IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

ANGEL McCLARY RAICH, et al.,

Plaintiffs-Appellants,

V.

ALBERTO GONZALES, as United States Attorney General, et al.,

Defendants-Appellees.

Remand from the United States Supreme Court, Case No. 03-1454 and Appeal from the United States District Court for the Northern District of California, Case No. C 02-4872 MJJ.

APPELLANTS' OPENING BRIEF

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Conant v. Walters, 309 F.3d 629 (9th Cir. 2002), cert. denied, 124 S. Ct. 387 (2003)	32, 36, 46
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Jacobson v. Massachusetts, 197 U.S. 11 (1905)	17
Koon v. United States, 518 U.S. 81 (1996)	9
Lawrence v. Texas, 539 U.S. 558 (2003)	passim
Leary v. United States, 395 U.S. 6 (1969)	27
Lovell v. Poway Unified School District, 90 F.3d 367 (9th Cir. 19	996)10
Loving v. Virginia, 388 U.S. 1 (1967)	16, 24
McConnell v. FEC, 540 U.S. 93 (2003)	54, 55

Meyer v. Nebraska, 262 U.S. 390 (1923)	16
Moore v. City of East Cleveland, 431 U.S. 494 (1977)	15, 23
New York v. United States, 505 U.S. 1447 (1992)	53, 54
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Pierce v. Society of Sisters, 268 U.S. 510 (1925)	16
Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992)	. passim
Prince v. Massachusetts, 321 U.S. 158 (1944)	16
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Raich v. Ashcroft, 352 F.3d 1222 (9th Cir. 2003)	1, 4
Raich v. Ashcroft, 248 F. Supp. 2d 918 (N.D. Cal. 2003)	.3, 8, 10
Rancho Viejo, LLC v. Norton, 334 F.3d 1158 (D.C. Cir. 2003)	56
Reninger v. Fagossa [1551] 1 Plowd. 1, 75 Eng. Rep. 1	48
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Reno v. Flores, 507 U.S. 292 (1993)	38
Richmond Newspapers v. Virginia, 448 U.S. 555 (1980)	11
Riggins v. Nevada, 504 U.S. 127 (1992)	21
Riley v. National Federation of the Blind of North Carolina, Inc., 487 U.S. 781 (1988)	46
Rochin v. California, 342 II.S. 165 (1952)	22

Roe v. Wade, 410 U.S. 113 (1973)	15, 28
Rutherford v. United States, 616 F.2d 455 (10th Cir. 1980)	33, 34
Sammartano v. First Judicial District Court, 303 F.3d 959 (9th Cir. 2002)	10
San Diego County Gun Rights Committee v. Reno, 98 F.3d 1121, 1125 (9th Cir. 1996)	12
Save Our Sonoran, Inc. v. Flowers, 408 F.3d 1113 (9th Cir. 2005)	8, 10
Schloendorff v. Society of New York Hospital, 105 N.E. 92 (N.Y. 1914)	18
Sell v. United States, 539 U.S. 166 (2003)	21
Skinner v. Oklahoma, 316 U.S. 535 (1942)	16
South Carolina v. Baker, 485 U.S. 505 (1988)	54
Sowell v. State, 738 So.2d 333 (Fla. Dist. Ct. App. 1998)	29
State v. Hastings, 801 P.2d 563 (Idaho 1990)	29
Stenberg v. Carhart, 530 U.S. 914 (2000)	passim
Thompson v. Western States Medical Center, 535 U.S. 357 (2002)	26, 41
Thornburgh v. American College of Obstetricians & Gynecologists, 476 U.S. 747 (1986)	37
Troxel v. Granville, 530 U.S. 57 (2000)	16
United States v. Aguilar, 883 F.2d 662 (9th Cir. 1989)	51
United States v. Arellano-Rivera, 244 F.3d 1119 (9th Cir. 2001)	51
United States v. Bailey, 444 U.S. 394 (1980)	, 49, 50
United States v. Jones, 231 F.3d 508 (9th Cir. 2000)	56

United States v. Mussari, 95 F.3d 787 (9th Cir. 1996)56, 57
United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483 (2001)
United States v. Oakland Cannabis Buyers' Cooperative, 190 F.3d 1109 (9th Cir. 1999), rev'd, 532 U.S. 483 (2001)
United States v. Peninsula Communications, Inc., 287 F.3d 832 (9th Cir. 2002)
United States v. Rutherford, 442 U.S. 544 (1979)
United States v. Rybar, 103 F.3d 273 (3d Cir. 1996)55
Washington v. Glucksberg, 521 U.S. 702 (1997)
Washington v. Harper, 494 U.S. 220 (1990)21, 45, 46
Whalen v. Roe, 429 U.S. 589 (1977)
Constitutional Provisions
U.S. Const. art. I, § 8, cl. 3 (Commerce Clause)
U.S. Const. art. I, § 8, cl. 18 (Necessary and Proper Clause)
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Codes and Statutes
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21 U.S.C. § 802(21)
21 U.S.C. § 812(b)(1)(B)

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21 U.S.C. § 844(a)	2, 52
28 U.S.C. § 1292(a)(1)	1
28 U.S.C. § 1331	1
28 U.S.C. § 2201	1
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Ala. Code § 20-2-111	29
Alaska Stat. § 11.71.090	29
Alaska Stat. § 17.37.010	29
Ariz. Rev. Stat. § 13-3412.01	29
Cal. Health & Safety Code § 11362.5	29
Cal. Health & Safety Code § 11362.81(d)	46
Colo. Const. Art. 18, § 4	29
Colo. Rev. Stat. § 18-18-406.3	29
Ga. Code Ann. § 43-34-120	29
Haw. Rev. Stat. Ann. § 329-121	29
720 Ill. Comp. Stat. 550/11	29
Iowa Code § 124.205	29
Iowa Code 8 124 206(7)(a)	29

La. Rev. Stat. Ann. § 40:1201
Mass. Gen. Law ch. 94D, §§ 1-3
Md. Code Crim. Law § 5-601(c)(3)29
Me. Rev. Stat. Ann. tit. 22, § 2383-B
Minn. Stat. § 152.21
Mont. Code Ann. § 50-46-102 et seq
Nev. Rev. Stat. Ann. § 453A.200
N.H. Rev. Stat. Ann. § 318-B:10(VI)
N.Y. Pub. Health Law § 3328(4) 3397-a et seq
Or. Rev. Stat. § 475.300 et seq
S.C. Code Ann. § 44-53-620
Va. Code Ann. § 18.2-251.1
Vt. Stat. Ann. tit. 18 § 4272
Wash. Rev. Code Ann. § 69.51.010 et seq
Other Authorities
Edward B. Arnolds & Norman F. Garland, <i>The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil</i> , 65 J. Crim. L. & Criminology 289 (1974)
BBC News, <i>The use of medicinal cannabis</i> (June 19, 2005), <i>available at</i> http://news.bbc.co.uk/1/hi/programmes/panorama/4104968.stm32
BBC News, <i>Timeline: the use of cannabis</i> (June 16, 2005), <i>available at</i> http://news.bbc.co.uk/1/hi/programmes/panorama/4079668.stm32

Dean Beeby, Select drugstores to sell pot: Feds starting pilot project early next year, Winnipeg Free Press, Sept. 14, 2005, at A3	1
Richard J. Bonnie & Charles H. Whitebread, <i>The Forbidden Fruit and the Tree of Knowledge: An Inquiry into the Legal History of American Marijuana Prohibition</i> , 56 Va. L. Rev. 971 (1970)	8
Guido Calabresi, A Common Law for the Age of Statutes (1982)4	9
Editorial, <i>Marijuana Research: Current restrictions on marijuana research are absurd</i> , Scientific American (Nov. 22, 2004), <i>available at</i> http://www.sciam.com/article.cfm?chanID=	
sa007&articleID=000A844E-8FBE-119B-8EA483414B7FFE9F	6
Editorial, Federal Foolishness and Marijuana, The New England Journal of Medicine, Vol. 336, No. 5 (Jan. 30, 1997)	6
Executive Office of the President, Office of National Drug Control Policy, Marijuana Fact Sheet (Feb. 2004), available at http://www.whitehousedrugpolicy.gov/publications/factsht/marijuana4.	2
nttp.// www.wintenousearagponey. gov/publications/ractsin/marijaana	_
The Gallup Poll, <i>Illegal Drugs</i> (Oct. 16, 2005)	0
General Accounting Office, Marijuana: Early Experiences with Four States' Laws that Allow Use for Medical Purposes (Nov. 2002), available at http://www.gao.gov/new.items/d03189.pdf	5
Lester Grinspoon & James B. Bakalar, <i>Marijuana as Medicine – A Plea for Reconsideration</i> , J. Am. Med. Ass'n, Vol. 273 No. 23 (June 21, 1995)25, 27	7
Jerome Hall, General Principles of the Criminal Law 416 (2d ed. 1960)4	8
The Harris Poll, Support for Roe vs. Wade Still Solid, But Not Overwhelming, on Twenty-Fifth Anniversary of Supreme Court Decision (Jan. 21, 1998)	0
Health Canada, <i>FAQ - Medical Use of Marihuana</i> (June 13, 2005), <i>available at</i> http://www.hc-sc.gc.ca/dhp-mps/marihuana/	1
about-apropos/faq e.html	1

Health Canada, Marihuana Medical Access Division, <i>Medical Use of Marihuana: Stakeholder Statistics – August 2005</i> , http://www.hc-sc.gc.ca/dhp-mps/marihuana/stat/2005/august-aout e.html (last visited	
Nov. 22, 2005)	31
Michael E. Hochman, <i>Native Americans' Use of Peyote Not Harmful</i> , Boston Globe, Nov. 7, 2005, at C3	47
Institute of Medicine, <i>Marijuana and Medicine: Assessing the Science Base</i> (Janet E. Joy <i>et al.</i> eds., 1999), <i>available at</i> http://www.nap.edu/books/0309071550/html	35 //5
nttp://www.nap.edu/000ks/03090/1330/ntmn	, 55, 45
Gary Lawson & Patricia B. Granger, The "Proper" Scope of Federal Power: A Jurisdictional Interpretation of the Sweeping Clause,	1.0
43 Duke L.J. 267 (1993)	12
<i>Matthew</i> , 12:3-4	48
Coleen McMurray, <i>Medicinal Marijuana: Is It What the Doctor Ordered?</i> , Gallup Poll Tuesday Briefing (Dec. 16, 2003)	30
Missouri Senate Concurrent Resolution 14 (1994)	29
New Mexico Senate Memorial 42 (1982), available at New Mexicans for Compassionate Use, http://www.sumeria.net/nmcu/memorial.html	29
Elizabeth Nash, <i>Spain's Health Ministry to allow doctors to prescribe cannabis</i> , The Independent on Sunday (UK), Feb. 6, 2005, at 22	32
Frank Newport, Six in 10 Americans Agree That Gay Sex Should Be Legal: Older Americans least likely to approve, Gallup News Service	
(June 27, 2003)	30, 31
Roger A. Nicoll & Bradley N. Alger, <i>The Brain's Own Marijuana</i> , Scientific American (Nov. 22, 2004)	36
Lars Noah, Challenges in the Federal Regulation of Pain Management Technologies, 31 J. Law, Med. & Ethics 55 (2003)	25, 27

