

No. 03-15481

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

ANGEL McCLARY RAICH, et al., *Plaintiffs-Appellants*

v.

**ALBERTO GONZALES, Attorney General of the United States, et al.,
*Defendants-Appellees***

**On Remand from the United States Supreme Court
and
On Appeal from the United States District Court
for the Northern District of California, No. C 02-4872 MJJ**

SUPPLEMENTAL BRIEF FOR THE APPELLEES

**PETER D. KEISLER
Assistant Attorney General
KEVIN V. RYAN
United States Attorney
MARK B. STERN
ALISA B. KLEIN
Attorneys, Appellate Staff, Civil Division
MARK T. QUINLIVAN
Assistant U.S. Attorney
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3606**

<u>People v. Urziceanu</u> , 132 Cal.App.4th 747, 33 Cal. Rptr.3d 859 (Cal. Ct. App. 2005)	27
<u>Planned Parenthood v. Casey</u> , 505 U.S. 833 (1992)	32
<u>Raich v. Ashcroft</u> , 352 F.3d 1222 (9th Cir. 2003), <u>vacated and remanded</u> , 125 S. Ct. 2195 (2005)	1, 3, 12, 13
<u>Raich v. Ashcroft</u> , 248 F. Supp.2d 918 (N.D. Cal. 2003), <u>rev'd</u> , 352 F.3d 1222 (9th Cir. 2003), <u>vacated and remanded</u> , 125 S. Ct. 2195 (2005)	<i>passim</i>
<u>Roe v. Wade</u> , 410 U.S. 113 (1973)	32
<u>Rutherford v. United States</u> , 616 F.2d 455 (10th Cir. 1980)	<i>passim</i>
<u>Sammon v. New Jersey Bd. of Med. Examiners</u> , 66 F.3d 639 (3d Cir. 1995)	19 n.6
<u>San Diego County Gun Rights Comm. v. Reno</u> , 98 F.3d 1121 (9th Cir. 1996)	33
<u>Schowengerdt v. United States</u> , 944 F.2d 483 (9th Cir. 1991)	33
<u>Seeley v. State of Washington</u> , 132 Wash. 2d 776, 794, 940 P.2d 604 (1997)	20
<u>Smith v. Marsh</u> , 194 F.3d 1045 (9th Cir. 1999)	41
<u>Smith v. Shalala</u> , 954 F. Supp. 1 (D.D.C. 1996)	19 n.6, 30
<u>Southwest Voter Registration Educ. Project v. Shelley</u> , 344 F.3d 914 (9th Cir. 2003)	14
<u>Stanton v. Astra Pharmaceutical Products, Inc.</u> , 718 F.2d 553 (3d Cir. 1983)	25
<u>Stenberg v. Carhart</u> , 530 U.S. 914 (2000)	31, 32

TABLE OF CONTENTS

TABLE OF CONTENTS	i
TABLE OF AUTHORITIES	ii
STATEMENT OF JURISDICTION	1
STATEMENT OF THE ISSUES	1
STATEMENT OF THE CASE	2
STATEMENT OF FACTS	3
A. The Controlled Substances Act	3
A. Facts and Proceedings	10
STANDARD OF REVIEW	14
SUMMARY OF ARGUMENT	15
ARGUMENT	16
I. THERE IS NO FUNDAMENTAL RIGHT TO OBTAIN OR USE MARIJUANA OR OTHER UNAPPROVED AND UNPROVEN MEDICAL TREATMENTS	16
II. THE SUPREME COURT'S DECISION IN <u>OAKLAND CANNABIS</u> FORECLOSES ANY DEFENSE OF MEDICAL NECESSITY	38
III. PLAINTIFFS HAVE WAIVED THEIR CONTENTION THAT THE CSA ALLOWS MS. RAICH TO USE MARIJUANA	40
IV. THE CSA DOES NOT RUN AFOUL OF THE TENTH AMENDMENT	42
CONCLUSION	46
CERTIFICATE OF SERVICE	47
CERTIFICATE OF COMPLIANCE	48

TABLE OF AUTHORITIES

CASES

<u>Alliance for Cannabis Therapeutics v. DEA,</u> 15 F.3d 1131 (D.C. Cir. 1994)	9
<u>Andrews v. Ballard,</u> 498 F. Supp. 1038 (S.D. Tex. 1980)	19 n.6
<u>Barton v. CIR,</u> 737 F.2d 822 (9th Cir. 1984)	33
<u>Benny v. U.S. Parole Comm'n,</u> 295 F.3d 977 (9th Cir. 2002)	27, 33
<u>Carnohan v. United States,</u> 616 F.2d 1120 (9th Cir. 1980)	<i>passim</i>
<u>Coeur d'Alene Tribe of Idaho v. Hammond,</u> 384 F.3d 674 (9th Cir. 2004), <u>cert. denied,</u> 125 S. Ct. 1397 (2005)	40
<u>County of Santa Cruz v. Ashcroft,</u> 279 F. Supp.2d 1192 (N.D. Cal. 2003), <u>reconsidered on other grounds,</u> 314 F. Supp.2d 1000 (N.D. Cal. 2004)	20, 30
<u>Demery v. Arpaio,</u> 378 F.3d 1020 (9th Cir. 2004), <u>cert. denied,</u> 125 S. Ct. 2961 (2005)	15
<u>E.E.O.C. v. Luce, Forward, Hamilton & Scripps,</u> 345 F.3d 742 (9th Cir. 2003)	27, 33
<u>FDA v. Brown & Williamson Tobacco Corp.,</u> 529 U.S. 120 (2000)	24
<u>Gettman v. DEA,</u> 290 F.3d 430 (D.C. Cir. 2002)	10
<u>Gonzales v. Oregon,</u> No. 04-623 (January 17, 2006)	44, 45, 46
<u>Gonzales v. Raich,</u> 125 S. Ct. 2195 (2005)	<i>passim</i>

<u>Gorbach v. Reno</u> , 219 F.3d 1087 (9th Cir. 2000)	14
<u>Gregory v. Ashcroft</u> , 501 U.S. 452 (1991)	43
<u>Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc.</u> , 452 U.S. 264 (1981)	43
<u>Kuromiya v. United States</u> , 37 F. Supp.2d 717 (E.D. Pa. 1999)	21 n.7
<u>Marshall v. United States</u> , 414 U.S. 417 (1974)	34
<u>McConnell v. FEC</u> , 540 U.S. 93 (2003)	42, 43, 44
<u>Miller v. Gammie</u> , 335 F.3d 889 (9th Cir. 2003)	27, 33
<u>Mitchell v. Clayton</u> , 995 F.2d 772 (7th Cir. 1993)	19, 19 n.6
<u>National Ass'n for the Advancement of Psychoanalysis v. California Bd. of Psychology</u> , 228 F.3d 1043 (9th Cir. 2000)	18, 19, 20, 27, 33
<u>New Orleans v. Dukes</u> , 427 U.S. 297 (1976)	34
<u>New York v. United States</u> , 505 U.S. 144 (1992)	43
<u>Pearson v. McCaffrey</u> , 139 F. Supp.2d 113 (D.D.C. 2001)	21 n.7
<u>People v. Bianco</u> , 93 Cal.App.4th 748, 113 Cal.Rptr.2d 392 (Cal. Ct. App. 2001), <u>review denied</u> (Jan. 16, 2002)	20
<u>People v. Privitera</u> , 23 Cal.3d 697, 591 P.2d 919, 153 Cal.Rptr. 431 (1979)	18, 29 n.8

<u>Treasury Employees v. Von Raab,</u> 489 U.S. 656 (1989)	36
<u>United Public Workers v. Mitchell,</u> 330 U.S. 75 (1947), <u>overruled in part on other grounds by</u> <u>Adler v. Board of Education,</u> 342 U.S. 485 (1952)	34
<u>United States v. An Article of Drug . . . Bacto-Unidisk,</u> 394 U.S. 784 (1969)	24
<u>United States v. Burzynski Cancer Research Inst.,</u> 819 F.2d 1301 (5th Cir. 1987)	19 n.6
<u>United States v. Cannabis Cultivators Club,</u> 1999 WL 111893 (N.D. Cal. Feb. 25, 1999), <u>vacated on other grounds,</u> 221 F.3d 1349 (9th Cir. 2000) (Mem.)	21, 28, 29, 30
<u>United States v. Fogarty,</u> 692 F.2d 542 (8th Cir. 1982)	37
<u>United States v. Jones,</u> 231 F.3d 508 (9th Cir. 2000)	44
<u>United States v. Kama,</u> 394 F.3d 1236 (9th Cir. 2005)	41
<u>United States v. Kiffer,</u> 477 F.2d 349 (2d Cir. 1972)	37
<u>United States v. Miroyan,</u> 577 F.2d 489 (9th Cir. 1978)	35
<u>United States v. Montero-Camargo,</u> 208 F.3d 1122 (9th Cir. 2000)	40
<u>United States v. Moore,</u> 423 U.S. 122 (1976)	4, 24
<u>United States v. Oakland Cannabis Buyers' Cooperative,</u> 532 U.S. 483 (2001)	<i>passim</i>
<u>United States v. Rodriguez-Camacho,</u> 468 F.2d 1220 (9th Cir. 1972)	35
<u>United States v. Rogers,</u> 549 F.2d 107 (9th Cir. 1976)	35

<u>United States v. Rutherford,</u> 442 U.S. 544 (1979)	30, 31
<u>United States v. Vital Health Prods., Ltd.,</u> 786 F. Supp. 761 (E.D. Wisc. 1992), <u>aff'd</u> , 985 F.2d 563 (7th Cir. 1993) (Mem.)	19 n.6
<u>United States v. Walsh,</u> 331 U.S. 432 (1947)	25
<u>Warsoldier v. Woodford,</u> 418 F.3d 989 (9th Cir. 2005)	14, 15
<u>Washington v. Glucksberg,</u> 521 U.S. 702 (1997)	17, 22, 23, 38
<u>Weinberger v. Hynson, Westcott & Dunning, Inc.,</u> 412 U.S. 609 (1973)	8

