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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

STATE OF OREGON,

Plaintiff,

&

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

Plaintiffs-Intervenors,

v.

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

Defendants.

Case No. CV01-1647-JO

OREGON'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION{ TC "INTRODUCTION" \f C \l "1" }

Two months ago, Attorney General John Ashcroft (Ashcroft) concluded—for the first time in history—that a state law authorizing a particular practice was effectively preempted by a 30-year-old federal regulation promulgated under the Controlled Substances Act (CSA). Ashcroft's directive to the head of the Drug Enforcement Administration (DEA) to that effect violates at least four principles of law.

First, the directive was issued without complying with the public notice and comment procedures required by federal law for such decisions. Second, the directive violates—both procedurally and substantively—the President's Executive Order on federalism.[1] Third, the directive violates the Supreme Court's rule that agency actions may not encroach upon areas traditionally reserved to the states without a "clear statement" from Congress that it intended such a result. Fourth, the directive exceeds the authority delegated by Congress and is inconsistent with Congress's intent as expressed in the CSA and pertinent legislative history.[2]

BACKGROUND{ TC "BACKGROUND" \f C \l "1" }

I. The Controlled Substances Act{ TC "I. The Controlled Substances Act" \f C \l "2" }.

A. The 1970 Act{ TC "A. The 1970 Act" \f C \l "3" }.

The CSA was enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[3] The seven parts of the CSA as enacted formed a comprehensive scheme to regulate and control the abuse of drugs trafficked in interstate commerce.[4] The Act established

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[1] *See* Exec. Order 13132, 64 Fed. Reg. 43255 (Aug. 4, 1999){ TA \l "64 Fed. Reg. 43255 (Aug. 4, 1999)" \s "64 Fed. Reg. 43255" \c 6 }.

[2] Oregon also contends that the CSA—if construed to authorize the Ashcroft directive—exceeds Congress's authority under the Commerce Clause and violates Oregon's sovereign rights as reflected in the constitutional structure and confirmed by the Tenth Amendment. This court will need to address the constitutional issues only if it declines to invalidate the Ashcroft directive on sub-constitutional grounds.

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970){ TA \l "Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970)" \s "91-513, 84 Stat. 1236 (1970)" \c 3 }.

[4] *See* CSA, Part A, containing introductory provisions; Part B, addressing the authority to control, standards and schedules; Part C, addressing the registration of manufacturers, distributors and dispensers of controlled substances; Part D, defining offenses and penalties;

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1 five schedules of controlled substances; listing a drug in one of these schedules depended on the
2 drug's potential for abuse, the extent to which it had a currently accepted medical use in
3 treatment in the United States, and the extent to which abuse of the drug could lead to
4 psychological or physical dependence.[5] The Attorney General was authorized to add any
5 substance to these schedules if he made similar findings.[6] Manufacturers, distributors, and
6 dispensers of controlled substances are required to register with the Attorney General under the
7 Act.[7]

8 Physicians who prescribe controlled substances, and pharmacists who fill such
9 prescriptions, are considered "practitioners" who "dispense" controlled substances as defined in
10 the Act.[8] Under the law as originally enacted, registration of practitioners to dispense controlled
11 substances was *required* as long as the practitioners were "authorized to dispense * * * under the
12 laws of the state in which they practice."[9] A practitioner's registration could be suspended or
13 revoked by the Attorney General only if the registrant (1) materially falsified an application;
14 (2) was convicted of a felony relating to controlled substances; or (3) had his state license
15 suspended or revoked.[10] Proceedings to suspend or revoke the registration would be conducted
16 as a formal adjudication under the Administrative Procedures Act (APA).[11] In addition,
17 physicians who dispensed drugs without a registration or in a manner inconsistent with the terms
18 of a registration were subject to criminal penalties under the Act.[12]

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Part E, addressing administrative and enforcement provisions; Part F, establishing an advisory commission; and Part G, containing general provisions.

[5] *See* CSA § 202(b), 21 U.S.C. § 812(b){ TA \l "21 U.S.C. § 812(b)" \s "21 U.S.C. § 812(b)" \c 2 }.

[6] CSA § 201(a), 21 U.S.C. § 811(a){ TA \l "21 U.S.C. § 811(a)" \s "21 U.S.C. § 811(a)" \c 2 }.

[7] CSA § 302, 21 U.S.C. § 822{ TA \l "21 U.S.C. § 822" \s "21 U.S.C. § 822" \c 2 }.

[8] *See* CSA § 102(10) & (20), 21 U.S.C. § 802(10){ TA \l "21 U.S.C. § 802(12)" \s "21 U.S.C. § 802(12)" \c 2 }{ TA \l "21 U.S.C. § 802(10)" \s "21 U.S.C. § 802(10)" \c 2 }, (21).

[9] CSA § 303(f).

[10] CSA § 304(a).

[11] CSA § 304(c).

[12] CSA § 401.

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An examination of the Act as a whole makes it clear that Congress was primarily concerned about the problem of illegal trafficking in drugs. This is confirmed by the congressional findings and declarations set forth in section 101 of the Act, which explicitly addressed the need to control the "traffic in controlled substances."[13] The legislative history indicates that the main purpose of the Act was "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States[.]"[14] The House Committee Report on the bill explains: "The bill provides for control * * * of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal."[15] The legislative history confirms that the registration of practitioners to dispense controlled substances was intended to be "as a matter of right where the individual or firm is *engaged in activities involving these drugs which are authorized or permitted under state law*."[16] Registration was a matter of right because Congress was "concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine[.]"[17]

The relationship between the CSA and state law was specifically addressed in the Act. Section 708 of the original Act provides:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any state law on the same subject matter which would otherwise be within the authority of the state, unless there is a positive conflict between that provision of this subchapter and that state law so that the two cannot consistently stand together.[18]

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[13] CSA § 101(3).

[14] H.R. Rep. No. 91-1444, 91st Cong. (2d Sess. 1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567{ TA \l "H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566" \s "1970 U.S.C.C.A.N." \c 3 }.

[15] 1970 U.S.C.C.A.N.{ TA \s "1970 U.S.C.C.A.N." } at 4569. *See also, United States v. Moore*, 423 U.S. 122, 135, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975){ TA \l "*United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975)" \s "Moore" \c 1 } ("Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels").

[16] 1970 U.S.C.C.A.N.{ TA \s "1970 U.S.C.C.A.N." } at 4590 (emphasis added).

[17] 1970 U.S.C.C.A.N.{ TA \s "1970 U.S.C.C.A.N." } at 4581.

[18] CSA § 708, 21 U.S.C. § 903{ TA \l "21 U.S.C. § 903" \s "21 U.S.C. § 903" \c 2 }.

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1 Congress delegated authority to the Attorney General in three different provisions of the
2 original Act. Section 201 authorizes the Attorney General to "apply the provisions of this
3 subchapter" to controlled substances and other drugs, and to add or remove drugs from the
4 schedules.[19] Section 301 authorizes the Attorney General to "promulgate rules and
5 regulations * * * relating to the registration and control of the manufacture, distribution and
6 dispensing of controlled substances and to the registration and control of regulated persons and
7 regulated transactions."[20] Section 501 authorizes the Attorney General to "promulgate and
8 enforce any rules, regulations and procedures which he may deem necessary for the efficient
9 execution of his functions under this subchapter."[21]

10 **B. Amendments to the CSA{** TC "B. Amendments to the CSA" \f C \l "3" **}.**

11 The CSA has been amended at least a dozen times since it was enacted in 1970. Each
12 amendment was a further attempt by Congress to address the problems of drug abuse and illegal
13 trafficking in drugs.[22] The 1984 amendment—known as the Dangerous Drug Diversion Control

