

1 HARDY MYERS
Attorney General
2 STEPHEN K. BUSHONG #85130
Assistant Attorney General
3 Department of Justice
1162 Court Street NE
4 Salem, OR 97301-4096
Telephone: (503) 378-6313
5
6 Attorneys for Plaintiff

7
8
9
10 IN THE UNITED STATES DISTRICT COURT
11 FOR THE DISTRICT OF OREGON

12 STATE OF OREGON,

13 Plaintiff,

14 &

15 RICHARD HOLMES; KARL STANSELL;
16 JAMES ROMNEY; JANE DOE #1;
17 PETER A. RASMUSSEN, M.D.; and
DAVID MALCOM HOCHHALTER, Rph,

18 Plaintiffs-Intervenors,

19 v.

20 JOHN ASHCROFT, in his official capacity as
United States Attorney General; ASA
21 HUTCHINSON, in his official capacity as
Administrator of the Drug Enforcement
22 Administration; KENNETH W. MAGEE, in his
official capacity as Director of the Drug
23 Enforcement Administration, Portland Office;
UNITED STATES OF AMERICA; UNITED
24 STATES DEPARTMENT OF JUSTICE; and
UNITED STATES DRUG ENFORCEMENT
25 ADMINISTRATION,

26 Defendants.

Case No. CV01-1647-JO

OREGON'S SUPPLEMENTAL
MEMORANDUM IN SUPPORT OF MOTION
FOR A PRELIMINARY INJUNCTION

TABLE OF CONTENTS

1

2 INTRODUCTION 1

3 BACKGROUND 1

4 I. Chronology of events..... 1

5 II. Contentions of the parties 3

6 III. Standards for a preliminary injunction 4

7 ARGUMENT 4

8 I. Oregon has standing..... 4

9 II. The TRO should be continued as a preliminary injunction pending

10 resolution of this case on the merits..... 7

11 A. The balance of interests and irreparable injury to terminally ill

12 Oregonians and health care providers support issuance of a

13 preliminary injunction..... 7

14 B. Oregon has demonstrated a sufficient likelihood of success on the

15 merits..... 9

16 1. The Ashcroft directive exceeds the authority delegated by

17 Congress..... 9

18 2. The Ashcroft directive is not entitled to any special

19 deference 13

20 3. The Ashcroft directive is invalid because the Attorney

21 General failed to comply with the APA’s rulemaking

22 procedures 16

23 4. If authorized by the CSA, Congress lacks the constitutional

24 authority to override Oregon’s determination that practices

25 authorized by the Oregon Act serve a legitimate medical

26 purpose 18

CONCLUSION..... 19

TABLE OF AUTHORITIES

Cases

1

2 **Cases**

3 *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 110 S.Ct. 1384, 108 L.Ed.2d 585 (1990)..... 16

4 *Alcaraz v. Block*, 746 F.2d 593 (9th Cir. 1984)..... 16, 17

5 *Alden v. Maine*, 527 U.S. 706, 119 S.Ct. 2240, 144 L.Ed.2d 636 (1999)..... 19

6 *Atlantic Coast Demo. v. Board of Freeholders*, 893 F.Supp. 301 (D. N.J. 1995)..... 8

7 *Auer v. Robbins*, 519 U.S. 452, 117 S.Ct. 905, 127 L.Ed.2d 79 (1997)..... 14

8 *Baltimore & Ohio Railroad Co. v. Oberly*, 606 F.Supp. 1340 (D. Del. 1985), *aff'd*, 782

9 F.2d 29 (3rd Cir.), *vacated on other grounds*, 479 U.S. 980 (1986) 8

10 *Blatchford v. Native Village of Noatak*, 501 U.S. 775, 111 S.Ct. 2578, 115 L.Ed.2d 686

(1991)..... 12

11 *Blattner & Sons, Inc. v. Secretary of Labor*, 152 F.3d 1102 (9th Cir. 1998)..... 13

12 *Bowen v. Public Agencies Opp. to Soc. Sec. Entrap.*, 477 U.S. 41, 106 S.Ct. 2390, 91

13 L.Ed.2d 35 (1986)..... 5

14 *Caraballo v. Reich*, 11 F.3d 186 (D.C. Cir. 1993)..... 17

15 *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct.

2778, 81 L.Ed.2d 694 (1984)..... 14

16 *Christensen v. Harris County*, 529 U.S. 576, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000)..... 14, 16

17 *Clean Ocean Action v. York*, 57 F.3d 328 (3rd Cir. 1995)..... 13

18 *Commonwealth of Massachusetts v. Laird*, 400 U.S. 886, 91 S.Ct. 128, 27 L.Ed.2d 140

19 (1970)..... 4

20 *Diamond v. Charles*, 476 U.S. 54, 106 S.Ct. 1697, 90 L.Ed.2d 48 (1986)..... 5

21 *Green v. Mansour*, 474 U.S. 64, 106 S.Ct. 423, 88 L.Ed.2d 371 (1985)..... 12

22 *Gregory v. Ashcroft*, 501 U.S. 452, 115 L.Ed.2d 410, 111 S.Ct. 2395 (1991)..... 19

23 *Hall v. United States Environmental Protection Agency*, 263 F.3d 926 (9th Cir. 2001)..... 14, 15

24 *Headwaters, Inc. v. B.L.M., Medford Dist.*, 665 F.Supp. 873 (D. Or. 1987)..... 8

25 *In re Arthur Treachers Franchise Litigation*, 689 F.2d 1137 (3rd Cir. 1982)..... 8