CONSTITUTIONAL PROVISIONS

U.S. Const. art. I, §8, cl.3 (Commerce Clause)	<i>passim</i>
U.S. Const. amend. V (Due Process Clause)	<i>passim</i>
U.S. Const. amend. IX	<i>passim</i>
U.S. Const. amend. X	<i>passim</i>

FEDERAL STATUTES

<u>Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq.</u>	7
21 U.S.C. §321(p)	7 n.4
21 U.S.C. §355(a)	7, 36
21 U.S.C. §355(b)	7, 36
21 U.S.C. §355(d)	7, 36
21 U.S.C. §355(h)	36
21 U.S.C. §355(i)	36
21 U.S.C. §393(b) (2)	24-25
<u>Controlled Substances Act, 21 U.S.C. § 801 et seq.</u>	3
21 U.S.C. §801(1)	4
21 U.S.C. §801(2)	4
21 U.S.C. §802(6)	4 n.2
21 U.S.C. §811(a)	6, 36
21 U.S.C. §811(b)	7, 36
21 U.S.C. §812(b)	4, 36

21 U.S.C. §812(b)(1)(A)	5, 35
21 U.S.C. §812(b)(1)(B)	5, 35
21 U.S.C. §812(b)(1)(C)	5, 35
21 U.S.C. §812(b)(2)(A)	5
21 U.S.C. §812(b)(2)(B)	5
21 U.S.C. §812(b)(3)	6
21 U.S.C. §812(b)(3)(B)	5
21 U.S.C. §812(b)(4)	6
21 U.S.C. §812(b)(4)(B)	5
21 U.S.C. §812(b)(5)	6
21 U.S.C. §812(b)(5)(B)	5
21 U.S.C. §812(c) (Schedule I(c)(10) and (17))	5
21 U.S.C. §822(a)	6
21 U.S.C. §823(f)	5, 26, 36, 42, 45
21 U.S.C. §824(a)(4)	45
21 U.S.C. §827(a)	6
21 U.S.C. §829)	42
21 U.S.C. §841(a)(1)	3, 5, 26, 42
21 U.S.C. §844(a)	3, 5, 26, 41, 42
21 U.S.C. §877	7, 36
28 U.S.C. §1292(a)(1)	1
28 U.S.C. §1331	1
28 U.S.C. §2201	1
Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236	4
Pub. L. No. 109-115, Division B--District of Columbia Appropriations Act, 2006, 119 Stat. 2396 (2005)	9 n.5
Pub. L. No. 108-335, District of Columbia Appropriations Act of 2005, 118 Stat. 1322 (2004)	9 n.5
Pub. L. No. 108-199, Division C--District of Columbia Appropriations Act, 2004, 118 Stat. 3 (2004)	9 n.5
Pub. L. No. 108-7, Division C-District of Columbia Appropriations, 2003, 117 Stat. 11 (2003)	9 n.5
Pub. L. No. 107-96, District of Columbia Appropriations Act, 2002, 115 Stat. 923 (2001)	9 n.5
Pub. L. No. 106-522, District of Columbia Appropriations Act, 2001, §143(b), 114 Stat. 2440 (2000)	9 n.5
Pub. L. No. 106-113, Division A: District of Columbia Appropriations, 113 Stat. 1501 (1999)	9 n.5

Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760	8
Drug Amendments of 1962, Pub. L. No. 87-871, 76 Stat. 780	25
Marihuana Tax Act, Pub. L. No. 75-238, 50 Stat. 551	25
Harrison Narcotics Act, Pub. L. No. 63-233, 38 Stat. 785	24
Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768	24
Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 728	24

LEGISLATIVE MATERIALS

H.R. Rep. No. 1444, 91st Cong., 2d Sess. (1970)	3, 4
---	------

REGULATIONS AND REGULATORY MATERIALS

28 C.F.R. §0.100(b)	6
66 Fed. Reg. 20,038 (April 18, 2001)	10
64 Fed. Reg. 35,928 (July 2, 1999)	6 n.3
57 Fed. Reg. 10,499 (March, 26, 1992)	9
51 Fed. Reg. 17,476 (May 13, 1986)	6 n.3

OTHER MATERIALS

Institute of Medicine, <u>Marijuana and Medicine: Assessing the Scientific Base</u> (Janet E. Joy, Stanley J. Watson & John A. Benson, Jr. eds. 1999)	32 n.9
National Comm'n on Marihuana & Drug Abuse, <u>Marihuana: A Signal of Misunderstanding</u> (March 1972)	25
David L. Cohen, <u>Pharmacy in History: The Development of State Pharmaceutical Law</u> (1995)	24
R.J. Bonnie & C.H. Whitebread, <u>The Marijuana Conviction</u> (1974)	25, 26

STATEMENT OF JURISDICTION

The district court had subject matter jurisdiction over the case pursuant to 28 U.S.C. §§1331 and 2201, because the complaint arises under federal law and seeks an injunction and declaratory judgment. The district court denied plaintiffs' motion for a preliminary injunction on March 5, 2003. See Raich v. Ashcroft, 248 F. Supp.2d 918 (N.D. Cal. 2003). On March 12, 2003, plaintiffs filed a timely notice of appeal. [ER 250].¹ On December 16, 2003, this Court reversed and remanded. See Raich v. Ashcroft, 352 F.3d 1222 (9th Cir. 2003). On June 6, 2005, the Supreme Court vacated this Court's opinion and remanded the case for disposition of plaintiffs' remaining claims. See Gonzales v. Raich, 125 S. Ct. 2195, 2215 (2005). On September 6, 2005, this Court directed the parties to submit briefs regarding plaintiffs' remaining claims. [G.Add. 1-3]. This Court continues to have jurisdiction over this interlocutory appeal pursuant to 28 U.S.C. §1292(a)(1).

STATEMENT OF THE ISSUES

In denying plaintiffs' motion for a preliminary injunction:

(1) 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 unapproved and unproven treatments;

¹ The Excerpts of Record are cited as "[ER _]". Docket entries are cited as "[D._]". Plaintiffs' supplemental brief is cited as "[Brief at_]". The government's addendum is cited as ["G.Add._]."

(2) Whether the district court correctly held that plaintiffs may not maintain a defense of medical necessity;

(3) Whether plaintiffs have waived their contention that the Controlled Substances Act allows the possession of marijuana pursuant to a physician's order by not pleading that claim in their complaint, presenting it to the district court, or arguing it in their original opening brief to this Court; and

(4) Whether the district court correctly held that, because Congress' regulation of the manufacture and possession of marijuana is a lawful exercise of Congressional authority under the Commerce Clause, it does not run afoul of the Tenth Amendment.

STATEMENT OF THE CASE

On October 9, 2002, plaintiffs Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two 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, plaintiffs 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 (Jenkins, J.) denied the motion for preliminary injunction. See Raich v. Ashcroft, 248 F. Supp.2d 918 (N.D. Cal. 2003). On March 12, 2003, plaintiffs filed a timely notice of appeal. [ER 268-73].

11 1222, 352 F.3d 1222 (9th Cir. 2003). On June 6, 2005, the Supreme Court vacated this Court's opinion and remanded the case for disposition of plaintiffs' remaining claims. See Gonzales v. Raich, 125 S. Ct. 2105 (2005). The Court directed the parties to submit briefs regarding plaintiffs' "remaining claims for declaratory and injunctive relief" on the basis of the Tenth Amendment, the Fifth and Ninth Amendments, and the doctrine of medical necessity, as set forth in their plaintiff Diane Monson's motion to withdraw as a party.

STATEMENT OF FACTS

A. The Controlled Substances Act

1. The Controlled Substances Act ("CSA" or "the Act"), 21 U.S.C. §§ 801-904, regulates the market in controlled substances. The CSA makes it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense" any controlled substance "except as authorized" under the Act. See 21 U.S.C. § 841(a)(1). The CSA also makes it a crime to possess any controlled substance "except as authorized" under the Act. See 21 U.S.C. § 844(a). The CSA thus establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 6 (1970). To effectuate that

closed system, the CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal." United States v. Moore, 423 U.S. 122, 141 (1976) (quoting H.R. Rep. No. 1444, supra, at Pt. 1, at 3).

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 therefore 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). Since Congress enacted the CSA in 1970, marijuana and tetrahydrocannabinols have been classified as Schedule I controlled substances, the most

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).

restrictive of the five schedules. See 21 U.S.C. §812(c) (Schedule I(c)(10) and (17)).

A drug is included in Schedule I if it (1) "has a high potential for abuse," (2) "has no currently accepted medical use in treatment in the United States," and (3) has "a lack of accepted safety for use * * * under medical 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, it is unlawful under the CSA to manufacture, distribute, dispense, or possess a Schedule I drug, except as part 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), 841(a)(1), 844(a); United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483, 492 (2001).

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).

2. When it enacted the CSA, 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 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

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). In 1999, DEA transferred Marinol from Schedule II to Schedule III, thereby lessening the CSA regulatory requirements governing its use as medicine. See 64 Fed. Reg. 35,928 (July 2, 1999).

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 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.

3. 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 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

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).

Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629-32 (1973) (holding that 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").

4. Since the enactment of the CSA, Congress has revisited the question of whether marijuana may be authorized for medicinal uses on several occasions. In 1998, 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 on November 3, 1998, from taking effect.⁵

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 (March 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) ("[T]he Administrator's findings are supported by substantial evidence," including "the testimony of numerous experts that marijuana's medicinal value has never been proven in sound scientific studies.").

