

ROBERT A. RAICH (State Bar No. 147515)
1970 Broadway, Suite 1200
Oakland, California 94612
Telephone: (510) 338-0700

DAVID M. MICHAEL (State Bar No. 74031)
The DeMartini Historical Landmark Building
294 Page Street
San Francisco, California 94102
Telephone: (415) 621-4500

RANDY E. BARNETT
Boston University School of Law
Boston, Massachusetts 02215
Telephone: (617) 353-3099

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANGEL McCLARY RAICH, DIANE _
MONSON, JOHN DOE NUMBER _
ONE, and JOHN DOE NUMBER TWO, _

Plaintiffs, _

v. _

JOHN ASHCROFT, as United States _
Attorney General, and ASA _
HUTCHINSON, as Administrator of the _
Drug Enforcement Administration, _

Defendants. _

Case No. C 02 4872 MJJ

**PLAINTIFFS' REPLY
MEMORANDUM OF LAW
IN SUPPORT OF MOTION FOR
PRELIMINARY INJUNCTION**

Date: December 10, 2002

Time: 9:30 a.m.

Dept.: Courtroom 11, 19th Floor
Honorable Martin J. Jenkins

TABLE OF CONTENTS

	<u>PAGES</u>
TABLE OF AUTHORITIES	iii
PRELIMINARY STATEMENT	1
I. THE CONTROLLED SUBSTANCES ACT DOES NOT GIVE CONGRESS PLENARY POLICE POWER OVER ALL COMMERCE.	2
II. THE SUPREME COURT’S DECISION IN <i>OCBC</i> DOES NOT PRECLUDE CONSTITUTIONAL SCRUTINY OF THE CONTROLLED SUBSTANCES ACT.	3
III. PLAINTIFFS’ CONDUCT IS A DISTINCT CLASS OF ACTIVITY BEYOND THE REACH OF CONGRESS UNDER THE COMMERCE CLAUSE.	4
IV. UNDER PRINCIPLES OF FEDERALISM, THE STATE HAS THE SOVEREIGN RIGHT TO CARE FOR THE HEALTH AND SAFETY OF ITS CITIZENS.	7
V. PLAINTIFFS POSSESS FUNDAMENTAL RIGHTS REQUIRING PROTECTION.	9
VI. THE CLASSIFICATION OF MARIJUANA UNDER SCHEDULE I OF THE CSA DOES NOT PRECLUDE APPLICATION OF THE MEDICAL NECESSITY DOCTRINE.	14
VII. ALL THE EQUITABLE FACTORS IN THIS CASE JUSTIFY THE ENTRY OF A PRELIMINARY INJUNCTION.	15
CONCLUSION	17

TABLE OF AUTHORITIES

CASES PAGES

<i>Alliance for Cannabis Therapeutics v. DEA</i> , 15 F.3d 1131 (D.C. Cir. 1994)	14
<i>Bertoldo v. United States</i> , 145 F. Supp.2d 111 (D. Mass. 2001)	6
<i>Carnohan v. United States</i> , 616 F.2d 1120 (9th Cir. 1980)	2, 10-12
<i>Conant v. Walters</i> , 329 F.3d 629, 2002 WL 31415494 (9th Cir. Oct. 29, 2002) <i>passim</i>	
<i>Eisenstadt v. Baird</i> , 405 U.S. 438 (1972)	10
<i>Gregory v. Ashcroft</i> , 501 U.S. 452 (1991)	7
<i>Griswold v. Connecticut</i> , 381 U.S. 479 (1965)	10
<i>In Re Seagate Technology II Secur. Litig.</i> , 843 F. Supp 1341 (N.D. Cal. 1994)	1
<i>Jacobson v. Massachusetts</i> , 197 U.S. 11 (1905)	10
<i>Linder v. United States</i> , 268 U.S. 5 (1925)	16
<i>Loving v. Virginia</i> , 388 U.S. 1 (1967)	10
<i>Meyer v. Nebraska</i> , 262 U.S. 390 (1923)	10
<i>Moore v. City of East Cleveland</i> , 431 U.S. 494 (1977)	10
<i>New York v. United States</i> , 505 U.S. 114 (1992)	1, 8
<i>Oregon v. Ashcroft</i> , 192 F.Supp.2d 1077 (D. Or. 2002)	12
<i>People v. Bianco</i> , 93 Cal.App.4th 748 (2001)	13
<i>People v. Mower</i> , 28 Cal.4th 457 (2002)	13
<i>People v. Trippet</i> , 56 Cal.App.4th 1532 (1997)	13
<i>Perez v. United States</i> , 402 U.S. 146 (1971)	6
<i>Piece v. Society of Sisters</i> , 268 U.S. 510 (1925)	10
<i>Printz v. United States</i> , 521 U.S. 898 (1997)	8
<i>Proeyct v. United States</i> , 101 F.3d 11 (2d Cir. 1996)	5
<i>Roe v. Wade</i> , 410 U.S. 113 (1973)	10
<i>Rutherford v. United States</i> , 616 F.2d 455 (10th Cir. 1980)	11, 12
<i>Trammel v. United States</i> , 445 U.S. 40 (1980)	10
<i>United States v. Bramble</i> , 103 F.3d 1475 (9th Cir. 1996)	1, 5
<i>United States v. Brown</i> , 276 F.3d 211 (6th Cir. 2002)	5
<i>United States v. Cannabis Cultivators Club</i> , 1999 WL 111893 (N.D. Cal. 1999), <i>vacated</i>	<i>and reman</i>
<i>United States v. Cannabis Cultivators Club</i> , 5 F. Supp.2d 1086 (N.D. Cal. 1998)	6, 7
<i>United States v. Cannabis Cultivator's Club</i> , No. C 98-00085, Memorandum and Order (N.D. Cal. June 10, 2002)	6
<i>United States v. Darby</i> , 312 U.S. 100 (1941)	7
<i>United States v. Edwards</i> , 98 F.3d 1364, (D.C. Cir. 1996), <i>cert. denied</i> , 520 U.S. 1170 (1997)	5
<i>United States v. Goodwin</i> , 141 F.3d 394 (2d Cir. 1997), <i>cert. denied</i> , 523 U.S. 1086, 525 U.S. 881 (1998)	5
<i>United States v. Guest</i> , 383 U.S. 745 (1966)	10
<i>United States v. Jackson</i> , 111 F.3d 101 (11th Cir.), <i>cert. denied</i> , 522 U.S. 878 (1997)	5
<i>United States v. Lerebours</i> , 87 F.3d 582, (1st Cir. 1996), <i>cert. denied</i> , 519 U.S. 1060 (1997)	5
<i>United States v. Leshuk</i> , 65 F.3d 1105 (4th Cir. 1995)	5
<i>United States v. Lopez</i> , 459 F.2d 949 (5th Cir.), <i>cert. denied</i> , 409 U.S. 878 (1972)	5
<i>United States v. Lopez</i> , 514 U.S. 549 (1995)	4-7
<i>United States v. Montes-Zarate</i> , 552 F.2d 1330, (9th Cir. 1977), <i>cert. denied</i> , 435 U.S. 947 (1978)	5
<i>United States v. Morrison</i> , 529 U.S. 598 (2000)	1, 3-7
<i>United States v. Oakland Cannabis Buyers' Coop.</i> , 532 U.S. 483 (2001)	2, 3, 5, 15
<i>United States v. Orozco</i> , 98 F.3d 105 (3d Cir. 1996)	5
<i>United States v. Patterson</i> , 140 F.3d 767 (8th Cir.), <i>cert. denied</i> , 525 U.S. 907 (1998)	5
<i>United States v. Pompey</i> , 264 F.3d 1176 (10th Cir. 2001), <i>cert. denied</i> , 122 S. Ct. 929 (2002)	5
<i>United States v. Price</i> , 265 F.3d 1097 (10th Cir. 2001), <i>cert. denied</i> , 122 S. Ct. 2299 (2002)	5
<i>United States v. Rodriguez-Camacho</i> , 468 F.2d 1220 (9th Cir. 1972), <i>cert. denied</i> , 410 U.S. 985 (1973)	5
<i>United States v. Tisor</i> , 96 F.3d 370 (9th Cir. 1996), <i>cert. denied</i> , 519 U.S. 1140 (1997)	5
<i>United States v. Westbrook</i> , 125 F.3d 996 (7th Cir.), <i>cert. denied</i> , 522 U.S. 1036 (1997)	5
<i>United States v. Zorrilla</i> , 93 F.3d 7 (1st Cir. 1997)	5

