal.Rptr.2d 392, 397-98 (Cal. Ct. App. 2001) (emphasis supplied) (citing Privitera, 23 Cal.3d at 703-05, 709-10, 591 P.2d at 919, 153

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[9] Professor Barnett has elsewhere acknowledged that this outcome would be compelled under the Ninth Amendment theory advanced by the plaintiffs in this case. See Randy E. Barnett, *Editorial: Case Should Give Ninth Amendment New Life*, Portland Oregonian, April 11, 1999 ("When the people pass an initiative protecting a particular liberty, judges should respect this unenumerated liberty as they would an enumerated right. * * * Does this mean that, if the people of the states voted to protect the liberty to use recreational drugs, or view child pornography, the courts should defer to their judgment? The simple answer is yes * * *.").

Cal.Rptr. at 431), *review denied* (Jan. 6, 2002). Hence, given that the cultivation or possession of marijuana is not recognized as a fundamental right even under *California* law, the plaintiffs' contention that this Court should discover an unenumerated fundamental right to cultivate and possess marijuana based on California law fails even on its own terms.

A. There is No Medical Necessity Defense Under the Controlled Substances Act

Plaintiffs further contend that, in Oakland Cannabis, the Ninth Circuit "specifically and expressly applied the medical necessity defense to those suffering patients who need medical cannabis," and that, although the Supreme Court unanimously reversed that decision, "the issue of the availability of a medial [sic] necessity defense for seriously ill patients was not addressed by the majority decision and was notably preserved by the Court's concurrence." Pl. Mem. at 24-25.

This contention, too, is devoid of merit. In Oakland Cannabis, the Supreme Court held that "a medical necessity exception for marijuana is at odds with the terms of the Controlled Substances Act" because "its provisions leave no doubt that the defense is unavailable." 532 U.S. at 491. In particular, the Supreme Court reasoned that:

> In the case of the Controlled Substances Act, the statute reflects a determination that marijuana has no medical benefits worthy of an exception (outside the confines of a Government-approved research project). Whereas some other drugs can be dispensed and prescribed for medical use, see 21 U.S.C. § 829, the same is not true for marijuana. *Indeed, for purposes of the Controlled Substances Act, marijuana has "no currently accepted medical use" at all. § 811*.

Id. (emphasis supplied). The Court therefore concluded that, "[b]ecause the statutory prohibitions cover even those who have what could be termed a medical necessity, *the Act precludes consideration of this evidence*." Id. at 499 (emphasis supplied).

The Supreme Court explained that this conclusion is compelled by marijuana's placement in Schedule I of the Controlled Substances Act because, "[u]nder the statute, the Attorney General could not put marijuana into schedule I if marijuana had any accepted medical use." Id. at 492. The Court therefore rejected the contention that marijuana and other Schedule I controlled

substances "can be medically necessary, notwithstanding that they have 'no currently accepted medical use.'" Id. at 493. In pertinent part, the Court held that:

> It is clear from the text of the Act that Congress has made a determination that marijuana has no medical benefits worthy of an exception. The statute expressly contemplates that many drugs 'have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people,' § 801(1), but it includes no exception at all for any medical use of marijuana.

Id. The Supreme Court therefore made clear that, "[u]nlike drugs in other schedules, see § 829, *schedule I drugs cannot be dispensed under a prescription*." Id. at 492 n.5 (emphasis supplied).

Finally, although plaintiffs argue that the Supreme Court's decision in Oakland Cannabis did not address whether medical necessity could be a defense to a charge of possession of marijuana, the language of that decision leaves no room for such a claim. The Supreme Court stated took pains to note that, "[l]est there be any confusion, we clarify that nothing in our analysis, or the statute, suggests that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act. Furthermore, the very point of our holding is that there is no medical necessity exception to the prohibitions at issue, even when the patient is "seriously ill" and lacks alternative avenues for relief." Id. at 494 n.7.

Accordingly, because the Controlled Substances Act "precludes consideration" of any alleged medicinal value to marijuana, the Supreme Court's decision in Oakland Cannabis forecloses plaintiffs' medical necessity argument.

III. THE REMAINING EQUITABLE FACTORS ALSO WEIGH STRONGLY AGAINST ENTRY OF A PRELIMINARY INJUNCTION

Plaintiffs have failed to demonstrate that any of the remaining equitable factors warrant the

entry of their proposed injunction. Plaintiffs first cannot establish irreparable injury. As set forth above, plaintiffs are not entitled to obtain a drug that has not been approved by the government as safe and effective for medical use. See, e.g., Carnohan, 616 F.2d at 1122; Rutherford, 616 F.2d at 457. Therefore, plaintiffs are not entitled to a preliminary injunction on the grounds that they must be protected from the injury that allegedly occurs when doctors are unable to provide, and patients unable to obtain, marijuana for "treatment."