26 *Kansas v. U.S.*, 249 F.3d 1213 (10th Cir. 2001)..... 5

Kansas v. United States, 748 F.Supp. 797 (D. Kan. 1990)..... 4

1	<i>Lee v. Oregon</i> , 107 F.3d 1382 (9 th Cir.), <i>cert. denied</i> , 522 U.S. 927 (1997).....	1
2	<i>Maine v. Taylor</i> , 477 U.S. 131 , 106 S.Ct. 2440, 91 L.Ed.2d 110 (1986)	5
3	<i>Malone v. Bureau of Indian Affairs</i> , 38 F.3d 433 (9 th Cir. 1994).....	17
4	<i>Massachusetts v. Mellon</i> , 262 U.S. 447, 43 S.Ct. 597, 67 L.Ed. 1078 (1923)	4
5	<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).....	12
6	<i>Nat’l Org. for the Reform of Marijuana Laws v. Muller</i> , 608 F.Supp. 945 (S.D. Cal. 1985).....	8
7	<i>New York v. United States</i> , 505 U.S. 144, 112 S.Ct. 2408, 120 L.Ed.2d 120 (1992).....	5, 19
8	<i>Ohio ex rel. Celebrezze v. U.S. Dept. of Transp.</i> , 766 F.2d 228 (6 th Cir. 1985).....	5
9	<i>Philadelphia Citizens in Action v. Schweiker</i> , 669 F.2d 877 (3 rd Cir. 1982).....	16
10	<i>Powderly v. Schweiker</i> , 704 F.2d 1092 (9 th Cir. 1983).....	17
11	<i>S. Cal. Aerial Advertisers’ Ass’n. v. FAA</i> , 881 F.2d 672 (9 th Cir. 1989).....	17
12	<i>Skidmore v. Swift & Co.</i> , 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944)	14, 15, 16
13	<i>South Carolina v. Katzenbach</i> , 383 U.S. 301, 86 S.Ct. 803, 15 L.Ed.2d 769 (1962).....	5
14	<i>State of Alaska v. U.S. Department of Transportation</i> , 868 F.2d 441 (D.C. Cir. 1989).....	5
15	<i>Thomas Jefferson Univ. v. Shalala</i> , 512 U.S. 504, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994).....	13
16	<i>Ty, Inc. v. Jones Group, Inc.</i> , 237 F.3d 891 (7 th Cir. 2001).....	8
17	<i>United States v. Lopez</i> , 514 U.S. 549, 115 S.Ct. 1624, 131 L.Ed.2d 626 (1995).....	18
18	<i>United States v. Mead Corp.</i> , 533 U.S. 218, 121 S.Ct. 2164 (2001)	13, 14, 16
19	<i>United States v. Moore</i> , 423 U.S. 122 , 96 S.Ct. 335, 46 L.Ed.2d 333 (1975).....	11
20	<i>United States v. Morrison</i> , 529 U.S. 598, 120 S.Ct. 1740, 146 L.Ed.2d 658 (2000).....	18
21	<i>United States v. Oakland Cannabis Buyers Cooperative</i> , 532 U.S. 483, 121 S.Ct. 1711 (2001).....	3, 9, 10
22	<i>United States v. Rosenberg</i> , 515 F.2d 190 (9 th Cir. 1975).....	11
23	<i>United States v. Vamos</i> , 797 F.2d 1146 (2 nd Cir. 1986).....	11
24	<i>Washington Utils. and Transp. Comm’n. v. FCC</i> , 513 F.2d 1142 (9 th Cir.), <i>cert. denied</i> , 423 U.S. 836 (1975).....	5, 6
25		
26		

Statutes

1	21 U.S.C. § 903.....	9
2	5 U.S.C. § 553.....	16
3	5 U.S.C. § 553(b)(A).....	16
4	ORS 127.800 through 127.995	1
5	ORS 127.815(7).....	12
6	ORS 127.830.....	12
7	ORS 127.840.....	12
8	ORS 127.845.....	12
9	ORS 127.850.....	12
10	ORS 127.885.....	12
11	Other Authorities	
12	21 C.F.R. § 1306.04.....	13
13	36 F.R. 7799 (April 24, 1971)	13
14	Darien S. Fenn & Linda Ganzini, <i>Attitudes of Oregon Psychologists Toward Physician-</i> <i>Assisted Suicide and the Oregon Death With Dignity Act</i> , 30 Am. Psychological A. J.	
15	235 (June 1999)	15
16	David Orentlicher, “ <i>The Legalization of Physician Assisted Suicide</i> ,” 335 New Eng. J.	
17	Med. 663 (August 29, 1996).....	15
18	L. Ganzini, H.D. Nelson, M.A. Lee, D.F. Kraemer, T.A. Schmidt, M.A. Delorit, <i>Oregon</i> <i>Physicians’ Attitudes About and Experiences With End-Of-Life Care Since Passage</i> <i>of the Oregon Death with Dignity Act</i> , 285 J. A.M.A. 2363 (May 9, 2001)	15
19	P.L. 98-473 (1984), <i>reprinted in</i> 98 Stat. 1976 <i>et seq.</i>	9
20	R. Jeffrey Kohlwes, et al., <i>Physicians’ Responses to Patients’ Requests for Physician-</i> <i>Assisted Suicide</i> , 161 Arch. Intern. Med. 657 (March 12, 2001).....	6
21		
22	Sen. Rep. No. 98-225, 98 th Cong., 2d Sess. (1984), <i>reprinted in</i> 1984 U.S.C.C.A.N.	
23	3182	9
24	Simon N. Whitney, Byron W. Brown, Howard Brody, Kirsten H. Alcser, Jerald G.	
25	Bachman & Henry T. Greely, <i>Views of United States Physicians and Members of the</i> <i>American Medical Association House of Delegates on Physician-assisted Suicide</i> , 16	
26	Journal of General Internal Medicine 290 (May 2001)	15
	<i>The Oregonian</i> , “Wyden Ready to Filibuster Over Suicide,” Oct. 27, 2000.....	2

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

1 **INTRODUCTION**

2 Oregon urges this court to convert the temporary restraining order (TRO) that was
3 entered last week into a preliminary injunction that will remain in effect until the case is resolved
4 on the merits. All the reasons justifying the issuance of a TRO continue to apply. The legal
5 issues presented in this case are significant, affecting the balance of power between the States
6 and the federal government in an area of particular concern to Oregonians facing critical end-of-
7 life decisions. Defendants have offered no compelling reason for declining to convert the TRO
8 into a preliminary injunction.

9 A preliminary injunction would continue the state of the law that has been in effect for
10 more than three years. It would continue to give effect to the legal policy of the United States
11 that prevailed until Attorney General Ashcroft (Ashcroft) abruptly announced—with no prior
12 public notice—that (in his view) the United States Attorney General, instead of the states or the
13 United States Congress, can decide which medical practices are “legitimate” and which are not.
14 A preliminary injunction would allow the parties and the court to fully address the legal
15 questions raised by that action. These issues should not be addressed hastily. Finally, and most
16 importantly, a preliminary injunction would allow terminally ill patients and the health care
17 providers who treat them to continue to make critical end-of-life decisions based on Oregon law,
18 without federal interference, until this case is decided on the merits.

19 **BACKGROUND**

20 **I. Chronology of events.**

21 Oregon’s Death with Dignity Act, codified as ORS 127.800 through 127.995 (the Oregon
22 Act), was enacted by the people of Oregon in November 1994. A proposal to repeal the Oregon
23 Act was rejected by Oregon voters in November 1997. The Oregon Act went into effect in late
24 1997, after a legal challenge to the validity of the Act was dismissed.¹

25
26 ¹ *Lee v. Oregon*, 107 F.3d 1382 (9th Cir.), *cert. denied*, 522 U.S. 927 (1997).