Washington v. Glucksberg, 521 U.S. 702 (1997) 10
Whalen v. Roe, 429 U.S. 589 (1977) 16

STATUTES

21 U.S.C. § 801 2, 3
21 U.S.C. § 811 14
21 U.S.C. § 812 14
Controlled Substances Act 1-3, 5, 6, 15
Pub. L. 98-329, 98 Stat. 280 (1984) 14
Cal. Health & Safety Code § 11362.5(b)(1)(A) 13
California’s Compassionate Use Act of 1996 2, 10, 13, 14

CONSTITUTIONAL PROVISIONS

U.S. Const., amend. IX 13
U.S. Const., amend. X 1, 7
U.S. Const., art. I, § 8 (Commerce Clause) 1, 4-9

OTHER MATERIALS

57 Federal Register 10,506 14
Arnolds & Garland, *The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil*, 65 J. Crim. L. & Criminology 289 (1974) 14
Barnett, *Case Should Give Ninth Amendment New Life*, Portland Oregonian, April 11, 1999 13
Commission on Marihuana and Drug Abuse (the “Shafer Commission”), *Marijuana: A Signal of Misunderstanding; First Report of the National Commission on Marihuana and Drug Abuse* (1972). 15
Common Sense for Drug Policy Research Report, *Nixon Tapes Show Roots of Marijuana Prohibition: Misinformation, Culture Wars and Prejudice* (March 2002) 15
Conde, *Necessity Defined: A New Role in the Criminal Defense System*, 29 UCLA L. Rev. 409 (1981)
H.R. Rep. No. 91-1444 (1970) reprinted in 1970 U.S.C.C.A.N. at 4579 & 4629 15
H.R. Rep. No. 98-534, 98th Congress, 2d Sess. 4 (1984), reprinted in 1984 U.S.C.C.A.N. 540 14
Parry, *The Virtue of Necessity: Reshaping Culpability and the Rule of Law*, 36 Houston L. Rev. 397 (1999) 14
Reeve, *Necessity: The Right to Present a Recognized Defense*, 21 New Eng. L. Rev. 779 (1986) 14

PRELIMINARY

Plaintiffs note that in Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion for Preliminary Injunction ("Def. Br.") Defendants do not challenge, contest, or even question the *facts* alleged by Plaintiffs. Accordingly, for the purposes of this motion, the facts introduced by Plaintiffs are all deemed to be true. *See In Re Seagate Technology II Secur. Litig.*, 843 F. Supp 1341, 1371, n.38 (N.D. Cal. 1994). Plaintiffs have described the tremendous suffering they have already experienced as a result of Defendants' actions. Unless enjoined, Defendants' actions would cause Plaintiffs to suffer even greater irreparable harm, including, in the case of Plaintiff Angel McClary Raich ("Angel"), an agonizing death. Although Defendants ignore the *facts* of the case, this Court, sitting as a chancellor in equity, is obliged to consider the tremendous human suffering that only an injunction protecting the Plaintiffs can alleviate.

Moreover, Plaintiffs Angel and Diane Monson (collectively "Plaintiff patients") have taken a tangible risk by coming forward with this action against the Defendants. By their Motion for Preliminary Injunction, Plaintiffs seek merely to preserve the *status quo* during the pendency of this action -- i.e., that Plaintiffs are not arrested or prosecuted, that their medicine is not seized, and that their property is not forfeited.

As applied to the facts of this case, Defendants' arguments are meritless. First, it would exceed Congress's authority under the Commerce Clause for the Controlled Substances Act ("CSA") to authorize Defendants to take action against Plaintiffs for the conduct at issue in this matter, and *United States v. Bramble*, 103 F.3d 1475 (9th Cir. 1996), does not hold otherwise. *Bramble* did not involve medical cannabis and was decided prior to *United States v. Morrison*, 529 U.S. 598 (2000).