Plaintiffs' assertion that the mere allegation of constitutional injury, standing alone, is sufficient to demonstrate irreparable injury fares no better. In cases in which a moving party's constitutional claim dovetails with the presumption of irreparable injury, "the presence of irreparable injury turns on whether the plaintiff has shown a clear likelihood of success on the merits." Beal v. Stern, 184 F.3d 117, 123-24 (2d Cir. 1999). Hence, because plaintiffs have failed to show a clear likelihood of success on the merits, their claim of irreparable injury fails as well.

The balance of hardships also weighs strongly against entry of plaintiffs' proposed injunction.

"[A] temporary injunction against enforcement is in reality a suspension of an act, delaying the date selected by Congress to put its chosen policies into effect. Thus judicial power to stay an act of Congress, like judicial power to hold that act unconstitutional, is an awesome responsibility calling for the utmost circumspection in its exercise." Heart of Atlanta Motel v. United States, 85 S. Ct. 1, 2 (1964) (Black, Circuit Justice). An Act of Congress is "presumptively constitutional," and this "presumption of constitutionality * * * [is] an equity to be considered in favor of [the government] in balancing hardships." Walters v. National Ass'n of Radiation Survivors, 468 U.S. 1323, 1324 (1984) (Rehnquist, Circuit Justice). Therefore, the challenged statute should "remain in effect pending a final decision on the merits by this Court." Turner Broadcasting Sys. v. FCC, 507 U.S. 1301, 1301 (1993) (Rehnquist, Circuit Justice) (internal quotation omitted).

And the public interest weighs strongly against entry of plaintiffs' proposed injunction. Congress has recently reiterated its continuing adherence to the existing FDA drug approval process, and its continuing opposition to any effort to allow the use of marijuana or other Schedule I controlled substances until they are proven safe and effective based on appropriate findings by the FDA. See Pub. L. No. 105-277, Div. F, 112 Stat. 2681, 760-61 (1998). In particular, Congress emphasized the fact that, "before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective," and stated its opposition to attempts to "circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration * * *." Id.

The United States relies upon this express declaration of the public interest by Congress, which is entitled to deference. The Supreme Court has held that, in considering the public interest, courts must defer to Congress' considered judgment when that judgment is clearly reflected in enacted legislation. The leading case is Virginian Ry. Co. v. System Federation No. 40, 300 U.S. 515 (1937), in which the Supreme Court stated that, "[i]n considering the propriety

of the equitable relief granted here, we cannot ignore the judgment of Congress" which is "deliberately expressed in legislation." Id. at 551. This is because "*[t]he fact that Congress has indicated its purpose [in a statute] is in itself a declaration of the public interest and policy which should be persuasive in inducing the courts to give relief*." Id. at 552 (emphasis supplied). Similarly, in United States v. Rutherford, 442 U.S. 544 (1979), a case in which a class of terminally ill cancer patients and their spouses brought suit to enjoin the government from interfering with the interstate shipment and sale of laetrile, the Supreme Court unanimously held that the Food, Drug and Cosmetic Act "makes no special provision for drugs used to treat terminally ill patients," and that "[w]hen construing a statute so explicit in scope," it is the incumbent upon the courts to give it effect. Id. at 552. See also Able, 44 F.3d at 132 (holding

that, where Congress has expressed itself clearly in enacted legislation, "it is inappropriate for this court to substitute its own determination of the public interest for that arrived at by the political branches, whether or not there may be doubt regarding the wisdom of their conclusion.").

Finally, it cannot escape mention that, although plaintiffs suggest that this case is limited to

the context of "medical" marijuana, a decision in favor of the plaintiffs could not be so easily cabined. As the Supreme Court explained in Rutherford:

> It bears emphasis that although the Court of Appeals' ruling was limited to Laetrile, its reasoning cannot be so readily contained. To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however, toxic or ineffectual, for such individuals. If history is any guide, this new market would not long be overlooked.

442 U.S. at 557-58. This reasoning is equally applicable in this case. If plaintiffs' proposed injunction were granted, there is no reason that a plaintiff seeking to use other Schedule I controlled substances or unapproved drugs -- such as laetrile -- would not similarly be able to bypass the carefully crafted statutory process established by Congress. Plaintiffs' proposed injunction therefore has the potential to significantly undermine the FDA drug approval process, a result patently at odds with the public interest as expressed by Congress and recognized by the Supreme Court in Rutherford.

CONCLUSION

For the foregoing reasons, the Court should deny plaintiff's motion for a preliminary injunction, and dismiss this action with prejudice.

Respectfully submitted,

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Dated: November 19, 2002

CERTIFICATE OF SERVICE

I, Mark T. Quinlivan, hereby certify that on the 19th day of November 2002, I caused to be served a copy of the foregoing Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction, and the accompanying [Proposed] Order, by overnight delivery, upon the following counsel of record:

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