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[19] CSA § 301, 21 U.S.C. § 811(a)**{** TA \s "21 U.S.C. § 811(a)" **}**.
15 [20] CSA § 301, 21 U.S.C. § 821**{** TA \l "21 U.S.C. § 821" \s "21 U.S.C. § 821" \c 2 **}**.
16 [21] CSA § 501(b), 21 U.S.C. § 871**{** TA \l "21 U.S.C. § 871" \s "21 U.S.C. § 871" \c 2 **}**.
17 [22] *See* Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124 (1974)**{** TA \l "Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124 (1974)" \s "93-281, 88 Stat. 124 (1974)" \c 3 **}**; Psychotropic Substances Act of 1978, Pub. L. No. 95-633, 92 Stat. 3768
18 (1978)**{** TA \l "Psychotropic Substances Act of 1978, Pub. L. No. 95-633, 92 Stat. 3768 (1978)" \s "95-633, 92 Stat. 3768 (1978)" \c 3 **}**; Controlled Substances Penalties Amendments Act of
19 1984, Pub. L. No. 98-473, 98 Stat. 2068 (1984)**{** TA \l "Controlled Substances Penalties Amendments Act of 1984, Pub. L. No. 98-473, 98 Stat. 2068 (1984)" \s "98-473, 98 Stat. 2068
20 (1984)" \c 3 **}**; Dangerous Drug Diversion Control Act of 1984, Pub. L. No. 98-473, 98 Stat. 2070 (1984)**{** TA \l "Dangerous Drug Diversion Control Act of 1984, Pub. L. No. 98-473, 98
21 Stat. 2070 (1984)" \s "98-473, 98 Stat. 2070 (1984)" \c 3 **}**; Narcotics Control Trade Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207 (1986)**{** TA \l "Narcotics Control Trade Act of 1986, Pub. L.
22 No. 99-570, 100 Stat. 3207 (1986)" \s "99-570, 100 Stat. 3207 (1986)" \c 3 **}**; Anti-drug Abuse Amendments Act of 1988, Pub. L. No. 100-690, 102 Stat. 4312 (1988)**{** TA \l "Anti-drug Abuse
23 Amendments Act of 1988, Pub. L. No. 100-690, 102 Stat. 4312 (1988)" \s "100-690, 102 Stat. 4312 (1988)" \c 3 **}**; Anabolic Steroids Control Act of 1990, Pub. L. No. 101-647, 104 Stat. 4851
24 (1990)**{** TA \l "Anabolic Steroids Control Act of 1990, Pub. L. No. 101-647, 104 Stat. 4851 (1990)" \s "101-647, 104 Stat. 4851 (1990)" \c 3 **}**; Domestic Chemical Diversion Control Act of
25 1993, Pub. L. No. 103-200, 107 Stat. 2333 (1993)**{** TA \l "Domestic Chemical Diversion Control Act of 1993, Pub. L. No. 103-200, 107 Stat. 2333 (1993)" \s "103-200, 107 Stat. 2333 (1993)" \c
26 3 **}**; Drug Free Truck Stop Act of 1994, Pub. L. No. 103-322, 108 Stat. 2046 (1994)**{** TA \l "Drug Free Truck Stop Act of 1994, Pub. L. No. 103-322, 108 Stat. 2046 (1994)" \s "103-322, 108 Stat. 2046 (1994)" \c 3 **}**; Comprehensive Methamphetamine Control Act of 1996, Pub. L. No. 104-

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Act of 1984—was part of the Comprehensive Crime Control Act passed by Congress that year. According to the legislative history, the purpose of that Act was "to make major comprehensive improvements to the Federal criminal laws."[23] One of these "improvements" was the addition of the "public interest" provisions in the CSA's registration and revocation provisions. Specifically, section 823(f) was amended to provide that the Attorney General "may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest."[24] In determining the public interest under the 1984 amendment, the Attorney General is required to consider five factors, including compliance with applicable state laws.[25] Section 824 provides that a registration under section 823 may be suspended or revoked upon a finding that the registrant "has committed such acts as would render his registration under section 823 of this Title inconsistent with the public interest as determined under such section[.]"[26]

The legislative history of this amendment states that it was one of the amendments that was "intended to address the severe problem of diversion of drugs of legitimate origin into the

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237, 110 Stat. 3099 (1996){ TA \l "Comprehensive Methamphetamine Control Act of 1996, Pub. L. No. 104-237, 110 Stat. 3099 (1996)" \s "104-237, 110 Stat. 3099 (1996)" \c 3 }; Drug Induced Rape Prevention and Punishment Act of 1996, Pub. L. No. 104-305, 110 Stat. 3807 (1996){ TA \l "Drug Induced Rape Prevention and Punishment Act of 1996, Pub. L. No. 104-305, 110 Stat. 3807 (1996)" \s "104-305, 110 Stat. 3807 (1996)" \c 3 }; Western Hemisphere Drug Elimination Act, Pub. L. No. 105-277, 112 Stat. 2681-693 (1998){ TA \l "Western Hemisphere Drug Elimination Act, Pub. L. No. 105-277, 112 Stat. 2681-693 (1998)" \s "105-277, 112 Stat. 2681-693 (1998)" \c 3 }; Controlled Substances Trafficking Prohibition Act, Pub. L. No. 105-357, 112 Stat. 3271 (1998){ TA \l "Controlled Substances Trafficking Prohibition Act, Pub. L. No. 105-357, 112 Stat. 3271 (1998)" \s "105-357, 112 Stat. 3271 (1998)" \c 3 }; Drug Addiction Treatment Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000){ TA \l "Drug Addiction Treatment Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000)" \s "106-172, 114 Stat. 7 (2000)" \c 3 }; Methamphetamine Anti-Proliferation Act of 2000, Pub. L. No. 106-310, 114 Stat. 1222 (2000){ TA \l "Methamphetamine Anti-Proliferation Act of 2000, Pub. L. No. 106-310, 114 Stat. 1222 (2000)" \s "106-310, 114 Stat. 1222 (2000)" \c 3 }.

[23] Sen. Rep. No. 98-225, 98th Cong. (2d Sess. 1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3184{ TA \l "Sen. Rep. No. 98-225, 98th Cong. (2d Sess. 1984), *reprinted in* 1984 U.S.C.C.A.N. 3182" \s "1984 U.S.C.C.A.N. 3182" \c 3 }.

[24] 21 U.S.C. § 823(f).

[25] 21 U.S.C. § 823(f){ TA \l "21 U.S.C. § 823(f)" \s "21 U.S.C. § 823(f)" \c 2 }.

[26] 21 U.S.C. § 824(1)(4){ TA \l "21 U.S.C. § 824(1)(4)" \s "21 U.S.C. § 824(1)(4)" \c 2 }.

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illicit market."[27] This diversion was considered to be "a major part of the drug abuse problem in the United States" and "evidences the same sort of large-scale trafficking more commonly associated with the trade in wholly illicit drugs."[28] The legislative history acknowledges that the current provisions of the Act "have been quite effective in meeting the diversion problem at the manufacturer and distributor levels," in part because the CSA as originally enacted allowed issuance of a registration to manufacture or distribute controlled substances "only when clearly consistent with the public interest."[29] The report explains that "the same strong regulatory authority to maintain a 'closed' distribution chain does not exist at the practitioner level," despite the fact that "80 to 90 percent of all current diversion occurs at this level."[30] Thus, according to the report, "one weakness of current law is that it has not been adequate to address the shift in the source of diversion from the manufacturer and distributor levels to the practitioner level."[31]

The "public interest" authority was specifically designed to address this "weakness." The limited grounds for revoking or denying a practitioner's registration set forth in the original Act was thought to be "contributing to the problem of diversion of dangerous drugs."[32] The report noted:

> [B]ecause of a variety of legal, organizational, and resource problems, many States are unable to take effective or prompt action against violating registrants. Since State revocation of a practitioner's license or registration is a primary basis on which Federal registration may be revoked or denied, problems at the state regulatory level have had a serious adverse impact on Federal antidiversion efforts.[33]

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[27] Sen. Rep. No. 98-225, 98th Cong. (2d Sess. 1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3442{ TA \s "1984 U.S.C.C.A.N. 3182" }.

[28] *Id.*

[29] *Id.* at 3443.

[30] *Id.* at 3443-44.

[31] *Id.* at 3444.

[32] *Id.*

[33] *Id.*

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The Drug Addiction Treatment Act of 2000[34] added to the registration provisions set forth in section 823 of the CSA. The 2000 Act authorized the Attorney General to adopt regulations or practice guidelines on registration requirements for dispensing narcotics for treatment or detoxification purposes. The 2000 Act further provides:

> Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.[35]

C. Formal regulations{ TC "C. Formal regulations" \f C \l "3" **}.**

In 1971, the Attorney General adopted formal regulations implementing the CSA.[36] One of those regulations, now codified at 21 C.F.R. § 1306.04**{** TA \l "21 C.F.R. § 1306.04" \s "21 C.F.R. § 1306.04" \c 6 **}**, provides in pertinent part:

> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. * * * An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 823) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Ashcroft relied on this “legitimate medical purpose” regulation in issuing his directive.