⁵ See Pub. L. No. 109-115, Division B--District of Columbia Appropriations Act, 2006, §128(b), 119 Stat. 2396, 2521 (2005); Pub. L. No. 108-335, District of Columbia Appropriations Act of 2005, Title III, §320(b), 118 Stat. 1322, 1343 (2004); Pub. L. No. 108-199, Division C--District of Columbia Appropriations Act, 2004, Title IV, §423(b), 118 Stat. 3, 139 (2004); Pub. L. No. 108-7, Division C--District of Columbia Appropriations, 2003, Title III, §126(b), 117 Stat. 11, 126 (2003); Pub. L. No. 107-96, District of Columbia Appropriations Act, 2002, §127(b), 115 Stat. 923, 953 (2001); Pub. L. No. 106-522, District of Columbia Appropriations Act, 2001, §143(b), 114 Stat. 2440, 2471 (2000); Pub. L. No. 106-113, Division A: District of Columbia Appropriations, Title I, §167(b), 113 Stat. 1501, 1530 (1999).

More recently, on March 20, 2001, the DEA Administrator 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, based on a comprehensive review by the FDA's Controlled Substance Staff, then-Surgeon General David Satcher recommended that marijuana "continue to be subject to control under Schedule I of the CSA." Id. at 20,039. The D.C. Circuit dismissed a petition for review challenging that determination for lack of standing. See Gettman v. DEA, 290 F.3d 430, 432-35 (D.C. Cir. 2002).

B. Facts and Proceedings

1. On October 9, 2002, plaintiffs Angel McClary Raich, Diane Monson, John Doe Number One, and John Doe Number Two filed suit against the Attorney General of the United States and the Administrator of the DEA, and thereafter moved for a preliminary injunction that sought to enjoin defendants from enforcing the provisions of the Controlled Substances Act against them. [ER 1-19, 22, 23, 24-58]. Specifically, plaintiffs sought a preliminary injunction that would have enjoined defendants, and any person acting in consort with them, from arresting or prosecuting plaintiffs, seizing their "medical" cannabis, forfeiting their property, or seeking civil or administrative sanctions against them, relating to plaintiffs' cultivation and possession of marijuana for alleged medicinal uses. [ER 21, 22-23].

2. On March 5, 2003, the district court denied the motion for preliminary injunction, holding that "the weight of precedent precludes a finding of likelihood of success on the merits * * *." 248 F. Supp.2d at 920. The district court first concluded that plaintiffs 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, holding 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.* at 925. The district court also found no merit to plaintiffs' 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." *Id.* at 927.

The district court next rejected plaintiffs' contention that the CSA interfered with their fundamental rights protected by the Ninth Amendment. *Id.* at 927-28. Placing reliance on this Court's decision in Carnohan v. United States, 616 F.2d 1120 (9th Cir. 1980) and the Tenth Circuit's decision in Rutherford v. United States, 616 F.2d 455 (10th Cir. 1980), the district court held

that, "[w]hile plaintiffs may vehemently 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 prescription to patients, they do not have a fundamental, constitutional right to obtain and use it for treatment." 248 F. Supp.2d at 928.

Finally, the district court found that the Supreme Court's decision in Oakland Cannabis was "dispositive" on the question whether there was a medical necessity defense for the manufacture and possession of marijuana, concluding that, "[a]s there is no distinction between manufacturing and distribution, it follows that there is no medical necessity defense for other prohibitions in the CSA, such as possession of marijuana." Id. at 929 (citing Oakland Cannabis, 532 U.S. at 494 n.7).

The district court therefore determined that, "[s]ince plaintiffs are unable to establish any likelihood of success on the merits, their motion for a preliminary injunction is denied." Id. at 931. On March 12, 2003, Appellants filed a timely notice of appeal. [ER 268-73].

3. On December 16, 2003, this Court reversed in a 2-1 decision, determining that the plaintiffs had demonstrated a strong likelihood of success on their claim that, "as applied to them, the [Controlled Substances Act] is an unconstitutional exercise of Congress' Commerce Clause authority." 352 F.3d at 1227. This

Court therefore "remand[ed] to the district court for entry of a preliminary injunction consistent with this opinion." Id. at 1235. This Court therefore "declined to reach the appellants' other arguments, which are based on the principles of federalism embodied in the Tenth Amendment, the appellants' alleged fundamental rights under the Fifth and Ninth Amendments, and the doctrine of medical necessity." Id. at 1227.

4. On May 14, 2004, the district court entered a Preliminary Injunction Order which provided, in relevant part, that "during the pendency of this action, Defendants, and their agents and officers, and any person acting in concert with them, are hereby enjoined from arresting or prosecuting Plaintiffs Angel McClary Raich and Diane Monson, seizing their medical cannabis, forfeiting their property, or seeking civil or administrative sanctions against them with respect to the intrastate, noncommercial cultivation, possession, use, and obtaining without charge of cannabis for personal medical purposes on the advice of a physician and in accordance with state law * * *." [D. 61]. On June 23, 2004, the government filed a timely notice of interlocutory appeal, which was docketed as Appeal No. 04-16296. [D. 64].

5. On June 6, 2005, the Supreme Court vacated and remanded this Court's decision, holding, in relevant part, that, "[t]he CSA is a valid exercise of federal power, even as applied to the troubling facts of this case." 125 S. Ct. at 2201. The Supreme

Court also noted that plaintiffs had raised a substantive due process claim and sought to avail themselves of the medical necessity defense, but did not address whether judicial relief was available on these alternative bases because they were not reached by this Court. Id. at 2215.

6. On September 6, 2005, this Court granted the government's motion for summary reversal and vacatur of the preliminary injunction entered by the district court in Appeal No. 04-16296. [G.Add. 1]. This Court further directed the parties to submit briefs "regarding the plaintiffs' remaining claims for declaratory and injunctive relief on the basis of the Tenth Amendment, the Fifth and Ninth Amendments, and the doctrine of medical necessity, as set forth in their complaint." [G. Add. 2].

7. On December 8, 2005, this Court granted plaintiff Diane Monson's motion to withdraw as a party.

STANDARD OF REVIEW

This Court reviews a district court's decision to grant or deny a preliminary injunction for abuse of discretion. See Warsoldier v. Woodford, 418 F.3d 989, 993 (9th Cir. 2005); Gorbach v. Reno, 219 F.3d 1087, 1091 (9th Cir. 2000) (en banc). This Court's review "is limited and deferential," Southwest Voter Registration Educ. Project v. Shelley, 344 F.3d 914, 918 (9th Cir. 2003) (en banc), and this Court will reverse the district court "only if it abused its discretion or based its decision on an

erroneous legal standard or on clearly erroneous findings of fact." Warsoldier, 418 F.3d at 993. This Court reviews de novo any underlying issues of law. See Demery v. Arpaio, 378 F.3d 1020, 1027 (9th Cir. 2004), cert. denied, 125 S. Ct. 2961 (2005).

SUMMARY OF ARGUMENT

Plaintiffs' contention that they have a fundamental right to obtain and use marijuana 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 to have considered the question has likewise held that there is no fundamental right to distribute, cultivate, or possess marijuana. Nor can plaintiffs establish that the use of any particular drug, free of a regulatory scheme designed to protect the public health and safety, is a fundamental right that is deeply rooted in our Nation's history, legal traditions, and practices.

Plaintiffs' contention that application of the CSA to Ms. Raich would violate the common-law doctrine of necessity 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.

Plaintiffs' contention that the CSA allows the possession of marijuana pursuant to a physician's order has been waived because it was not pled in their complaint, presented to the district court, or argued to this Court in plaintiffs' original opening brief, nor was it included amongst the issues that this Court directed the parties to brief in its Order of September 6, 2005.

Finally, the conclusion that the CSA is a lawful exercise of Congressional authority under the Commerce Clause disposes of plaintiffs' Tenth Amendment claim. The Supreme Court has rejected the suggestion that Congress invades areas reserved to the States simply because it exercises its authority under the Commerce Clause in a manner that displaces the States' exercise of their police powers, and this is not a case in which the federal government has commandeered the State of California or California officials in carrying out the federal regulatory scheme.

ARGUMENT

I. THERE IS NO FUNDAMENTAL RIGHT TO OBTAIN OR USE MARIJUANA OR OTHER UNAPPROVED AND UNPROVEN MEDICAL TREATMENTS

Plaintiffs contend (Brief at 11-47) that application of the CSA to Ms. Raich would violate the Due Process Clause of the Fifth Amendment and the Ninth Amendment by infringing on her "fundamental right to life itself and fundamental liberty interests in taking the only medication that allows her to avoid intolerable pain and death." This contention lacks 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 to have considered the question has likewise held that there is no fundamental right to distribute, cultivate, or possess marijuana. Plaintiffs also cannot establish that the use of any particular drug, free of a regulatory scheme designed to protect the public health and safety, is a fundamental right that is deeply rooted in "our Nation's history, legal traditions, and practices." Washington v. Glucksberg, 521 U.S. 702, 710 (1997).

1. In Carnohan v. United States, 616 F.2d 1120 (9th Cir. 1980), this Court affirmed the dismissal of a declaratory judgment action in which the plaintiff had sought to secure the right to obtain and use laetrile for the prevention of cancer. Among other claims, the plaintiff argued that the regulatory scheme established by the FDA was so burdensome as applied to individuals that it infringed upon his fundamental right to privacy. This Court rejected this claim, holding that, "[w]e need not decide whether Carnohan has a constitutional right to treat himself with home remedies of his own confection. Constitutional 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 (emphasis supplied).

In so ruling, this Court cited with approval the Tenth Circuit's decision in Rutherford v. United States, 616 F.2d 455

(10th Cir. 1980), and the California Supreme court's decision in People v. Privitera, 23 Cal.3d 697, 591 P.2d 919, 153 Cal.Rptr. 431 (1979). In Rutherford, the Tenth Circuit reversed an injunction entered on behalf of a class of terminally ill cancer patients who sought to obtain laetrile, holding 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." 616 F.2d at 457. Similarly, 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.

