No. 03-15481

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ANGELA McCLARY RAICH; DIANE MONSON,
JOHN DOE NUMBER ONE, and JOHN DOE NUMBER TWO,
Plaintiffs-Appellants,

v.

JOHN ASHCROFT, Attorney General of the United States,
and WILIAM B. SIMPKINS, Acting Administrator of the
Drug Enforcement Administration
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
Case No. C 02-4872 MJJ

BRIEF FOR APPELLEES

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STATEMENT OF JURISDICTION

Appellants Angela McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two appeal from the district court's denial of their motion

[1] Pursuant to Fed. R. App. P. 43(c)(2), William B. Simpkins, the current Acting Administrator of the Drug Enforcement Administration, is automatically substituted as a defendant-appellee in this case.

for a preliminary injunction. The district court denied Appellants' motion for a preliminary injunction on March 5, 2003. ER 250-67; Raich v. Ashcroft, 248 F. Supp.2d 918 (N.D. Cal. 2002), *on appeal*, No. 03-15481 (9th Cir.). On March 12, 2003, Appellants filed a timely notice of appeal. ER 268. This Court has jurisdiction over that appeal pursuant to 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

In denying Appellants' motion for a preliminary injunction:

(1) Whether the district court correctly held, in accordance with longstanding circuit precedent, that the Controlled Substances Act's prohibition on the cultivation and possession of marijuana is a lawful exercise of Congressional authority under the Commerce Clause;

(2) Whether the district court correctly held that, because the Controlled Substances Act is a lawful exercise of Congressional authority under the Commerce Clause, the Tenth Amendment disclaims any reservation of that power to the States, in the absence of federal commandeering;

(3) Whether the district court correctly held, in accordance with longstanding circuit precedent, that there is no fundamental right to obtain or use marijuana or other unproven treatments;

(4) Whether the district court correctly held, in accordance with the Supreme Court's decision in United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001), that Appellants may not maintain a claim of medical necessity; and

(5) Whether the district court correctly held that to be entitled to preliminary injunctive relief, Appellants must establish, at an "irreducible minimum," a possibility of success on the merits.

STATEMENT OF THE CASE

On October 9, 2002, Appellants filed suit against the Attorney General of the United States and the Administrator of the Drug Enforcement Administration ("DEA"), seeking declaratory relief and preliminary and permanent injunctive relief. ER 1-19. On October 30, 2002, Appellants moved for a preliminary injunction that sought to enjoin defendants from enforcing the provisions of the Controlled Substances Act against them. ER 22, 23, 24-58. On March 5, 2003, the district court denied the motion for preliminary injunction, holding that "[a]ll of plaintiffs' arguments in support of their position are unavailing: the weight of precedent precludes this Court from determining that Congress' findings in support of the CSA are insufficient to survive constitutional challenge [and] the CSA is not a violation of the Tenth Amendment or the Ninth Amendment." ER 266; 248 F.

Supp.2d at 931. On March 12, 2003, Appellants filed a timely notice of appeal. ER 268-73.

STATEMENT OF FACTS

A. The Controlled Substances Act.

The Controlled Substances Act ("CSA" or "the Act"), 21 U.S.C. § 801, *et seq.*, makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [the Act]." 21 U.S.C. § 841(a)(1). The CSA also makes it a crime to possess any controlled substances "except as authorized" under the Act. *See* 21 U.S.C. § 844(a). The CSA imposes criminal and civil penalties for violations of the Act. *See* 21 U.S.C. §§ 841-863.

Congress enacted the CSA in 1970 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).[2] Congress also made express legislative findings that the intrastate distribution, cultivation, and possession of controlled substances have a direct effect on interstate commerce. *See* 21 U.S.C. §§ 801(3)-(6).

Congress therefore established "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) (CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal." (quoting H.R. Rep. No. 1444, *supra*)). 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).

A drug is included in Schedule I, the most restrictive Schedule, if it "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

[2] 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).

supervision." 21 U.S.C. §§ 812(b)(1)(A)-(C). Given these characteristics, Congress mandated that substances in Schedule I be subject to the most stringent regulation. In particular, 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 ("HHS"), acting through the Food and Drug Administration ("FDA"). *See* 21 U.S.C. § 823(f).