D. Interpretive rules{ TC "D. Interpretive rules" \f C \l "3" **}.**

The Ashcroft directive purports to set forth Ashcroft’s “interpretation” of 21 C.F.R. § 1306.04**{** TA \s "21 C.F.R. § 1306.04" **}**.[37] This is the only interpretive rule ever issued as to that regulation. The only other interpretive rule issued as to any aspect of the CSA was issued

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[34] Pub. L. No. 106-310**{** TA \s "106-310, 114 Stat. 1222 (2000)" **}**, § 3502, 114 Stat. 1222 (2000).

[35] 21 U.S.C. § 823(g)(2)(H)(i)**{** TA \l "21 U.S.C. § 823(g)(2)(H)(i)" \s "21 U.S.C. § 823(g)(2)(H)(i)" \c 2 **}**.

[36] *See* 36 Fed. Reg. 7799 (April 24, 1971)**{** TA \l "36 Fed. Reg. 7799 (April 24, 1971)" \s "36 Fed. Reg. 7799 (April 24, 1971)" \c 6 **}**.

[37] *See* Fed. Reg., Vol. 66, No. 218, Friday, November 9, 2001**{** TA \l "Fed. Reg., Vol. 66, No. 218, Friday, November 9, 2001" \s "Fed. Reg., Vol. 66, No. 218, Friday, November 9, 2001" \c 6 **}** (publication of the Ashcroft directive as an “interpretive rule”).

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1 one month before the Ashcroft directive. That rule interprets the definition of "marijuana" in the
2 CSA to include paper, rope and other industrial products made from hemp.[38]

3 **II. The Oregon Death with Dignity Act{** TC "II. The Oregon Death with Dignity Act"
4 \f C \l "2" **}.**

5 Oregon's Death with Dignity Act (ORS 127.800 through 127.995**{** TA \l "ORS 127.800
6 through 127.995" \s "ORS 127.800 through 127.995" \c 2 **}**) (the Oregon Act), was enacted in
7 1994 through the initiative power reserved to the people of Oregon. In 1997, Oregon voters
8 overwhelmingly rejected a proposal to repeal the Oregon Act. The Oregon Act establishes
9 comprehensive procedures by which competent, terminally ill adults may obtain a prescription
10 for the purpose of hastening their death. Physicians, pharmacists, and others who participate in
11 compliance with the Oregon Act are not subject to civil or criminal sanctions or professional
12 disciplinary actions based on that conduct. Health care providers are required by the Oregon Act
13 to file reports with the Department of Human Services documenting the actions that were taken
14 under the Oregon Act.[39]

15 In the first three years after the Oregon Act took effect, 70 terminally ill
16 Oregonians—most of them suffering in the final stages of terminal cancer—utilized the Oregon
17 Act to hasten death.[40] In each instance, a controlled substance listed under the CSA was
18 utilized.[41]

19 **III. The Ashcroft directive{** TC "III. The Ashcroft directive" \f C \l "2" **}.**

20 The Ashcroft directive was the culmination of a series of actions taken by federal
21 officials in response to the Oregon Act. Shortly before the Oregon Act went into effect,
22 Representative Henry Hyde and Senator Orrin Hatch asked for an opinion from the DEA on

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[38] *See* 66 Fed. Reg. 51530 (Oct. 9, 2001){ TA \l "66 Fed. Reg. 51530 (Oct. 9, 2001)" \s "66 Fed. Reg. 51530 (Oct. 9, 2001)" \c 6 }. DEA issued, in a separate document, an interim substantive regulation that exempts industrial products from control under the CSA.

[39] *See* ORS 127.865(1)(b)**{** TA \l "ORS 127.865(1)(b)" \s "127.865(1)(b)" \c 2 **}**.

[40] *See* Hedberg Aff., Exhibit 4.

[41] Hedberg Aff., ¶ 6.

whether actions taken by Oregon physicians and pharmacists under the Oregon Act would violate the CSA.[42] The DEA opined at that time that such actions would violate the CSA.[43] Oregon Attorney General Hardy Myers (Myers) promptly asked the United States Department of Justice to reconsider the DEA's interpretation of the CSA.[44] On June 5, 1998, Attorney General Janet Reno concluded that Congress did not intend to delegate authority to the Attorney General to regulate medical practices within the states or to override a state's determination as to what constituted a legitimate medical practice.[45]

The federal efforts then shifted to Congress. First, a bill known as the "Lethal Drug Abuse Prevention Act" was introduced.[46] After the American Medical Association objected to that bill, it was rewritten as the "Pain Relief Promotion Act." That bill would have amended the CSA to give DEA the authority to prohibit the use of controlled substances for purposes of hastening the death of terminally ill patients notwithstanding state law.[47] Congressional action on the issue ended after Oregon Senator Ron Wyden announced his intention to filibuster if the Pain Relief Promotion Act reached the Senate floor for debate.[48]

After the Bush administration took office, Myers wrote to Ashcroft, the new Attorney General, requesting an opportunity to be heard in the event that Ashcroft decided to reconsider Attorney General Janet Reno's opinion regarding the Oregon Act.[49] The response to this request was a letter indicating that Ashcroft "would be happy to include [Oregon's] views" if he ever

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[42] Bushong Aff., Exs. 1 & 2.

[43] Bushong Aff., Ex. 3.

[44] Bushong Aff., Ex. 4.

[45] Bushong Aff., Exs. 5 & 6.

[46] H.R. 4006, 105th Cong. (1998){ TA \l "H.R. 4006, 105th Cong. (1998)" \s "H.R. 4006, 105th Cong. (1998)" \c 3 }.

[47] *See* H.R. 2260, 106th Cong. (1999){ TA \l "H.R. 2260, 106th Cong. (1999)" \s "H.R. 2260, 106th Cong. (1999)" \c 3 }.

[48] *See The Oregonian*, "Wyden Ready to Filibuster Over Suicide," October 27, 2000{ TA \l "*The Oregonian*, \"Wyden Ready to Filibuster Over Suicide,\" October 27, 2000" \s "Wyden" \c 3 }.

[49] Bushong Aff., Ex. 7.

decided to review Reno's interpretation of the CSA.[50] In the meantime, unbeknownst to Oregon and the public, Deputy Assistant Attorney General Sheldon Bradshaw and Special Counsel Robert J. Delahunty were working on a comprehensive legal opinion addressing the issue of Ashcroft's authority under the CSA to override the Oregon Act. Bradshaw and Delahunty submitted their legal opinion to Ashcroft on June 27, 2001; the opinion concluded that practices authorized by the Oregon Act do not constitute "a legitimate medical purpose" and therefore violate the CSA.[51] The opinion was not released to the public until November 6, 2001, when Ashcroft issued the directive to DEA administrator Asa Hutchinson that is at issue in this case. The directive concludes that actions taken by Oregon physicians and pharmacists under the Oregon Act would violate the CSA. The directive was published in the Federal Register on November 9, 2001, but it has not taken effect because of the temporary restraining order issued in this case.

IV. The APA's public notice and comment requirement{ TC "IV. The APA's public notice and comment requirement" \f C \l "2" **}.**

The Administrative Procedures Act (APA) establishes a statutory scheme for informal, "notice-and-comment" rulemaking.[52] Public notice and comment is not required, however, for "interpretative rules, general statements of policy, or rules of agency organization, procedure or practice."[53]

The Supreme Court has not established a clear test for distinguishing between substantive, "legislative" rules—which require public notice and comment—and interpretive rules (which do not). In the only Supreme Court case in recent years to confront the

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[50] Bushong Aff., Ex. 8.

[51] Bushong Aff., Ex. 9.

[52] 5 U.S.C. § 553(b) and (c){ TA \l "5 U.S.C. § 553(b) and (c)" \s "5 U.S.C. § 553(b) and (c)" \c 2 }.

[53] 5 U.S.C. § 553(b)(A){ TA \l "5 U.S.C. § 553(b)(A)" \s "5 U.S.C. § 553(b)(A)" \c 2 }. *See also* 5 U.S.C. § 553(d)(2){ TA \l "5 U.S.C. § 553(d)(2)" \s "5 U.S.C. § 553(d)(2)" \c 2 }.