This Court again held that there is no fundamental right to any particular form of treatment in National Ass'n for the Advancement of Psychoanalysis v. California Bd. of Psychology, 228 F.3d 1043 (9th Cir. 2000). In that case, in upholding California's mental health licensing laws against constitutional challenge, this Court stated: "We further conclude that substantive due process rights do not extend to the choice of type of treatment or of a particular health care provider." Id. at 1050 (emphasis added). This Court also quoted with approval and expressly "agree[d]" with

Mitchell v. Clayton, 995 F.2d 772, 775 (7th Cir. 1993), in which the Seventh Circuit, citing, inter alia, Carnohan and Rutherford, stated that "most federal courts have held that 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." 228 F.3d at 1050 (quoting Mitchell, 995 F.2d at 775).

These decisions are consistent with the overwhelming weight of authority. Every other court of appeals to have considered the question has likewise held that individuals do not have a fundamental right to obtain particular medical treatments free of the lawful exercise of the government's police power.⁶ Similarly,

⁶ See 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, 995 F.2d at 775-76; United States v. Burzynski Cancer Research Inst., 819 F.2d 1301, 1313-14 (5th Cir. 1987) (rejecting cancer patients' claim of constitutional right to obtain antineoplastic drugs); see also Smith v. Shalala, 954 F. Supp. 1, 3 (D.D.C. 1996) (quoting Carnohan for proposition that there is no substantive due process right "to obtain [unapproved drugs] free of the lawful exercise of government police power" (alteration in original)); United States v. Vital Health Prods., Ltd., 786 F. Supp. 761, 777 (E.D. Wisc. 1992) ("[A] claim that American citizens have the freedom to choose whatever medication or treatment they desire is not grounded in the Fifth, Ninth or Fourteenth Amendments."), aff'd, 985 F.2d 563 (7th Cir. 1993) (Mem.). We are aware of only one district court decision to the contrary, Andrews v. Ballard, 498 F. Supp. 1038 (S.D. Tex. 1980) (finding decision to obtain acupuncture treatment encompassed by the right of privacy), a case that did not involve the use of any drug, and the continued viability of which is questionable after the Fifth Circuit's decision in Burzynski.

the California courts have held that, even following the passage of the Compassionate Use Act in that State, "[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), review denied (Jan. 16, 2002); accord Seeley v. State of Washington, 132 Wash. 2d 776, 782, 794, 940 P.2d 604, 607, 612 (1997) (holding that plaintiff suffering from terminal bone cancer had no "fundamental right to have marijuana prescribed as his preferred treatment" notwithstanding his claim that "smoking marijuana has been more effective in relieving his symptoms than other antiemetics.")

This Court's decisions in Carnohan and National Ass'n for the Advancement of Psychoanalysis foreclose plaintiffs' contention that they have a fundamental right to obtain and use marijuana. As in Carnohan, neither the Fifth nor Ninth Amendment gives Ms. Raich, or any other individual, the right to obtain and use marijuana "free of the lawful exercise of the government's police power," 616 F.2d at 1122, inasmuch as the decision to use a particular drug "is within the area of governmental interest in protecting public health." Rutherford, 616 F.2d at 457. Indeed, like the district court below, courts in this circuit have rejected like claims on the ground that they are incompatible with Carnohan. See County of Santa Cruz v. Ashcroft, 279 F. Supp.2d 1192, 1204 (N.D. Cal. 2003) ("Because it concludes that the fundamental right articulated by

Plaintiffs--the right of terminally ill persons to use physician-recommended medication to alleviate their pain and suffering and to control the circumstances of their own deaths--is not 'deeply rooted in this Nation's history and tradition' and that recognition of such a constitutionally-protected right under the circumstances of this case would be inconsistent with the holding of Carnohan, this Court concludes that Plaintiffs cannot demonstrate a likelihood of success on this aspect of their claim."), reconsidered on other grounds, 314 F. Supp.2d 1000 (N.D. Cal. 2004); United States v. Cannabis Cultivators Club, 1999 WL 111893, at *3 (N.D. Cal. Feb. 25, 1999) (attached in Addendum) ("Carnohan and Rutherford hold, however, that there is no fundamental right to obtain the medication of choice. Accordingly, the Intervenors' claim that they do have such a right, and that the United States should be enjoined from interfering with that right, will be dismissed without leave to amend."), vacated on other grounds, 221 F.3d 1349 (9th Cir. 2000) (Mem.).⁷

⁷ Courts in other circuits are in accord. See 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 CSA. 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, 726 (E.D. Pa. 1999) (citing, e.g., Carnohan and holding that, "there is no fundamental right of privacy to select one's medical treatment without regard to criminal laws, and courts have consequently applied only rational review to regulations affecting these matters.").

2. The correctness of this Court's decision in Carnohan is underscored by the Supreme Court's decision Glucksberg, in which the Court held that there is no fundamental right to obtain medical treatment which would alleviate suffering by causing death. Of particular relevance here, the Court stressed that there must be a "careful description" of the asserted fundamental liberty interest in substantive due process cases, and that the asserted interest must be viewed with reference to historical tradition. Id. at 720-21, 722-23. The Court therefore rejected the various descriptions of the interest at stake offered by the respondents in that case -- including the claimed right to "determin[e] the time and manner of one's death," "right to die," "liberty to choose how to die," right to "control of one's final days," "the right to choose a humane, dignified death," and "the liberty to shape death" -- as running counter to this requirement. See id. at 721-22. Rather, the Court explained, because "[t]he Washington statute at issue in this case prohibits 'aid[ing] another person to attempt suicide,' * * * the question before us is whether the 'liberty' specially protected by the Due Process Clause includes a right to commit suicide which itself includes a right to assistance in doing so." Id. at 723 (internal citation omitted).

As with the claimed liberty interests asserted in Glucksberg, plaintiffs' assertion of a "fundamental right to life itself" and "fundamental liberty interests in taking the only medication that

allows [Ms. Raich] to avoid intolerable pain and death" runs afoul of the Supreme Court's admonition that there be a "careful description" of the asserted fundamental liberty interest at stake. Rather, following the methodology outlined by the Court in Glucksberg, because the statute at issue in these cases prohibits the distribution, manufacture, and possession of marijuana and other Schedule I controlled substances for any purpose (unless otherwise authorized by the CSA), the question must be whether the liberty protected by the Due Process Clause includes a right for Ms. Raich to use a particular unapproved drug, marijuana, for asserted medicinal purposes, which itself includes the right to obtain the drug from third parties who cultivate the drug for her, in this case the John Doe plaintiffs. This is precisely the asserted liberty interest which this Court rejected Carnohan.

Moreover, such a right would be inconsistent with this country's history of restrictions on the distribution and use of medicinal and "street" drugs. As early as 1736, Virginia began to regulate the practice of pharmacy, and by the time of the Civil War, four States had similar laws. Pharmaceutical regulation intensified in the period after the Civil War, such that by 1900, every State (with the exception of Nevada) had passed laws regulating the practice of pharmacy, and at least 25 States or territories had passed laws prohibiting drug adulteration and

regulating the sale of poisons. See David L. Cohen, Pharmacy in History: The Development of State Pharmaceutical Law 49-56 (1995).

In the fall of 1902, after thirteen children had died in the fall of 1901 of tetanus after being treated with a diphtheria antitoxin made from the blood of an infected milk wagon horse, Congress enacted the Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 728, which regulated the interstate traffic in the sale of viruses, serums, toxins, and analogous products. In 1906, Congress passed the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, to prohibit the manufacture of adulterated or misbranded food or drugs. In 1914, Congress passed the predecessor to the CSA, the Harrison Narcotics Act, Pub. L. No. 63-233, 38 Stat. 785, which restricted the use of narcotics such as opium, morphine, and cocaine in order to combat the problem of abuse and addiction. Cf. Moore, 423 U.S. at 132 (noting that "[p]hysicians who stepped outside the bounds of professional practice could be prosecuted under the [Harrison Act].").

In 1938, following the death of more than 100 persons in the United States who consumed elixir-sulfanilamide, an untested drug, see United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 n.17 (1969), Congress passed the FDCA, which requires FDA approval of drugs in order to "'protect[] the public health by ensuring that * * * drugs are safe and effective.'" FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 134 (2000) (quoting 21

U.S.C. §393(b)(2)); accord United States v. Walsh, 331 U.S. 432, 434 (1947). Thereafter, in 1962, in the aftermath of the thalidomide tragedies in the early 1960s, Congress enacted the Drug Amendments of 1962, Pub. L. No. 87-871, 76 Stat. 780, which required that manufacturers demonstrate that drugs are both safe and effective before they can be marketed. See generally Stanton v. Astra Pharmaceutical Products, Inc., 718 F.2d 553, 559 (3d Cir. 1983).

The regulation of marijuana in the United States followed a similar pattern. After marijuana use in this country first became popular in the 1920s, the National Conference of Commissioners on Uniform State Laws recommended passage of the Uniform Narcotic Drug Act, which included an optional provision to list marijuana as a narcotic subject to strict controls. By 1937, every State, either by adoption of the Uniform Act or by separate legislation, had restricted or prohibited marijuana use. See R.J. Bonnie & C.H. Whitebread, The Marijuana Conviction 31-52, 79-91 (1974); National Comm'n on Marihuana & Drug Abuse, Marihuana: A Signal of Misunderstanding 13-14, 104-105 (March 1972). In 1937, Congress also passed the Marihuana Tax Act, Pub. L. No. 75-238, 50 Stat. 551, which severely restricted the use of and trafficking in marijuana, even for medical purposes. See Raich, 125 S. Ct. 2202 (noting that doctors wishing to prescribe marijuana for medical purposes were required to comply with "rather burdensome

administrative requirements"); see also R.J. Bonnie & C.H. Whitebread, supra, at 165. With the enactment of the CSA in 1970 and marijuana classification as a Schedule I drug, the manufacture, distribution, or possession of marijuana was prohibited, with the sole exception being use of the drug as part of an FDA-approved research study. See Raich, 125 S. Ct. at 2204 (citing 21 U.S.C. §§ 823(f), 841(a)(1), 844(a)).