1 The debate then shifted to the United States Department of Justice and Congress. The
2 following sequence of events occurred:

- 3 • **November 5, 1997** – Drug Enforcement Administration (DEA) opines in response to
4 questions posed by two congressmen that actions taken by Oregon physicians and
pharmacists under the Oregon Act would violate the Controlled Substances Act (CSA).²
- 5 • **December 3, 1997** – Oregon’s Attorney General asks United States Department of Justice to
6 reconsider DEA’s interpretation of the CSA.³
- 7 • **June 5, 1998** – Attorney General Janet Reno concludes that, in adopting the CSA, Congress
8 did not intend to delegate authority to DEA to regulate medical practices within states or to
9 override a state’s determination as to what constitutes a legitimate medical practice.⁴
- 10 • **June 17, 1999** – Legislation known as the “Pain Relief Promotion Act” is introduced in
11 Congress; bill would amend the CSA to give DEA authority to prohibit use of controlled
substances for purpose of hastening death of terminally ill patients.⁵
- 12 • **October 27, 2000** – Senator Ron Wyden announces his intention to filibuster if the Pain
Relief Promotion Act reaches the House floor for debate.⁶
- 13 • **December 15, 2000** – Congress adjourns without enacting the Pain Relief Promotion Act.
- 14 • **June 27, 2001** – Deputy Assistant Attorney General Sheldon Bradshaw and Special Counsel
15 Robert J. Delahunty submit legal opinion to Ashcroft, concluding that practices authorized by
the Oregon Act do not constitute “a legitimate medical purpose” and therefore violates the
16 CSA.⁷
- 17 • **November 6, 2001** – Ashcroft issues directive to DEA Administrator Asa Hutchinson,
concludes that actions taken by Oregon physicians under the Death with Dignity Act would
18 violate the CSA (the Ashcroft directive).⁸
- 19 • **November 7, 2001** – Oregon files suit challenging the Ashcroft directive.
- 20 • **November 8, 2001** – Terminally ill patients and health care providers intervene; TRO issued.

21 ² See Complaint, ¶ 14.

22 ³ Letter from Deputy Attorney General David Schuman, attached as Exhibit 4 to Defendants’
Memorandum in Opposition to Motion for Temporary Restraining Order (Defendants’
23 Opposition to TRO).

24 ⁴ See Defendants’ Opposition to TRO, Exhibit 5; Complaint, Exhibit 1.

25 ⁵ H.R. 2260.

26 ⁶ See *The Oregonian*, “Wyden Ready to Filibuster Over Suicide,” Oct. 27, 2000, available on the
internet at http://oregonlive.com/printer2.ssf?/news/oregonian/00/10/wr_62s.

⁷ See Complaint, Exhibit 3.

⁸ See Complaint, Exhibit 2.

1 **II. Contentions of the parties.**

2 Oregon contends that the Ashcroft directive is invalid because (1) Congress did not
3 intend to delegate to the Attorney General the authority to override a state’s determination as to
4 the “legitimacy” of a medical practice; (2) if Congress intended to delegate that authority to the
5 Attorney General, it did not effectuate that intent in the CSA; (3) if Congress intended to
6 delegate the authority to the Attorney General and effectively did so in the CSA, then the
7 directive is invalid because the Attorney General failed to engage in formal rule-making
8 procedures as necessary to exercise his delegated authority; (4) Congress has no constitutional
9 authority under the Commerce Clause to regulate the medical practices of Oregon doctors and
10 pharmacists; and (5) any attempt by Congress to invalidate medical practices authorized by
11 Oregon law impermissibly intrudes into areas reserved to the States in violation of the Tenth
12 Amendment to the United States Constitution.

13 Oregon further contends that the TRO entered last week should be converted to a
14 preliminary injunction that remains in effect until these legal issues are resolved because (1) a
15 preliminary injunction properly preserves the status quo in Oregon; (2) a preliminary injunction
16 avoids irreparable injury to terminally ill Oregonians, health care providers, and Oregon’s
17 sovereign and regulatory interests; and (3) Oregon and the plaintiff-intervenors have shown a
18 sufficient probability of success on the merits to justify converting the TRO to a preliminary
19 injunction.

20 In response to Oregon’s motion for a TRO, defendants argued that (1) Oregon lacks
21 standing; (2) the Ashcroft directive is entitled to substantial deference and must be upheld unless
22 it is “plainly erroneous”; (3) a 1984 amendment to the CSA, the Supreme Court’s recent decision
23 in the *Oakland Cannabis* case,⁹ and other CSA cases confirm that Ashcroft had authority under
24 the CSA to issue his directive; (4) there is “no basis” in current Supreme Court jurisprudence for
25

26 ⁹ *United States v. Oakland Cannabis Buyers Cooperative*, 532 U.S. 483, 121 S.Ct. 1711 (2001).

1 concluding that Congress exceeded its Commerce Clause powers if it authorized the Attorney
2 General to regulate medical practices; and (5) the balance of hardships and public interest tips in
3 favor of the United States because it “seeks to preserve lives” while Oregon is asking the court to
4 find “that there is harm in living.”¹⁰ Defendants are wrong on all accounts, as discussed in
5 Oregon’s opening brief and more fully below.¹¹

6 **III. Standards for a preliminary injunction.**

7 Oregon addressed the standards for a TRO and a preliminary injunction at pages 5-6 of
8 its opening brief. The same standards apply here. Oregon met the prerequisites for a TRO;
9 nothing has changed since then.

10 **ARGUMENT**

11 **I. Oregon has standing.**

12 Defendants argue that Oregon lacks standing to assert claims against the United States on
13 a *parens patriae* theory.¹² But Oregon is not asserting claims solely on a *parens patriae* theory.¹³
14 Rather, Oregon contends that the Ashcroft directive has directly affected Oregon’s regulatory
15 and sovereign interests sufficient to establish standing. The Supreme Court routinely addresses
16 challenges brought by states against the United States, federal officials, and federal agencies to

17
18
19
20 ¹⁰ Defendants’ Opposition to TRO, p. 2.

21 ¹¹ See Plaintiff’s Memorandum in Support of Motions for a TRO and a Preliminary Injunction,
22 filed November 7, 2001. Oregon relies on and incorporates the arguments and authorities set
23 forth in that memorandum without repeating them here.

24 ¹² See Defendants’ Opposition to TRO at 15, citing *Massachusetts v. Mellon*, 262 U.S. 447, 43
25 S.Ct. 597, 67 L.Ed. 1078 (1923).

26 ¹³ Oregon does not concede, however, that it cannot rely in part on the *parens patriae* doctrine.
See *Kansas v. United States*, 748 F.Supp. 797, 802 (D. Kan. 1990) (holding that Governor of
Kansas has standing in part under *parens patriae* doctrine to sue United States); *Commonwealth
of Massachusetts v. Laird*, 400 U.S. 886, 888, 91 S.Ct. 128, 27 L.Ed.2d 140 (1970) (Douglas, J.,
dissenting) (noting that *Mellon* “did not announce a *per se* rule to bar all suits against the Federal
Government as *parens patriae*”).