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1 issue—*Shalala v. Guernsey Memorial Hospital*[54]—the Court held in a five to four decision that a
2 Medicare reimbursement guideline adopted without public notice and comment was a valid
3 interpretive rule "issued by an agency to advise the public of the agency's construction of the
4 statutes and rules which it administers."[55] The Court did not promulgate a test for distinguishing
5 between substantive and interpretive rules, though the Court was careful to note that
6 (1) interpretive rules "do not have the force and effect of law and are not accorded that weight in
7 the adjudication process"; and (2) "APA rulemaking would still be required if [the guideline]
8 adopted a new position inconsistent with any of the Secretary's existing regulations."[56]
9 The Ninth Circuit has addressed the distinction between substantive and interpretive rules
10 on several occasions. In *Alcaraz v. Block*, the court—citing earlier authorities—stated that
11 exceptions to the APA's public notice and comment requirement "will be narrowly construed
12 and only reluctantly countenanced."[57] This was consistent "with Congress's clear intent to
13 preserve the statutory purpose of informal rulemaking by making sure those exceptions did not
14 become 'escape clauses' which an agency could utilize at its whim."[58]
15 The *Alcaraz* court explained that the APA's informal, notice and comment rulemaking
16 reflected "a judgment by Congress that the public interest is served by a careful and open review
17 of proposed administrative rules and regulations."[59] This
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> "allows the agency to educate itself on the full range of interests the rule affects, and reintroduces a representative public voice, thus ensuring fairness to affected

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[54] *Shalala v. Guernsey Mem'l. Hosp.*, 514 U.S. 87, 115 S.Ct. 1232, 131 L.Ed.2d 106 (1995){ TA \l "*Shalala v. Guernsey Mem'l. Hosp.*, 514 U.S. 87, 115 S.Ct. 1232, 131 L.Ed.2d 106 (1995)" \s "Guernsey" \c 1 }.

[55] 514 U.S. at 99 (internal quotes and citations omitted). The Court used the term "interpretive" rather than the APA's term, "interpretative." Other courts have adopted this practice. For the sake of consistency, Oregon uses the word "interpretive" in this brief when referring to the authority granted under the APA.

[56] 514 U.S. at 99-100.

[57] *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984){ TA \l "*Alcaraz v. Block*, 746 F.2d 593 (9th Cir. 1984)" \s "Alcaraz" \c 1 } (citations omitted).

[58] *Id*. (citations omitted).

[59] *Id*. at 610 (internal quote and citation omitted).

> parties after governmental authority has been delegated to unrepresentative agencies, through sensitive efficient governmental decision-making."[60]

In *Malone v. Bureau of Indian Affairs*,[61] the Ninth Circuit held that two internal Bureau of Indian Affairs memoranda that "interpreted" a formal regulation on Native American eligibility for higher education grants were invalid because the BIA failed to comply with the APA's notice and comment requirement. The court explained that the BIA memos did not fit within the "interpretive rule" exception because they established a new eligibility standard that "goes beyond faithful implementation of a pre-existing rule[.]"[62] The new standard was substantive because it "both forecloses other options, and conclusively affects the rights of individuals[.]"[63]

In *Chief Probation Officers of California v. Shalala*,[64] the Ninth Circuit addressed the interplay between the Supreme Court's decision in *Guernsey***{** TA \s "Guernsey" **}** and the earlier Ninth Circuit decisions on the distinction between legislative and interpretive rules. The issue in *Chief***{** TA \s "Chief" **}** *Probation Officers* was the validity of an "Action Transmittal" (AT-95-9) issued by the Department of Health and Human Services (HHS). AT-95-9 effectively terminated federal matching funds for state juvenile justice programs because it set forth a new interpretation of the existing matching funds regulation. Under the new interpretation, the matching funds regulation simply did not apply to the juvenile justice program.

The Ninth Circuit held that AT-95-9 was a valid interpretive rule. The court cited three factors supporting that conclusion. First, AT-95-9, like the guideline at issue in *Guernsey***{** TA \s "Guernsey" **}**, "was issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers."[65] Second, AT-95-9 "is not inconsistent with a regulation

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[60] *Id*. at 611 (internal quotes and citations omitted).

[61] *Malone v. Bureau of Indian Affairs*, 38 F.3d 433 (9th Cir. 1994)**{** TA \l "*Malone v. Bureau of Indian Affairs*, 38 F.3d 433 (9th Cir. 1994)" \s "Malone" \c 1 **}**.

[62] *Malone***{** TA \s "Malone" **}**, 38 F.3d at 438.

[63] *Id*. (internal quotes omitted).

[64] *Chief Probation Officers of California v. Shalala*, 118 F.3d 1327 (9th Cir. 1997)**{** TA \l "*Chief Probation Officers of California v. Shalala*, 118 F.3d 1327 (9th Cir. 1997)" \s "Chief" \c 1 **}**.

[65] *Chief***{** TA \s "Chief" **}** *Probation Officers*, 118 F.3d at 1333.

having the force of law."[66] Third, "AT-95-9 itself does not purport to have the force of law or to warrant the deference accorded a regulation that is challenged in the courts."[67]

The *Chief{* TA \s "Chief" *} Probation Officers* court went on to examine whether earlier Ninth Circuit decisions were overruled by *Guernsey{* TA \s "Guernsey" *}*, "or whether, upon a careful reading, they are in fact consistent with *Guernsey*."[68] The court concluded that its prior precedents were not overruled by *Guernsey{* TA \s "Guernsey" *}* because they did not "stand for the blanket proposition that any change in policy constitute[d] a legislative rule[.]"[69] Under *Chief{* TA \s "Chief" *} Probation Officers*, in order for a rule to be invalid on the grounds of inconsistency with a prior rule, "the rule would have to be inconsistent with another rule having the force of law, not just any interpretation regardless of whether it had been codified."[70]

Subsequent Ninth Circuit cases have applied different criteria in deciding the issue. In one case, the court—relying on *Alcaraz{* TA \s "Alcaraz" *}* and other pre-*Guernsey{* TA \s "Guernsey" *}* cases—concluded that an agency's administrative interpretation of a mine safety statute and regulations was a valid interpretive rule.[71] The court stated that interpretive rules "merely clarify or explain existing law or regulations," while "a rule that effects a change in existing law or policy is legislative."[72]

In another case, the court affirmed a preliminary injunction that stayed action under two Bureau of Immigration Affairs' directives that were adopted without complying with the APA's notice and comment requirements.[73] The United States argued that the BIA directives were

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[66] *Id*. at 1334.

[67] *Id*. at 1335.

[68] *Id*. at 1335.

[69] *Id*. at 1335-36.

[70] *Id*. at 1337.

[71] *Blattner & Sons, Inc. v. Secretary of Labor*, 152 F.3d 1102, 1109 (9th Cir. 1998){ TA \l "*Blattner & Sons, Inc. v. Secretary of Labor*, 152 F.3d 1102 (9th Cir. 1998)" \s "Blattner" \c 1 }.

[72] *Id*. (citations and internal quotes omitted).

[73] *Barahona-Gomez v. Reno*, 167 F.3d 1228, 1238 (9th Cir. 1999){ TA \l "*Barahona-Gomez v. Reno*, 167 F.3d 1228 (9th Cir. 1999)" \s "Barahona-Gomez" \c 1 }.

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general policy statements that did not require public notice and comment. The Ninth Circuit disagreed, stating:

> Determining whether a directive is a substantive rule or a general policy requires the reviewing court to examine the amount of discretion retained by the recipients of the directive.[74]

In remanding for further examination by the district court, the court noted that the directives "were purportedly temporary and internal, but they did not leave any real discretion to the BIA board members or the immigration judges."[75]

In another case, the court acknowledged that "[c]ourts have struggled with identifying the difference between 'legislative rules' and 'interpretative rules.'"[76] The court held in that case that a Bureau of Prisons program statement addressing an early release program was a valid interpretive rule because "the program statement is not inconsistent with" the existing substantive regulation.[77]

V. The President's Executive Order on federalism{ TC "V.The President's Executive Order on federalism" \f C \l "2" }.

Executive Order 13132 (copy attached) addresses federal "policies that have federalism implications." These are defined as "regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Section 2 of the Executive Order lists a number of "fundamental federalism principles" that agencies "shall be guided by" in formulating and implementing policies that have federalism implications. Several of those principles are relevant here. One guiding principle states:

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[74] *Id.* at 1235.

[75] *Id.*

[76] *Gunderson v. Hood*, 268 F.3d 1149, 1154 (9th Cir. 2001){ TA \l "*Gunderson v. Hood*, 268 F.3d 1149 (9th Cir. 2001)" \s "Gunderson" \c 1 }.

[77] *Id.* at 1154.

> The national government should be deferential to the States when taking action that affects the policymaking discretion of the States and should act only with the greatest caution where state or local governments have identified uncertainties regarding the constitutional or statutory authority of the national government.[78]

Section 3 of the Executive Order establishes "federalism policymaking criteria" to which agencies "shall adhere" to the extent permitted by law. One of those criteria states:

> National action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance.[79]

The Executive Order also includes procedural requirements—including prior consultation with States—that must be followed before an agency adopts policies that have federalism implications or takes actions that preempt state law.