Second, "principles of federalism" discussed in *Conant v. Walters*, 329 F.3d 629, No. 00-17222, 2002 WL 31415494, slip op. at 18 (9th Cir. Oct. 29, 2002) (Schroeder, C.J.), provide an additional and independent basis supporting issuance of the injunction. According to *New York v. United States*, 505 U.S. 114, 157 (1992), "the Tenth Amendment confirms that the power of the Federal Government is subject to limits that may, in a given instance, reserve power to the States." Such "a given instance" includes an intrusion into State sovereignty and interference

with a State’s police power to regulate matters of public safety and public health. Courts “must ‘show[] respect for the sovereign States that comprise our Federal Union.’” *Conant*, slip op. at 19, quoting *United States v. Oakland Cannabis Buyers’ Coop.* (“*OCBC*”), 532 U.S. 483, 501 (2001) (Stevens, J., concurring).

Third, Plaintiffs’ conduct constitutes the exercise of constitutionally protected fundamental liberties. The undisputed facts in this case demonstrate that cannabis is *not* an “unproven medical treatment[]” (Def. Br. at 1) for Plaintiff patients. Unlike the plaintiff in *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980), Plaintiffs herein do not seek to obtain any drug commercially, do not seek administrative approval for any substance by the federal government, and do not seek any action by the federal government whatsoever. Indeed, through the injunction sought herein, Plaintiffs simply seek to preserve the *status quo* -- to be left alone, unarrested and unmolested by Defendants.

Fourth, the medical necessity doctrine protects the Plaintiffs in this case. Unlike the situation in *OCBC*, in which medical “necessity was raised in this case as a defense to *distribution*,” *OCBC* at 501 (emphasis added), Plaintiffs herein are not distributors. As explained in *OCBC*, “This case does not require us to rule on the scope of the District Court’s discretion to enjoin, or to refuse to enjoin, the possession of marijuana or other potential violations of the Controlled Substances Act by *a seriously ill patient* for whom the drug may be a necessity.” *OCBC* at 502-3 (Stevens, J., concurring) (emphasis added).

Finally, not once in Defendants’ brief do they mention the leading Ninth Circuit case on medical cannabis: *Conant v. Walters, supra* (affirming injunction against Ashcroft, Hutchinson and others; vindicating rights under California’s Compassionate Use Act). That relevant and instructive authority is entirely and inexplicably absent from Defendants’ memorandum of law.

I. THE CONTROLLED SUBSTANCES ACT DOES NOT GIVE CONGRESS PLENARY POLICE POWER OVER ALL COMMERCE.

At the onset, it is clear that almost all the congressional findings in the Controlled Substances Act do not apply to the facts in this case but rather address the interstate trafficking in controlled

substances or local manufacturing that is later transported in interstate commerce. 21 U.S.C. § 801(3), (4), and (6).

Section 801(5), on the other hand, more broadly addresses intrastate manufacturing and distribution:

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

21 U.S.C. § 801(5). Yet, if in seeking to prohibit some form of interstate commerce, Congress attempts to prohibit the wholly intrastate commerce of particular goods on the unsupported speculation that such goods might leak out of a state and into interstate commerce, or because there is no way to distinguish between goods produced within a state and those imported from other states, that would effectively give Congress the plenary police power over *all* commerce. That police power the Constitution explicitly denies to Congress, despite Defendants' claims otherwise. *United States v Morrison*, 529 U.S. 598, 615 (2000) (Congress must exercise its power so as to preserve the Constitution's distinction between national and local authority).

In this case, the cannabis grown and used by Plaintiffs for the limited purpose of medical use would never be traded between states. The supposition that this *might* occur does not give Congress police power over this class of activity and all cases cited by the government are easily distinguished, as set forth herein.

II. THE SUPREME COURT'S DECISION IN *OCBC* DOES NOT PRECLUDE CONSTITUTIONAL SCRUTINY OF THE CONTROLLED SUBSTANCES ACT.

Although the U.S. Supreme Court decided that the Controlled Substances Act cannot bear a medical necessity defense to distribution of cannabis, the Court also declined to address the underlying Constitutional issues presented in this case.

[T]he Cooperative asserts that, shorn of a medical necessity defense, the statute exceeds Congress' Commerce Clause powers, violates the substantive due process rights of patients, and offends the fundamental liberties of the people under the

Fifth, Ninth, and Tenth Amendments. . . . Because the Court of Appeals did not address these claims, we decline to do so in the first instance.

OCBC, 532 U.S. at 494.

III. PLAINTIFFS' CONDUCT IS A DISTINCT CLASS OF ACTIVITY BEYOND THE REACH OF CONGRESS UNDER THE COMMERCE CLAUSE.

An unspoken, but underlying, current driving the Defendants' arguments is the suggestion that life, thus law, is moribund and dead, with neither pulse nor a vibrant energy flow of thoughts and ideas and that, ultimately, transformation, and the ability to adapt to new ideas and phenomena is non-existent. In other words, the Constitution, and the laws that give it meaning, are not amenable to the changing world.

Yet, as the United States Supreme Court explained in *Morrison*, a case somewhat ignored by the Defendants here, the Constitution and the laws that pay it homage, are quite alive and dynamic and, in fact, subject to change and interpretative transformation. And, at least to the Supreme Court, the interpretation of the Commerce Clause, itself, has changed just as this Nation has changed.

As we discussed at length in *Lopez*, our interpretation of the Commerce Clause has changed as our Nation has developed. . . . [E]ven under our modern, expansive interpretation of the Commerce Clause, Congress' regulatory authority is not without effective bounds.

Morrison at 607-608.

The Court has defined these Commerce Clause boundaries: If Congress through its Commerce Power seeks by law to regulate activities that do not "use the channels of interstate commerce," that are not the "instrumentalities of interstate commerce," or do not "substantially affect interstate commerce," then such a law exceeds Congress's authority under the Commerce Clause. *Id.* at 608-609.

As set forth by Plaintiffs in their motion, the activities for which Plaintiffs seek protection in this case are purely intrastate actions pursuant to valid California State law -- the personal cultivation and personal use of cannabis for medical purposes. Pursuant to *Morrison*, this wholly intrastate, non-commercial activity is beyond the power of Congress "to regulate Commerce . . . among the several States," U.S. Const., art. I, § 8.