1 protect such interests.¹⁴ Moreover, several cases have held that a state has standing to assert the
2 rights of its citizens to be protected against illegal or unconstitutional acts of the federal
3 government, in part because “a State clearly has a legitimate interest in the continued
4 enforceability of its own statutes.”¹⁵

5 Lower federal courts have also recognized, in a variety of circumstances, that states have
6 standing to sue the United States, federal officials and federal agencies to protect their sovereign
7 and regulatory interests.¹⁶ For example, in *State of Alaska v. U.S. Department of*
8 *Transportation*,¹⁷ 27 states challenged the validity of Department of Transportation orders
9 regarding airline advertising. The Department asserted that its orders preempted state consumer
10 protection statutes. The court found that the states had standing because “the states have suffered
11 injury to their sovereign power to enforce state law.”¹⁸ The court explained that, because the
12 “preemptive effect is the injury of which petitioners complain, we are satisfied that the states

13 _____
14 ¹⁴ See, e.g., *New York v. United States*, 505 U.S. 144, 112 S.Ct. 2408, 120 L.Ed.2d 120 (1992)
15 (declaratory judgment action brought by State of New York, alleging that federal statute violates
16 Tenth Amendment); *Bowen v. Public Agencies Opp. to Soc. Sec. Entrap.*, 477 U.S. 41, 51 n. 17,
17 106 S.Ct. 2390, 91 L.Ed.2d 35 (1986) (affirming district court’s conclusion that State of
18 California had standing to challenge validity of federal statute because it alleged “a judicially
19 cognizable interest in the preservation of its own sovereignty”); *South Carolina v. Katzenbach*,
20 383 U.S. 301, 324, 86 S.Ct. 803, 15 L.Ed.2d 769 (1962) (State of South Carolina had standing to
21 challenge validity of Voting Rights Act based on state’s interest in the continued operation of its
22 election laws).

23 ¹⁵ *Maine v. Taylor*, 477 U.S. 131, 137, 106 S.Ct. 2440, 91 L.Ed.2d 110 (1986). See also,
24 *Diamond v. Charles*, 476 U.S. 54, 62, 106 S.Ct. 1697, 90 L.Ed.2d 48 (1986) (“a State has
25 standing to defend the constitutionality of its statute”); *Ohio ex rel. Celebrezze v. U.S. Dept. of*
26 *Transp.*, 766 F.2d 228, 232-33 (6th Cir. 1985) (“since Ohio is litigating the constitutionality of its
own statute, [it] has a sufficient stake in the outcome of this litigation to give it standing to seek
judicial review of the rule making action of the U.S. Department of Transportation[.]”).

¹⁶ See *Kansas v. U.S.*, 249 F.3d 1213, 1223-24 (10th Cir. 2001) (holding that Kansas had standing
to challenge a federal action that affected the state’s “sovereign rights and regulatory powers”
and “affects the state’s public policy concerns and significant governmental interests”); *Ohio ex*
rel. Celebrezze, 766 F.2d at 233 (“Ohio has standing to challenge the Department’s regulation
and undertake to vindicate its own law”); *Washington Utils. and Transp. Comm’n. v. FCC*, 513
F.2d 1142, 1151 (9th Cir.), cert. denied, 423 U.S. 836 (1975) (“A public agency has standing to
seek judicial review of government action that affects the performance of its duties”).

¹⁷ *State of Alaska v. U.S. Department of Transportation*, 868 F.2d 441 (D.C. Cir. 1989).

¹⁸ 868 F.2d at 443.

1 meet the standing requirements of Article III.”¹⁹ Oregon complains of a similar “preemptive
2 effect” in this case.

3 Oregon also contends that the Ashcroft directive impairs the regulatory obligations
4 imposed by Oregon law on its Board of Medical Examiners, Board of Pharmacy, and
5 Department of Human Services. In *Washington Utils. v. FCC*, the Ninth Circuit recognized that
6 “impairment of an administrative agency’s interest in the effective discharge of the obligations
7 imposed upon the agency by law is the equivalent of the ‘personal stake,’ ‘injury-in-fact,’ or
8 ‘concrete injury’ that would support standing of a private plaintiff.”²⁰

9 Thus, it is clear that Oregon has standing in this case. Oregon’s sovereign interest in the
10 continued validity of its own duly enacted laws, standing alone, is sufficient to confer standing to
11 sue. Oregon’s regulatory interests in the “effective discharge of the obligations imposed by law”
12 on its Board of Medical Examiners, Board of Pharmacy, and Department of Human Services²¹
13 are also sufficient to confer standing.

14 These interests are particularly important in this case. By enacting the Oregon Act, the
15 people of Oregon chose to authorize Oregon health care providers to assist in hastening the death
16 of those terminally ill adults who choose to utilize the law. The people also enacted the
17 safeguards—e.g., waiting periods, reporting requirements—the Oregon Act includes. As
18 explained more fully in intervenors’ supplemental brief, it is well-recognized in the medical
19 literature that dying patients sometimes seek to hasten their deaths even in the absence of an
20 authorizing law.²² Under those circumstances, the practical effect of the Ashcroft directive will
21 be to eliminate the waiting periods and other safeguards included in Oregon’s law. Oregon has

22 ¹⁹ 868 F.2d at 444.

23 ²⁰ *Washington Utils. v. FCC*, 513 F.2d at 1149.

24 ²¹ Formerly known as the Health Division.

25 ²² See R. Jeffrey Kohlwes, et al., *Physicians’ Responses to Patients’ Requests for Physician-*
26 *Assisted Suicide*, 161 Arch. Intern. Med. 657 (March 12, 2001) (noting that requests for
assistance in hastening death “are being received by physicians and, in some case, are being
acceded to”).

1 standing not only to defend the validity of its law and the discharge of its regulatory obligations,
2 but also to preserve the safeguards contained in the Oregon Act.

3 **II. The TRO should be continued as a preliminary injunction pending resolution of this**
4 **case on the merits.**

5 **A. The balance of interests and irreparable injury to terminally ill Oregonians**
6 **and health care providers support issuance of a preliminary injunction.**

7 In granting Oregon’s motion for a TRO, the court properly noted the irreparable injury
8 that will be suffered by terminally ill Oregonians and the health care providers who treat them if
9 the Ashcroft directive takes effect. The United States asserts a more general interest in
10 “preserving life.” That interest, while important, is insufficient to tip the balance in defendants’
11 favor, for several reasons. First, as the court noted, the legal opinion that purports to justify the
12 Ashcroft directive was issued in June 2001. More than four months passed before the United
13 States took any action to “preserve” the lives of terminally ill Oregonians who utilized the
14 Oregon Act after that opinion was issued. The United States offers no reason why the Oregon
15 Act could not be allowed to remain in effect during the additional period of time it will take to
16 resolve this case on the merits.²³

17 Second, the reality facing terminally ill Oregonians is that the Ashcroft directive cannot
18 prevent them from dying. They will die anyway. To be sure, the Ashcroft directive would
19 prevent them from choosing to hasten death in accordance with the Oregon Act, but it cannot
20 save them. In most cases, the Ashcroft directive’s only effect would be to prolong the lives of a
21 few terminally ill individuals for a short period of time against their wishes, and to eliminate the
22 Oregon Act’s reporting requirements and other safeguards. Under these circumstances, the
23 United States’ general interest in preserving life does not clearly outweigh the specific interests
24 of the few terminally ill Oregonians who might choose to utilize the Oregon Act, and the health
25 care providers who treat them, while this case is pending.