VI. The Supreme Court's "clear statement" requirement{ TC "VI. The Supreme Court's \"clear statement\" requirement" \f C \l "2" }.

The Supreme Court's "clear statement" rule provides as follows:

> Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. This requirement stems from our prudential desire not to needlessly reach constitutional issues and our assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority. This concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power.[80]

In *Solid{* TA \s "Solid" *} Waste Agency*, the Court applied this rule to invalidate an interpretive rule adopted by the Army Corps of Engineers (Corps). The Corps' interpretive rule—known as the "Migratory Bird Rule"—purported to interpret the jurisdictional provisions of the Clean Water Act (CWA) and its implementing regulations. Under the CWA and its regulations, the

[78] Executive Order 13132, § 2(i).

[79] Executive Order 13132, § 3(b).

[80] *Solid Waste Agency v. Army Corps of Eng'rs*, 531 U.S. 159, 172-173, 121 S.Ct. 675 (2001){ TA \l "*Solid Waste Agency v. Army Corps of Eng'rs*, 531 U.S. 159, 121 S.Ct. 675 (2001)" \s "Solid" \c 1 } (citations omitted).

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1 Corps' jurisdiction applied to "the waters of the United States."[81] The Migratory Bird Rule
2 extended that jurisdiction to intrastate waters that, among other things, would be used as habitat
3 by migratory birds that cross state lines. The Court held that the existing regulation, "as clarified
4 and applied * * * pursuant to the Migratory Bird Rule exceeds the authority granted to [the
5 Corps] under section 404(a) of the CWA."[82]

6 The Court explained that the Migratory Bird Rule raises "significant constitutional
7 questions" as to whether the Corps' interpretation of the CWA exceeded the grant of authority to
8 Congress under the Commerce Clause, yet the Court found "nothing approaching a clear
9 statement from Congress that it intended" the CWA to reach that far.[83] Such an extension
10 "would result in a significant impingement of the States' traditional and primary power over land
11 and water use."[84] In the absence of such a "clear statement from Congress," the court concluded
12 that it must "read the statute as written to avoid the significant constitutional and federalism
13 questions raised by respondents' interpretation[.]"[85]

14 The "clear statement" rule has been applied in other contexts that raise similar federalism
15 concerns. For example, in *Gregory v. Ashcroft*, the Court's concerns about preserving a "healthy
16 balance of power" between States and the federal government led to its refusal to supercede
17 Missouri law in applying the federal Age Discrimination in Employment Act absent a clear
18 statement from Congress that that was its intent.[86] In addition, "Congress may abrogate the
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20 [81] *See id.* at 163, *citing* 33 U.S.C. §§ 1344(a) **{** TA \l "33 U.S.C. § 1344(a)" \s "33 U.S.C. § 1344(a)" \c 2 **}**; 1362(7) **{** TA \l "33 U.S.C. § 1362(7)" \s "33 U.S.C. § 1362(7)" \c 2 **}**; and 33
21 C.F.R. § 328.4(a)(3) (1999)**{** TA \l "33 C.F.R. § 328.4(a)(3) (1999)" \s "33 C.F.R. § 328.4(a)(3) (1999)" \c 6 **}**.
22 [82] *Solid{* TA \s "Solid" *} Waste Agency*, 531 U.S. at 174 (citation omitted).
23 [83] *Id.* at 174.
24 [84] *Id.*
[85] *Id.*
25 [86] *Gregory v. Ashcroft*, 501 U.S. 452, 467, 111 S.Ct. 2395, 115 L.Ed.2d 410 (1991)**{** TA \l
26 "*Gregory v. Ashcroft*, 501 U.S. 452, 111 S.Ct. 2395, 115 L.Ed.2d 410 (1991)" \s "Gregory" \c 1 **}**
("We will not read the ADEA to cover state judges unless Congress has made it clear that judges are *included*") (emphasis in original).

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States' constitutionally-secured immunity from suit in federal court only by making its intention unmistakably clear in the language of the statute."[87] That rule preserves "the usual constitutional balance between the States and the Federal Government."[88]

Similarly, in interpreting the scope of a statutory preemption provision, the Court presumes that matters traditionally left to the states are "not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[89] That presumption is "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety."[90]

Oregon contends in this case that the "legitimate medical purpose" regulation, as interpreted by the Ashcroft directive, raises similar federalism concerns but is not supported by the requisite "clear statement" from Congress.

VII. The standard of review{ TC "VII. The standard of review" \f C \l "2" }.

Courts may review agency actions to determine if they are consistent with Congress's intent,[91] or with a president's Executive Order.[92] Courts often defer to an agency's interpretation

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[87] *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242, 105 S.Ct. 3142, 87 L.Ed.2d 171 (1985){ TA \l "*Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 105 S.Ct. 3142, 87 L.Ed.2d 171 (1985)" \s "Scanlon" \c 1 }.

[88] *Id.*

[89] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996){ TA \l "*Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)" \s "Medtronic" \c 1 }.

[90] *Id.*

[91] *See Lyng v. Payne*, 476 U.S. 926, 937, 106 S.Ct. 2333, 90 L.Ed.2d 921 (1986){ TA \l "*Lyng v. Payne*, 476 U.S. 926, 106 S.Ct. 2333, 90 L.Ed.2d 921 (1986)" \s "Lyng" \c 1 } ("an agency's power is no greater than that delegated to it by Congress"); *Japan Whaling Ass'n. v. Amer. Cetacean Soc'y.*, 478 U.S. 221, 233, 106 S.Ct. 2860, 92 L.Ed.2d 166 (1986){ TA \l "*Japan Whaling Ass'n. v. Amer. Cetacean Soc'y.*, 478 U.S. 221, 106 S.Ct. 2860, 92 L.Ed.2d 166 (1986)" \s "Japan Whaling" \c 1 } ("The Secretary, of course, may not act contrary to the will of Congress when exercised within the bounds of the Constitution. If Congress has directly spoken to the precise issue in question, if the intent of Congress is clear, that is the end of the matter.").

[92] *Carmel-By-The-Sea v. U.S. Dept. of Transp.*, 123 F.3d 1142, 1150 (9th Cir. 1997){ TA \l "*Carmel-By-The-Sea v. U.S. Dept. of Transp.*, 123 F.3d 1142 (9th Cir. 1997)" \s "Carmel-By-The-Sea" \c 1 }.

1 of a statute and its own regulations.[93] The greatest level of deference—described in the *Chevron*
2 case—requires courts to give effect to any reasonable interpretation offered by the agency.[94] But
3 the Supreme Court and the Ninth Circuit have made it clear that the level of deference owed—if
4 any—depends on a number of factors.

5 For example, in *United States v. Mead Corp.*,[95] the Supreme Court held that tariff
6 classification rulings issued by the United States Customs Service are not entitled to *Chevron*
7 deference because the rulings had not been promulgated pursuant to the authority delegated to
8 the agency to make rules carrying the force of law or issued in the context of a formal
9 adjudication. Similarly, in *Christensen v. Harris County*,[96] the Supreme Court held that a
10 Department of Labor opinion letter interpreting a DOL regulation did not "warrant *Chevron*{ TA
11 \s "Chevron" }-style deference."[97] Instead, such interpretations are "entitled to respect * * * but
12 only to the extent that those interpretations have the power to persuade."[98] The Court also
13 declined to give deference under the standard set forth in *Auer*{ TA \s "Auer" } *v. Robbins*
14 because "to defer to the agency's position would be to permit the agency, under the guise of
15 interpreting a regulation, to create *de facto* a new regulation."[99]
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[93] *See Auer v. Robbins*, 519 U.S. 452, 461, 117 S.Ct. 905, 137 L.Ed.2d 79 (1997){ TA \l "*Auer v. Robbins*, 519 U.S. 452, 117 S.Ct. 905, 137 L.Ed.2d 79 (1997)" \s "Auer" \c 1 }; *Chevron, USA, Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984){ TA \l "*Chevron, USA, Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984)" \s "Chevron" \c 1 }; *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944){ TA \l "*Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944)" \s "Skidmore" \c 1 }.

[94] *Chevron*{ TA \s "Chevron" }, 467 U.S. at 842-844.

[95] *United States v. Mead Corp.*, 533 U.S. 218, 121 S.Ct. 2164 (2001){ TA \l "*United States v. Mead Corp.*, 533 U.S. 218, 121 S.Ct. 2164 (2001)" \s "Mead" \c 1 }.