It was this remarkable shift by the Supreme Court in *United States v. Lopez*, 514 U.S. 549 (1995), and *Morrison*, that led Judge Kozinski to conclude as he did in *Conant*:

Medical marijuana, when grown locally for personal consumption, does not have any direct or obvious effect on interstate commerce. *Cf. Oakland Cannabis Buyers' Coop.*, 532 U.S. at 495 n.7 (reserving “whether the Controlled Substances Act exceeds Congress’ power under the Commerce Clause”). Federal efforts to regulate it considerably blur the distinction between what is national and what is local.

Conant, slip op. at 33 (emphasis added).

Yet, the government in its Response completely and totally fails to address the concerns of both *Lopez* and *Morrison* in analyzing the facts in this case. Virtually all the cases cited by the government in support of its Commerce Clause argument (Def. Br. at 8-10 & n.5) are not only pre-*Morrison* but only concern themselves with commercial drug trafficking, such as sales of cocaine, methamphetamine, possession with intent to distribute, distribution, drug trafficking, or non-drug offenses -- not the non-economic, non-commercial, non-distribution, personal cultivation and use of medical cannabis pursuant to valid State law.¹

¹ *United States v. Tisor*, 96 F.3d 370 (9th Cir. 1996), *cert. denied*, 519 U.S. 1140 (1997) (conspiracy to distribute methamphetamine, distribution of methamphetamine, use of communication facility in drug trafficking); *United States v. Bramble*, 103 F.3d 1475 (9th Cir. 1996) (possession of a firearm by a felon, possession of eagle feathers, possession and cultivation of nonmedical marijuana); *United States v. Montes-Zarate*, 552 F.2d 1330, (9th Cir. 1977), *cert. denied*, 435 U.S. 947 (1978) (possession of marijuana with intent to distribute); *United States v. Rodriguez-Camacho*, 468 F.2d 1220 (9th Cir. 1972), *cert. denied*, 410 U.S. 985 (1973) (possession of 99 pounds of marijuana with intent to distribute); *United States v. Edwards*, 98 F.3d 1364, (D.C. Cir. 1996), *cert. denied*, 520 U.S. 1170 (1997) (distribution of cocaine base); *United States v. Lerebours*, 87 F.3d 582, (1st Cir. 1996), *cert. denied*, 519 U.S. 1060 (1997); (cocaine and cocaine base); *Proyect v. United States*, 101 F.3d 11 (2d Cir. 1996) (manufacturing over 100 marijuana plants); *United States v. Orozco*, 98 F.3d 105 (3d Cir. 1996) (trafficking in sale of 1080 grams of cocaine); *United States v. Leshuk*, 65 F.3d 1105 (4th Cir. 1995) (manufacturing approximately 100 marijuana plants); *United States v. Lopez*, 459 F.2d 949 (5th Cir.), *cert. denied*, 409 U.S. 878 (1972) (multiple controlled substances violations including conspiring to possess with intent to distribute cocaine and distributing cocaine and heroin); *United States v. Brown*, 276 F.3d 211 (6th Cir. 2002) (aiding and abetting in the attempt to possess cocaine with the intent to distribute); *United States v. Westbrook*, 125 F.3d 996 (7th Cir.), *cert. denied*, 522 U.S. 1036 (1997) (conspiracy to distribute cocaine base); *United States v. Patterson*, 140 F.3d 767 (8th Cir.), *cert. denied*, 525 U.S. 907 (1998) (intent to distribute methamphetamine and distributing methamphetamine, use and carrying of firearm in relation to drug offense); *United States v. Price*, 265 F.3d 1097 (10th Cir. 2001), *cert. denied*, 122 S. Ct. 2299 (2002) (conspiracy to distribute cocaine, use of a communication facility in committing a felony); *United States v. Jackson*, 111 F.3d 101 (11th Cir.), *cert. denied*, 522 U.S. 878 (1997) (possession with intent to distribute cocaine base); *United States v. Kim*, 94 F.3d 1247 (9th Cir. 1996) (drug trafficking); *United States v. Goodwin*, 141 F.3d 394 (2d Cir. 1997), *cert. denied*, 523 U.S. 1086, 525 U.S. 881 (1998) (narcotics trafficking); *United States v. Zorrilla*, 93 F.3d 7 (1st Cir. 1997) (drug trafficking); *United States v. Davis*, 288 F.3d 359 (8th Cir. 2002) (manufacturing methamphetamine); *United States v. Pompey*, 264 F.3d 1176 (10th Cir. 2001), *cert. denied*, 122 S. Ct. 929 (2002) (drug trafficking); *Bertoldo v. United States*, 145 F. Supp.2d 111 (D. Mass. 2001) (narcotics distribution).

The activities of Plaintiffs here have nothing to do with distribution, have nothing to do with drug sales, have nothing to do with drug trafficking, and have nothing to do with any economic activity whatsoever.

The Defendants do correctly cite, as do Plaintiffs, to *Lopez* for the proposition that ““where a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of individual instances arising under that statute is of no consequence.”” 514 U.S. at 558 (emphasis in original). Def. Br. at 12. Plaintiffs also do not dispute here the general language in *Perez v. United States*, 402 U.S. 146, 154 (1971) that “[w]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power ‘to excise, as trivial, individual instances’ of the class.” *Id.*

But, Defendants miss the point with this argument. The activities of Plaintiffs here -- the completely intrastate personal cultivation and personal use of cannabis for medical purposes as recommended by the patients’ physicians and pursuant to valid California State law -- are of a separate and distinct class than the class of activity that involves trafficking in illegal drugs. It is Plaintiffs’ “class” of activity that is beyond the reach of Congress under the Commerce Clause.

Even Judge Breyer, cited by the Defendants, makes clear that his medical cannabis opinions were limited to the distribution of cannabis, not its personal possession and use:

Plaintiff filed these related actions to enjoin the distribution of marijuana, not possession for personal use. The issue of personal use is not before the Court and the Court declines to reach that issue.