By contrast, a drug is included in Schedule II if it "has a high potential for abuse," but "has a currently accepted medical use in treatment in the United States" or "a currently accepted medical use with severe restrictions." 21 U.S.C. §§ 812(b)(2)(A) & (B). Schedules III through V consist of drugs that similarly have "a currently accepted medical use in treatment in the United States," 21 U.S.C. §§ 812(b)(3)(B), (4)(B) & (5)(B), but for which the respective potential for abuse is lower, and the degree of potential dependence more limited, than they are for drugs listed in the preceding schedule. *See* 21 U.S.C. §§ 812(b)(3)-(5). Given their potential for abuse, the CSA requires that all persons involved in the distribution of controlled substances be registered with the DEA, *see* 21 U.S.C. § 822(a), and that they keep records of all transfers of controlled substances. *See* 21 U.S.C. § 827(a).

Congress also recognized 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 HHS for a scientific and medical evaluation and a recommendation as to whether the substance should be reclassified or decontrolled. The recommendation of the Secretary is binding on the Administrator with respect to scientific and medical

[3] For example, in 1986, the DEA Administrator rescheduled "Marinol," 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.

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.

When it enacted the CSA in 1970, Congress specified certain substances to be included in each of the Schedules as an initial matter. *See* Pub. L. No. 91-513, Tit. II, § 202, 84 Stat. 1248-1252 (1970); 21 U.S.C. § 812(a). Congress classified marijuana and tetrahydrocannabinols as Schedule I controlled substances from the outset, and they have remained Schedule I substances ever since 1970. *See* 21 U.S.C. § 812(c) (Schedule I(c)(10) and (17)).

In addition to the restrictions under the CSA, controlled substances in Schedule I are subject to control under 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

[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).

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)

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 entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress declared, *inter alia*, that:

> (5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;
>
> * * * * *
>
> (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. Congress also has repeatedly enacted legislation prohibiting the "Legalization of Marijuana for Medical Treatment Initiative of 1998," which was approved by the electors of the District of Columbia, from taking effect. *See* Pub. L. No. 108-7, Division C, Title III, § 126(b), 117 Stat. 11 (2003); Pub. L. No. 107-96, § 127(b), 115 Stat. 923 (2001); Pub. L. No. 106-522, § 143(b), 114 Stat. 2440 (2000); Pub. L. No. 106-113, § 167(b), 113 Stat. 1501 (1999).

The DEA and FDA also have consistently determined that marijuana should remain in Schedule I because it has "no currently accepted medical use for treatment in the United States." In 1992, the DEA 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. *See* Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1137 (D.C. Cir. 1994).

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. 20,038 (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 a petition challenging the DEA Administrator's determination for lack of standing. *See* Gettman v. DEA, 290 F.3d 430, 432-35 (D.C. Cir. 2002).

B. Facts and Proceedings Below

On October 9, 2002, Appellants filed suit against the Attorney General of the United States and the Administrator of the DEA, seeking declaratory relief and preliminary and permanent injunctive relief. ER 1-19. On October 30, 2002, Appellants moved for a preliminary injunction that sought to enjoin defendants from enforcing the provisions of the Controlled Substances Act against them. ER 22, 23, 24-58. Specifically, Appellants sought a preliminary injunction that would have enjoined defendants, and any person acting in consort with them, from arresting or prosecuting Appellants, seizing their "medical" cannabis, forfeiting their property,

or seeking civil or administrative sanctions against them, relating to Appellants' cultivation and possession of marijuana for alleged medicinal uses. ER 21, 22-23.