[96] *Christensen v. Harris County*, 529 U.S. 576, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000){ TA \l "*Christensen v. Harris County*, 529 U.S. 576, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000)" \s "Harris" \c 1 }.

[97] *Id*. at 587.

[98] *Id*. at 587 (citations and internal quotes omitted).

[99] *Id*. at 588.

The lower level of deference—known as *Skidmore{* TA \s "Skidmore" *}* deference—gives an agency interpretation “a respect proportional to its power to persuade”[100] Whether *Skidmore{* TA \s "Skidmore" *}* deference applies depends upon such factors as “its writer’s thoroughness, logic and expertise, its fit with prior interpretations, and any other sources of weight.”[101] In *Hall v. EPA*,[102] the Ninth Circuit held that the Environmental Protection Agency’s (EPA) interpretation of the Clean Air Act was not even entitled to *Skidmore{* TA \s "Skidmore" *}* deference because (1) the interpretation “does not fit with prior interpretations” adopted by the EPA; and (2) the court had “no basis to conclude that the EPA has drawn on any special expertise in advocating this interpretation.”[103] Moreover, an agency’s interpretation of its regulation is not entitled to any deference “when an alternative reading is compelled by * * * other indications of the [agency’s] intent at the time of the regulation’s promulgation.”[104] Similarly, the Supreme Court in *Solid{* TA \s "Solid" *} Waste Agency* held that no deference was owed to an interpretation that “invokes the outer limits of Congress’s power” in the absence of a “clear indication that Congress intended such a result.”[105]

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[100] *Mead{* TA \s "Mead" *}*, 121 S.Ct. at 2175.

[101] *Mead* at 2175-76.

[102] *Hall v. United States Envtl. Prot. Agency*, ___ F.3d ___, 2001 WL 1568335 (9th Cir. 2001){ TA \l "*Hall v. United States Envtl. Prot. Agency*, ___ F.3d ___, 2001 WL 1568335 (9th Cir. 2001)" \s "Hall" \c 1 }.

[103] *Id*. at p. 8.

[104] *Blattner{* TA \s "Blattner" *}*, 152 F.3d at 1106, *quoting Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994){ TA \l "*Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994)" \s "Shalala" \c 1 }.

[105] *Solid{* TA \s "Solid" *} Waste Agency*, 531 U.S. at 172.

1 **ARGUMENT{ TC "**ARGUMENT**" \f C \l "1" }**

2 **I. The Ashcroft directive is invalid because defendants failed to comply with the**
3 **APA's rulemaking requirements{ TC "**I. The Ashcroft directive is invalid because defendants failed to comply with the APA's rulemaking requirements**" \f C \l "2" }.**

4 **A. Defendants did not comply with the APA's public notice and comment**
5 **requirements{** TC "A. Defendants did not comply with the APA's public notice and comment requirements" \f C \l "3" **}.**

6 It is undisputed that defendants did not even attempt to comply with the APA's public
7 notice and comment requirements. The directive was issued without any prior public notice
8 whatsoever. The legal analysis on which Ashcroft relies to support the directive was formulated
9 by two government lawyers, without notifying Myers, the medical community, or the general
10 public. Defendants contend that public notice and comment was not required because the
11 directive was an "interpretive" rule that did not require public notice and comment.

12 **B. Public notice and comment was required by law{** TC "B.Public notice and
13 comment was required by law" \f C \l "3" **}.**

14 The distinction between agency actions that require public notice and
15 comment—substantive or "legislative-type" rules—and "interpretive" rules that can be adopted
16 without public notice and comment, "is notoriously hazy."[106] The Supreme Court and Ninth
17 Circuit authorities summarized above provide some analytical assistance, but none of those cases
18 fully resolves the issue as it is presented here.

19 For example, it is clear that, under *Guernsey{* TA \s "Guernsey" *}* and *Chief{* TA \s
20 "Chief" *} Probation Officers*, the fact that the Ashcroft directive is inconsistent with former
21 Attorney General Reno's interpretation is not enough—standing alone—to make the Ashcroft
22 directive "substantive." But it does not follow that the directive was therefore "interpretive."

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26 [106] *Orengo Caraballo v. Reich*, 11 F.3d 186, 194 (D.C. Cir. 1993)**{** TA \l "*Orengo Caraballo v. Reich*, 11 F.3d 186 (D.C. Cir. 1993)" \s "Caraballo" \c 1 **}**. *See also, Alcaraz{* TA \s "Alcaraz" *}*, 746 F.2d at 613 (difference is "not distinguishable with bright-line clarity").

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1 Other cases have analyzed a variety of factors in distinguishing between substantive and
2 interpretive rules.[107]
3 The better analysis examines *all* of the pertinent factors in light of the underlying purpose
4 of the public notice and comment requirement. This is consistent with the Ninth Circuit's
5 analysis in *Alcaraz{* TA \s "Alcaraz" *}*. Judge Posner followed a similar approach in concluding
6 that a Department of Agriculture rule governing the minimum height of enclosures for dangerous
7 animals was not a valid interpretive rule.[108] As Judge Posner put it, the court's task "is not to
8 plumb the mysteries of legal theory; it is merely to give effect to a distinction that the
9 Administrative Procedure Act makes, and we can do this by referring to the purpose of the
10 distinction."[109]
11 Applying that analysis here, it is clear that public notice and comment was required. The
12 issue addressed by the Ashcroft directive is the subject of substantial debate among doctors,
13 medical ethicists, politicians, and the general public.[110] The purpose of the notice and comment
14 requirement—allowing the agency to "educate itself on the full range of interests" affected by
15 the directive, "thus ensuring fairness to affected parties"[111]—would be served by giving all sides
16 to this debate an opportunity to be heard.
17 Other factors support this conclusion. First, the directive affects the balance of
18 state/federal power, effectively preempting state law in an area traditionally reserved to the
19 states. Congress authorized federal agencies to act through interpretive rules when it adopted the
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[107] *See Barahona-Gomez{* TA \s "Barahona-Gomez" *}*, 167 F.3d at 1235 (directive that "did not leave any real discretion" to the recipient is substantive); *Malone{* TA \s "Malone" *}*, 38 F.3d at 438 (directive that "forecloses other options" or "conclusively affects the rights of individuals" is substantive).

[108] *Hoctor v. U.S. Dep't. of Agric.*, 82 F.3d 165, 172 (7th Cir. 1996){ TA \l "*Hoctor v. U.S. Dep't. of Agric.*, 82 F.3d 165 (7th Cir. 1996)" \s "Hoctor" \c 1 }.

[109] *Id*. at 170.

[110] *See Washington v. Glucksberg*, 521 U.S. 702, 716, 117 S.Ct. 2258, 138 L.Ed.2d 772 (1997){ TA \l "*Washington v. Glucksberg*, 521 U.S. 702, 117 S.Ct. 2258, 138 L.Ed.2d 772 (1997)" \s "Glucksberg" \c 1 }.

[111] *Alcaraz{* TA \s "Alcaraz" *}*, 746 F.2d at 611.

1 APA in 1946. Since that time, the Supreme Court has never held that a federal agency can
2 exercise this limited authority in a way that preempts state law. The APA's notice and comment
3 procedures are also consistent with the consultation requirements in the President's Executive
4 Order on federalism. Second, the directive is inconsistent with the CSA and Congress's intent,
5 as explained in section IV below. Third, the directive effectively "forecloses other options" for
6 practitioners and terminally ill Oregonians, and "conclusively affects" their previously-existing
7 right to utilize the Oregon Act.[112] Fourth, the directive does not "leave any real discretion" to the
8 DEA agents who will apply it.[113] Fifth, the directive "effects a change in existing law or
9 policy[.]"[114]

10 Finally, the "chilling effect" the Ashcroft directive has by virtue of its mere existence
11 weighs in favor of requiring public notice and comment. Agency actions that have been upheld
12 as interpretive rules are not binding in any formal adjudication proceedings. If an agency's
13 interpretation is subsequently applied in an adjudication, the substantive validity of the
14 interpretation—and whether substantial evidence supports that interpretation in a specific
15 context—will be addressed in a formal adjudication, subject to judicial review. But that type of
16 weighing and evaluation of evidence is not likely to occur here because, as a practical matter, no
17 Oregon doctor is likely to risk losing his prescription-writing privileges in order to "test" the
18 validity of Ashcroft's interpretation or the sufficiency of the evidence supporting it.