Office of Medicinal Cannabis, <i>Frequently asked questions about Medicinal Cannabis</i> , http://www.cannabisoffice.nl/eng/index.html (last visited Nov. 22, 2005)	32
The Polling Report, Inc., <i>Illegal Drugs</i> (CNN/Time poll conducted by Harri Interactive from Oct. 23-24, 2002), <i>available at</i> http://www.pollingreport.com/drugs.htm	
State of California, Office of the Attorney General, Attorney General Bill Lockyer Releases Results From Student Drug and Alcohol Survey Showing Substantial Decline in Overall Alcohol and Drug Use (Sept. 18, 2000), available at http://caag.state.ca.us/newsalerts/2000/00-123.htm	,
State of California, Office of the Attorney General, Campaign Against Marijuana Planting Achieves Milestone for 2004 Eradication Season (Sept. 9, 2004), available at http://ag.ca.gov/newsalerts/2004/04-103.htm.	44, 45
Subcommittee on Alcoholism & Narcotics, Committee on Labor & Public Welfare of the U.S. Senate, <i>Marijuana and Health: A Report to the Congress from the Secretary, Department of Health, Education, and Welfare</i> (1971)	, 26, 27
United Kingdom Parliament, House of Lords, Select Committee on Science & Technology, <i>Ninth Report, Cannabis: The Scientific and Medical Evidence</i> (Nov. 4, 1998), <i>available at</i> http://www.publications.parliament.uk/pa/ld199798/ldselect/ldsctech/151/15101.htm	1
United States Department of Justice, Federal Bureau of Investigation, <i>Crime in the United States 2004, Section IV: Persons Arrested</i> , Table 46, <i>available at</i> http://www.fbi.gov/ucr/cius_04/documents/CIUS_2004_Section4.pdf	

STATEMENT OF JURISDICTION

The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 2201 because the Complaint arises under federal law and seeks an injunction and declaratory judgment. Excerpts of Record ("ER") 1. (The Excerpts of Record were filed with this Court on April 23, 2003.) This Court has jurisdiction under 28 U.S.C. § 1292(a)(1) because this is an appeal of the District Court's order of March 5, 2003, which denied Appellants' motion for a preliminary injunction. ER 250. Appellants filed a timely notice of appeal on March 12, 2003. ER 268. After this Court ruled for Appellants on Commerce Clause grounds, *Raich v. Ashcroft*, 352 F.3d 1222, 1234 (9th Cir. 2003), the Supreme Court vacated this Court's opinion and remanded the case to this Court for disposition of Appellants' remaining arguments, *Gonzales v. Raich*, 125 S. Ct. 2195, 2215 (2005).

STATEMENT OF ISSUES

1. Whether the Due Process Clause of the Fifth Amendment and the Ninth Amendment to the United States Constitution allow the federal government to prohibit a seriously ill patient from taking the only physician-recommended medication that enables her to avoid intolerable suffering and death, where such use of that medication is supported by a substantial body of medical opinion and an overwhelming majority of public opinion, and is authorized by the laws of ten States and other Western nations.

- 2. Whether the Controlled Substances Act (the "CSA") is subject to the common-law doctrine of necessity, so that the federal government may not prohibit a seriously ill individual patient from taking the only physician-recommended medication that enables her to avoid intolerable suffering and death.
- 3. Whether the CSA, which does not apply to medical use pursuant to a "valid" physician's "order" that complies with State law, 21 U.S.C. §§ 802(21), 844(a), nonetheless prohibits the possession and cultivation of cannabis pursuant to a physician's recommendation, as authorized by California law.
- 4. Whether the Tenth Amendment to the United States Constitution allows the federal government to control or influence a State's regulation of private parties' personal, non-commercial medical activities within its borders.

STATEMENT OF THE CASE

Angel Raich suffers from serious medical conditions. Decl. of Frank Lucido, M.D. ("Lucido Decl."), ER 88-91. Cannabis is the only medication that enables her to avoid intolerable pain and death. *Id.* As part of the federal government's still-ongoing campaign to use the Controlled Substances Act (the "CSA") to prohibit the medical use of cannabis, Drug Enforcement Administration agents raided former co-plaintiff Diane Monson's home on August 15, 2002, and

seized her cannabis.¹ Compl. ¶ 7, ER 3. Mrs. Raich, Mrs. Monson, and Mrs. Raich's caregivers filed the Complaint in this action on October 9, 2002, seeking a preliminary and permanent injunction barring the federal government from applying the CSA to their medically necessary activities and a declaratory judgment that such an application of the CSA would violate the Due Process Clause of the Fifth Amendment, the Ninth Amendment, the Tenth Amendment, the Commerce Clause, and the common-law doctrine of necessity. ER 10-13.

Appellants moved for a preliminary injunction on October 30, 2002. ER 20-21. The District Court found that the balance of hardships and the public interest tip sharply in favor of granting Appellants injunctive relief. It found that the interests asserted by the federal government "wane in comparison with the public interests enumerated by plaintiffs and by the harm that they would suffer if denied medical marijuana." *Raich v. Ashcroft*, 248 F. Supp. 2d 918, 931 (N.D. Cal. 2003). It further found that Appellants have submitted "strong evidence that [they] will suffer severe harm and hardship if denied use of [cannabis]." *Id.* at 930.

Nevertheless, it refused to issue a preliminary injunction on the ground that Appellants had not shown "a likelihood of success on the merits." *Id.* at 931.

Mrs. Monson recently decided to withdraw from this case.

This Court reversed, holding that Appellants were likely to succeed on their Commerce Clause argument, and determining that it was thus unnecessary to address their remaining arguments. *Raich*, 352 F.3d at 1234. This Court directed the District Court to enter a preliminary injunction "consistent with this opinion." *Id.* at 1235. The federal government petitioned for a writ of *certiorari*, which was granted. *Raich v. Ashcroft*, 542 U.S. 936 (2004). On May 14, 2004, while the *certiorari* petition was pending, the District Court entered a preliminary injunction barring the federal government from enforcing the CSA against Mrs. Raich and Mrs. Monson, and the federal government filed a separate appeal contesting the injunction. *Raich v. Gonzales*, No. 04-16296 (9th Cir. filed June 28, 2004).

On June 6, 2005, the Supreme Court held that "[t]he CSA is a valid exercise of federal power, even as applied to the troubling facts of this case," and remanded the case for disposition of the remaining issues raised the Appellants. *Raich*, 125 S. Ct. at 2201, 2215. The federal government moved in this Court for summary reversal and vacatur of the preliminary injunction entered by the district court. This Court granted the motion on September 6, 2005, in an order that also denied Appellants' motion to consolidate case numbers 03-15481 and 04-16296. On September 16, 2005, this Court ordered the proceedings in case number 04-16296 held in abeyance pending the disposition of the instant matter.

STATEMENT OF FACTS

The facts in this case are undisputed. Mrs. Raich has a daunting array of serious medical conditions, including a life-threatening wasting disorder. Her physician has determined that Mrs. Raich would suffer intolerable pain and death if she were prohibited from taking cannabis.

Mrs. Raich's physician, who is licensed by the State of California and is a Board-certified family practitioner, has determined that she suffers from medical conditions including:

life-threatening weight loss, nausea, severe chronic pain (from scoliosis, temporomandibular joint dysfunction and bruxism, endometriosis, headache, rotator cuff syndrome, uterine fibroid tumor causing severe dysmenorrheal, chronic pain combined with an episode of paralysis that confined her to a wheelchair), post-traumatic stress disorder, non-epileptic seizures, fibromyalgia, inoperable brain tumor (probable meningioma or Schwannoma), paralysis on at least one occasion (the diagnosis of multiple sclerosis has been considered), multiple chemical sensitivities, allergies, and asthma.

Lucido Decl. ¶ 3, ER 88. Mrs. Raich "has tried essentially all other legal alternatives to cannabis and the alternatives have been ineffective or result in intolerable side effects." *Id.* ¶ 7, ER 89-90. Her physician has provided a list of 35 medications that Mrs. Raich has tried, all of which cause her "unacceptable adverse side effects." *Id.* Most of them cause her to "vomit violently." *Id.* Other adverse side effects include "shakes," "itching," "nausea," "rapid heart

palpitations," and "insomnia." *Id.*² Mrs. Raich's physician has determined that she "has no reasonable legal alternative to cannabis for effective treatment or alleviation of her medical conditions or symptoms." *Id.*

From 1996 to 1999, Mrs. Raich was partially paralyzed and confined to a wheelchair. Decl. of Angel Raich ("Raich Decl.") ¶¶ 3, 22-23, ER 62, 70-72. In August 1997, after her physician concluded that her pain could not be controlled using conventional medications, Mrs. Raich attempted suicide to end her "excruciating" pain and suffering. *Id.* ¶ 28, ER 72. Thereafter, Mrs. Raich began using cannabis on her physician's recommendation, and her medical condition improved significantly. *Id.* ¶ 47, ER 79. She is no longer confined to a wheelchair. *Id.* ¶¶ 3, 23-24, ER 62, 71. She is better able to cope with her medical

One of these medications is Marinol, an FDA-approved medication that contains THC, a psychoactive component of cannabis and one of its medically beneficial compounds. Marinol is also an unacceptable alternative because it is less effective than cannabis. "It is well recognized that Marinol's oral route of administration hampers its effectiveness because of slow absorption and patients' desire for more control over dosing." Institute of Medicine, Marijuana and *Medicine: Assessing the Science Base* 205-06 (Janet E. Joy et al. eds., 1999) ("IOM Report"), available at http://www.nap.edu/books/0309071550/html. Because Marinol "is difficult to titrate," it "is not widely prescribed" and "patients are often disappointed with Marinol as compared with marijuana," which is "more likely to be therapeutic." Editorial, Marijuana Research: Current restrictions on marijuana research are absurd, Scientific American (Nov. 22, 2004), available at http://www.sciam.com/article.cfm?chanID= sa007&articleID=000A844E-8FBE-119B-8EA483414B7FFE9F (quoting Editorial, Federal Foolishness and Marijuana, The New England Journal of Medicine, Vol. 336, No. 5, at 366-367 (Jan. 30, 1997)).

conditions and plays a more active role in the lives of her two children. *Id.* $\P\P$ 3, 59-63, ER 62, 82, 84-85.

Mrs. Raich self-administers her medication using several delivery mechanisms. She often uses a vaporizer, *id.* ¶ 54, ER 82, which heats her cannabis to a temperature – below the burning point for combustible plant material – that evaporates the medically valuable cannabinoids without creating smoke. Mrs. Raich also takes her cannabis through other delivery mechanisms, including smoking, oils, balm, and foods. *Id.* ¶¶ 51, 54, ER 81-82.

Without cannabis, Mrs. Raich suffers from intolerable pain that "flares up immediately and becomes unmanageable." Lucido Decl. ¶ 4, ER 89. Among other things, Mrs. Raich's temporomandibular joint dysfunction and bruxism cause "severe chronic pain in [her] face and jaw muscles," Raich Decl. ¶ 36, ER 75, her fibromyalgia causes "severe chronic pain and chronic burning" that forces her to "be flat on [her] back for days," *id.* ¶ 39, ER 77, her non-epileptic seizures cause "excruciating pain," *id.* ¶ 42, ER 78, and her uterine fibroid tumor causes "heavy bleeding" and "severely painful menstrual periods," *id.* ¶ 45, ER 79.

In addition, cannabis is the only medication that has controlled Mrs. Raich's life-threatening wasting disorder. Her physician has concluded that she would likely suffer rapid death if she is denied medical cannabis. Lucido Decl. ¶ 8, ER 91 ("It could very well be fatal for Angel to forego cannabis treatments."). "It is

[his] opinion that Angel cannot be without cannabis as medicine because of the precipitous medical deterioration that would quickly develop." Id. ¶ 2, ER 88. "Angel becomes debilitated from severe chronic pain." Id. ¶ 4, ER 89. "[S]he clearly loses weight, and would risk wasting syndrome and death, without cannabis." Id., ER 88.