On March 5, 2003, the district court (Jenkins, J.) denied the motion for preliminary injunction, holding that "the weight of precedent precludes a finding of likelihood of success on the merits * * *." ER 251; 248 F. Supp.2d at 920. The district court first concluded that Appellants had failed to establish a likelihood of success on the merits of their claim that the CSA's prohibitions on the cultivation and possession of marijuana exceeded Congressional authority under the Commerce Clause, determining that it was "constrained from such a determination by the weight of precedent." ER 257; 248 F. Supp.2d at 925. The district court explained that "[t]he Ninth Circuit has repeatedly upheld the constitutionality of the CSA as applied to marijuana," and "[t]he Court of Appeals has confirmed the validity and adequacy of Congress' findings in support of the CSA, including its application to wholly intrastate cultivation of marijuana." *Id.*

The district court next found no merit to Appellants' contention that the CSA interferes with principles of state sovereignty protected by the Tenth Amendment, holding that "[a]s the promulgation of the CSA was a legitimate exercise of Congressional power under the Commerce Clause, the Tenth Amendment is not implicated." ER 260; 248 F. Supp.2d at 927. The district court also determined

that there was no federal "commandeering" involved at issue in the case, "for the federal government is not forcing California, or any other State, to take any action." *Id.*

The district court also found no merit to Appellants contention that the CSA interfered with fundamental rights, holding that "[w]hile plaintiffs may disagree with the wisdom of the federal government's determination that marijuana has no medical efficacy and therefore, that federal law renders it unavailable for patients, they do not have a fundamental, constitutional right to obtain and use it for treatment." ER 261-62; 248 F. Supp.2d at 928. Finally, the district court determined that the Supreme Court's decision in Oakland Cannabis was "dispositive" of Appellants' contention that they had a medical necessity to possess marijuana. ER 263; 248 F. Supp.2d at 929.

Turning to the equitable factors, the district court stated that, "[s]ince the binding effect of prior decisions indicates that plaintiffs have demonstrated no likelihood of success on the merits, the Court need not address the issue of irreparable harm, the balance of hardships, or the impact of an injunction upon the public interest." ER 263; 248 F. Supp.2d at 930. The district court indicated, however, that "the importance of this case dictates that these factors merit some brief attention," *id.*, and found that the equitable factors tipped in plaintiffs' favor.

ER 265; 248 F. Supp.2d at 931. The district court nonetheless concluded that, because "[p]laintiffs are unable, on this record, to establish the required 'irreducible minimum' of a likelihood of success on the merits under the law of this Circuit * * * the request for injunctive relief must be denied." *Id.*

On March 12, 2003, Appellants filed a timely notice of appeal from the denial of their motion for a preliminary injunction. ER 268-73.

STANDARD OF REVIEW

This Court reviews the district court's denial of Appellants' motion for a preliminary injunction for abuse of discretion, *see* Walters v. Reno, 145 F.3d 1032, 1047 (9th Cir. 1998), *cert. denied*, 526 U.S. 1003 (1999), and reviews the rulings of law relied upon by the district court de novo, *see* Hilao v. Estate of Marcos, 95 F.3d 848, 851 (9th Cir. 1996).

SUMMARY OF ARGUMENT

I. The district court correctly determined that Appellants failed had to establish any chance of success on the merits, and that this failure required the denial of their motion for a preliminary injunction.

A. In a series of decisions, this Court has upheld the CSA's prohibition on the cultivation and possession of marijuana and other controlled substances against Commerce Clause challenges, and the district court correctly

determined that these decisions foreclosed Appellants' Commerce Clause challenge to the Act. The Supreme Court's recent Commerce Clause jurisprudence does not call this existing body of circuit authority into doubt.

B. The conclusion that the CSA is a lawful exercise of Congressional authority under the Commerce Clause disposes of Appellants' contention that the Act's prohibition on the cultivation and possession of marijuana infringes upon the sovereign power reserved to the States by the Tenth Amendment. This Court has rejected the argument that section 841(a)(1) improperly intrudes into an area traditionally regulated by the States, and the Supreme Court has 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.

C. Appellants' contention that they have a fundamental right to obtain and use marijuana also is without merit. This Court has held that constitutional rights of privacy and personal liberty do not give individuals the right to obtain unproven medications free of the lawful exercise of the government's police power, and every other court of appeals to have considered the question has held that there is no fundamental right to distribute, cultivate, or possess marijuana. This Court

also has repeatedly upheld Congress' legislative assessment of marijuana under rational basis review.