United States v. Cannabis Cultivator’s Club, No. C 98-00085, Memorandum and Order at 6, n.2 (N.D. Cal. June 10, 2002).²

² Judge Breyer’s earlier published opinion in *United States v. Cannabis Cultivators Club*, 5 F. Supp.2d 1086, 1098 (N.D. Cal. 1998), also limits it’s concerns to distribution. (“[I]t did not follow that the class of activities within which defendants’ conduct falls--non-profit **distribution** of medical marijuana--necessarily does not affect interstate commerce”) (emphasis added).

Furthermore, this Court should reexamine Judge Breyer’s earlier pre-*Morrison* reasoning, also cited by the Defendants:

To hold that the Controlled Substances Act is unconstitutional as applied here would mean that in every action in which a plaintiff seeks to prove a defendant violated federal law, an element of every case-in-chief would be that the defendant’s specific conduct at issue, based on the facts proved at an evidentiary hearing or trial, substantially affected interstate commerce. No case so holds and the Court declines to do so for the first time here.

Cannabis Cultivators Club, 5 F. Supp.2d at 1098.; Def. Br. at 13.

IV. UNDER PRINCIPLES OF FEDERALISM, THE STATE HAS THE SOVEREIGN RIGHT TO CARE FOR THE HEALTH AND SAFETY OF ITS CITIZENS.

Principles of federalism provide a separate and independent justification for granting the injunction Plaintiffs seek. Defendants contend that the Tenth Amendment “states but a truism” (Def. Br. 14, quoting *United States v. Darby*, 312 U.S. 100 (1941) (federal regulation of wages and hours in manufacture of goods shipped through interstate commerce was valid exercise of Commerce Power)), suggesting that that provision in the Constitution is but a dead letter if federal conduct does not offend the Commerce Clause. In fact, the powers reserved to the States and to the People are not so limited. “[A] healthy balance of power between the State and the Federal Government will reduce the risk of tyranny and abuse from either front.” *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) (right of States to govern their own affairs supported by Defendant Ashcroft).

Serious concerns of federalism (and individual rights) must inform any analysis of claimed implied powers by the federal government. *Cf. Conant*, slip op. at 32, (“The commandeering problem becomes even more acute where Congress legislates [through the CSA] at the periphery of its powers.”) (Kozinski, J., concurring). States cannot exercise their police powers to interfere with the power of Congress over *interstate* commerce. Conversely, however, Congress cannot exercise its power over interstate commerce to interfere with a State’s police power by prohibiting *wholly intrastate* conduct a State endorses in the interest of health and safety. Given the absence of a general congressional police power, it is essential for the welfare of the people that the States be allowed to exercise their police powers effectively and without interference from the federal government. Precisely because Congress has no comparable police power, it may not use its implied penumbral powers as a pretext to countermand a decision by a sovereign State and its People that a particular activity is needed to protect health and safety. That is precisely the abuse for which Plaintiffs seek protection in this case.

In fact, what Judge Breyer had then dismissed is now, pursuant to *Morrison*, precisely what every Court must do in examining the Constitutional boundaries of any law -- consider whether or not the specific conduct is of a class that “substantially affects interstate commerce.” This is exactly the determination, commanded by *Lopez* and *Morrison*, which Plaintiffs seek from this Court. Without that exercise of its authority, the judicial branch of government would be granting Congress a plenary police power denied it under Article I of the Constitution.

Here the State of California, and its People through the initiative process, have determined that the health and safety of the State’s citizens are best served by allowing seriously ill patients access to cannabis for medical purposes. Under the circumstances of this case, the Court should respect the choice made by both a Sovereign State and the sovereign People of that State. As the Ninth Circuit recognizes, respect for sovereign States “imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to serve as a laboratory in the trial of novel social and economic experiments” *Conant*, slip op. at 19 (Schroeder, C.J.).³

Invoking the Supreme Court’s rationale in *New York v. United States*, 505 U.S. 144 (1992) and *Printz v. United States*, 521 U.S. 898 (1997), Judge Kozinski identified the constitutional problem in his concurring opinion in *Conant*:

Applied to our situation, this means that, much as the federal government may prefer that California keep medical marijuana illegal, it cannot force the state to do so. . . . [T]he federal policy makes it impossible for the state to exempt the use of medical marijuana from the operation of its drug laws. In effect, the federal government is forcing the state to keep medical marijuana illegal.

Conant, slip op. at 29-30 (Kozinski, J., concurring). What the federal government may not impose on the State indirectly (through doctors, as in *Conant*), the federal government may not impose on the State directly (through patients, in this case).

When properly interpreted, there is no conflict between the Commerce Clause and the police power of the States to protect public health and safety. A conflict only arises when Congress goes *beyond its authority under the Commerce Clause* over “commerce . . . among the several states,” U.S. Const. art. I, § 8, cl. 3, to reach wholly intrastate activity in a manner that improperly interferes with the exercise of a vital police power of a State. Our system of dual sovereignty prevents one

³ The principle of federalism at issue in these proceedings extends far beyond medical cannabis. The power claimed by the government to interfere with State police power would extend to traditional State functions such as licensing of doctors, attorneys, and other professionals. All these activities are “economic.” The only constitutional doctrine preventing federal usurpation of these traditionally State-regulated activities is that such federal laws would improperly violate the principles of federalism affirmed in *New York* and *Printz*.

sovereign from obstructing the vital jobs assigned by the Constitution to the other, while still imposing on both sovereigns the obligation to respect the fundamental rights of the citizenry.