This longstanding tradition of governmental regulation of drugs to protect the public from unsafe or improperly diverted drugs (including marijuana) cannot be reconciled with the assertion of a fundamental right to use a particular drug (including marijuana) "free of the lawful exercise of the government's police power," Carnohan, 616 F.2d at 1122, as evidenced by the near-universal rejection of like claims by the federal and state courts.

Plaintiffs contend (Brief at 28-29) that there is an emerging awareness that liberty gives substantive protection to Ms. Raich's activities, and place emphasis on the fact that "California is one of ten States that have enacted laws authorizing the use of cannabis for medical purposes." But the fact that California and other States have decriminalized the use of marijuana for specified medical purposes under state law does not support the altogether different question whether plaintiffs have a fundamental, constitutional right to obtain and use unapproved drugs such as marijuana free from government regulation. As the California Court

of Appeal, Third District has explained, "the Compassionate Use Act created a limited defense to crimes, not a constitutional right to obtain marijuana." People v. Urziceanu, 132 Cal.App.4th 747, 774, 33 Cal. Rptr.3d 859, 874 (Cal. Ct. App. 2005) (emphasis added).

3. Plaintiffs' efforts (Brief at 33-34) to distinguish Carnohan are unpersuasive. At the outset, we note this Court's longstanding rule that, "[a] three-judge panel can overrule a prior decision of this court [only] when an intervening Supreme Court decision undermines an existing precedent of the Ninth Circuit, and both cases are closely on point." E.E.O.C. v. Luce, Forward, Hamilton & Scripps, 345 F.3d 742, 744 n.1 (9th Cir. 2003) (en banc) (internal quotation marks and citations omitted); accord Miller v. Gammie, 335 F.3d 889, 899-900 (9th Cir. 2003) (en banc) (same); Benny v. U.S. Parole Comm'n, 295 F.3d 977, 983 (9th Cir. 2002) (panel bound by the decisions of prior panels "unless an en banc decision, Supreme Court decision or subsequent legislation undermines those decisions."). Plaintiffs do not argue that any of these exceptions apply, or that any intervening Supreme Court decision is "closely on point" with Carnohan; indeed, plaintiffs make no attempt to distinguish this Court's decision in National Ass'n for the Advancement of Psychoanalysis, and attempt to distinguish Carnohan and Rutherford on the facts. As we now show, each of these attempts is unavailing.

Plaintiffs assert (Brief at 33) that, in contrast to Carnohan, this case presents the question "whether Ms. Raich has a constitutional right to use a needed medication cultivated by her caregivers in their home gardens specifically for her." That question is indistinguishable from the situation presented in Carnohan, in which a terminally ill cancer patient sought the right to secure and use laetrile for the treatment of cancer, or in Rutherford, in which the plaintiff class consisted of terminally ill cancer patients seeking to obtain laetrile. Like those plaintiffs, Ms. Raich is asserting a fundamental right to obtain marijuana from the John Doe plaintiffs, the very claim which this Court rejected in Carnohan. As Judge Breyer has persuasively analyzed in rejecting a like claim, "the Intervenor's complaint seeks an order that they have a fundamental right to obtain a particular medication, marijuana, from a particular source, the medical cannabis cooperatives. Carnohan, however, holds that there is no constitutional right to obtain medication free from the lawful exercise of the government's police powers." Cannabis Cultivators Club, 1999 WL 111893, at *2.

Plaintiffs also contend (Brief at 34-35) that, in contrast to marijuana, substances such as laetrile are not effective in alleviating or treating serious medical conditions, and thus do not implicate the "liberty" protected by the Due Process Clause. This contention, too, is misplaced. Putting aside the fact that a

claimed right to use a particular unapproved drug can often be re-characterized as the right to the only effective medical treatment, both the plaintiff in Carnohan⁸ and the plaintiff class in Rutherford were terminally ill cancer patients who had no other conventional treatments available, and who alleged that laetrile was effective in treating their cancers. Nonetheless, both this Court in Carnohan and the Tenth Circuit in Rutherford held that there is no fundamental right to obtain a particular unapproved and unproven drug free from the lawful exercise of the government's regulatory authority. As Judge Breyer observed in rejecting this very argument, "[t]he Rutherford plaintiffs had no other treatment available. They believed that without the laetrile they would die. The Tenth Circuit nonetheless held that the Rutherford plaintiffs did not have a constitutional right to obtain laetrile." Cannabis Cultivators Club, 1999 WL 111893, at *3.

Moreover, the principle enunciated in Carnohan -- that there is no fundamental constitutional right to obtain unapproved and unproven medications free of the lawful exercise of the government's police power -- does not change medication by medication, and courts applying this Court's ruling have found it applicable not only in cases alleging a fundamental right to use

⁸ See Privitera, 23 Cal.3d at 734-35, 591 P.2d at 942, 153 Cal.Rptr. at 454 (Bird, C.J., dissenting) (discussing proceedings in Carnohan and noting that plaintiff was a terminally ill cancer patient).

marijuana, see County of Santa Cruz, 279 F. Supp.2d at 1204; Cannabis Cultivators Club, 1999 WL 111893, at **1-3, but also in cases alleging a fundamental right to use treatments. Thus, in Smith v. Shalala, for example, the United States District Court for the District of Columbia denied a motion for a preliminary injunction brought by a plaintiff who suffered from advanced stage of Hodgkin's lymphoma, and who sought to allow his continued treatment with an experimental anticancer agent (antineoplastons) that had not been approved for general use by the FDA. Relying in large part on Carnohan and Rutherford, Judge Robertson reasoned:

While there are decisions recognizing that competent adults have a fundamental right to refuse medical treatment, and to determine the time and manner of their death, free from governmental interference, nothing in those decisions suggests that the government has an affirmative obligation to set aside its regulations in order to provide dying patients access to experimental medical treatments. On the contrary, where courts have been presented with claims like Smith's they have refused to find a "right" to receive unapproved drugs. The constitutional rights to privacy and personal liberty "do not give individuals the right to obtain [unapproved drugs] free of the lawful exercise of government police power."

954 F. Supp. at 3 (internal citations omitted) (quoting Carnohan, 616 F.2d at 1122).

Indeed, although plaintiffs suggest that this case is limited to the context of "medical" marijuana, a decision in their favor could not be so easily cabined. In United States v. Rutherford, 442 U.S. 544 (1979), the Supreme Court rejected the contention that the FDCA had no application to a plaintiff class consisting of

terminally ill cancer patients. Of particular relevance here, Justice Marshall's opinion for a unanimous Court cautioned that:

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.

Id. at 557-58. Justice Marshall's admonition applies with equal force in this case. If plaintiffs' arguments were to be accepted, and this Court were to supplant the role of the FDA and determine for itself that marijuana has medicinal value, there is no limiting principle that would prevent individuals seeking to use other Schedule I controlled substances or unapproved drugs -- such as heroin or laetrile -- from likewise claiming a fundamental right to use the treatment of their choice, thereby bypassing the carefully crafted FDA drug approval process fashioned by Congress to protect the public health and safety, a result patently at odds with the public interest as expressed by Congress and recognized by the Supreme Court in Rutherford.

Plaintiffs assert (Brief at 19-20 & n.6, 34-35) that, in Stenberg v. Carhart, 530 U.S. 914 (2000), the Supreme Court held that the Due Process Clause "forbids the government from impeding an individual's decision to obtain necessary medical care," and that "substantial medical authority" supports Ms. Raich's medical use of marijuana. That assertion also is misplaced. In Carhart,

the Supreme Court, in striking down a Nebraska statute prohibiting partial-birth abortions, and in applying its decisions in Roe v. Wade, 410 U.S. 113 (1973), and the plurality opinion in Planned Parenthood v. Casey, 505 U.S. 833 (1992), held that, "where substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health, Casey requires the statute to include a health exception when the procedure is 'necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.'" Id. at 938 (emphasis added) (quoting Casey, 505 U.S. at 879). The Court in Carhart nowhere suggested that this principle has application outside the specialized context of abortion, nor have plaintiffs cited to any authority that would support that proposition.⁹

In sum, plaintiffs have failed to offer any principled distinction between this case and Carnohan, have failed to identify any intervening Supreme Court authority that both calls Carnohan

⁹ In any event, in disagreeing with Congress' judgment that marijuana has no medical utility, plaintiffs principally rely (Brief at 35) on the report commissioned by the White House Office of National Drug Control Policy, and issued by the Institute of Medicine. The Institute of Medicine, after reviewing the existing scientific evidence concerning possible medical uses of marijuana, recommended that further research be devoted not to developing marijuana as a licensed drug, but to developing a method of delivering cannabinoids without the serious adverse health consequences associated with smoking marijuana. See Institute of Medicine, Marijuana and Medicine: Assessing the Science Base 10-11 (Janet E. Joy, Stanley J. Watson, Jr. & John A. Benson, Jr. eds. 1999) ("Because marijuana is a crude THC delivery system that also delivers harmful substances, smoked marijuana should generally not be recommended for medical use.").

into question and which is "closely on point." Plaintiffs also have failed to make any attempt to distinguish this Court's decision in National Ass'n for the Advancement of Psychoanalysis. Under these circumstances, stare decisis compels the rejection of their substantive due process claim. See E.E.O.C. v. Luce, Forward, Hamilton & Scripps, 345 F.3d at 744 n.1; Miller v. Gammie, 335 F.3d at 899-900; Benny, 295 F.3d at 983.