26 ²³ Oregon does not expect that will take more than 2-4 months to fully brief and argue this case
on cross-motions for summary judgment.

1 In deciding whether to issue a preliminary injunction, courts generally take into account
2 both the public interest and “the possibility of harm to other interested parties[.]”²⁴ Thus, while
3 Oregon is relying on its sovereign and regulatory interests to give it standing to bring this case, it
4 may properly rely on the harm to terminally ill Oregonians and their health care providers as a
5 basis for granting a preliminary injunction.²⁵ An example of this principle is demonstrated by
6 *Nat’l Org. for the Reform of Marijuana Laws v. Muller*,²⁶ in which a district court granted a
7 preliminary injunction based in part on harm to nonparties who submitted affidavits in support of
8 the plaintiff’s motion. The court issued a broad preliminary injunction, noting that “all
9 California residents necessarily will be protected” by the injunction.

10 That the court must also consider the public interest supports the conclusion that the
11 requisite “harm” sufficient to support a preliminary injunction is broader than the injury
12 sufficient to give a plaintiff standing to bring the action in the first instance.²⁷ Thus, Oregon has
13 standing to bring this action because of the injury to its sovereign and regulatory interests, but
14 Oregon may properly rely on harm to terminally ill patients, health care providers, and the public
15 in support of its request for a preliminary injunction.

16

17

18

19 ²⁴ *In re Arthur Treachers Franchise Litigation*, 689 F.2d 1137, 1143 (3rd Cir. 1982). *See also*,
20 *Atlantic Coast Demo. v. Board of Freeholders*, 893 F.Supp. 301, 307 (D. N.J. 1995) (“Where
relevant, the court should also take into account * * * the possibility of harm to other interested
parties”).

21 ²⁵ *See Ty, Inc. v. Jones Group, Inc.*, 237 F.3d 891, 895 (7th Cir. 2001) (affirming preliminary
22 injunction granted by trial court: “the court must consider the public interest (non-parties) in
denying or granting the injunction”); *Headwaters, Inc. v. B.L.M., Medford Dist.*, 665 F.Supp.
23 873, 875 (D. Or. 1987) (considering the “hardship to outdoor enthusiasts and the public as a
whole” in deciding preliminary injunction motion).

24 ²⁶ *Nat’l Org. for the Reform of Marijuana Laws v. Muller*, 608 F.Supp. 945, 964 (S.D. Cal.
1985).

25 ²⁷ *See Baltimore & Ohio Railroad Co. v. Oberly*, 606 F.Supp. 1340, 1347-48 (D. Del. 1985),
26 *aff’d*, 782 F.2d 29 (3rd Cir.), *vacated on other grounds*, 479 U.S. 980 (1986) (considering harm to
non-parties when assessing the public interest in granting a preliminary injunction).

1 **B. Oregon has demonstrated a sufficient likelihood of success on the merits.**

2 1. The Ashcroft directive exceeds the authority delegated by Congress.

3 Oregon demonstrated in its opening memorandum that Congress intended to address
4 national problems of drug abuse and trafficking in narcotics when it enacted the CSA. Oregon
5 also demonstrated that Congress did not intend to preempt state laws regulating medical
6 practices within their borders.²⁸ The Ashcroft directive exceeds the authority delegated by
7 Congress because it effectively preempts state law on one issue—the legitimacy of medical
8 practices—that Congress intended to leave to the states. Defendants’ only response is to suggest
9 that (1) a 1984 amendment to the CSA and the *Oakland Cannabis* decision evidence a broader
10 delegation of power; (2) other cases applying the CSA demonstrate that regulation of medical
11 practices is a “federal” issue; and (3) the Ashcroft directive does not really “preempt” Oregon
12 law because physicians may still assist in hastening the deaths of terminally ill patients as long as
13 they do not use controlled substances in doing so.

14 The first argument is wrong. The 1984 amendment to the CSA was part of the
15 Comprehensive Crime Control Act of 1984.²⁹ According to the legislative history, the purpose
16 of that Act was “to make major comprehensive improvements to the Federal criminal laws.”³⁰
17 The amendments to the CSA were contained in Part B of Title V (§§ 505-526) of that Act. The
18 legislative history of those sections revealed that the amendments to the CSA “are intended to
19 address the severe problem of diversion of drugs of legitimate origin into the illicit market.”³¹
20 Such a diversion was considered “a major part of the drug abuse problem in the United States”

21
22
23 ²⁸ See 21 U.S.C. § 903.

24 ²⁹ P.L. 98-473 (1984), *reprinted in* 98 Stat. 1976 *et seq.* .

25 ³⁰ Sen. Rep. No. 98-225, 98th Cong., 2d Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182,
3184.

26 ³¹ 1984 U.S.C.C.A.N. at 3442.

1 and “evidences the same sort of large-scale trafficking more commonly associated with the trade
2 in wholly illicit drugs.”³²

3 Notably absent from the legislative history of the 1984 amendments is any mention of a
4 Congressional intent to authorize the Attorney General or the DEA to regulate medical practices
5 to the exclusion of the states, or to declare that medical practices authorized by state law could
6 nevertheless be considered “illegitimate” under federal law. The “public interest” revocation
7 authority that was added in 1984³³ does not expand the Attorney General’s authority because
8 (1) the revocation authority—set forth in section 224 of the CSA—is expressly based on the
9 registration provision in section 823 of the CSA; and (2) under the registration provision,
10 “compliance with applicable State and local law” is one of the factors that “shall be considered”
11 in determining the public interest. The Ashcroft directive thus directly conflicts with the statute
12 because, under the directive, compliance with Oregon law is *not* to be considered in determining
13 the public interest.

14 Defendants’ reliance on the *Oakland Cannabis* case is similarly misplaced. In that case,
15 the Supreme Court held that there was no “medical necessity” defense to a criminal charge of
16 distributing marijuana, a Schedule I substance under the CSA. The Court explained that, by
17 listing marijuana as a CSA Schedule I substance, “*Congress* has made a determination that
18 marijuana has no medical benefits worthy of an exception.”³⁴ Congress has made no such
19 determination as to Schedule II controlled substances. Those substances—not Schedule I
20 drugs—are used to hasten a terminally ill patient’s death under the Oregon Act; Congress’s only
21 determination about Schedule II substances is that *those* substances generally have medical
22 benefits justifying an exception to the ban on dispensing controlled substances. Congress has not
23

24 ³² *Id.*

25 ³³ *See* 21 U.S.C. § 824(a)(4).