V. PLAINTIFFS POSSESS FUNDAMENTAL RIGHTS REQUIRING PROTECTION.

The uncontroverted evidence in this case demonstrates that Plaintiff patients require cannabis to ameliorate pain, to permit the use and integrity of their bodies, and, in the case of Angel, to remain alive. The Complaint and declarations in the case provide a glimpse into the tremendous suffering that the Plaintiff patients must endure daily. Angel suffers from a long list of serious, debilitating, and life-threatening medical conditions. Complaint (“Comp.”) ¶ 13, Declaration of Angel McClary Raich (“Angel Decl.”) ¶ 1. For example, Angel was confined to a wheelchair for years until discovering cannabis as the only treatment to help bring her paralysis into complete remission. Comp. ¶ 13, Angel Decl. ¶¶ 3, 22-24. Without access to cannabis, Angel would suffer serious medical consequences within a matter of hours, ultimately leading to horrible pain, suffering, and death. Comp. ¶¶ 18, 16, Angel Decl. ¶¶ 6, 20, 21, 36, 39. Angel has great difficulty maintaining a healthy weight, and without cannabis her weight can quickly drop precipitously, causing her to run the risk of starvation and death. Comp. ¶ 52, Angel Decl. ¶¶ 6, 33, 36, 37. Every second that she is awake, Angel experiences pain from one or more of her many chronic pain conditions, which medical cannabis helps alleviate. Comp. ¶¶ 54-54H, Angel Decl. ¶¶ 7, 15, 17, 18, 20, 21, 29, 30, 32, 36, 38, 39, 46. The pain sometimes becomes so overpowering that Angel becomes completely debilitated. Comp. ¶ 54, Angel Decl. ¶¶ 16, 21, 45. Before discovering cannabis, her pain levels were so high for such a prolonged period of time that, her body and soul racked with agony, Angel attempted suicide -- as a desperate attempt at the only escape she could perceive from her torment. Comp. ¶ 54, Angel Decl. ¶ 28.

Similarly, Monson suffers from severe chronic back pain and spasms. Comp. ¶¶ 7, 21, Declaration of Diane Monson (“Monson Decl.”) ¶¶ 2, 6. They are extremely painful, torturous, and unbearable without cannabis. Comp. ¶ 21, Monson Decl. ¶¶ 3, 7.

These patients have a liberty interest in being free from pain and in preserving their lives with the assistance of their physicians. *See Washington v. Glucksberg*, 521 U.S. 702, 745 (1997)

(Stevens, J., concurring) (“Avoiding intolerable pain and . . . agony is certainly “[a]t the heart of [the] liberty . . . to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life.”) (citation omitted). There can be no right more fundamental than the right to preserve one’s life.⁴

The Ninth Circuit’s recent *Conant* decision affirms the sanctity of the physician-patient relationship in the context of the Compassionate Use Act, explicitly recognizing the importance of communication between physician and patient unimpeded by government interference:

The doctor-patient privilege reflects “the imperative need for confidence and trust” inherent in the doctor-patient relationship and recognizes that “a physician must know all that a patient can articulate in order to identify and to treat disease; barriers to full disclosure would impair diagnosis and treatment.” *Trammel v. United States*, 445 U.S. 40, 51 (1980).

Conant slip op. at 14 (Schroeder, C.J.). In his concurring opinion, Judge Kozinski emphasized the critical role of physicians in the context of medical cannabis under California law: “Those immediately and directly affected by the federal government’s policy [of intimidating doctors] are the patients . . . and the State of California” *Conant*, slip op. at 20-21 (Kozinski, J., concurring).

The Defendants rely (Def. Br. at 16) on *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980) and *Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980), two cases that are plainly distinguishable from the instant case. In *Carnohan*, the plaintiff brought a declaratory action “to secure the right to obtain and use laetrile [commercially] in a nutritional program” 616 F.2d at 1121. The relief sought (a declaration that laetrile was not a “new drug” within the meaning of the Food, Drug and Cosmetic Act) fell squarely within the rulemaking authority of the Food and Drug

⁴ The Due Process Clause protects other important, but less vital, liberty interests as fundamental rights. See, e.g., *Moore v. City of East Cleveland*, 431 U.S. 494 (1977) (right to keep extended family together); *Roe v. Wade*, 410 U.S. 113 (1973) (right to abortion); *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (right to bear child); *Loving v. Virginia*, 388 U.S. 1 (1967) (right to marry); *United States v. Guest*, 383 U.S. 745 (1966) (right to travel); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (right to purchase contraceptives); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (right to choose education); *Meyer v. Nebraska*, 262 U.S. 390 (1923) (right to teach foreign languages); *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (right to refuse medical treatment).

Administration. *Id.* The court rejected this claim, finding that the plaintiff was required to exhaust his administrative remedies. *Id.* at 1122. The court, however, expressly declined to consider whether the plaintiff had “a constitutional right to treat himself with home remedies of his own confection.” *Id.*

Unlike *Carnohan*, the Plaintiffs here do not seek reclassification of any drug, do not seek to obtain any substance in commerce or through pharmacies, and do not seek to compel the government affirmatively to give them access to any medication. The Plaintiffs simply seek to be left alone, asserting their fundamental constitutional right to be free from governmental interference with the medication that is effective in easing the suffering and prolonging the lives of the Plaintiff patients. The Plaintiff patients need this Court’s protection to treat themselves with “remedies of [their] own confection:” natural medicinal herbs that Monson grows for herself and plants of Angel grown by two caregivers.⁵ These key facts distinguish *Carnohan*.

Rutherford, the other laetrile case relied upon by the Defendants, explicitly affirmed that “[t]he 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 (emphasis added). There is no indication that the plaintiff in *Rutherford* attempted to establish that the drug at issue represented the *only* effective treatment for him. Instead, he simply sought to have a particular type of treatment option declared to be a fundamental right.

This is a crucial distinction. Here, uncontroverted evidence establishes that cannabis is the only effective treatment for the Plaintiff patients.⁶ Therefore, to permit the government to interfere with their use of cannabis is to deny them the right explicitly recognized by *Rutherford* as “protected:” the right to decide whether or not to have medical treatment. Because cannabis is the *only* effective treatment for the Plaintiff patients, to deny them the right to use cannabis is to deny them any

⁵ Angel additionally processes cannabis oil for cooking, bakes cannabis foods, and makes therapeutic cannabis massage oil and skin balm. Angel Decl. ¶ 51. These certainly qualify as home remedies of her own confection.

⁶ Angel Decl. ¶¶ 2, 4, 6, 7, 8, 21, 23, 24, 32, 33, 36, 37, 39, 53, 55, 64; Declaration of Frank Henry Lucido, M.D. (“Lucido Decl.”) ¶¶ 6, 7; Monson Decl. ¶¶ 3, 9; Declaration of Dr. John Rose (“Rose Decl.”) ¶¶ 4, 5.

medical treatment at all. Cannabis is not simply their “medication of choice,” it is their only effective medication.