4. Plaintiffs can find no additional support in the Ninth Amendment. This Court has repeatedly observed that the Ninth Amendment "has not been interpreted as independently securing any constitutional rights for purposes of making out a constitutional violation." Schowengerdt v. United States, 944 F.2d 483, 490 (9th Cir. 1991); accord San Diego County Gun Rights Comm. v. Reno, 98 F.3d 1121, 1125 (9th Cir. 1996) (holding that "the Ninth Amendment does not encompass an unenumerated, fundamental, individual right to bear firearms"). Hence, so long as Congress does not exceed a "specific limitation" on a grant of power, it does not violate the Ninth Amendment. See Barton v. CIR, 737 F.2d 822, 823 (9th Cir. 1984) (rejecting Ninth Amendment challenge to federal tax laws because Congress had acted within its Article I authority in enacting such laws). As the Supreme Court long ago 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 the CSA does not exceed Congress' power to regulate interstate commerce, see Raich, 125 S. Ct. at 2207, plaintiffs have no Ninth Amendment right to obtain and use marijuana even for medicinal purposes.

5. Because there is no merit to plaintiffs' contention that they have a fundamental right to obtain or use marijuana, the CSA's prohibitions on such activities is subject only to rational basis review. See New Orleans v. Dukes, 427 U.S. 297, 303 (1976) ("[T]he judiciary may not sit as a superlegislature to judge the wisdom or desirability of legislative policy determinations made in areas that neither affect fundamental rights nor proceed along suspect lines* * *"); see also Marshall v. United States, 414 U.S. 417, 427 (1974) (judicial self-restraint is especially appropriate where the challenged classification entails legislative judgments on controversial medical, scientific, and social issues). The CSA easily passes muster under this deferential standard of review. Indeed, this Court has expressly rejected the contention that the CSA "unreasonably and irrationally categorize[s] marijuana as a Schedule I controlled substance," holding that, "[w]e need not

again engage in the task of passing judgment on Congress' legislative assessment of marijuana. As we recently declared, '[t]he constitutionality of the marijuana laws has been settled adversely to [the defendant] in this circuit.'" United States v. Miroyan, 577 F.2d 489, 495 (9th Cir. 1978) (quoting United States v. Rogers, 549 F.2d 107, 108 (9th Cir. 1976)); see also United States v. Rodriquez-Camacho, 468 F.2d 1220, 1222 (9th Cir. 1972) (rejecting contention that Congressional findings were inapplicable to marijuana on ground that "[t]his is a matter * * * whose ultimate resolution lies in the legislature and not in the courts. It is sufficient that Congress had a rational basis for making its findings.").

Nor is there any basis for concluding that Congress' restriction on the use of unapproved drugs is irrational. Neither the CSA nor the FDCA deprives citizens of the ability to obtain medication to treat disease or relieve pain and suffering. Rather, the CSA outlaws the unauthorized use of a particular unapproved drug, marijuana, based on Congress's judgment that marijuana has a high potential for abuse, no currently accepted medical use, and a lack of accepted safety for use under medical supervision. See 21 U.S.C. §§812(b)(1)(A)-(C). Congress made that determination in furtherance of its obvious and compelling interest in combating drug abuse and protecting the public from the physical dangers associated with the use of unsafe drugs that may be diverted for

improper purposes. See Raich, 125 S. Ct. at 2209 ("Given the enforcement difficulties that attend distinguishing between marijuana cultivated locally and marijuana grown elsewhere, 21 U.S.C. §801(5), and concerns about diversion into illicit channels, we have no difficulty concluding that Congress had a rational basis for believing that failure to regulate the intrastate manufacture and possession of marijuana would leave a gaping hole in the CSA.") (internal footnote omitted); Treasury Employees v. Von Raab, 489 U.S. 656, 668, 674 (1989) (observing that drug trafficking is "one of the greatest problems affecting the health and welfare of our population" and that "drug abuse is one of the most serious problems confronting our society today").

Moreover, the CSA and FDCA authorize research with respect to possible medical uses of marijuana, albeit under the strict confines of those Acts. See 21 U.S.C. §§355(i) and 823(f). The CSA also permits the Attorney General to reschedule marijuana if he or she determines, inter alia, that marijuana has a currently accepted medical use. See 21 U.S.C. §§811, 812(b). The FDCA similarly authorizes the FDA to approve marijuana for medical use if it finds that marijuana is safe and effective for any intended medical use. See 21 U.S.C. §§355(a), (b), (d). And Congress has authorized the courts of appeals to review arbitrary or unsubstantiated final agency action under those Acts. See 21 U.S.C. §§355(h) and 877. The availability of this statutory and

regulatory process for reclassifying marijuana, should scientific or medical evidence warrant such a change, with review in the court of appeals, sufficiently guards against unlawful or irrational governmental action. As the Second Circuit has observed:

The provisions of the Act allowing periodic review of the control and classification of allegedly dangerous substances create a sensible mechanism for dealing with a field in which factual claims are conflicting and the state of scientific knowledge is still growing. * * * [T]he very existence of the statutory scheme indicates that, in dealing with this aspect of the "drug" problem, Congress intended flexibility and receptivity to the latest scientific information to be the hallmarks of its approach. This, while not necessary to the decision here, is the very antithesis of the irrationality appellants attribute to Congress.

United States v. Kiffer, 477 F.2d 349, 357 (2d Cir. 1972) (emphasis supplied); accord United States v. Fogarty, 692 F.2d 542, 548 (8th Cir. 1982) (holding that, in establishing the reclassification scheme, "Congress provided an efficient and flexible means of assuring the continued rationality of the classification of controlled substances, such as marijuana").

Finally, there is nothing inherently suspect about Congress' medical and policy judgments regarding marijuana. All citizens have an interest in obtaining medication that is "proven" to treat disease or to relieve the pain and suffering of those who are sick or terminally ill. Therefore, "[t]here is no reason to think the democratic process will not strike the proper balance" between the interest of those individuals and Congress' interest in ensuring that drugs are safe and effective and are not used or diverted for

improper purposes. Glucksberg, 521 U.S. at 737 (O'Connor, J., concurring). As the Supreme Court itself recognized in Raich, "perhaps even more important than these legal avenues is the democratic process, in which the voices of voters allied with these respondents may one day be heard in the halls of Congress." 125 S. Ct. at 2215.

II. THE SUPREME COURT'S DECISION IN OAKLAND CANNABIS FORECLOSES ANY DEFENSE OF MEDICAL NECESSITY

Plaintiffs also contend (Brief at 47-52) that application of the CSA to Ms. Raich would violate the common-law doctrine of necessity. This contention, too, lacks 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 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).

Moreover, the Supreme Court specifically rejected the distinction between a claimed medical necessity to manufacture and distribute marijuana and a claimed medical necessity to possess marijuana, declaring 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." Id. at 494 n.7. This is so, the Court explained, because, "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. Indeed, it is the Cooperative's argument that its patients are 'seriously ill,' and lacking 'alternatives.' We reject the argument that these factors warrant a medical necessity exception." Id. (emphasis added, internal citations omitted). This language leaves no room for plaintiffs' contention that they are entitled to injunctive relief to protect a "medical necessity" defense to the CSA's prohibitions on the manufacture or possession of marijuana.

Plaintiffs insist (Brief at 50 n.16) that the foregoing language is merely dicta and is not controlling, but that cannot be squared with the Court's unambiguous rejection of any distinction "between the prohibitions on manufacturing and distributing and the other prohibitions in the Controlled Substances Act," and the

Court's equally unambiguous rejection of the Cooperative's argument that a medical necessity exception was warranted because its patients "are 'seriously ill' and lack[] 'alternatives.'" Id. Indeed, even if this language were considered a dictum, "that would be of little significance because our precedent requires that we give great weight to dicta of the Supreme Court." Coeur d'Alene Tribe of Idaho v. Hammond, 384 F.3d 674, 683 (9th Cir. 2004), cert. denied, 125 S. Ct. 1397 (2005); see United States v. Montero-Camargo, 208 F.3d 1122, 1132 n.17 (9th Cir. 2000) (en banc) ("Supreme Court dicta have a weight that is greater than ordinary judicial dicta as prophecy of what that Court might hold; accordingly, we do not blandly shrug them off because they were not a holding.") (internal quotation marks and citations omitted). Here, given the clarity of the Court's command that, "the very point of our holding is that there is no medical necessity exemption to the prohibitions at issue, even when the patient is 'seriously ill' and lacks alternative avenues for relief," id. (emphasis added), plaintiff's invocation of the medical necessity defense must fail.

**III. PLAINTIFFS HAVE WAIVED THEIR CONTENTION THAT THE CSA
ALLOWS MS. RAICH TO USE MARIJUANA**

Plaintiffs next contend (Brief at 52) that the "plain text" of the CSA shows that it does not disallow Ms. Raich from possessing and using marijuana pursuant to her physician's recommendation. That claim was not pled in plaintiffs' complaint, was never

presented to the district court, was not argued in plaintiffs' original opening brief to this Court, and runs afoul of this Court's Order dated September 6, 2005, which directs the parties to brief only "plaintiffs' remaining claims for declaratory and injunctive relief on the basis of the Tenth Amendment, the Fifth and Ninth Amendments, and the doctrine of medical necessity, as set forth in their complaint." This claim therefore has been waived. See United States v. Kama, 394 F.3d 1236, 1238 (9th Cir. 2005) ("Generally, an issue is waived when the appellant does not specifically and distinctly argue the issue in his or her opening brief."); Smith v. Marsh, 194 F.3d 1045, 1052 (9th Cir. 1999) ("An appellate court will not consider issues not properly raised before the district court. Furthermore, on appeal, arguments not raised by a party in its opening brief are deemed waived."). Plaintiffs also do not argue that any exception to this general rule applies, and this Court consequently should "not apply an exception on [its] own accord." Kama, 394 F.3d at 1238.