D. Appellants' assertion that the government's actions threatens their rights under the "medical necessity" defense is foreclosed by the Supreme Court's decision in Oakland Cannabis, in which the Court expressly stated that nothing in its analysis suggested that a distinction should be drawn between the prohibitions on manufacturing and distributing and the other prohibitions in the CSA.

II. The district court also correctly determined that Appellants' failure to establish an "irreducible minimum" of success on the merits required that their motion for a preliminary injunction be denied. In any event, the CSA's prohibition on the cultivation and possession of marijuana precludes a finding that entry of a preliminary injunction to allow the use of marijuana as a medical treatment is in the public interest. As the Supreme Court explained in Oakland Cannabis, courts of equity cannot, in their discretion, reject the balance that Congress has struck in a statute, and may only exercise their discretion to choose one means of enforcement over another, not to choose nonenforcement of a statute.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY DETERMINED THAT APPELLANTS FAILED TO SHOW ANY POSSIBILITY OF SUCCESS ON THE MERITS

A. The Controlled Substances Act is a Lawful Exercise of Congressional Authority under the Commerce Clause

Appellants first contend (Br. at 8-27) that application of the CSA to their particular conduct constitutes an unlawful exercise of Congressional authority under the Commerce Clause. This contention is foreclosed by binding circuit precedent.

1. It has long been established in this circuit that the CSA's prohibition on the distribution, cultivation, and 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) (upholding constitutionality of 21 U.S.C. §§ 841(a)(1), 844(a) against Commerce Clause challenge); *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). This Court is not alone in reaching this conclusion; all eleven other regional courts of appeals have likewise upheld the constitutionality of section 841(a)(1) or other provisions of the CSA against Commerce Clause challenges.[5]

Thus, in Rodriquez-Camacho, this Court held that "[m]arijuana is listed among the controlled substances in the challenged statute, and Congress has made specific findings as to the effect of intrastate activities in controlled substances on interstate commerce." 468 F.2d at 1221 & n.5 (internal footnote omitted, citing 21 U.S.C. §§ 801(3)-(6)). While recognizing that this Court was not required to defer to these findings if "'the relation of the subject to interstate commerce and its effect upon it are clearly nonexistent,'" this Court held that "[s]uch is not the case as

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[5] *See, e.g.*, 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.), *cert. denied*, 535 U.S. 1079, 535 U.S. 1087 (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*, 535 U.S. 1099 (2002); United States v. Jackson, 111 F.3d 101, 102 (11th Cir.) (per curiam), *cert. denied*, 522 U.S. 878 (1997).

regards controlled substances. * * * It is sufficient that Congress had a rational basis for making its findings." 468 F.2d at 1222 (quoting Stafford v. Wallace, 258 U.S. 495, 521 (1922)).

Similarly, in Montes-Zarate, this Court rejected the contention that a district court did not have jurisdiction over the crime of possession with the intent to distribute marijuana because no interstate nexus had been established, holding that section 841(a) "is constitutional and that no proof of interstate nexus is required to establish jurisdiction." 552 F.2d at 1331. Adopting the reasoning of the Fourth Circuit, this Court held that:

> Congressional findings on which the legislation rested disclosed that intrastate possession, distribution and sale of drugs such as heroin directly and injuriously effected the introduction of them into other States to the injury of the public health and welfare there. 21 U.S.C. §§ 801, 812. Thus the statutory definition and proscription of transactions of 'controlled substances,' 21 U.S.C. § 812(b), entirely within a State is altogether constitutional.'

Id. at 1331 (quoting United States v. Atkinson, 513 F.2d 38, 39-40 (4th Cir. 1975)).

In Visman, this Court again turned away a Commerce Clause challenge to the CSA, finding no merit to the contention that section 841(a)(1) exceeded Congressional authority because there allegedly was no reasonable basis to assume that "marijuana plants found rooted in the soil" affected interstate commerce.