Moreover, as discussed in the preceding section, *supra*, this case, unlike the laetrile cases, presents a federal threat to the sovereign powers of the States. Unlike *Carnohan* and *Rutherford*, it is not merely an individual or small group who have asserted the value of cannabis to alleviate their suffering or prolong their lives. Here, the People of the State of California have made this judgment in exercising their reserved police power. Recently in *Oregon v. Ashcroft*, 192 F.Supp.2d 1077 (D. Or. 2002), the district court explicitly rejected the CSA as a federal edict that decides which medications are acceptable, and affirmed State sovereignty in the realm of regulation of the practice of medicine. “The determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. State statutes, state medical boards, and state regulations control the practice of medicine. The CSA was never intended . . . to establish a national medical practice or act as a national medical board.” *Id.* at 1092. To the States’ judgment, this Court should likewise defer.

Similarly distinguishable is *United States v. Cannabis Cultivators Club*, 1999 WL 111893 (N.D. Cal. 1999), *vacated and remanded*, 221 F.3d 1349 (9th Cir. 2000). In that suit patients promoted a right to *obtain* cannabis in commerce *from distributors*, not to treat themselves with remedies of their own confection, as is the case here.

Defendants misinterpret (Def. Br. at 18-20) the significance of the fact that the State of California and its voters recognize “*the right*” to use cannabis for medical purposes.⁷ Cal. Health & Safety Code § 11362.5(b)(1)(A) (emphasis added). The fact does not mean that a State law can somehow preempt a federal statute. Rather, its relevance is in providing invaluable guidance to judges in identifying fundamental rights.⁸ If a right is fundamental, then neither Congress (or people

⁷ Indeed, in every State in which voters have been given the opportunity, they overwhelmingly passed initiatives similar to California’s Proposition 215. See Plaintiffs’ opening Memorandum of Law in Support of Motion for Preliminary Injunction at 1, n.1.

⁸ Defendants (at Def. Br. 20, n.9) quote Professor Barnett out of context. In *Case Should Give Ninth Amendment New Life*, Portland Oregonian, April 11, 1999, Professor Barnett explained that judges should respect a liberty protected by the People when the People pass an initiative. In pertinent part, Defendants quote one and one-half sentences as follows: “* * * Does this mean that, if the people of the states voted to protect the liberty to use recreational drugs, or view child pornography, the courts should defer to their judgment? The simple answer is yes * * *.” Immediately following Defendants’ ellipsis, however,

such as Defendants, purporting to act pursuant to a congressional edict) nor a State legislature may “deny or disparage” such a right retained by the People, U.S. Const., Amend. IX, absent a compelling interest justifying a narrowly tailored statute.

Finally, Defendants (at Def. Br. 20) are, themselves, “remarkably unfamiliar” with the fact that California courts have consistently upheld the validity of the Compassionate Use Act. From the very first case interpreting the then-newly passed Act, (*People v. Trippet*, 56 Cal.App.4th 1532 (1997)) (transportation of medical cannabis is “an implied defense” under the Act) through the most recent case (*People v. Mower*, 28 Cal.4th 457 (2002) (protection provided under the Act is in the nature of immunity, not mere affirmative defense) (unanimous California Supreme Court)), no court has questioned the validity of the Act under the state or federal constitution. The California case cited by Defendants, *People v. Bianco*, 93 Cal.App.4th 748 (2001), involved a court’s discretion to impose *probation conditions* on a man convicted of cultivating nonmedical marijuana. Moreover, the case involved a claimed right to privacy, an issue not in question here.

VI. THE CLASSIFICATION OF MARIJUANA UNDER SCHEDULE I OF THE CSA DOES NOT PRECLUDE APPLICATION OF THE MEDICAL NECESSITY DOCTRINE.

The terms “medical necessity” under common law and “currently accepted medical use” under the CSA, 21 U.S.C. § 811, refer to two distinct concepts. Necessity is one of the oldest and most revered doctrines in Anglo-Saxon common law, and is frequently analyzed as a “balancing of harms” or a “choice of evils.”⁹ In contrast, “currently accepted medical use” is a technical five-part test promulgated by the DEA under which it may reclassify drugs from one schedule to another

Professor Barnett continued, “though it is hard to imagine a successful initiative on behalf of child pornography.” The omitted language, far from the extreme result implied by Defendants, buttresses Plaintiffs’ point -- that the initiative process is a safe, reasonable, and practical way for judges to defer to the judgment of the People when identifying unenumerated rights.

⁹ See e.g. Parry, *The Virtue of Necessity: Reshaping Culpability and the Rule of Law*, 36 Houston L. Rev. 397 (1999); Reeve, *Necessity: The Right to Present a Recognized Defense*, 21 New Eng. L. Rev. 779 (1986); Conde, *Necessity Defined: A New Role in the Criminal Defense System*, 29 UCLA L. Rev. 409 (1981); Arnolds & Garland, *The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil*, 65 J. Crim. L. & Criminology 289 (1974).

pursuant to criteria contained in 21 U.S.C. § 812(b).¹⁰ When the Supreme Court stated that “for purposes of the Controlled Substances Act, marijuana has ‘no currently accepted medical use’” *OCBC* at 491, the Court was essentially merely restating the obvious fact that marijuana was placed on Schedule I. Section 812(b), however, merely establishes the criteria for *administrative* classification or reclassification of drugs pursuant to 21 U.S.C. § 811. When *Congress directly* classifies a drug, as it did with marijuana in 1970, it is not bound by the criteria in Section 812(b).¹¹ Thus, mere placement of a substance on Schedule I *by Congress* implicates no congressional finding as to its currently accepted medical use, and that placement implies no judgment regarding the availability of medical necessity to justify use in exceptional specific circumstances that Congress could not have envisioned.

In fact, Congress placed marijuana on Schedule I at the specific behest of the Nixon administration, allegedly due to a “void in our knowledge of the plant and . . . at least until the completion of certain studies” H.R. Rep. No. 91-1444 (1970) *reprinted in* 1970 U.S.C.C.A.N. at 4579 & 4629.¹² Recently declassified Oval Office tapes reveal that the scheduling of marijuana was based on Richard Nixon’s racism, bigotry, misinformation, and hatred of political enemies, rather than on any factual findings regarding the medical use of cannabis. *See* Common Sense for Drug Policy (“CSDP”) Research Report, *Nixon Tapes Show Roots of Marijuana Prohibition: Misinformation, Culture Wars and Prejudice* (March 2002). The history of the scheduling of cannabis reveals no explicit or implicit rejection of the medical necessity doctrine by Congress.