In any event, plaintiffs' statutory argument is incorrect. The CSA prohibits the possession of marijuana "unless such substance was obtained * * * pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional duties." 21 U.S.C. §844(a) (emphasis added). As the Supreme Court confirmed in Raich, "[b]y classifying marijuana as a Schedule I drug, as opposed to listing it on a lesser schedule, the

manufacture, distribution, or possession of marijuana became a criminal offense, with the sole exception being use of the drug as part of a Food and Drug Administration pre-approved research study." 125 S. Ct. at 2204 (emphasis added) (citing 21 U.S.C. §§823(f), 841(a)(1), 844(a)); accord Oakland Cannabis, 532 U.S. at 490. Thus, while the CSA provides for the prescription of controlled substances in Schedules II-V, it makes no such allowance for drugs listed in Schedule I. See 21 U.S.C. §829. Hence, regardless of how characterized, Ms. Raich's physician's recommendation that she use marijuana is not a "valid prescription or order" within the meaning of the CSA.

IV. THE CSA DOES NOT RUN AFOUL OF THE TENTH AMENDMENT

Plaintiffs lastly contend (Brief at 53-57) that application of the CSA would violate the Tenth Amendment by controlling California's regulation of private parties' medical practices. Plaintiffs acknowledge (Brief at 54) that this contention is at odds with McConnell v. FEC, 540 U.S. 93 (2003), but nonetheless reassert this argument in order to preserve it for Supreme Court review. As plaintiffs have rightly conceded, their Tenth Amendment claim is foreclosed by Supreme Court authority.

The Tenth Amendment provides: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. amend. X. As the language of the Tenth Amendment

evinces, "[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). In other words, "[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).

The Supreme Court therefore "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." Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc., 452 U.S. 264, 291 (1981). As the Court adumbrated in McConnell:

It is not uncommon for federal law to prohibit private conduct that is legal in some States. Indeed, such conflict is inevitable in areas of law that involve both state and federal concerns. It is not in and of itself a marker of constitutional infirmity.

540 U.S. at 186-87 (citing Oakland Cannabis, 532 U.S. 483); accord Hodel, 452 U.S. at 290 ("Although such congressional enactments obviously curtail or prohibit the States' prerogatives to make legislative choices respecting subjects the States may consider important, the Supremacy Clause permits no other result.").

Hence, because Congress' regulation of the manufacture and possession of marijuana "is squarely within Congress' commerce power," Raich, 125 S. Ct. at 2207, it does not violate the Tenth Amendment.

Nor is this a case in which the federal government has "commandeer[ed] the States and state officials in carrying out federal regulatory schemes." McConnell, 540 U.S. at 186. As the district court correctly analyzed, federal commandeering is "not at issue in this case, for the federal government is not forcing California, or any other State, to take any action. The CSA regulates individual behavior, and plaintiffs are asking the Court to prevent the government from applying those regulations to their conduct." Raich, 248 F. Supp.2d at 927 (emphasis supplied); accord McConnell, 540 U.S. at 186 (Title I of Bipartisan Campaign Reform Act did not run afoul of Tenth Amendment because it "only regulates the conduct of private parties" and "imposes no requirements whatsoever upon States or state officials"); United States v. Jones, 231 F.3d 508, 515 (9th Cir. 2000) (federal statute regulating possession of firearms did not violate Tenth Amendment because it is "a federal criminal statute to be implemented by federal authorities; it does not attempt to force the states or state officers to enact or enforce any federal regulation.").

Finally, nothing in Gonzales v. Oregon, No. 04-623 (January 17, 2006), suggests a contrary result. In that case, the Supreme

Court held that a November 9, 2001 Interpretive Rule issued by the Attorney General, which addressed the implementation and enforcement of the CSA with respect to the use of controlled substances by Oregon physicians acting in compliance with the Oregon Death With Dignity Act, was invalid under the CSA as a matter of statutory construction under the CSA. See slip op. at 1 (stating that resolution of this case "requires an inquiry familiar to the courts; interpreting a federal statute to determine whether Executive action is authorized by, or otherwise consistent with, the enactment."). Specifically, the Court held that the Interpretive Rule could not be justified on the basis of 21 U.S.C. §§823(f) & 824(a)(4), which authorize the Attorney General to revoke or suspend a physician's registration upon consideration of five enumerated factors. See slip op. at 14-28.

In contrast to the instant case, at issue in Gonzales v. Oregon was the use of Schedule II controlled substances, see slip op. at 3 ("The present dispute involves controlled substances listed in Schedule II, substances generally available only pursuant to a written, nonrefillable prescription by a physician."), and the Court's statutory analysis consequently has no bearing on Schedule I controlled substances such as marijuana. As the Court made clear, "Congress' express determination that marijuana had no accepted medical use foreclosed any argument about statutory

coverage of drugs available by a doctor's prescription." Slip op. at 23 (citing Oakland Cannabis, 532 U.S. 483).

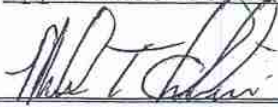
Moreover, the Court did not hold that the Interpretive Rule ran afoul of the Tenth Amendment or any other provision of the Constitution. To the contrary, the Court expressly reaffirmed that, "[e]ven though regulation of health and safety is primarily, and historically, a matter of local concern, there is no question that the Federal Government can set uniform national standards in these areas." Slip op. at 24 (internal quotation omitted) (citing Raich, 125 S. Ct. 2195). Gonzales v. Oregon, therefore, provides no support to plaintiffs' constitutional claims.

CONCLUSION

For the foregoing reasons, the district court's denial of plaintiffs' motion for a preliminary injunction should be affirmed.

Respectfully submitted,

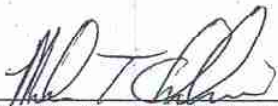
PETER D. KEISLER
Assistant Attorney General
KEVIN V. RYAN
United States Attorney
MARK B. STERN
ALISA B. KLEIN
Attorneys
Appellate Staff, Civil Division



MARK T. QUINLIVAN
Assistant U.S. Attorney
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3606

CERTIFICATE OF COMPLIANCE

Counsel for the appellees hereby certifies that the foregoing Supplemental Brief for the Appellees satisfies the requirements of Federal Rule of Appellate Procedure 32(a)(7)(B) and Ninth Circuit Rule 32-1. The brief was prepared in Courier New monospaced font, has 10.5 or fewer characters per inch (twelve-point font), and, excluding parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), contains 11,157 words, according to the count of Corel Wordperfect 12.



MARK T. QUINLIVAN
Assistant U.S. Attorney

CERTIFICATE OF SERVICE

I certify that on January 20, 2006, I filed and served the foregoing Supplemental Brief for the Appellees, by causing an original and fifteen copies to be delivered to the Clerk of the Court, and by further causing two paper copies to be delivered to the following counsel for appellants and for the amici curiae:

Plaintiffs Angel McClary Raich, et al.

By Overnight Delivery

Robert A. Raich
1970 Broadway, Suite 1200
Oakland, CA 94612

Patrick S. Davies
Joshua D. Greenberg
Covington & Burling
1200 Pennsylvania, Ave., N.W.
Washington, D.C. 20004

By First-Class Mail, Postage Prepaid

Randy Barnett
Boston University School of Law
765 Commonwealth Ave.
Boston, MA 02215

Amicus Curiae Reason Foundation and the Cato Institute

By Overnight Delivery

Erik S. Jaffe
Erik S. Jaffe, P.C.
5101 34th Street, N.W.
Washington, D.C. 20008

Amicus Curiae ACLU Foundation and Drug Policy Alliance

By Overnight Delivery

Graham A. Boyd
M. Allen Hopper
American Civil Liberties Union
Foundation
1101 Pacific Avenue, Ste. 333
Santa Cruz, CA 95060

Daniel N. Abrahamson
Drug Policy Alliance
Office of Legal Affairs
717 Washington Street
Oakland, CA 94607

Amicus Curiae California Medical Ass'n and California Nurses Ass'n


By Overnight Delivery

David A. Handzo
Julie M. Carpenter
Jenner & Block
601 13th Street, N.W.
Washington, D.C. 20005

Amicus Curiae Marijuana Policy Project and Rick Doblin, Ph.D.

By Overnight Delivery

Frederick L. Goss
Law Office of Frederick L. Goss
1 Kaiser Plaza, Suite 1750
Oakland, CA 94612



MARK T. QUINLIVAN
Assistant U.S. Attorney

GOVERNMENT'S ADDENDUM

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ANGEL McCLARY RAICH, et al., *Plaintiffs-Appellants*

v.

ALBERTO GONZALES, Attorney General of the United States, et al.,
Defendants-Appellees

ADDENDUM TABLE OF CONTENTS

1. Order, Raich v. Gonzales, Nos. 03-15481, 04-16296 (Sept. 6, 2005) G.Add. 1
2. United States v. Cannabis Cultivators Club,
1999 WL 111893 (N.D. Cal. Feb. 25, 1999), vacated on other grounds,
221 F.3d 1349 (9th Cir. 2000) (Mem.) G. Add. 4

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

SEP 06 2005

CATHY A. CATTERSON, CLERK
U.S. COURT OF APPEALS

ANGEL MCCLARY RAICH; DIANE
MONSON; JOHN DOE, Number One;
JOHN DOE, Number Two,

Plaintiffs - Appellants,

v.

ALBERTO R. GONZALES, Attorney
General, as United States Attorney
General; ASA HUTCHINSON, as
Administrator of the Drug Enforcement
Administration,

Defendants - Appellees.

Nos. 03-15481, 04-16296

D.C. No. CV-02-04872-MJJ
Northern District of California,
San Francisco

ORDER

Before: PREGERSON, BEAM,^{*} and PAEZ, Circuit Judges.

Plaintiffs' motion to consolidate proceedings in case numbers 03-15481 and 04-16296 is DENIED.

Pursuant to the Supreme Court's decision in Gonzalez v. Raich, 125 S. Ct. 2195, 2215 (2005), the Defendants' motion for summary reversal and vacatur of the preliminary injunction entered by the district court is GRANTED.