Mrs. Raich is unable to cultivate her cannabis. Raich Decl. ¶ 48, ER 80. She relies on her two caregivers, Appellants John Doe Number One and John Doe Number Two, to cultivate it for her. *Id.* ¶ 49, ER 80. Mrs. Raich's caregivers grow her cannabis specifically for her, pursuant to her instructions and on her physician's written recommendation, and they do so free of charge. *Id.*

SUMMARY OF ARGUMENT

Because the District Court has found that the interests asserted by the federal government "wane in comparison" with the harm that Mrs. Raich "would suffer if denied medical marijuana," *Raich*, 248 F. Supp. at 931, the only issue here is whether Appellants make a legal argument that presents "serious questions." *Save Our Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1120 (9th Cir. 2005). Appellants make four such arguments. *First*, the Due Process Clause of the Fifth Amendment and the Ninth Amendment bar the federal government from prohibiting Mrs. Raich from taking the only medication that enables her to avoid intolerable pain and death. Such a prohibition would violate Mrs. Raich's fundamental right to life and

her fundamental liberty interests in making life-shaping decisions, preserving bodily integrity, and avoiding intolerable pain. Nothing in the Constitution, however, prevents the federal government from regulating the medical activities at issue here, so long as any regulations do not substantially impede the exercise of the fundamental rights at issue. Second, the common-law doctrine of necessity bars the federal government from applying the CSA to prohibit the medically necessary activities at issue here. Third, the plain text of the CSA does not authorize the federal government to prohibit those activities. *Fourth*, and finally, the Tenth Amendment bars the federal government from enforcing the CSA against Appellants because such enforcement would control or influence California's regulation of private parties' personal, non-commercial medical activities within its borders. Accordingly, this Court should direct the District Court preliminary to enjoin the federal government from interfering with Mrs. Raich's medical cannabis activities.

ARGUMENT

Standards of Review. This Court reviews the denial of a preliminary injunction for abuse of discretion. *See United States v. Peninsula Communications, Inc.*, 287 F.3d 832, 839 (9th Cir. 2002). A ruling based on an erroneous legal conclusion is "by definition" an abuse of discretion. *Koon v. United States*, 518 U.S. 81, 100 (1996). This Court reviews a district court's legal

conclusions *de novo*. *See Lovell v. Poway Unified Sch. Dist.*, 90 F.3d 367, 370 (9th Cir. 1996). Here *de novo* review applies to all aspects of the District Court's ruling because it rests entirely on legal conclusions and the facts are "undisputed." *Sammartano v. First Judicial Dist. Court*, 303 F.3d 959, 964-65 (9th Cir. 2002).

"[T]he standard for granting a preliminary injunction balances the plaintiff's likelihood of success against the relative hardship to the parties." *Save Our Sonoran*, 408 F.3d at 1120 (internal quotation marks omitted). Under this standard, a preliminary injunction is proper where the plaintiff *either* satisfies the traditional four-factor test (which requires, among other things, a "strong likelihood of success on the merits") *or* "demonstrates *either* a combination of probable success on the merits and the possibility of irreparable injury *or* that serious questions are raised and the balance of hardships tips sharply in his favor." *Id.* (internal quotation marks omitted). Because the District Court found that the balance of hardships sharply favors Appellants, *Raich*, 248 F. Supp. 2d at 931, the issue here is whether it erred as a matter of law in determining that none of their legal arguments presents "serious questions."

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For ease of readability, Appellants do not refer to the "serious questions" standard throughout this brief, but instead present their arguments as if they must show that they *will* prevail on each argument. As explained in the text, however, they need only show "serious questions" on one of their arguments to prevail.

I. APPLICATION OF THE CSA TO MRS. RAICH WOULD VIOLATE THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT AND THE NINTH AMENDMENT.

It is improper for Congress to use its enumerated powers to violate fundamental rights. The Fifth Amendment's Due Process Clause and the Ninth Amendment preclude the federal government from applying the CSA to prohibit Appellants' activities. The Supreme Court has held "[i]n a long line of cases," Washington v. Glucksberg, 521 U.S. 702, 720-21 (1997), the most recent of which is Lawrence v. Texas, 539 U.S. 558 (2003), that neither the rights enumerated in the Constitution nor "the specific practices" that were approved at a particular time in our nation's history "marks the outer limits of the substantive sphere of liberty" that the Due Process Clause protects, Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 848 (1992) (citing U.S. Const. amend. IX); see also Richmond Newspapers v. Virginia, 448 U.S. 555, 579 (1980) (relying in part on the Ninth Amendment to protect an unenumerated right of access to public trials).

The Supreme Court's opinions in this "long line of cases" establish that Mrs. Raich has fundamental liberty interests in making life-shaping medical decisions that are necessary to preserve the integrity of her body, avoid intolerable physical pain, and preserve her life. As applied here, these broader fundamental liberty interests protect Mrs. Raich's decision to take the medication she needs. No longstanding historical prohibition suggests otherwise. To the contrary, the federal

government and the States have historically left such decisions to seriously ill patients and their physicians. Moreover, there is an emerging awareness that "liberty" protects such decisions in cases where, as here, a seriously ill patient's physician has determined that no other medication can save her from intolerable pain and death.

Under the "undue burden" standard set forth in *Casey*, *prohibiting* Mrs.

Raich from taking cannabis – which is what the federal government threatens to do – would violate the Due Process Clause. (Prohibiting her from taking cannabis would also violate the Ninth Amendment. However, because the Supreme Court has relied primarily on the Due Process Clause when protecting unenumerated rights, for simplicity Appellants will refer only to that constitutional provision for the remainder of this brief.⁴) Stringent *regulations* of medical cannabis use,

As a matter of original meaning, the protection of fundamental individual rights from federal interference resides in the word "proper" in the Necessary and Proper Clause and the Ninth Amendment rather than in the Due Process Clause of the Fifth Amendment. *See generally* Gary Lawson & Patricia B. Granger, *The "Proper" Scope of Federal Power: A Jurisdictional Interpretation of the Sweeping Clause*, 43 Duke L.J. 267, 297 (1993) ("the law would have to be within the 'proper' scope of the federal government's limited jurisdiction with respect to the people's retained rights"); Amicus Br. of Reason Foundation (discussing original meaning of the Ninth Amendment). In any event, the textual warrant to protect the rights at issue here does not affect the analysis. *See Casey*, 505 U.S. at 848 (citing Ninth Amendment as well as Due Process Clause). *But see San Diego County Gun Rights Committee v. Reno*, 98 F.3d 1121, 1125 (9th Cir. 1996) (rejecting a claim that "the Ninth Amendment protects an individual right to possess firearms").

however, are consistent with Mrs. Raich's fundamental liberty interests. So long as such regulations are "not designed to strike at the right itself" and do not have the "effect" of creating "a substantial obstacle" to its exercise, *Casey*, 505 U.S. at 874, 877, nothing in the Constitution prevents the federal government from requiring *extensive* safeguards to ensure that medical cannabis is not diverted or abused.

For instance, it would not violate the Due Process Clause to require that, after a licensed physician has recommended cannabis for a seriously ill patient, she must obtain a similar recommendation from one or more other licensed physicians before she can use or cultivate the medication. *Compare* Health Canada, *FAQ* - *Medical Use of Marihuana* (June 13, 2005), *available at* http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos/faq_e.html (requiring declaration from treating physician and confirmation from specialist). The Due Process Clause would also allow a requirement that a physician cannot recommend medical cannabis for a patient unless she has tried to obtain relief from a reasonable number of mass-produced synthetic medications.

The constitutional permissibility of such regulations – and of other, more demanding regulations – shows that the federal government can exercise its powers to promote its interests in preventing abuse and diversion of medical cannabis without trampling on Mrs. Raich's fundamental liberty interests. Recognizing

those interests forecloses *only* laws that completely prohibit or unduly burden their exercise,⁵ unless such laws are narrowly tailored to advance a compelling government interest. That is the only line this Court must draw.

A. Mrs. Raich Has a Fundamental Right to Life Itself and Fundamental Liberty Interests in Taking the Only Medication That Allows Her to Avoid Intolerable Pain and Death.

This case involves a right that is enumerated in the Due Process Clause – the right to "life" itself. *See* Lucido Decl. ¶¶ 2, 8, ER 88, 91 (without cannabis, Mrs. Raich's wasting disorder would likely kill her). The Due Process Clause also protects acts that involve one or more of three aspects of "liberty": making a critical decision about the course of one's life, preserving the integrity of one's body, or avoiding substantial physical pain. Mrs. Raich's interests in taking the only medication that enables her to avoid intolerable pain and death involve all three aspects of "liberty," and are thus "'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.'" *Glucksberg*, 521 U.S. at 721 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)). There is no longstanding history of prohibiting the activities at issue, and

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For example, although the John Does who enable Mrs. Raich to exercise her fundamental rights have no *independent* right to do so, denying Mrs. Raich any means by which she can have the cannabis she needs would unduly burden *her* fundamental rights. However, the Due Process Clause allows the federal government to regulate strictly the supply of cannabis to prevent it from being diverted to constitutionally unprotected uses.

there is an emerging awareness that liberty protects the right to engage in those activities. Mrs. Raich thus has fundamental liberty interests at stake here.

- 1. Mrs. Raich's freedom to engage in her medically necessary activities is implicit in the concept of ordered liberty.
 - a) The Due Process Clause protects acts that involve one or more of three aspects of liberty: making lifealtering decisions, preserving bodily integrity, and avoiding physical suffering.

The Supreme Court's opinions show that, in addition to life itself, the Due Process Clause protects acts that involve one or more of three separate, but often interrelated, aspects of "liberty."

The first aspect of "liberty" recognized in the Supreme Court's opinions is decisional autonomy – the individual's interest in making basic decisions about the course of her life without government interference. In part because "the Constitution demands [respect] for the autonomy of the person in making" lifeshaping "personal decisions," *Lawrence*, 539 U.S. at 573-74 (citing *Casey*, 505 U.S. at 851), the Supreme Court has held that the Due Process Clause protects such decisions on a wide range of matters, including:

- entering into intimate same-sex relationships, id. at 578;
- obtaining an abortion, *Roe v. Wade*, 410 U.S. 113, 153 (1973), and "choos[ing]" a particular medical procedure for doing so, *Stenberg v. Carhart*, 530 U.S. 914, 930 (2000);
- choosing the relatives with whom one wants to reside, *Moore v. City of East Cleveland*, 431 U.S. 494, 499 (1977);

- marrying the person of one's choice, without regard to race, *Loving v. Virginia*, 388 U.S. 1, 12 (1967);
- deciding "whether or not to beget or bear a child," *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977), and using contraceptives to avoid an unwanted pregnancy, *Griswold v. Connecticut*, 381 U.S. 479, 485-86 (1965);
- directing the upbringing of one's children and instilling preferred values in them, *Troxel v. Granville*, 530 U.S. 57, 65 (2000); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944); *Pierce v. Society of Sisters*, 268 U.S. 510, 534-35 (1925); *Meyer v. Nebraska*, 262 U.S. 390, 399-403 (1923); and
- retaining the ability to have children, *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942).

Because such decisions "involv[e] the most intimate and personal choices a person may make in a lifetime," they are "central to the liberty protected by" the Due Process Clause. *Lawrence*, 539 U.S. at 574 (quoting *Casey*, 505 U.S. at 851).