26 ³⁴ 121 S.Ct. at 1719 (emphasis added).

1 gone beyond this general determination to specify what uses would be “legitimate.” Instead,
2 Congress left that to the States.

3 Moreover, whether Congress *could* make such a determination in exercising its
4 Commerce Clause powers, consistent with the Tenth Amendment, has never been decided. The
5 Supreme Court expressly left that issue unresolved with respect to the medical use of marijuana
6 authorized by California law. The constitutional limitations apply with greater force to the
7 Schedule II substances typically utilized under the Oregon Act because—by definition—such
8 substances have many accepted medical uses. Whether this particular use is one of them is an
9 issue that Congress intended to, and must, leave to the states.

10 The other CSA cases cited by defendants all involved criminal prosecutions against
11 doctors who were found guilty of illegal trafficking in drugs.³⁵ None of those cases stand for the
12 proposition that Congress, in enacting the CSA, intended to regulate medical practices at a
13 federal level. The question of whether state or federal law would determine the standard of
14 acceptable medical care was not decided in any of those cases.³⁶

15 Defendants’ suggestion that the Ashcroft directive does not really preempt the Oregon
16 Act ignores Oregon’s law and reality. If defendants are suggesting that physicians can still
17 participate in hastening the death of dying patients as long as they do not use controlled
18 substances for that purpose, then dying patients will be deprived of the most effective method
19 available. Surely defendants do not wish to prolong or enhance a terminal patient’s end-of-life
20 suffering in this fashion. Moreover, the Oregon Act authorizes the attending physician to write a
21 “prescription for medication” to hasten the patient’s death, indicating that only controlled
22

23 ³⁵ *United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975); *United States v.*
24 *Vamos*, 797 F.2d 1146 (2nd Cir. 1986); *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975).

25 ³⁶ In *Moore*, for example, the defendant physician conceded that he did not observe generally
26 accepted medical practices in dispensing methadone to addicts. 423 U.S. at 126. *Vamos* and
Rosenberg both involved physicians who were caught trafficking in drugs. None of those cases
involved medical practices that were authorized by state law.

1 substances are authorized by the Oregon law.³⁷ Finally, even if a physician *could* utilize the
2 Oregon Act without using controlled substances, the physician would still be compelled to file
3 reports with the Oregon Department of Human Services that could be used against him in
4 administrative or criminal proceedings.

5 Even if a Congressional intent to authorize federal regulation of medical practices can be
6 gleaned from the legislative history, Congress did not effectuate that intent in the CSA.
7 Regulating medical practices and establishing applicable standards of care are areas that are
8 ordinarily left to the States; any attempt by Congress to deprive States of this power should be
9 expressed in clear, unequivocal terms in the statute itself. This follows from the principles of
10 federalism expressed by the Supreme Court in analogous situations.

11 For example, when Congress acts to abrogate a state’s sovereign immunity, it is well-
12 established that such an intention must be clearly and unequivocally expressed in the statute
13 itself.³⁸ Similarly, federal statutes will not be deemed to preempt state regulation in areas
14 historically reserved to the States “unless that was the clear and manifest purpose of Congress.”³⁹
15 That is “consistent with both federalism concerns and the historic primacy of state regulation of
16 matters of health and safety.”⁴⁰

17 Congress did not expressly demonstrate that its “clear and manifest purpose” in enacting
18 the CSA was to give the DEA authority to regulate medical practices at a federal level, thus
19 displacing states as the governmental entity with the paramount authority for deciding the
20

21
22 ³⁷ See ORS 127.815(7); 127.830; 127.840; 127.845; 127.850; and 127.885 (all referring to the
writing of “a prescription”).

23 ³⁸ See *Blatchford v. Native Village of Noatak*, 501 U.S. 775, 786, 111 S.Ct. 2578, 115 L.Ed.2d
24 686 (1991) (Congress’s intent must be in a “clear legislative statement”); *Green v. Mansour*, 474
U.S. 64, 68, 106 S.Ct. 423, 88 L.Ed.2d 371 (1985) (Congress must “unequivocally express” its
25 intent to abrogate the state’s immunity).

26 ³⁹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486, 116 S.Ct. 2240, 135 L.Ed.2d 700, 715 (1996).

⁴⁰ *Id.*

1 legitimacy of particular medical practices. If that was Congress’s intent, it should have said so,
2 expressly.

3 2. The Ashcroft directive is not entitled to any special deference.

4 Defendants argue that the Ashcroft directive is an interpretation of the “legitimate
5 medical purpose” regulation⁴¹ that is entitled to “deference” and must be upheld unless it is
6 “plainly erroneous or inconsistent with the regulation.”⁴² Defendants are wrong.

7 First, it is well recognized that courts “should not defer to an agency’s interpretation of its
8 regulations when an alternative reading is compelled by * * * other indications of the [agency’s]
9 intent at the time of the regulation’s promulgation.”⁴³ Oregon contends in this case that the
10 Ashcroft directive is invalid because an alternative reading—one that would leave the
11 determination of what medical practices are “legitimate” to the states—is compelled by other
12 indications of Congress’s intent when it enacted the CSA in 1970, and the Attorney General’s
13 intent when he promulgated the regulation in 1971.⁴⁴

14 Second, recent case law demonstrates that the Ashcroft directive is entitled to no
15 deference whatsoever as an “authoritative” interpretation of either the CSA or the “legitimate
16 medical purpose” regulation. In *United States v. Mead Corp.*,⁴⁵ the Supreme Court held that
17 tariff classification rulings issued by the United States Customs Service are not entitled to
18

19 _____
20 ⁴¹ 21 C.F.R. § 1306.04.

21 ⁴² Defendants’ Opposition to TRO at 17.

22 ⁴³ *Blattner & Sons, Inc. v. Secretary of Labor*, 152 F.3d 1102, 1106 (9th Cir. 1998), *quoting*
23 *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994). *See*
24 *also, Clean Ocean Action v. York*, 57 F.3d 328, 333 (3rd Cir. 1995) (“An agency guideline or
25 directive that conflicts with the plain meaning of a regulation is invalid”).

26 ⁴⁴ The “legitimate medical purpose” regulation was promulgated in 1971. *See* 36 F.R. 7799
(April 24, 1971). The Federal Register includes no public comments whatsoever on
“federalizing” the regulation of medical practices. Surely at least one state or other interested
party would have commented if the regulation was intended to displace states from their
traditional role in regulating medical practices.

⁴⁵ *United States v. Mead Corp.*, 533 U.S. 218, 121 S.Ct. 2164 (2001).