19 Requiring the Attorney General to comply with notice and comment rulemaking in this
20 context is consistent with other aspects of the CSA that require resolution through more formal
21 procedures. Practitioners who are denied a DEA registration—or who have their registrations
22 revoked—are entitled to a formal adjudication. The Attorney General or his designee is required
23 to go through a formal notice and comment rulemaking process before placing a substance on
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25 [112] *Malone{* TA \s "Malone" *}*, 38 F.3d at 438.
26 [113] *Barahona-Gomez*,**{** TA \s "Barahona-Gomez" **}** 167 F.3d at 1235.
[114] *Blattner{* TA \s "Blattner" *}*, 152 F.3d at 1109.

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one of the five schedules of controlled substances listed in the CSA.[115] It makes no sense to require the Attorney General to utilize formal procedures in these situations but not when taking an action that effectively preempts state law and eliminates options previously available to Oregon practitioners and terminally ill patients.

II. The Ashcroft directive is invalid because it violates the President's Executive Order on federalism{ TC "II. The Ashcroft directive is invalid because it violates the President's Executive Order on federalism" \f C \l "2" }.

The Ashcroft directive violates Executive Order 13132 in several respects. There is no question that the Ashcroft directive "affects the policymaking discretion of the States."[116] Oregon identified—before the directive was issued—"uncertainties regarding the constitutional or statutory authority of the national government."[117] Yet Ashcroft clearly was not "deferential" to Oregon's policy decision, nor did he "act only with the greatest caution" in addressing this issue.[118] In addition, there has been no showing that the directive was necessary to address "a problem of national significance" as required by section 3(b) of the Executive Order. Oregon is the only state that has legalized the practice of physician aid in dying for the terminally ill. The Ashcroft directive thus affects only Oregon. Finally, Ashcroft did not even attempt to comply with the consultation requirements set forth in sections 3, 4 and 6 of the Executive Order. Instead, Ashcroft essentially ignored Oregon's request for consultation.[119] An agency's violation of an Executive Order is sufficient, standing alone, to render the agency's action invalid under the APA.[120]

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[115] *See* 21 U.S.C. § 811{ TA \l "21 U.S.C. § 811" \s "21 U.S.C. § 811" \c 2 }; *Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881 (1st Cir. 1987){ TA \l "*Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881 (1st Cir. 1987)" \s "Grinspoon" \c 1 } (describing process).

[116] Executive Order 13132, § 2(i).

[117] *See* Bushong Aff., Ex. 4 (letter from Oregon Deputy Attorney General David Schuman explaining the statutory and constitutional "uncertainties").

[118] Executive Order 13132, § 2(i).

[119] *See* Bushong Aff., Exs. 7 & 8.

[120] *See Carmel-By-The-Sea{* TA \s "Carmel-By-The-Sea" *}*, 123 F.3d at 1166.

III. The Ashcroft directive is invalid because there is no "clear statement" from Congress that it intended such a result{ TC "III. The Ashcroft directive is invalid because there is no \"clear statement\" from Congress that it intended such a result" \f C \l "2" **}.**

If the Ashcroft directive is not invalid because of Ashcroft's failure to comply with the APA's public notice and comment requirements and the President's Executive Order on federalism, the directive is invalid because it violates the "clear statement" rule. *Solid{* TA \s "Solid" *} Waste Agency* is controlling on this issue. There, the Supreme Court invalidated an agency's interpretive rule because it (1) "invokes the outer limits of Congress's power" under the Commerce Clause;[121] (2) "alters the federal-state framework by permitting federal encroachment upon a traditional state power";[122] and (3) did so without "a clear statement from Congress" that Congress intended such a result.[123]

The same is true here. Oregon contends that the Ashcroft directive not only "invokes" the outer limits of Congress's Commerce Clause power, it *exceeds* those limits. At the very least, the directive "push[es] the limit of congressional authority."[124] It also encroaches upon a traditional state power—regulation of medical practices—without any "clear statement" from Congress that it intended such a result. Under *Solid{* TA \s "Solid" *} Waste Agency*—and other decisions applying the "clear statement" rule in similar contexts[125]—the directive is invalid as a matter of law.

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[121] *Solid{* TA \s "Solid" *} Waste Agency*, 531 U.S. at 172-73.

[122] *Id*. at 172.

[123] *Id*. at 173.

[124] *Id*.

[125] *E.g.*, *Gregory{* TA \s "Gregory" *} v. Ashcroft*, 501 U.S. at 467; *Medtronic{* TA \s "Medtronic" *}, Inc. v. Lohr*, 518 U.S. at 485.

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IV. The Ashcroft directive is invalid because it exceeds Congress's intent as expressed in the CSA{ TC "IV. The Ashcroft directive is invalid because it exceeds Congress's intent as expressed in the CSA**" \f C \l "2" }.**

A. The Ashcroft directive is not entitled to deference{ TC "A. The Ashcroft directive is not entitled to deference" \f C \l "3" **}.**

Defendants have suggested that (1) public notice and comment is not required because the Ashcroft directive is an interpretive rule; and (2) the directive is entitled to substantial deference under *Chevron{* TA \s "Chevron" *}* and *Auer{* TA \s "Auer" *}*. They cannot have it both ways. The Supreme Court held in *Mead{* TA \s "Mead" *}* and *Harris{* TA \s "Harris" *}*, and the Ninth Circuit held in *Hall{* TA \s "Hall" *}*, that an agency's "interpretation" that is not promulgated through APA rulemaking or issued in a formal adjudication is not entitled to *Chevron{* TA \s "Chevron" *}/Auer{* TA \s "Auer" *}* deference. Those decisions are controlling here.

If the Ashcroft directive is not an interpretive rule, it is invalid because of defendants' failure to comply with the APA. If it *is* an interpretive rule, it is entitled—at most—to *Skidmore{* TA \s "Skidmore" *}* deference, which gives the directive "a respect proportional to its power to persuade."[126] Even that level of deference does not apply here, under the Ninth Circuit's decisions in *Hall{* TA \s "Hall" *}* and *Blattner{* TA \s "Blattner" *}*, and the Supreme Court's decision in *Solid{* TA \s "Solid" *} Waste Agency*, because (1) Ashcroft's interpretation of the CSA and the "legitimate medical purpose" regulation "does not fit with" the prior interpretation of former Attorney General Reno;[127] (2) there is no basis to conclude that Ashcroft "has drawn on any special expertise in advocating this interpretation";[128] (3) an alternative reading—the one given by former Attorney General Reno—is compelled by "other indications of the [agency's] intent at the time of the regulation's promulgation";[129] and (4) Ashcroft's interpretation "invokes

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[126] *Mead{* TA \s "Mead" *}*, 121 S.Ct. at 2175.
[127] *Hall{* TA \s "Hall" *}*, 263 F.3d at 934.
[128] *Id*. at 935.

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1 the outer limits of Congress' power" without any "clear indication that Congress intended" such
2 a result.[130]

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B. In enacting the CSA, Congress did not intend to preempt state laws regulating the practices of doctors and pharmacists{ TC "B. In enacting the CSA, Congress did not intend to preempt state laws regulating the practices of doctors and pharmacists" \f C \l "3" }.

6 Defendants cannot dispute that Congress intended to address a specific national
7 problem—illegal trafficking in drugs—when it enacted the CSA in 1970. Congress further
8 intended to respect and rely on state law in registering doctors and pharmacists under the CSA.
9 Federal registration was *required*—and could not be revoked—under the original Act as long as
10 the practitioner was licensed by the state. Thus, the 1970 Act does not authorize the DEA to take
11 the "administrative action" that it is directed to take under the Ashcroft directive.
12 Congress's use of the phrase "currently accepted medical use in the United States" in
13 section 202 of the 1970 Act does not change that conclusion. That section addresses *listing*
14 substances on CSA schedules, not *registering* practitioners. Courts applying that phrase have
15 concluded that it does *not* evidence a congressional intent to establish a national standard of
16 "currently accepted medical use."[131] Listing a drug on the CSA schedules requires formal
17 proceedings and *findings* as to its "accepted medical use in the United States";[132] there were no
18 formal proceedings or findings here. And a state law authorizing a particular use can make that
19 use "accepted" as a matter of state policy consistent with the CSA.
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22 [129] *Blattner{* TA \s "Blattner" *}*, 152 F.3d at 1106. 21 C.F.R. § 1306.04{ TA \s "21 C.F.R. § 1306.04" } was promulgated in 1971; at that time, as defendants concede, the Attorney General
23 had no authority to revoke a practitioner's DEA registration as long as the practitioner was licensed under state law.
24 [130] *Solid{ TA \s "Solid" } Waste Agency*, 531 U.S. at 172.
25 [131] *Grinspoon{* TA \s "Grinspoon" *}*, 828 F.2d at 891 (holding that absence of approval by the federal Food and Drug Administration (FDA) is not enough to conclusively establish that a drug
26 has no "currently accepted medical use in treatment in the United States").