The second aspect of "liberty" is the individual's interest in preserving bodily integrity. This interest has arisen mainly in cases involving medical procedures. For example, in *Casey*, the Supreme Court emphasized that "the Constitution places limits on [the government's] right to interfere with a person's most basic decisions about . . . bodily integrity," and that prohibiting a pregnant woman from obtaining an abortion would violate her "very bodily integrity." 505 U.S. at 849, 896 (citations omitted). Similarly, the Supreme Court has indicated that the Due Process Clause requires judicial intervention to "protect the health and life of the individual concerned" when the government attempts to compel

vaccination of a person who is "not a fit subject of vaccination," *i.e.*, someone for whom, because of "a particular condition of his health or body," vaccination "would seriously impair his health, or probably cause his death." *Jacobson v. Massachusetts*, 197 U.S. 11, 36-39 (1905). Further, the Supreme Court has held that a patient's interest in obtaining medical care that is necessary to preserve bodily integrity is so fundamental that it trumps the government's interest in potential life – even *after* a fetus becomes viable. Thus, the government cannot ban a medical procedure that is "*necessary, in appropriate medical judgment, for the preservation of the life of the mother,*" because the Due Process Clause forbids the government from "endanger[ing] a woman's health" when regulating abortion methods. *Stenberg*, 530 U.S. at 930-31 (quoting *Casey*, 505 U.S. at 879) (emphasis in original).

The third aspect of "liberty" is the individual's interest in avoiding physical suffering. *Casey* shows that "liberty" includes the ability to obtain relief from pain, particularly when such relief is inextricably intertwined with preserving decisional autonomy and bodily integrity. In reaffirming the fundamental liberty interest in obtaining an abortion, the Supreme Court emphasized that forcing a pregnant woman to give birth would subject her "to pain that only she must bear," and that such "suffering is too intimate and personal" for the government to

prohibit the only medical procedure that can enable her to avoid it. *Casey*, 505 U.S. at 852.

In addition, five Justices on the current Supreme Court strongly suggested in their concurring opinions in *Glucksberg* that seriously ill persons have a fundamental liberty interest in taking a medication that is necessary to alleviate their severe pain. Justice O'Connor, joined by Justices Ginsburg and Breyer, indicated that "[a] patient who is suffering from a terminal illness and who is experiencing great pain" has a "constitutionally cognizable interest" in "obtaining medication, from qualified physicians, to alleviate that suffering." Glucksberg 521 U.S. at 736-37. Justice Souter similarly suggested that, for seriously ill patients suffering from intolerable pain, "liberty" includes "a right to determine what shall be done with [one's] own body' in relation to his medical needs." *Id.* at 777 (quoting Schloendorff v. Society of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.)). Finally, Justice Stevens said that "[a]voiding 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." Id. at 745 (quoting *Casey*, 505 U.S. at 851).

(Unlike *Glucksberg*, where the majority emphasized that the States had "consistently condemned and continue[d] to prohibit[] assisting suicide," *id.* at 719, the States have historically *allowed* – and during the past decade have

removed recently-minted prohibitions of – the activities at issue here. See Part I.A.2, infra at 23-29.)

b) Mrs. Raich's fundamental liberty interests are at stake because her medically necessary activities involve all three aspects of liberty.

All of the aspects of "liberty" discussed above are implicated here. Mrs. Raich seeks (1) the freedom to decide to take the only physician-recommended medication that can (2) preserve her bodily integrity by (3) enabling her to avoid intolerable pain and death.

First, applying the CSA to Mrs. Raich would prohibit her from making a fundamental decision about the course of her life – the decision to take the only physician-recommended medication that can enable her to avoid intolerable pain and death. The Supreme Court has assumed that "total prohibition" of "the right to decide independently, with the advice of his physician, to acquire and to use needed medication" would violate the Due Process Clause. Whalen v. Roe, 429 U.S. 589, 603 (1977). 6 More recently, it has held that the Due Process Clause

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Explicitly distinguishing cases "in which the Court held that a *total prohibition* of certain conduct was an impermissible deprivation of liberty," *Whalen* upheld regulations that applied to Schedule II controlled substances. 429 U.S. at 603-04 (emphasis added). It is unclear what was meant by the statement that the government "no doubt could prohibit entirely the use of *particular* Schedule II drugs." *Id.* (emphasis added). This may have been intended to point out that, depending on the circumstances, a particular drug can be classified in Schedule I without necessarily violating the Due Process Clause, or perhaps that (continued...)

forbids the government from impeding an individual's decision to obtain necessary medical care – even when, as with Mrs. Raich, the care at issue is "rarely used" and "most people do not need it." *Stenberg*, 530 U.S. at 934. Prohibiting this patient from choosing to take the medication she needs would override her "urgent claims" to "retain the ultimate control over her destiny and her body, claims implicit in the meaning of liberty." *Casey*, 505 U.S. at 869.

Second, prohibiting Mrs. Raich from taking her medication would violate her liberty interest in preserving her bodily integrity. "Liberty" equally protects the rights to act and to refrain from acting. The Due Process Clause equally forbids the government from compelling a person to refrain from acting and from compelling her to act. Prohibiting a person from choosing to undergo a medical procedure violates her liberty interest in preserving her bodily integrity just as much as does requiring her to undergo that procedure. For this reason, the Due Process Clause confers not only a right to avoid medical care, but also a right to obtain medical care. See Casey, 505 U.S. at 859 (if there were no right to an abortion, the government "might as readily restrict a woman's right to choose to

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the federal government can prohibit the use of a particular drug so long as an equally effective alternative is available for medical use by the individual patient at issue. In any event, this case involves a "total prohibition" of the sort that the *Whalen* Court condemned, *id.*, and the more recent decision in *Stenberg* confirms that the government cannot prohibit a person from choosing to obtain medical care that is necessary to avoid serious injury or death, *see* 530 U.S. at 930.

carry a pregnancy to term as to terminate it"). Therefore, the Supreme Court's opinions that "support the recognition of a general liberty interest in refusing medical treatment," *Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 278 (1990), also support "the patient's liberty, dignity, and freedom to determine the course of her own treatment," *id.* at 289 (O'Connor, J., concurring); *see also Glucksberg*, 521 U.S. at 777 (Souter, J., concurring in the judgment) (the "liberty interest in bodily integrity" includes "a right to determine what shall be done with [one's] own body in relation to his medical needs") (internal quotation marks omitted).

Likewise, because Mrs. Raich has a fundamental liberty interest in *avoiding* "forced medication," *Sell v. United States*, 539 U.S. 166, 179 (2003); *Riggins v. Nevada*, 504 U.S. 127, 134-35 (1992); *Washington v. Harper*, 494 U.S. 220, 221-22 (1990), she must also have a liberty interest in *taking* a medication that is necessary to avoid "a threat to her health," *Casey*, 505 U.S. at 880. Even prisoners have the right, albeit under the Eighth Amendment rather than the Due Process Clause, to be free of government interference with their physicians' medical decisions. *See Estelle v. Gamble*, 429 U.S. 97, 104-05 (1976) (prison guards violate Eighth Amendment by "denying or delaying access to medical care or intentionally interfering with the treatment once prescribed") (footnote omitted).

The same "liberty" that protects a competent person's right "to refuse lifesaving hydration and nutrition," *Cruzan*, 497 U.S. at 279, must also protect her right to take the only medication that can preserve her bodily integrity, *see* Lucido Decl. ¶ 7, ER 89 ("Angel has no reasonable legal alternative to cannabis"). Likewise, because "liberty" protects the individual from being forced by the government to vomit, *Rochin v. California*, 342 U.S. 165, 166 (1952), it must also protect her from being forced by the government to succumb to a wasting disorder, *see* Lucido Decl. ¶¶ 2, 8, ER 88, 91 (without cannabis, Mrs. Raich's wasting disorder would likely kill her).

Third, applying the CSA to Mrs. Raich would violate her "constitutionally cognizable interest" in taking the medication that a qualified physician has determined is necessary to alleviate her "great pain." Glucksberg 521 U.S. at 736-37 (O'Connor, J., joined by Ginsburg & Breyer, JJ., concurring). Without cannabis, her pain would "flare[] up immediately and become[] unmanageable." Lucido Decl. ¶ 4, ER 89. If the federal government applied the CSA to prevent Mrs. Raich from taking the medication she needs, she would be condemned to live the remainder of her days as "a captive" of intolerable pain and to suffer an avoidable death. Cruzan, 497 U.S. at 288 (O'Connor, J., concurring). Such "suffering is too intimate and personal" for the federal government "to insist" that Mrs. Raich endure it. Casey, 505 U.S. at 852.

Because all three central aspects of "liberty" are implicated here, Mrs. Raich has fundamental liberty interests at stake. *See id.* at 896 (restrictions on abortion were "doubly deserving of scrutiny" because they would interfere with multiple aspects of liberty). As Justice Powell wrote for the Court in one of the cases underlying its current approach to "liberty," "unless [this Court] close[s] [its] eyes to the basic reasons why certain rights . . . have been accorded shelter under the . . . Due Process Clause, [it] cannot avoid applying the[ir] force and rationale" here. *Moore*, 431 U.S. at 501.

2. History and tradition support protecting the activities at issue here.

To assess whether the prohibition of a particular activity is consistent with the Due Process Clause, the Supreme Court examines whether there is a "longstanding history in this country of laws directed at" those activities, and, if not, whether there is "an emerging awareness that liberty gives substantial protection to" those activities. *Lawrence*, 539 U.S. at 568, 572 (examining whether sodomy laws targeted "homosexual conduct as a distinct matter").⁷ As

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In *Lawrence*, the Supreme Court overruled *Bowers v. Hardwick*, 478 U.S. 186 (1986), in part because it concluded that historical prohibitions of sodomy were not targeted at homosexual conduct *per se*, *see Lawrence*, 539 U.S. at 568, but primarily because it concluded that, under *Casey*, such prohibitions violate the liberty interest in making life-shaping decisions about one's body, *see Lawrence*, 539 U.S. at 574 (Due Process Clause protects "the most intimate and personal (continued...)

explained below, there is no "longstanding history in this country" of laws prohibiting the medical use of cannabis by seriously ill patients. Moreover, there is an "emerging awareness" – as illustrated by recently enacted State laws and nationwide public opinion polls – that such use "is within the liberty of persons to choose without being punished as criminals." *Id.* at 567.

a) There is no longstanding history or tradition of prohibiting seriously ill persons from using cannabis on a physician's recommendation to avoid intolerable pain and death.

There is no longstanding history in this country of laws prohibiting the medical use of cannabis. It cannot be claimed, therefore, that such a prohibition is constitutional because it has existed traditionally or because its constitutionality has traditionally been accepted. To the contrary, no federal law regulated the

choices a person may make in a lifetime") (quoting *Casey*, 505 U.S. at 851); *id.* at 578 ("there is a realm of personal liberty which the government may not enter") (quoting *Casey*, 505 U.S. at 847). Significantly, it did so without finding that the particular liberty in question was deeply rooted in the nation's tradition and history and thus "fundamental."

Moreover, before and after *Glucksberg*, the Court has repeatedly recognized fundamental liberty interests in engaging in certain activities that were historically prohibited. *E.g.*, *Casey*, 505 U.S. at 846-53 (reaffirming fundamental liberty interest in obtaining abortion despite history of prohibiting it); *Loving*, 388 U.S. at 12 (recognizing "freedom to marry" person of one's choice as fundamental liberty interest despite States' centuries-old history of barring interracial marriage). Decisions such as these show that the Due Process Clause protects particular acts if the interests they implicate – not the particular acts themselves – have received historical recognition.

medical use of cannabis until 1937, no federal law prohibited the medical use of cannabis until the CSA was enacted in 1970, and the States generally allowed medical use of cannabis at least through the 1960s.