¹ The Honorable Arlen C. Beam, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

The Supreme Court's decision in Gonzalez v. Raich concerned only plaintiffs' claims for relief under the Commerce Clause. Neither the Supreme Court, nor this court, have ruled on plaintiffs' remaining claims for declaratory and injunctive relief. See Gonzalez v. Raich, 125 S. Ct. 2195, 2215 (2005) ("Respondents also raise a substantive due process claim and seek to avail themselves of the medical necessity defense. These theories of relief were set forth in their complaint but were not reached by the Court of Appeals. We therefore do not address the question whether judicial relief is available to respondents on these alternative bases."); Raich v. Ashcroft, 352 F.3d 1222, 1227 (9th Cir. 2003), rev'd 125 S. Ct. at 2215 ("We decline to reach the appellants' other arguments, which are based on the principles of federalism embodied in the Tenth Amendment, the appellants' alleged fundamental rights under the Fifth and Ninth Amendments, and the doctrine of medical necessity.").

The parties are therefore directed to submit briefs in case number 03-15481 regarding plaintiffs' remaining claims for declaratory and injunctive relief on the basis of the Tenth Amendment, the Fifth and Ninth Amendments, and the doctrine of medical necessity, as set forth in their complaint.

Plaintiffs' opening brief shall be filed twenty days from the date this order is entered. Defendants' answering brief shall be due twenty days after Plaintiff's

opening brief is filed. Plaintiffs' reply brief shall be filed ten days after
Defendants' answering brief is filed. The parties' briefs shall conform to the
requirements of Fed. R. App. P. 32.

H

Only the Westlaw citation is currently available.
 United States District Court, N.D. California.
 UNITED STATES of America, Plaintiff,
 v.
 CANNABIS CULTIVATOR'S CLUB, et al.,
 Defendants. and Related Actions
 No. C 98-00085 CRB, C 98-00086 CRB, C 98-
 00087 CRB, C 98-00088 CRB, C 98-00245 CRB.

Feb. 25, 1999.

MEMORANDUM AND ORDER

BREYER, District J.

*1 Now before the Court is plaintiff's motion to dismiss the complaint-in-intervention in its entirety. After carefully considering the papers submitted by the parties, and having had the benefit of oral argument on February 5, 1999, the motion to dismiss is GRANTED.

BACKGROUND

In early 1998, plaintiff filed separate lawsuits against six medical cannabis cooperatives and several individuals associated with those cooperatives, alleging that the defendants' distribution of marijuana violated the Controlled Substances Act, 21 U.S.C. § 841(a)(1), and that their illegal conduct should be enjoined pursuant to 21 U.S.C. § 882(a). In May 1998, the Court granted a preliminary injunction enjoining all defendants from engaging in the distribution of marijuana in violation of 21 U.S.C. § 841(a)(1).

Several months later, the Court granted the motion of four individuals, Edward Neil Brundridge, Ima Carter, Rebecca Nikkel, and Lucia Y. Vier ("Intervenors"), to intervene as defendants in the government's action pursuant to Federal Rule of Civil Procedure 24(b). The Intervenors are members of the defendant Oakland, Marin or Ukiah medical cannabis cooperatives. They seek a judicial declaration that they have a fundamental right "to be free from governmental interdiction of their personal, self-funded medical choice, in consultation with their personal physician, to alleviate suffering through the only effective treatment available for them." They

also seek an order enjoining the United States from interfering with the Intervenors' exercise of this fundamental right, and in particular, they seek to enjoin the United States from prohibiting the cooperatives from distributing marijuana to the Intervenors.

Plaintiff subsequently moved to dismiss the Intervenors' complaint in its entirety.

DISCUSSION

Plaintiff contends that under the Ninth Circuit's decision in *Carnohan v. United States*, 616 F.2d 1120 (9th Cir.1980), the Intervenors' complaint fails as a matter of law. In *Carnohan*, the plaintiff brought a declaratory proceeding to secure the right to obtain and use laetrile in a nutritional program for the prevention of cancer. The court held that since the Food and Drug Administration ("FDA") had determined that laetrile was a new drug, and laetrile did not meet the standards for distribution of a new drug, the plaintiff had to bring an Administrative Procedure Act ("APA") action to challenge the FDA's decision. The plaintiff argued further that the FDA's regulatory scheme is so burdensome as applied to individuals that it infringes upon constitutional rights. The Ninth Circuit responded: We need not decide whether Carnohan has a constitutional right to treat himself with home remedies of his own confection. *Constitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power.*

Id. at 1121 (emphasis added).

Carnohan disposes of the Intervenors' claims. Regardless of whether the Intervenors have a right to treat themselves with marijuana which they themselves grow (a remedy of their own confection), the Ninth Circuit has held that they do not have a constitutional right to *obtain* marijuana from the medical cannabis cooperatives free of government police power. To hold otherwise would directly contradict the *Carnohan* holding.

*2 The Intervenors attempt to distinguish *Carnohan* and the other cases cited by plaintiff on the grounds that the Intervenors (1) do not seek to compel

government action and are not asserting that they have a fundamental constitutional right to obtain a particular medication, and (2) seek to use cannabis upon the recommendation of their personal physicians to alleviate their suffering through the only effective treatment available for them. Neither of these alleged distinctions persuades the Court than *Carnohan* is not controlling here.

First, the Intervenor's characterization of their complaint as not seeking a declaration of a right to obtain a particular medication is belied by the plain language of their complaint and their arguments in support of their motion to intervene. If the issue before the Court were whether the Intervenor has a right to use marijuana which they have grown themselves, the Court would not have granted them leave to intervene since such a claim is not related to the claims raised by the United States' lawsuits. By their complaint, however, the Intervenor seek an order enjoining the United States from enforcing the Controlled Substances Act against the medical cannabis cooperatives in which they are members. Complaint in Intervention at ¶¶ 19-21. Indeed, in their motion to intervene, they emphasized that their complaint alleges that they have a "protectable interest in obtaining cannabis." Motion to Intervene at 11 (emphasis added); see also *id.* at 5 ("If the cooperatives are prevented from distributing cannabis, the [Intervenor] will not be able to legally obtain cannabis that is safe and effective."). Thus, the Intervenor's complaint seeks an order that they have a fundamental right to obtain to a particular medication, marijuana, from a particular source, the medical cannabis cooperatives. *Carnohan*, however, holds that there is no constitutional right to obtain medication free from the lawful exercise of the government's police powers.

The fact that California law does not prohibit the distribution of medical marijuana under certain circumstances is not relevant as to whether the Intervenor has 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.

Second, that the Intervenor's personal physicians recommended marijuana is not a material distinction. If 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. In *Kulsar v. Ambach*, 598 F.Supp. 1124 (W.D.N.Y.1984), for example, medical patients alleged that New York laws that prohibited their

personal physician from administering a particular treatment for their hypoglycemic disorders were unconstitutional. The court dismissed their constitutional claim on the ground that the "constitutional right of privacy does not give individuals the right to obtain a particular medical treatment 'free of the lawful exercise of government police power.'" *Id.* at 1126 (citing *Carnohan*, 616 F.2d 1120).

*3 The Intervenor's argument that marijuana is the only effective treatment for their symptoms is also not persuasive. In *Rutherford v. United States*, 616 F.2d 455 (10th Cir.1980), a case relied upon by the *Carnohan* court, terminally ill cancer patients brought suit to enjoin the United States from interfering with interstate shipments of the sale of laetrile. The trial court had held that the cancer patients had a right "to be let alone," or "a constitutional right of privacy to permit them, as terminally ill cancer patients, to take whatever treatment they wished regardless of whether the FDA regarded the medication as 'effective' or 'safe.'" *Id.* at 456. The Tenth Circuit reversed:

It is apparent in the context with which we are here concerned 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. The premarketing requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, is an exercise of Congressional authority to limit the patient's choice of medication.

Id. at 457. The *Rutherford* plaintiffs had no other treatment alternative. They believed that without the laetrile they would die. The Tenth Circuit nonetheless held that the *Rutherford* plaintiffs did not have a constitutional right to obtain laetrile. See also *Smith v. Shalala*, 954 F.Supp. 1, 3 (D.D.C.1996) ("While there are decisions recognizing that competent adults have a fundamental right to refuse medical treatment, *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990), and to determine the time and manner of their death, free from governmental interference, ... nothing in those decisions suggests that the government has an affirmative obligation to set aside its regulations in order to provide dying patients access to experimental medical treatments").

Here, the plaintiffs similarly believe, and on a motion to dismiss the Court must assume they could prove, that marijuana is the only effective treatment for their symptoms. Congress and the FDA disagree. If the Intervenor believe the FDA and Congress are

wrong, they should challenge the legal prohibition on the distribution of marijuana through an APA or similar action. *Carnohan* and *Rutherford* hold, however, that there is no fundamental right to obtain the medication of choice. Accordingly, the Intervenor's claim that they do have such a right, and that the United States should be enjoined from interfering with that right, will be dismissed without leave to amend.

As is set forth above, the Court does not interpret the Intervenor's complaint as alleging a fundamental right to treat themselves with cannabis which they themselves have grown. The Intervenor's motion to intervene was based on their assertion that if the cooperatives are closed, they will not be able to treat their symptoms with cannabis. Nonetheless, to the extent the complaint does make such claim, such claim does not raise a question of fact or law in common with the claims or defenses in these related lawsuits. See Fed.R.Civ.P. 24(b)(2). Accordingly, to the extent the complaint-in-intervention makes such a claim, it shall be dismissed without prejudice.

CONCLUSION

*4 For the foregoing reasons, plaintiff's motion to dismiss is GRANTED. Intervenor's claims for a declaration that they have a fundamental right to obtain marijuana for their personal, medical use without interference from the United States, and their claims seeking to enjoin the United States' efforts to close the cooperatives, are DISMISSED without leave to amend. Intervenor's claims seeking an order that they have a fundamental right to treat themselves with marijuana which they themselves have grown, to the extent the Intervenor's complaint makes such claims, are DISMISSED without prejudice.

IT IS SO ORDERED.

N.D.Cal., 1999.
U.S. v. Cannabis Cultivator's Club
Not Reported in F.Supp.2d, 1999 WL 111893
(N.D.Cal.)

END OF DOCUMENT