¹⁰ *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994); 57 Fed. Reg. 10,506.

¹¹ In fact, Congress has directly classified drugs on Schedule I precisely because they *did* have an accepted medical use, and for that very reason they could not be *administratively* placed on Schedule I. For example, in 1984, Congress by statute ordered the transfer of methaqualone from Schedule II to Schedule I, even though it was universally acknowledged to have an accepted medical use. *See* Pub. L. 98-329, 98 Stat. 280 (1984); H.R. Rep. No. 98-534, 98th Congress, 2d Sess. 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 540.

¹² After thorough study, the Commission on Marijuana and Drug Abuse (the “Shafer Commission” created with the CSA) ultimately recommended the decriminalization of marijuana. *Marijuana: A Signal of Misunderstanding; First Report of the National Commission on Marijuana and Drug Abuse* (1972). Despite the Commission’s recommendation, Congress did not revisit the scheduling of cannabis.

Moreover, this Court of equity need not shut its eyes to the tremendous efficacy of cannabis for the specific Plaintiffs before this Court.¹³

OCBC, 532 U.S. 483 (Thomas, J.), was a case involving a distribution cooperative. As Justice Stevens pointed out in his concurrence, to the extent the Justice Thomas’s opinion may have purported to limit the application of the medical necessity doctrine beyond the facts of that case, the “opinion on this point is pure dictum,” 532 U.S. at 502 (Stevens, J., concurring), and in that regard it is not binding precedent.

VII. ALL THE EQUITABLE FACTORS IN THIS CASE JUSTIFY THE ENTRY OF A PRELIMINARY INJUNCTION.

Plaintiffs have demonstrated they meet all of the equitable factors justifying entry of the preliminary injunction. For the reasons stated herein and in the other pleadings and evidence filed with the Court, Plaintiffs have amply demonstrated their *likelihood of success* on the merits.

Plaintiffs face enormous *irreparable injury*. For example, “Chronic severe pain constitutes harm. Nausea and anorexia resulting in weight loss, risking malnutrition, cachexia, starvation, and *death*, constitute harm. Untreated seizures constitute harm. Post-traumatic stress disorder, inadequately treated, constitutes harm. . . . Angel could become *gravely ill* if she loses too much more weight.” Declaration of Frank Henry Lucido, M.D. ¶ 4 (emphasis added). It would be difficult to imagine a case involving greater irreparable harm than does this case, which literally concerns matters of life and death. Moreover, Plaintiffs require protection for constitutionally protected rights.

Similarly, the *balance of hardships* tips decisively for Plaintiffs. Plaintiffs face extreme suffering, pain, and death as actual or imminent realities. To countervail the genuine agony of Plaintiffs’ torment, the Defendants have adduced not one single shred of evidence to suggest what possible hardship they might encounter as a result of entry of the preliminary injunction.

¹³ Angel and Monson are seriously ill; will suffer imminent harm without access to cannabis; need cannabis to alleviate their medical conditions or their symptoms; and have no reasonable legal alternative to cannabis, having tried all other legal alternatives, which resulted in unacceptable side effects. Lucido Decl. ¶¶ 2, 3, 4, 6, 7; Rose Decl. ¶¶ 3-6.

The *public interest* positively compels granting the preliminary injunction. Not only will the injunction vindicate the policy enacted by the public itself -- in California and numerous other States -- in favor of the obvious interest in assuring that medical patients have access to medicine they need, but the injunction will also vindicate “principles of federalism that have left states as the primary regulators of professional conduct” involving public health matters. *Conant*, slip op. at 18 (Schroeder, C.J.), *citing Whalen v. Roe*, 429 U.S. 589 (1977) and *Linder v. United States*, 268 U.S. 5 (1925). As with the injunction affirmed in *Conant*, the injunction here will show “respect for the sovereign States that comprise our Federal Union.” *Conant*, slip op. at 19. Judge Kozinski eloquently described the public interest, with particular relevance to this case:

Those immediately and directly affected by the federal government’s policy are the patients . . . and the State of California, whose policy of exempting certain patients from the sweep of its drug laws will be thwarted. In my view, it is the vindication of these latter interests -- those of the patients and of the state -- that primarily justifies the district court’s highly unusual exercise of discretion in enjoining the federal defendants from even investigating possible violations of the federal criminal laws.

Id., slip op. at 21. Defendants quote from a congressional enactment that seems to imply there is not “valid scientific evidence” justifying the medical use of cannabis. Def. Br. at 23. Any such enactment would simply be factually incorrect. In fact, there is a large body of “valid scientific evidence” recognizing the therapeutic value of cannabis. *See, e.g., Conant*, slip op. at 21-26 (referring to various scientific studies). Defendants also indicate that Congress is the only source to which courts may refer when examining the public interest, and that “courts must defer to Congress’ considered judgment when” it is reflected in legislation. Def. Br. at 23. Such bootstrapping by Defendants is unavailing. Congress can no more be the sole judge of whether its legislation (or an action ostensibly taken pursuant thereto) is in the public interest than Congress can be the sole judge of whether its legislation is constitutional. That is especially true in a case such as this one, where the very constitutionality of legislation is in question.

Finally, Defendants claim that granting the preliminary injunction would provide a rationale for other plaintiffs to use drugs such as laetrile and that the injunction would undermine the FDA drug approval process. In the first place, any patients who cannot currently use or manufacture laetrile for their personal intrastate use without interference by the Defendants; those patients simply cannot buy the substance in commerce through drug stores. Secondly, Plaintiffs are not here seeking to alter the FDA approval process one whit. The FDA regulates the marketing of drugs in commerce; in contrast, the Plaintiff patients here simply need the safety to medicate with their own herbal treatments. The Plaintiff patients have actual and serious medical needs, and they would suffer the most grievous of consequences if Defendants deny them access to their medicine.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant the preliminary injunction to preserve the *status quo* during the pendency of these proceedings.

Dated: November 26, 2002

ROBERT A. RAICH
DAVID M. MICHAEL
RANDY E. BARNETT

By: _____
Robert A. Raich

Attorneys for Plaintiffs