In the nineteenth century, American physicians "commonly" prescribed cannabis, and "[n]umerous reports in the literature described its therapeutic effectiveness [for] an extensive range of ailments." Subcommittee on Alcoholism & Narcotics, Committee on Labor & Public Welfare of the U.S. Senate, Marijuana and Health: A Report to the Congress from the Secretary, Department of Health, Education, and Welfare ("Subcommittee Report") 53 (1971). "Between 1840 and 1900, European and American medical journals published more than 100 articles on the therapeutic use of the drug known then as Cannabis indica (or Indian hemp) and now as marihuana." Lester Grinspoon & James B. Bakalar, Marijuana as Medicine – A Plea for Reconsideration, J. Am. Med. Ass'n, Vol. 273 No. 23 (June 21, 1995). Further, "the United States Pharmacopeia (U.S.P.), which Congress has cross-referenced in other statutes as a source for information about therapeutic products, [listed] marijuana as a drug for almost a century." Lars Noah, Challenges in the Federal Regulation of Pain Management Technologies, 31 J. Law, Med. & Ethics 55, 59 (2003).

Cannabis's popularity waned around the turn of the twentieth century, when mass-produced synthetic medications became available, although these synthetic

medications were "not always as effective and usually more toxic than Cannabis." Subcommittee Report at 54. The advantages of the mass-produced medications were that they were thought to be "easier to produce" and "more efficient to administer." Id. As the Supreme Court has recognized, however, such massproduced medications do not work for some "individual patient[s]." *Thompson v*. W. States Med. Ctr., 535 U.S. 357, 361 (2002) (recognizing importance of ensuring that such patients have access to compounded drugs). Perhaps for this reason, or perhaps because of the historical support for the medical use of cannabis, in 1915, when Utah became the first State to prohibit marijuana use, it "provided for medical use under a system of prescriptions and order blanks." Richard J. Bonnie & Charles H. Whitebread, The Forbidden Fruit and the Tree of Knowledge: An Inquiry into the Legal History of American Marijuana Prohibition, 56 Va. L. Rev. 971, 1012 & n.14 (1970). Likewise, when New Mexico and Texas enacted laws targeting marijuana in 1923, they "exempted medical purposes." *Id.* at 1013 n.18. This trend continued at least into the 1930s. By that time, a total of twenty-two States prohibited marijuana use – and *all* specifically exempted the medical use of cannabis. *Id.* at 1010, 1027, 1167.

"The first assertion of federal authority over marijuana use was the Marihuana Tax Act, passed in 1937." *Id.* at 1048. At the time, "there were 28 pharmaceutical preparations containing cannabis in use" in the United States.

Subcommittee Report at 54. The Marihuana Tax Act was directed at the abuse of marijuana for recreational purposes. See Leary v. United States, 395 U.S. 6, 23 (1969). It had the effect, however, of discouraging physicians from recommending the medical use of cannabis. Under the Act, persons could legally obtain marijuana only if they (1) paid a transfer tax of \$100 per ounce or (2) paid a transfer tax of \$1 per ounce, registered with the Internal Revenue Service, and filled out burdensome paperwork. Bonnie & Whitebread, *supra*, at 1062, 1084 n.6. Complying with these requirements was "expensive and inconvenient." IOM Report at 16. As a result, physicians stopped recommending cannabis for their patients, and marijuana was removed from the United States Pharmacopeia in 1941. Noah, supra, at 59; see also Grinspoon & Bakalar, supra ("Designed to prevent nonmedical use, [the Marihuana Tax Act] made cannabis so difficult to obtain for medical purposes that it was removed from the pharmacopeia.").

The States, however, continued to exempt the medical use of cannabis from their general marijuana prohibitions. By "late 1965, possession of any quantity of marihuana was apparently a crime in every one of the 50 States" – but "almost all States" had "exceptions" for "physicians," "certain other medical personnel," and "persons for whom the drug had been prescribed or to whom it had been given by an authorized medical person." *Leary*, 395 U.S. at 16-17. Medical use of cannabis did not become illegal under federal law until the CSA was enacted in 1970.

Bonnie & Whitebread, *supra*, at 1161, 1165. Thus, as with the laws at issue in *Lawrence*, laws prohibiting seriously ill patients from using cannabis on the recommendation of a licensed physician "did not develop until the last third of the 20th century." 539 U.S. at 570.

In sum, laws prohibiting the medical use of cannabis by seriously ill persons are of "relatively recent vintage." *Roe*, 410 U.S. at 129. Indeed, the history of such laws is much shorter than was the history of laws banning abortion at the time the Supreme Court recognized a fundamental liberty interest in that activity. Whereas the prohibitions on abortion that existed in 1973 "derive[d] from statutory changes effected, for the most part, in the latter half of the 19th century," *id.*, the federal prohibition on medical use of cannabis that exists today is only about 35 years old.

b) There is an emerging awareness of seriously ill patients' liberty interest in using cannabis on a physician's recommendation.

There is "an emerging awareness that liberty gives substantial protection" to Mrs. Raich's activities, *Lawrence*, 539 U.S. at 572, as evidenced by the recent and growing trend among the States and among other Western nations of allowing seriously ill patients like her to use cannabis on the recommendation of licensed physicians, *compare id.* at 570-73, 576-77 (examining State laws and decisions by European governments).

California is one of ten States that have enacted laws authorizing the use of cannabis for medical purposes. *See* Alaska Stat. §§ 11.71.090, 17.37.010; Cal. Health & Safety Code § 11362.5; Colo. Const. Art. 18, § 4; Colo. Rev. Stat. § 18-18-406.3; Haw. Rev. Stat. Ann. § 329-121; Me. Rev. Stat. Ann. tit. 22, § 2383-B; Mont. Code Ann. §§ 50-46-102 to -207; Nev. Rev. Stat. Ann. § 453A.200; Or. Rev. Stat. §§ 475.300 to .346; Vt. Stat. Ann. tit. 18 § 4272; Wash. Rev. Code Ann. §§ 69.51.010-.080. Each of these laws was enacted "[o]ver the course of the last decade []." *Lawrence*, 539 U.S. at 570.

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A total of 27 States recognize the medical benefits of cannabis in some form. In addition to the States whose laws authorize medical use in practice, five States recognize the medical benefits of cannabis but defer to the federal regime by authorizing use only by "prescription," Ariz. Rev. Stat. § 13-3412.01; La. Rev. Stat. Ann. § 40:1201; N.H. Rev. Stat. Ann. § 318-B:10(VI); Va. Code Ann. § 18.2-251.1, or by classifying cannabis as having "currently accepted medical uses," Iowa Code §§ 124.205, 124.206(7)(a). Two other States have passed resolutions urging the federal government to allow the medical use of cannabis. Mo. Sen. Con. Res. 14 (1994); N.M. Senate Memorial 42 (1982), available at http://www.sumeria.net/nmcu/memorial.html. Seven more States have enacted laws recognizing cannabis's potential medical benefits for persons suffering from various conditions. See Ala. Code § 20-2-111; Ga. Code Ann. §§ 43-34-120; 720 Ill. Comp. Stat. 550/11; Mass. Gen. Law ch. 94D, §§ 1-3; N.Y. Pub. Health Law §§ 3328(4) 3397-a to 3397-f; Minn. Stat. § 152.21; S.C. Code Ann. §§ 44-53-620. Courts in two additional States have allowed cannabis patients to raise a necessity defense to charges of marijuana possession. Sowell v. State, 738 So.2d 333, 334 (Fla. Dist. Ct. App. 1998); State v. Hastings, 801 P.2d 563, 565 (Idaho 1990). Finally, Maryland recently limited the penalty for possessing cannabis for medical purposes to a \$100 fine. Md. Code Crim. Law § 5-601(c)(3).

Additional States are likely to enact similar laws in the near future.

Nationwide public opinion polls show that an overwhelming majority of

Americans favors allowing medical use of cannabis. Last month, a poll found that
78% of Americans favor "making marijuana legally available for doctors to
prescribe in order to reduce pain and suffering." The Gallup Poll, *Illegal Drugs*(Oct. 16, 2005). Polls conducted in 2002 and 2003 found similar levels of support
– 80% and 75%, respectively – for taking cannabis to alleviate "pain and
suffering." The Polling Report, Inc., *Illegal Drugs* (CNN/Time poll conducted by
Harris Interactive from Oct. 23-24, 2002), *available at*http://www.pollingreport.com/drugs.htm; Coleen McMurray, *Medicinal Marijuana: Is It What the Doctor Ordered?*, Gallup Poll Tuesday Briefing (Dec.
16, 2003).

These levels of support for the medical use of cannabis are higher than both the level of support for abortion when *Casey* was decided and the level of support for intimate same-sex relationships when *Lawrence* was decided. *See* The Harris Poll, *Support for Roe vs. Wade Still Solid, But Not Overwhelming, on Twenty-Fifth Anniversary of Supreme Court Decision* (Jan. 21, 1998) (recounting 1992 poll's finding that 61% of Americans supported the part of *Roe* "making abortions up to three months of pregnancy legal"); Frank Newport, *Six in 10 Americans Agree That Gay Sex Should Be Legal: Older Americans least likely to approve*, Gallup

News Service (June 27, 2003) ("About 6 out of 10 Americans believe that homosexual relations between consenting adults should be legal, essentially the Supreme Court's position in its decision in the Lawrence v. Texas case.").

Further, other Western nations' governments have recently authorized the medical use of cannabis by seriously ill patients who have conditions that cause them severe pain or suffer from a life-threatening wasting disorder, and for whom other medications are ineffective or cause intolerable side effects. For instance, since 2001, Health Canada – the Canadian equivalent of the U.S. Department of Health and Human Services – has authorized patients suffering from "[s]evere pain, cachexia, anorexia, weight loss, and/or severe nausea" to take cannabis "if a specialist confirms the diagnosis and that conventional treatments have failed or judged inappropriate to relieve symptoms of the medical condition." Health Canada, *FAQ - Medical Use of Marihuana*, *supra*. Similarly, since 2003, the Netherlands has allowed the medical use of cannabis, pursuant to a physician's

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The Canadian government currently authorizes 858 patients to possess cannabis for their medical use. Health Canada, Marihuana Medical Access Division, *Medical Use of Marihuana: Stakeholder Statistics – August 2005*, http://www.hc-sc.gc.ca/dhp-mps/marihuana/stat/2005/august-aout_e.html (last visited Nov. 22, 2005). Most of these patients "grow the plant themselves," while the remainder obtain it from government-approved growers. Dean Beeby, *Select drugstores to sell pot: Feds starting pilot project early next year*, Winnipeg Free Press, Sept. 14, 2005, at A3. Health Canada recently announced a plan to sell government-certified cannabis in pharmacies. *Id.*

prescription, for serious medical conditions including "long term pain." BBC News, *The use of medicinal cannabis* (June 19, 2005), *available at* http://news.bbc.co.uk/1/hi/programmes/panorama/4104968.stm. ¹⁰ Earlier this year, Spain established a pilot project under which "60 pharmacies and four hospitals in Catalonia are to prescribe marijuana for therapeutic use where other treatments have failed." Elizabeth Nash, *Spain's Health Ministry to allow doctors to prescribe cannabis*, The Independent on Sunday (UK), Feb. 6, 2005, at 22. One of the indications for cannabis approved by Spanish authorities is "constant pain" that "has been unresponsive to other treatments." *Id*. ¹¹

In sum, a substantial and growing number of States and foreign governments authorize seriously ill patients like Mrs. Raich to engage in the activities at issue.

Because her activities are also implicit in the concept of ordered liberty, her fundamental liberty interests are at stake.