1 *Chevron* deference⁴⁶ because the rulings had not been promulgated pursuant to the authority
2 delegated to the agency to make rules carrying the force of law. That authority, the Court
3 explained, could be exercised through formal notice-and-comment rulemaking, formal
4 adjudications, or “some other indication of a comparable congressional intent.”⁴⁷ Because the
5 Ashcroft directive was not promulgated through notice-and-comment rulemaking, formal
6 adjudication, or any other comparable formal proceedings, it is not entitled to *Chevron* deference
7 under the square holding of *Mead*.

8 That conclusion is confirmed by *Christensen v. Harris County*.⁴⁸ There, the Supreme
9 Court held that a Department of Labor (DOL) opinion letter interpreting a DOL regulation did
10 not “warrant *Chevron*-style deference.”⁴⁹ Instead, such interpretations are “entitled to respect * *
11 * but only to the extent that those interpretations have the power to persuade.”⁵⁰ The Court also
12 declined to give deference under the standard cited by defendants—set forth in *Auer v.*
13 *Robbins*⁵¹—because “to defer to the agency’s position would be to permit the agency, under the
14 guise of interpreting a regulation, to create *de facto* a new regulation.”⁵²

15 The same is true here. Moreover, as an interpretation of the CSA, the Ashcroft directive
16 is not even entitled to the lesser level of deference, known as *Skidmore* deference.⁵³ A recent
17 Ninth Circuit decision supports that conclusion. In *Hall v. EPA*,⁵⁴ the Ninth Circuit held that the
18 Environmental Protection Agency’s (EPA) interpretation of the Clean Air Act was not even

19 _____
20 ⁴⁶ *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778,
81 L.Ed.2d 694 (1984).

21 ⁴⁷ *Mead*, 121 S.Ct. at 2171.

22 ⁴⁸ *Christensen v. Harris County*, 529 U.S. 576, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000).

23 ⁴⁹ 529 U.S. at 587.

24 ⁵⁰ *Id.* at 587 (citations and internal quotes omitted).

25 ⁵¹ *Auer v. Robbins*, 519 U.S. 452, 117 S.Ct. 905, 127 L.Ed.2d 79 (1997).

26 ⁵² *Christensen*, 529 U.S. at 588.

⁵³ See *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944).

⁵⁴ *Hall v. United States Environmental Protection Agency*, 263 F.3d 926 (9th Cir. 2001).

1 entitled to *Skidmore* deference, because (1) the interpretation “does not fit with prior
2 interpretations” adopted by the EPA,⁵⁵ and (2) the court had “no basis to conclude that the EPA
3 has drawn on any special expertise in advocating this interpretation.”⁵⁶

4 Similarly, the Ashcroft directive “does not fit” with Attorney General Reno’s prior
5 interpretation of the same statutory and regulatory scheme. Nor can Ashcroft claim to have
6 drawn on any “special expertise” in interpreting the “legitimate medical purpose” regulation.
7 The Department of Justice and the DEA are law enforcement agencies; they have absolutely no
8 expertise in which medical practices are “legitimate” and which are not. The legal opinions,
9 citation to articles and studies on one side of this hotly debated issue do not equate to the type of
10 “expertise” that qualifies for deference. Indeed, as amply demonstrated in the materials
11 submitted by intervenor-plaintiffs, there is clearly another side to this debate.⁵⁷ Thus,
12 defendants’ suggestion that the medical community is lined up unanimously in support of the
13 Ashcroft directive—and in opposition to Oregon’s law—is just wrong.

14 ⁵⁵ *Hall*, 263 F.3d at 934.

15 ⁵⁶ *Id.* at 935.

16 ⁵⁷ See Darien S. Fenn & Linda Ganzini, *Attitudes of Oregon Psychologists Toward Physician-*
17 *Assisted Suicide and the Oregon Death With Dignity Act*, 30 *Am. Psychological A. J.* 235 (June
18 1999) (finding seventy-eight percent of respondents favored the enactment of the Oregon Act);
19 Simon N. Whitney, Byron W. Brown, Howard Brody, Kirsten H. Alcer, Jerald G. Bachman &
20 Henry T. Greely, *Views of United States Physicians and Members of the American Medical*
21 *Association House of Delegates on Physician-assisted Suicide*, 16 *Journal of General Internal*
22 *Medicine* 290 (May 2001) (finding that 44.5% of respondents of nationwide random sample of
23 physicians favored legalization of physician assisted suicide while among members of AMA
24 House of Delegates 23.5% favored legalization: “The AMA leadership has emphasized that it
25 believes physician-assisted suicide to be morally wrong and poor public policy; our results
26 suggest that this view is probably not shared by most practicing physicians.”); L. Ganzini, H.D.
Nelson, M.A. Lee, D.F. Kraemer, T.A. Schmidt, M.A. Delorit, *Oregon Physicians’ Attitudes*
About and Experiences With End-Of-Life Care Since Passage of the Oregon Death with Dignity
Act, 285 *J. A.M.A.* 2363 (May 9, 2001) (finding that, of those responding (66% of all Oregon
physicians who were eligible to prescribe under the Oregon Act) that 59% disagreed with a
statement that writing a lethal prescription for a patient under the Oregon Act was immoral
and/or unethical; 51% supported the Oregon Act while 32% opposed it, and 17% neither
supported nor opposed); David Orentlicher, “*The Legalization of Physician Assisted Suicide*,”
335 *New Eng. J. Med.* 663 (August 29, 1996) (finding that, contrary to the description by the
AMA, doctors are, among other things, relievers of discomfort so that assisted suicide is
compatible with this role; surveys of physicians and the public show a majority support for the
right to assisted suicide for terminally ill patients).

1 As an interpretation of the “legitimate medical purpose” regulation, the Ashcroft directive
2 would be entitled to *Skidmore* deference only if (1) it was within the scope of delegated
3 authority;⁵⁸ and (2) it was not an attempt to create *de facto* a new regulation in the guise of an
4 “interpretation.”⁵⁹ The Ashcroft directive was outside the scope of delegated authority. The
5 Ashcroft directive is also like the DOL legal opinion overturned in *Christensen*. Even if
6 *Skidmore* deference applies, that only means that the directive would be entitled to the “respect
7 proportional to its power to persuade[.]”⁶⁰ In making that determination, courts examine a
8 variety of factors, including “the degree of the agency’s care, its consistency, formality, relative
9 expertness, and to the persuasiveness of the agency’s position.”⁶¹ Most of those factors—
10 consistency, formality, expertise—do not support giving any “deference” here.

11 3. The Ashcroft directive is invalid because the Attorney General failed to
12 comply with the APA’s rulemaking procedures.