The Dutch government has sold government-certified cannabis in pharmacies since 2003. *See* Office of Medicinal Cannabis, *Frequently asked questions about Medicinal Cannabis*, http://www.cannabisoffice.nl/eng/index.html (last visited Nov. 22, 2005).

Further, the British House of Lords has recommended that the British government allow the medical use of cannabis. *See Conant v. Walters*, 309 F.3d 629, 641-42 (9th Cir. 2002) (Kozinski, J., concurring), *cert. denied*, 124 S. Ct. 387 (2003). Parliament has yet to follow that recommendation, though Prime Minister Tony Blair has agreed that medical use of cannabis should be permitted. *See* BBC News, *Timeline: the use of cannabis* (June 16, 2005), *available at* http://news.bbc.co.uk/1/hi/programmes/panorama/4079668.stm.

c) The substantial evidentiary and governmental support for Mrs. Raich's medical use of cannabis limits the effects of recognizing her fundamental liberty interests.

This would be a very different case if Mrs. Raich were asserting a right to use a substance for which there is no medical evidence of effectiveness.

Prohibiting a person from using a drug that has no substantiated medical benefits cannot violate her constitutional rights, which is one reason why classifying drugs such as LSD in Schedule I does not present a constitutional issue. There is substantial evidence supporting the medical use of cannabis, however, which renders the prohibition of such use unconstitutional as applied to Mrs. Raich.

Before examining this evidence, it is helpful to recognize that this case differs in several respects from the cases involving laetrile, a cyanide-producing plant compound (usually derived from apricot pits) that – without any scientific support – was claimed to prevent and treat cancer. *First*, in *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980), the plaintiff was seeking to legalize "laetrile traffic" so he could "obtain" laetrile in commerce. *Id.* at 1121-22. The Court thus said it "need not decide" whether there is a constitutional right to use "home remedies of [one's own] confection." *Id.* The issue here, by contrast, is whether Mrs. Raich has a constitutional right to use a needed medication cultivated by her caregivers in their home gardens specifically for her. *Second*, Mrs. Raich is not asserting a right to the "selection of a particular treatment," *Rutherford v. United*

States, 616 F.2d 455, 457 (10th Cir. 1980) (emphasis added), because her physician has determined that cannabis is the *only* medication that can alleviate her conditions. *Third*, Mrs. Raich is not seeking to compel the federal government to authorize the marketing of any substance or to take any other affirmative action. Instead, she seeks only to be left alone so she may follow her physician's recommendation by using the medication she needs. *Compare United States v. Rutherford*, 442 U.S. 544, 552 (1979) (rejecting attempt to compel FDA to promulgate regulations allowing laetrile to be *marketed* to terminally-ill cancer patients, without deciding any constitutional issue).

More fundamentally, substances such as laetrile that are not *effective* in alleviating or treating serious medical conditions *cannot* preserve a person's bodily integrity or enable him to avoid intolerable pain, and thus do not implicate the "liberty" protected by the Due Process Clause. The freedom to ingest a substance for which there is "no affirmative, reliable evidence of effectiveness," *Rutherford*, 616 F.2d at 457 (internal quotation marks omitted), therefore is not implicit in the concept of ordered liberty.

Here, however, "substantial medical authority," *Stenberg*, 530 U.S. at 938, supports Mrs. Raich's medical use of cannabis and substantially undermines the federal government's decision – as applied to her – to classify marijuana as a Schedule I controlled substance with "no currently accepted medical use in

treatment in the United States," 21 U.S.C. § 812(b)(1)(B), (c). For example, a report commissioned by the White House Office of National Drug Control Policy and carried out by the Institute of Medicine – the medical component of the National Academy of Sciences – concluded that "the accumulated data suggest a variety of indications, particularly for pain relief, antiemesis, and appetite stimulation," and that "[f]or patients such as those . . . who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broadspectrum relief *not found in any other single medication*." IOM Report at 177 (emphasis added).

The Institute of Medicine also concluded that currently "there is *no clear alternative* for people suffering from *chronic* conditions that might be relieved by smoking marijuana, such as pain and AIDS wasting." *Id.* at 179 (first emphasis added). Moreover, the Institute of Medicine found that, "except for the harm associated with smoking, the adverse effects of marijuana use are within the range tolerated for other medications," and in any event, "for certain patients, such as the terminally ill or those with debilitating symptoms, the long-term risks are not of great concern." *Id.* at 126. Mrs. Raich is one of these patients. She takes cannabis largely through delivery mechanisms other than smoking – a vaporizer, oils, foods, and balms, Raich Decl. ¶¶ 51, 54, ER 81-82 – and without cannabis she would suffer from "unmanageable" pain and likely die, Lucido Decl. ¶¶ 4, 8, ER 89, 91.

Other government reports and many peer-reviewed studies also have found that cannabis is effective in alleviating conditions such as severe pain, nausea, and wasting. For example, Britain's House of Lords reviewed the scientific evidence and reported that it was "convince[d]" that "cannabis almost certainly does have genuine medical applications, especially in treating the painful muscular spasms and other symptoms of [multiple sclerosis] and in the control of other forms of pain." United Kingdom Parliament, House of Lords, Select Committee on Science & Technology, Ninth Report, Cannabis: The Scientific and Medical Evidence, § 8.2 (Nov. 4, 1998) (emphasis added), available at http://www.publications.parliament.uk/pa/ld199798/ldselect/ldsctech/151/15101.ht m. Similarly, "[n]umerous" studies "support the use of medical marijuana" by patients who, like Mrs. Raich, are among the "small class of patients who do not respond well to, or do not tolerate, available prescription drugs." Conant, 309 F.3d at 640-42 (Kozinski, J., concurring). For these patients, "medical marijuana can make the difference between a relatively normal life and a life marred by suffering." *Id.* at 643. More recently, studies reported in well-known medical journals have found that cannabis "has clear medicinal benefits" – among other things, it "alleviates pain," "suppresses vomiting," and "enhances appetite." Roger A. Nicoll & Bradley N. Alger, The Brain's Own Marijuana, Scientific American (Nov. 22, 2004).

The Supreme Court has observed in this case that such evidence of the medical benefits of cannabis, if established at trial, "would cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I." *Raich*, 125 S. Ct. at 2211 n.37. To prevail here, however, Mrs. Raich need not establish that marijuana's Schedule I classification is erroneous. It is sufficient that she demonstrate, as she has done, that "a significant body of medical opinion," *Stenberg*, 530 U.S. at 937, supports her medical use of cannabis, and that the undisputed evidence in this case shows that cannabis enables Mrs. Raich to avoid intolerable pain and death.¹²

Moreover, as explained above, a substantial number of States and other Western nations allow seriously ill patients to take cannabis to alleviate various conditions – including those from which Mrs. Raich suffers – on the recommendation of a licensed physician. *See supra* at 28-29, 31-32. That so many sovereign governments have authorized Mrs. Raich's medical uses of cannabis provides "easily ascertainable boundaries," *Thornburgh v. Am. College of Obstetricians & Gynecologists*, 476 U.S. 747, 771 (1986) – *i.e.*, objective markers

The Supreme Court has recognized that Appellants have made "strong arguments" that "marijuana does have valid therapeutic purposes." *Raich*, 125 S. Ct. at 2201. These arguments are supported by the declarations of Mrs. Raich and her physician, and are not disputed by any evidence in the record. At this stage of the proceedings, the federal government must take the record as it stands.

– for determining when the fundamental liberty interests at issue here are infringed. A simple inquiry into whether the objective markers are present forecloses claims to use Schedule I controlled substances that lack any medical value. For instance, because no State or foreign nation authorizes the use of Schedule I controlled substances such as LSD, GHB, or peyote for medical purposes, a claim that "liberty" protects such use would quickly be dismissed because the objective markers would be absent. By contrast, the objective markers' presence here means that the Court need not rely solely on its own judgment about the medical efficacy of cannabis to protect Mrs. Raich's fundamental liberty interests.

B. Prohibiting Mrs. Raich From Taking the Medication She Needs to Avoid Intolerable Pain and Death Would Violate the Due Process Clause.

When a government action infringes on a fundamental liberty interest, the Supreme Court generally applies strict scrutiny, meaning that the action is unconstitutional unless it is narrowly tailored to serve a compelling government interest. *Reno v. Flores*, 507 U.S. 292, 302 (1993). In medical contexts, however, the government has a countervailing interest in protecting the public health. The Supreme Court has accounted for this by applying the "undue burden" test, which allows the government to impose regulations that do not prohibit or substantially impede the exercise of the fundamental liberty interests at issue. *See Stenberg*, 530

U.S. at 930; *Casey*, 505 U.S. at 871-79.¹³ The undue burden test is the appropriate means of reconciling the government's countervailing interest in protecting the public health with Mrs. Raich's fundamental liberty interests.

Under the "undue burden" test, "not every law which makes [the] right more difficult to exercise is, *ipso facto*, an infringement of that right." *Casey*, 505 U.S. at 873. Regulations that do not prohibit or substantially impede the exercise of the right are permissible. *See id.* at 878 (regulation is permissible so long as "its purpose or effect" does not "present[] a substantial obstacle" to a woman seeking an abortion). Such regulations reconcile the government's interest in promoting the public health – its "legitimate interests in the health of the woman" – with the individual's fundamental liberty interests. *Id.* at 871.

Indeed, the government may *prohibit* (as opposed to merely regulate) an individual's exercise of her fundamental liberty interest when it directly threatens another life or potential life – so long as it does not prohibit an individual from deciding to obtain medical care that "is necessary, in appropriate medical judgment," to "preserv[e]" *her own* "life or health." *Stenberg*, 530 U.S. at 931 (quoting *Casey*, 505 U.S. at 879). The Court's holdings in *Casey* and *Stenberg* that

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The "undue burden" standard applies not only in medical contexts, but also in some other contexts where the government has a powerful countervailing interest, such as the voting context. *See Casey*, 505 U.S. at 873-74 ("not every ballot access limitation amounts to an infringement of the right to vote").

the government cannot prohibit an individual from preserving her "life or health" underscore the fundamental nature of the liberty interests that are threatened here.

Although *prohibiting* Mrs. Raich from taking the medication she needs would unduly burden her fundamental liberty interests, ruling in her favor would *not* prevent the federal government from imposing *regulations* short of complete prohibition on the medical use of cannabis to serve its legitimate interest in protecting the public health. Indeed, the federal government can *heavily* regulate the activities at issue without unduly burdening the fundamental liberty interests at stake, so long as it does not "plac[e] a substantial obstacle in the path of" Mrs. Raich's ability to avoid intolerable pain and death. *Casev*, 505 U.S. at 877.¹⁴

1. Prohibiting Mrs. Raich from taking the medication she needs unduly burdens her fundamental liberty interests.

Prohibiting Mrs. Raich from taking the only medication that enables her to avoid intolerable pain and death would constitute not only a "substantial obstacle" to the exercise of her fundamental liberty interests in obtaining necessary medical care, *Casey*, 505 U.S. at 877, but also a complete denial of those interests. The

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For this reason, the federal government's classification of cannabis in Schedule I is not at issue. The question here is whether the federal government can *apply* the CSA to prohibit Mrs. Raich from taking the cannabis she needs to maintain her health, or to prohibit her caregivers from growing it for her in their home gardens and thereby enabling her to avoid intolerable pain and death.

federal government would unduly burden Mrs. Raich's fundamental liberty interests if it applied the CSA to her.

2. The federal government cannot justify prohibiting Mrs. Raich from taking her medication.

The federal government cannot justify condemning Mrs. Raich to intolerable pain and death. It has no countervailing interest that compares to the powerful government interests, such as the interests in protecting potential and actual human life, that were involved in cases upholding restrictions on the types of fundamental liberties at issue here. See Casey, 505 U.S. at 871; Cruzan, 497 U.S. at 281; see also Glucksberg, 521 U.S. at 767 n.8 (Souter, J., concurring in the judgment) (a "law that creates a 'substantial obstacle' for the exercise of a fundamental liberty interest requires a *commensurably substantial* justification") (quoting *Casey*, 505) U.S. at 877) (emphasis added). To the contrary, though it does not assert it in this case, the federal government actually "has an important interest" in *enabling* patients like Mrs. Raich – "patients with particular needs" that cannot be addressed with mass-produced conventional medications – to use "medications suited to those needs." *Thompson*, 535 U.S. at 369. The federal government can fully realize its legitimate interests in preventing abuse of cannabis by imposing stringent regulations on medical use, just as it has done with other controlled substances that are susceptible to abuse, such as cocaine, oxycodone, morphine, methadone, and methamphetamine.

Moreover, unlike a Commerce Clause challenge subject to mere "rational basis" review, *Raich*, 125 S. Ct. at 2208, the "undue burden" standard applies here because fundamental liberty interests are at issue. Thus, the federal government must introduce *empirical evidence* to justify applying its complete prohibition on the medical use of cannabis to Mrs. Raich. *See Stenberg*, 530 U.S. at 931-38 (rejecting the government's rational reasons for prohibiting the medical procedure at issue, examining the evidence in the record, and concluding that it did not support the prohibition that the government was attempting to defend).

Further, "[t]he quantum of empirical evidence needed to satisfy heightened judicial scrutiny . . . will vary up or down with the . . . plausibility of the justification raised." *Nixon v. Shrink Mo. Gov't PAC*, 528 U.S. 377, 391 (2000). It is implausible that seriously ill patients like Mrs. Raich threaten to undermine law enforcement efforts against marijuana, given factors including (i) the small number of such medical cannabis patients, as contrasted with the vast scope of the illegal traffic and non-medical use of marijuana, ¹⁵ (ii) their inability, because of their

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The federal government reports that 40.4% of Americans over age 12 – approximately 94,900,000 people – have used marijuana for recreational purposes. Executive Office of the President, Office of National Drug Control Policy, *Marijuana Fact Sheet* (Feb. 2004), *available at* http://www.whitehousedrugpolicy. gov/publications/factsht/marijuana. By contrast, medical cannabis patients constituted "0.5 percent or less" of the population in each of the four California counties that maintained patient registries as of 2002. GAO, *Marijuana: Early* (continued…)

conditions, to engage in crime, and (iii) the current availability for medical use of other controlled substances that are subject to abuse. Because the undisputed evidence shows that cannabis is necessary to preserve Mrs. Raich's life and to alleviate her severe pain and suffering, the federal government must meet an especially heavy burden of evidentiary proof before it may constitutionally prohibit her medical cannabis activities. In this context, it should be dispositive that the federal government has failed to introduce *any* evidence to justify applying the CSA to Mrs. Raich.

In any event, the federal government could not have substantiated its position even if it had tried to do so. As discussed above, the federal government can prevent abuse and diversion of medical cannabis by implementing commonsense regulations that stop short of prohibiting the medically necessary activities at issue here. Moreover, there is simply no evidence that allowing seriously ill patients to take cannabis undermines law enforcement efforts against marijuana.

Medical cannabis patients such as Mrs. Raich are unlikely to cause problems for law enforcement officials for two reasons. *First*, their serious illnesses render them physically unable to engage in trafficking or diversion. *Second*, they are generally more than 40 years old, *see* GAO Report at 23 ("[m]ost" medical

Experiences with Four States' Laws that Allow Use for Medical Purposes 22 (Nov. 2002) ("GAO Report"), available at http://www.gao.gov/new.items/d03189.pdf.

cannabis registrants in Hawaii and Oregon are "over 40 years old"), and persons over age 40 are much less likely than younger persons to commit crimes, *see* Dep't of Justice, Fed. Bureau of Investigation, *Crime in the United States 2004, Section IV: Persons Arrested*, Table 46, *available at* http://www.fbi.gov/ucr/cius_04/docu ments/CIUS_2004_Section4.pdf (approximately 80% of arrests in 2004 were of persons younger than age 40). There is no evidence that law enforcement interests, such as targeting drug trafficking or preventing abuse or diversion of marijuana, justify prohibiting Mrs. Raich from taking the medication she needs. To the contrary, the public record indicates that allowing such seriously ill patients to take the medication they need does not adversely affect law enforcement efforts against trafficking, abuse, and diversion.

The medical use of cannabis in the States that allow such use has not impeded federal law enforcement efforts, as illustrated by the GAO's finding that "the federal process of using a case-by-case review of potential marijuana prosecutions *has not changed* as a consequence of the states' medical marijuana laws." GAO report at 32 (emphasis added). Indeed, California officials have had *more* success against illegal marijuana trafficking since the State enacted the Compassionate Use Act. Last year, they announced record-breaking seizures of 471,128 plants "worth an estimated \$1.88 billion" from "large-scale illegal marijuana grows." State of California, Office of the Attorney General, *Campaign*

Against Marijuana Planting Achieves Milestone for 2004 Eradication Season (Sept. 9, 2004), available at http://ag.ca.gov/newsalerts/2004/04-103.htm.

There is also no evidence that allowing the medical use of cannabis results in a material increase in abuse or diversion of marijuana. The Institute of Medicine found "no convincing data to support th[e] concern that sanctioning medical use of marijuana might increase its use among the general population." IOM Report at 104. Similarly, "none of the federal officials [the GAO] spoke with provided information to support a statement that abuse of medical marijuana laws was routinely occurring in any of the states including California." GAO Report, supra, at 37. To the contrary, after California enacted the Compassionate Use Act in 1996, adolescents' use of marijuana "substantial[ly] decline[d]." State of California, Office of the Attorney General, Attorney General Bill Lockyer Releases Results From Student Drug and Alcohol Survey Showing Substantial Decline in Overall Alcohol and Drug Use (Sept. 18, 2000), available at http://caag.state.ca.us/ newsalerts/2000/00-123.htm (from 1997-98 to 1999-2000, the percentage of students who had used marijuana declined from 32.5% to 20% for 9th-graders, and from 42% to 35% for 11th-graders).

Nor is there any evidence – either in the record or elsewhere – that a significant number of physicians are abusing or diverting cannabis, and this Court should not assume that physicians will abuse their responsibilities. *See Harper*,

494 U.S. at 222-23 n.8 ("we will not assume that physicians will prescribe . . . drugs for reasons unrelated to the medical needs of the[ir] patients"). Moreover, California law bars physicians from abusing their authority to recommend cannabis, *see Conant*, 309 F.3d at 647 (physician "will run afoul of state as well as federal law" if he recommends cannabis improperly), and this Court must "presume that [State] law enforcement officers are ready and able to enforce" the law, *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988).

Because there is no evidence that patients are abusing or diverting cannabis, this Court must also presume that the California Attorney General is implementing its statutory mandate to "ensure the security and nondiversion of marijuana grown for medical use by patients qualified under the Compassionate Use Act." Cal. Health & Safety Code § 11362.81(d). If the federal government deems California's efforts to regulate medical use of cannabis insufficient, it can impose stringent regulations of the sorts discussed above without infringing the fundamental rights at issue here.

In this context, it is notable that the religious use of peyote shows that a narrow right to use a Schedule I controlled substance for a discrete purpose does not adversely affect law enforcement efforts. Federal law authorizes "the use, possession, or transportation of peyote by an Indian for bona fide traditional ceremonial purposes in connection with the practice of a traditional Indian

religion." 42 U.S.C. § 1996a(b)(1); see also 21 C.F.R. § 1307.31. An estimated 300,000 members of the Native American Church "regularly ingest peyote during religious ceremonies." Michael E. Hochman, Native Americans' Use of Pevote Not Harmful, Boston Globe, Nov. 7, 2005, at C3. Estimates vary, but thousands, and perhaps hundreds of thousands, of members of other "traditional Indian religion[s]" also use peyote for ceremonial purposes. 42 U.S.C. § 1996a(b)(1). Even though the number of religious users may approach *one million* nationwide – and even though they can legally "transport[]" peyote, id. – there is no evidence that such use (or even such transport) has undermined federal law enforcement efforts. Thus, with Schedule I controlled substances, as with the military's former prohibition on yarmulkes, "the Government's asserted need for absolute uniformity is contradicted by the Government's own exceptions to its rule." Goldman v. Weinberger, 475 U.S. 503, 532 (1986) (O'Connor, J., dissenting).

II. APPLICATION OF THE CSA TO MRS. RAICH WOULD VIOLATE THE COMMON-LAW DOCTRINE OF NECESSITY.

The common-law doctrine of necessity bars the federal government from enforcing the CSA against Mrs. Raich's medically necessary activities. Her Statelicensed physician has determined that she *must* take cannabis to avoid extraordinary suffering and death, and the federal government has not disputed that determination.

The doctrine of necessity "has been 'anciently woven into the fabric of our culture." See Edward B. Arnolds & Norman F. Garland, The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil, 65 J. Crim. L. & Criminology 289, 291 (1974) (quoting Jerome Hall, General Principles of the Criminal Law 416 (2d ed. 1960)). It "traditionally covered the situation where physical forces beyond the actor's control rendered illegal conduct the lesser of two evils" and the actor had no "reasonable, legal alternative to violating the law." United States v. Bailey, 444 U.S. 394, 410 (1980). As one early case put it, the doctrine provides that "[a] man may break the words of the law, and yet not break the law itself . . . where the words of them are broken . . . through necessity." Reninger v. Fagossa [1551] 1 Plowd. 1, 75 Eng. Rep. 1 (citing Matthew, 12:3-4).

Because "Congress in enacting criminal statutes legislates against a background of Anglo-Saxon common law," *Bailey*, 444 U.S. at 415-16 & n.11, Mrs. Raich may invoke the common-law doctrine of necessity under the CSA. The Supreme Court's "precedent has expressed no doubt about the viability of the common-law defense [of necessity], even in the context of federal criminal statutes that," like the CSA, "do not provide for it in so many words." *United States v. Oakland Cannabis Buyers' Co-op.* ("*OCBC*"), 532 U.S. 483, 501 (2001) (Stevens, J., concurring in the judgment). No Justice in *Bailey* doubted "the existence of such a defense," even though the statute at issue – like the CSA – did not mention

necessity. 444 U.S. at 415-16 n.11; *see also* Guido Calabresi, *A Common Law for the Age of Statutes* 287 n.33 (1982) (defenses such as necessity have been "routinely allowed against federal criminal prosecutions without explicit statutory basis"). There is no reason to single out the CSA as the only federal criminal statute to preclude the necessity doctrine.

In *OCBC*, the Supreme Court held that the necessity doctrine did not provide a defense to charges of "manufacturing and distributing marijuana" in violation of the CSA for a medical cannabis *cooperative* and its executive director, because they faced no physical harm *to themselves*. 532 U.S. at 486-87, 494. They had not "been forced to confront a choice of evils," but instead had "thrust that choice upon themselves by *electing* to become distributors for [seriously ill] patients." *Id.* at 500 n.1 (Stevens, J., concurring in the judgment) (emphasis added). Because the cooperative and its executive director were acting on behalf of "numerous" *other* people, the *OCBC* Court had no occasion to decide the "difficult issue" of whether the necessity doctrine "might be available to a seriously ill patient for whom there is no alternative means of avoiding starvation or extraordinary suffering." *Id.* at 501.