13 The notice-and-comment provisions of the Administrative Procedures Act (APA)⁶²
14 reflect “a judgment by Congress that the public interest is served by a careful and open review of
15 the proposed administrative rules and regulations.”⁶³ Under the APA, interpretative rules and
16 statements of general policy may be issued without going through the formal notice-and-
17 comment procedures.⁶⁴ Presumably, defendants are relying on this exception to formal
18 rulemaking. But such exceptions are to be “narrowly construed and only reluctantly
19

20 _____
21 ⁵⁸ *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 650, 110 S.Ct. 1384, 108 L.Ed.2d 585 (1990)
22 (“agency determinations within the scope of delegated authority are entitled to deference”).

23 ⁵⁹ *Christensen*, 529 U.S. at 588.

24 ⁶⁰ *Mead*, 121 S.Ct. at 2175-2176 (discussing *Skidmore* deference).

25 ⁶¹ *Mead*, 121 S.Ct. at 2171-72 (footnotes omitted).

26 ⁶² 5 U.S.C. § 553.

⁶³ *Alcaraz v. Block*, 746 F.2d 593, 610 (9th Cir. 1984), quoting *Philadelphia Citizens in Action v. Schweiker*, 669 F.2d 877, 881 (3rd Cir. 1982).

⁶⁴ See 5 U.S.C. § 553(b)(A).

1 countenanced.”⁶⁵ The distinction between substantive “legislative-type” rules and interpretative
2 rules “is notoriously hazy.”⁶⁶ In general, substantive rules “are those which effect a change in
3 existing law or policy.”⁶⁷ Interpretative rules “are those which merely clarify or explain existing
4 law or regulations.”⁶⁸

5 A substantive agency action that was not promulgated through formal notice-and-
6 comment rulemaking, and that does not fit within the “interpretative rule” exception, is invalid.⁶⁹
7 In *Malone v. Bureau of Indian Affairs*,⁷⁰ the Ninth Circuit reviewed two internal memoranda
8 issued by the Bureau of Indian Affairs (BIA). The memos set forth new eligibility criteria for
9 grants available to tribal members under a federal higher education grant program. The BIA
10 contended that formal rulemaking was not required to adopt the new eligibility standards because
11 the internal memos were merely “interpretative rules.” The Ninth Circuit disagreed, holding that
12 the new standards were invalid for failure to comply with the APA’s notice-and-comment
13 rulemaking procedures.⁷¹ The court explained that the BIA memos did not fit the “interpretative
14 rule” exception because interpretative rules “merely clarify or explain existing law or
15 regulations, and do not foreclose alternative courses of action or conclusively affect rights of
16 private parties.”⁷²

17 The Ashcroft directive is like the BIA memos at issue in *Malone*. The directive does not
18 merely “clarify” or “explain” existing law; it announces a completely new interpretation of the

19 ⁶⁵ *Alcaraz*, 746 F.2d at 612 (internal quotes and citations omitted).

20 ⁶⁶ *Caraballo v. Reich*, 11 F.3d 186, 194 (D.C. Cir. 1993). *See also*, *Alcaraz*, 746 F.2d at 613
(difference is “not distinguishable with bright-line clarity”).

21 ⁶⁷ *Alcaraz*, 746 F.2d at 613, quoting *Powderly v. Schweiker*, 704 F.2d 1092, 1098 (9th Cir. 1983).

22 ⁶⁸ *Id.*

23 ⁶⁹ *See S. Cal. Aerial Advertisers’ Ass’n. v. FAA*, 881 F.2d 672, 677 (9th Cir. 1989) (“A
substantive rule is invalid if the agency has failed to comply with APA requirements”).

24 ⁷⁰ *Malone v. Bureau of Indian Affairs*, 38 F.3d 433 (9th Cir. 1994).

25 ⁷¹ *Malone*, 38 F.3d at 439 (“We reverse the district court and declare invalid the standard adopted
in the internal BIA memoranda.”).

26 ⁷² *Malone*, 38 F.3d at 438.

1 CSA and its implementing regulations, an interpretation that is the exact opposite of the
2 interpretation issued by the Attorney General just three years earlier. Moreover, the Ashcroft
3 directive on its face forecloses alternative courses of action and conclusively affects the rights of
4 terminally ill Oregonians and health care providers who seek to rely on the Oregon Act (and on
5 the Attorney General’s prior interpretation of the CSA). The purpose of the notice-and-comment
6 requirement—an open and careful *public* review of the issue—would be served by requiring
7 defendants to comply with formal rulemaking procedures. Thus, the Ashcroft directive is invalid
8 because the Attorney General failed to comply with the notice-and-comment requirements of the
9 APA.

10 4. If authorized by the CSA, Congress lacks the constitutional authority to
11 override Oregon’s determination that practices authorized by the Oregon
Act serve a legitimate medical purpose.

12 Oregon contends that Congress exceeded its Commerce Clause powers, and violated the
13 Tenth Amendment, in enacting the CSA to the extent that statute effectively delegated authority
14 to the Attorney General and DEA to override a state’s determination regarding the “legitimacy”
15 of medical practices within the state. Defendants’ only response is to suggest that (1) there is
16 “no basis” in the Supreme Court’s Commerce Clause jurisprudence for Oregon’s position; and
17 (2) the court should “disregard” Oregon’s references to the Tenth Amendment.⁷³

18 With respect to the Commerce Clause, Oregon continues to assert that the *Lopez* and
19 *Morrison* cases⁷⁴ support Oregon’s position, as explained in its opening brief. The United
20 States’ contention that the practices regulated here are intrastate activities that substantially affect
21 interstate commerce is the same argument that was rejected by the Supreme Court in those cases.
22 Thus, there is clearly a “basis” for Oregon’s position regarding the limitations of Congress’s
23 Commerce Clause powers.

24 _____
25 ⁷³ See Defendants’ Opposition to TRO at 22 and n. 5.

26 ⁷⁴ *United States v. Lopez*, 514 U.S. 549, 115 S.Ct. 1624, 131 L.Ed.2d 626 (1995); *United States*
v. Morrison, 529 U.S. 598, 120 S.Ct. 1740, 146 L.Ed.2d 658 (2000).

1 medical profession to the states. If the CSA is interpreted to “federalize” that issue, it is
2 unconstitutional.

3 To grant a preliminary injunction, the court need only reaffirm what it decided on
4 November 8—that Oregon has a *chance* of prevailing on the merits, and that the balance of
5 harms tips in favor of preserving the status quo until the legal issues presented here can be fully
6 addressed on the merits. Nothing more is required. Oregon, and the intervenor-plaintiffs, have
7 met their burden.

8 Accordingly, Oregon’s motion for a preliminary injunction should be granted.

9 DATED this ____ day of November, 2001.

10 Respectfully submitted,

11 HARDY MYERS
12 Attorney General

13
14

STEPHEN K. BUSHONG #85130
15 Attorney-in-Charge
16 Trial Attorney
17 Of Attorneys for Plaintiff
1162 Court Street NE
Salem, OR 97301-4096
(503) 378-6313

18
19
20
21
22
23
24
25
26