Unlike *OCBC*, here Mrs. Raich has not "elected" to violate the CSA. Her physician's undisputed declaration attests that she *must* use cannabis as a matter of medical necessity and has no reasonable legal alternative – she "cannot be without

cannabis as medicine" because she would "quickly" suffer "precipitous medical deterioration" and "could very well" die. Lucido Decl. ¶¶ 2, 8, ER 88, 91.

Moreover, whereas in *OCBC* the cooperative "distribut[ed] marijuana to numerous persons," 532 U.S. at 487 (emphases added), Mrs. Raich's cannabis is grown by her caregivers in their home gardens specifically for her. Under these circumstances, the "difficult issue" left open in *OCBC* is squarely presented. 16

This Court strongly suggested, in a portion of its *OCBC* opinion left intact by the Supreme Court, that the necessity doctrine protects medical cannabis patients such as Mrs. Raich. As this Court explained, patients such as her constitute:

a class of people with *serious medical conditions* for whom the use of cannabis is *necessary* in order to treat or alleviate those conditions or their symptoms; who will suffer *serious harm* if they are denied cannabis; and for whom there is *no legal alternative to cannabis* for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects.

A footnote in *OCBC* states 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." 532 U.S. at 494 n.7. This is a "glaring example of the Court's dicta" because the CSA's prohibition on possession was not at issue in *OCBC*. 532 U.S. at 501 n.2 (Stevens, J., concurring in the judgment). Moreover, the *OCBC* Court did not purport to depart from *Bailey*'s recognition that the common-law necessity doctrine applies under federal statutes that say nothing about it. *See* 444 U.S. at 416 n.11.

United States v. OCBC, 190 F.3d 1109, 1115 (9th Cir. 1999) (emphases added), rev'd, 532 U.S. 483 (2001). Under this Court's precedent, its reasoning in OCBC is correct as applied to Mrs. Raich.

This Court has held that the doctrine of necessity applies to a person's conduct if she (1) "'was faced with a choice of evils and chose the lesser evil," (2) "'acted to prevent imminent harm," (3) "'reasonably anticipated a causal relation between [her] conduct and the harm to be avoided," and (4) "'there were no other legal alternatives to violating the law." *United States v. Arellano-Rivera*, 244 F.3d 1119, 1126 (9th Cir. 2001) (quoting *United States v. Aguilar*, 883 F.2d 662, 693 (9th Cir. 1989)). Each element is present here.

First, Mrs. Raich chose to violate the CSA instead of suffering intolerable pain and death. Second, those harms were imminent when she began taking cannabis and would manifest themselves "quickly" if she were forced to stop. Lucido Decl. ¶ 2, ER 88. Third, Mrs. Raich reasonably anticipates a causal relationship between taking cannabis and avoiding intolerable pain and death because her own experiences prove that cannabis alleviates her conditions and prolongs her life, and because her State-licensed physician recommends that she take cannabis. Fourth, Mrs. Raich's physician recommended cannabis only after determining that she has "no reasonable legal alternative to cannabis for effective treatment or alleviation of her medical conditions or symptoms." Id. ¶ 7, ER 89-

90. Accordingly, the doctrine of necessity prohibits the federal government from enforcing the CSA against Mrs. Raich.

III. THE CSA ALLOWS MRS. RAICH TO POSSESS CANNABIS PURSUANT TO HER PHYSICIAN'S VALID ORDER.

The plain text of the CSA shows that it does not apply to Mrs. Raich's activities. The CSA prohibits a person from knowingly possessing a controlled substance "unless such substance was obtained . . . pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice." 21 U.S.C. § 844(a) (emphases added). The CSA defines a "practitioner" to include "a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice." Id. § 802(21) (emphases added).

Sections 802(21) and 844(a) place Mrs. Raich's activities outside the CSA's reach. Her medical cannabis activities are pursuant to a valid "order" from Dr. Lucido. *Id.* § 844(a). He is a "practitioner" because he is "a physician" who is "otherwise permitted" by the laws of California – "the jurisdiction in which he practices" – to "administer . . . a controlled substance in the course of [his] professional practice." *Id.* § 802(21). By adopting this plain-meaning interpretation of the CSA, the Court can avoid reaching the constitutional issues discussed herein.

IV. APPLICATION OF THE CSA TO MRS. RAICH WOULD VIOLATE THE TENTH AMENDMENT BY CONTROLLING CALIFORNIA'S REGULATION OF PRIVATE PARTIES' MEDICAL PRACTICES.

The Supreme Court's decision in this case did not address whether applying the CSA to Mrs. Raich would violate the Tenth Amendment, because the Commerce Clause issue was the only "question presented." *Raich*, 125 S. Ct. at 2198-99; *see also id.* at 2237 (Thomas, J., dissenting) ("This Court is willing neither to enforce limits on federal power, nor to declare the Tenth Amendment a dead letter."). ¹⁷

Maintaining the liberty, health, and safety of citizens requires that the State and federal governments exercise power only within their respective spheres of sovereignty. "Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power

The Supreme Court's Tenth Amendment jurisprudence is based not on the Amendment's text or original meaning, but on the principle of dual sovereignty that underlies and informs it:

The Tenth Amendment . . . restrains the power of Congress, but this limit is not derived from the text of the Tenth Amendment itself Instead, 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. The Tenth Amendment thus directs us to determine, as in this case, whether an incident of state sovereignty is protected by a limitation on an Article I power.

New York v. United States, 505 U.S. 144, 156-57 (1992). Like the Supreme Court, Appellants refer to the cases discussed in the text as resting on the Tenth Amendment.

in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front." *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991); *see also New York*, 505 U.S. at 181 ("[f]ederalism secures to citizens the liberties that derive from the diffusion of sovereign power") (internal quotation marks omitted).

Under the Tenth Amendment, the federal government cannot "control or influence the manner in which States regulate private parties." *Reno v. Condon*, 528 U.S. 141, 150 (2000) (quoting *South Carolina v. Baker*, 485 U.S. 505, 514-15 (1988)). In *McConnell v. FEC*, 540 U.S. 93 (2003), however, five Justices suggested, in an opinion coauthored by Justices Stevens and O'Connor, that they do not believe the Tenth Amendment bars the federal government from prohibiting medical cannabis use in a State that has chosen to authorize it. *See id.* at 186-87 (observing that in examining the Tenth Amendment the Court has focused on federal "laws that commandeer the States and state officials in carrying out federal regulatory schemes," citing *OCBC* to support the proposition that "[i]t is not uncommon for federal law to prohibit private conduct that is legal in some States," and noting that this "is not in and of itself a marker of constitutional infirmity").

Nevertheless, Appellants reassert their Tenth Amendment argument to preserve it for Supreme Court review, in the event such review proves necessary.

Appellants hope that such an evaluation by the Court will result in (i) a

reassessment of its current, recently formulated understanding of the Tenth Amendment in McConnell, (ii) a recognition that, properly understood, that Amendment does not allow the federal government to apply a federal statute in a manner that controls or influences a State's regulation of private parties' noncommercial medical practices within its borders, because such regulation has traditionally been the exclusive domain of the States, (iii) that such a law is "improper" under the Necessary and Proper Clause, and (iv) a holding that, as Justice Thomas has explained, applying the CSA to Appellants would "encroach[]" on California's "traditional police powers to define the criminal law and to protect the health, safety, and welfare of [its] citizens," and would thus "subvert [the] basic principles of federalism and dual sovereignty" protected by the Tenth Amendment. Raich, 125 S. Ct. at 2234 (Thomas, J., dissenting) (citing, inter alia, Printz v. United States, 521 U.S. 898 (1997)).

Appellants' hopes are not unfounded. The Commerce Clause opinions of Chief Justice Roberts, who was recently confirmed, and Judge Alito, who was recently appointed to replace Justice O'Connor, suggest that they may have different views of "our system of constitutional federalism" than the Justices who formed the majority in *McConnell v. FEC. See United States v. Rybar*, 103 F.3d 273, 287 (3d Cir. 1996) (Alito, J., dissenting) (arguing that Commerce Clause does not empower federal government to regulate private intrastate possession of

machineguns); *compare Rancho Viejo*, *LLC v. Norton*, 334 F.3d 1158, 1160 (D.C. Cir. 2003) (Roberts, J., dissenting from denial of rehearing en banc) (arguing that "regulating the taking of a hapless toad that, for reasons of its own, lives its entire life in California" does not constitute "regulating 'Commerce . . . among the several States'") (quoting U.S. Const. art. I, § 8, cl. 3), *cert. denied*, 504 U.S. 1218 (2004).

This case is unlike *United States v. Jones*, 231 F.3d 508 (9th Cir. 2000), and *United States v. Mussari*, 95 F.3d 787 (9th Cir. 1996). Neither of those cases involved an application of federal law that controlled or influenced a State's regulation of an area traditionally within its control. Moreover, here the State itself objects to the threatened application of the CSA, as evidenced by the amicus brief it filed in this case on April 30, 2003.

In *Jones*, this Court rejected a Tenth Amendment challenge to 18 U.S.C. § 922(g)(8), which bars felons from possessing firearms if they are subject to a domestic violence protection order. The Court explained that § 922(g)(8) "does not attempt to regulate domestic relations" – "an area traditionally left to the states" – but instead "accepts the validity of domestic abuse restraining orders that have been issued under state law." 231 F.3d at 515. In contrast, here the federal government threatens to apply the CSA in a manner that would thwart California's attempt to protect the health of its citizens, which is at the core of its traditional

police power.

In *Mussari*, this Court rejected a Tenth Amendment challenge to the Child Support Recovery Act (the "Act"), stating that "[t]here is no doubt that Congress, in furtherance of its control of an interstate activity, may criminalize what a state has left without criminal sanction, *e.g.*, drug laws." 95 F.3d at 791. The Court emphasized, however, that the Act did "*not* disparage[]" the States' roles, but rather "manifested" "[r]espect for [their] competency." *Id.* (emphasis added). Indeed, the Act *helped* the States compel parents to pay child support by removing "interstate impediments to the fulfillment of domestic duties that the courts of the states have imposed." *Id.* At the same time, the Act did *not* control or influence the States' *authorization* of any private conduct. *Id.* In contrast, applying the CSA to the Appellants would directly prevent California from using its traditional police powers to implement its legitimate health objectives.

Accordingly, Appellants respectfully submit that applying the CSA to them would violate the Tenth Amendment.¹⁸

Entirely different Tenth Amendment issues would arise if a State or local government distributed medical cannabis and the federal government tried to apply the CSA to bar such distribution, in which event the federal government would violate the "anti-commandeering" doctrine.

CONCLUSION

For the reasons stated above, this Court should direct the District Court preliminarily to enjoin the federal government from interfering with Mrs. Raich's medical cannabis activities.

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

I certify that, pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, the attached Appellants' Opening Brief is proportionally spaced and has a typeface of 14 points. According to the word processing software used to prepare the brief (Microsoft Word 2000), the brief – including both text and footnotes, and excluding this Certificate of Compliance, the cover page, the Table of Contents, the Table of Authorities, the Statement of Related Cases, and the Certificate of Service – contains 13,973 words.

Robert A.	Raich

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6(c), this case may be deemed to raise "related issues" to other cases pending in this Court: *Raich v. Gonzales*, No. 04-16296, *United States v. Oakland Cannabis Buyers' Cooperative*, No. 05-16466, *United States v. Marin Alliance for Medical Marijuana*, No. 05-16547, and *United States v. Ukiah Cannabis Buyer's Club*, No. 05-16556. Unlike the entities involved in the latter three cases, however, the Appellants herein are not organizations that exist for the primary purpose of distributing cannabis.