[132] *Id.*

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1 In short, nothing in the original Act evidences a congressional intent to authorize
2 defendants to ignore—indeed, override—state laws in deciding whether practitioners should be
3 registered to dispense controlled substances under the Act. Thus, if defendants have any
4 authority to revoke practitioners' registrations in accordance with the Ashcroft directive, that
5 authority must come from the 1984 amendment to the Act.

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C. The 1984 amendment did not give defendants the authority to preempt the Oregon Act{ TC "C. The 1984 amendment did not give defendants the authority to preempt the Oregon Act" \f C \l "3" **}.**

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The legislative history to the 1984 amendment—the Dangerous Drug Diversion Control Act of 1984—demonstrates that the 1984 Act was part of the continuing federal effort begun by the CSA's enactment to address the national "drug abuse problem" reflected by "large-scale trafficking" of drugs of legitimate origin into the "illicit market."[133] The "public interest" authority included in the 1984 Act was designed to address a particular "weakness" in the original Act—the fact that state regulators were unable to take effective or prompt action "against violating registrants" because of "a variety of legal, organizational, and resource problems."[134] Authorizing federal officials to take action in "the public interest" where state regulators are unable to take action against "violators" because of "resource problems" does not authorize federal agents to take action against practitioners who are in *compliance* with state law. The legislative history does not support reading the "public interest" provision to give defendants sweeping authority to preempt state law defining the lawful practice of medicine.

If *that* is what Congress intended by the 1984 Act, it would have said so, expressly. It did not. Moreover, interpreting the "public interest" provision to give defendants unlimited authority to override state law in the "public interest" is actually inconsistent with other aspects of the 1984 Act. The 1984 Act defines the "public interest" in terms of compliance with

[133] 1984 U.S.C.C.A.N.{ TA \s "1984 U.S.C.C.A.N. 3182" } at 3442.

[134] 1984 U.S.C.C.A.N.{ TA \s "1984 U.S.C.C.A.N. 3182" } at 3448.

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1 "applicable State, Federal, or local laws."[135] The "public interest" provision *requires* the

2 Attorney General to consider compliance with state law in determining the public interest.[136]

3 Typically, such a determination would come in the context of a registration denial or revocation

4 adjudication, subject to "a searching and careful inquiry of the record to determine whether the

5 agency's decision was based on a consideration of the relevant factors and whether there was a

6 clear error of judgment."[137] Yet under the Ashcroft directive, compliance with the Oregon Act is

7 *not* considered. Nor is there any "careful and searching inquiry" of any record, as Congress

8 intended.

9 In addition, Congress's reference to "Federal" laws must be read as a reference to *other*

10 federal laws, not the "public interest" provision itself, or the regulation Ashcroft is attempting to

11 "interpret" and enforce under the "public interest" authority. If the Pain Relief Promotion Act

12 (PRPA) had been enacted, for example, then there would have been a "federal law" that would

13 be violated by practitioners who complied with the Oregon Act. Assuming for the sake of

14 argument that Congress had the constitutional authority to enact the PRPA, an Oregon

15 practitioner attempting to utilize the Oregon Act could have his registration revoked under the

16 "public interest" authority adopted in 1984 because his actions would not be in compliance with

17 a federal law enacted by Congress. *That* was the intent of the 1984 Act. There is no indication

18 anywhere in the 1984 Act or its legislative history that Congress intended to authorize the

19 Attorney General to both *create* the federal law that defines "the public interest" and then *revoke*

20 a practitioner's registration as contrary to that interest.

21 That conclusion is confirmed by section 903 of the CSA and federal preemption law.

22 Section 903 clearly expresses Congress's intent *not* to preempt state law "unless there is a

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24 [135] Pub. L. No. 98-473{ TA \s "98-473, 98 Stat. 2070 (1984)" }, section 511, 21 U.S.C. § 823(f){ TA \s "21 U.S.C. § 823(f)" }.

25 [136] *Id.* (stating that compliance with applicable state laws is one of the factors that "shall be considered" in determining the public interest).

26 [137] *Trawick v. Drug Enforcement Admin.*, 861 F.2d 72, 76 (4th Cir. 1988){ TA \l "*Trawick v. Drug Enforcement Admin.*, 861 F.2d 72 (4th Cir. 1988)" \s "Trawick" \c 1 } (internal quote and citation omitted).

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positive conflict between [a] provision of this subchapter" and state law so that the two "cannot consistently stand together."[138] An actual or positive conflict with federal law sufficient to preempt state law arises only "when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full powers and objectives of Congress."[139]

Neither situation is present here. Compliance with both the CSA and the Oregon Act is certainly not a "physical impossibility." Nor does the Oregon Act stand as an "obstacle" to the accomplishment of Congress's efforts to control illegal trafficking in drugs. And under *Medtronic*, in both determining *whether* state law is preempted, and interpreting the *scope* of any preemption under section 903, the court must presume that matters traditionally left to the States "were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[140] There is no such "clear and manifest purpose" here.

Indeed, defendants' interpretation of the "public interest" authority granted by the 1984 Act would give the Attorney General *greater* authority in the area of registering practitioners than he has with respect to listing substances on CSA schedules. Under sections 811 and 812 of the CSA, the Attorney General must determine in listing a substance whether the substance has a "currently accepted medical use in the United States." In making that determination, the absence of FDA approval does not "conclusively establish" that a substance has no currently accepted medical use in the United States; fact-finding on a case-by-case basis is required.[141] Yet the

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[138] 21 U.S.C. § 903{ TA \s "21 U.S.C. § 903" }.

[139] *Hillsborough County v. Automated Med. Labs*, 471 U.S. 707, 713, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985){ TA \l "*Hillsborough County v. Automated Med. Labs*, 471 U.S. 707, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985)" \s "Hillsborough" \c 1 } (internal quotes and citations omitted). Federal law can also supercede state law (1) when Congress so states "in express terms"; (2) "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation"; or (3) "where the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id.*

[140] *Medtronic{* TA \s "Medtronic" *}*, 518 U.S. at 485.

[141] *Grinspoon{* TA \s "Grinspoon" *}*, 828 F.2d at 890-91.

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Ashcroft directive purports to conclusively establish—with *no* fact-finding, *no* prior public notice, and *no* formal adjudication—that the use of controlled substances authorized by the Oregon Act is not "legitimate" or is contrary to the "public interest." That interpretation of the CSA is wrong.

D. The CSA's delegation provisions do not give defendants the authority to preempt the Oregon Act{ TC "D. The CSA's delegation provisions do not give defendants the authority to preempt the Oregon Act" \f C \l "3" }.

The authority delegated to Ashcroft by Congress, while broad, is not unlimited. For example, in *Grinspoon{* TA \s "Grinspoon" *} v. Drug Enforcement Administration*, the First Circuit explained that the "explicit delegation of authority [in section 811 of the CSA] to *apply* prescribed statutory criteria is not equivalent to an explicit delegation of authority to *define* those criteria."[142]

Here, the explicit delegation of authority to the Attorney General in the CSA does not include the authority to define—by interpretive rule—what practices will be deemed to be "legitimate" medical practices. The delegation of authority in section 811 to *apply* statutory criteria in deciding whether a substance should be listed certainly does not extend that far, as explained in *Grinspoon{* TA \s "Grinspoon" *}*. Nor does the seemingly broad authority in section 821.

The section 821 authority to adopt rules and regulations "relating to the registration and control of the manufacture, distribution and dispensing of controlled substances" says nothing about regulating a terminally-ill patient's *use* of those substances or a doctor's *intent* in prescribing them. Such use—and intent—has nothing to do with the "manufacture" or "distribution" of controlled substances as those terms are defined in the CSA. Nor does it fall within the authority to "control" the dispensing of drugs because "control" as defined in the CSA

[142] *Id*. at 885, n. 5 (emphasis in original).

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"means to add a drug or other substance * * * to a schedule under part B" of the CSA.[143] Defining what uses are "legitimate" has nothing to do with adding drugs to a CSA schedule.

Whether such a determination falls within the Attorney General's section 871 authority requires an examination of the Attorney General's "functions" under the CSA.[144] When the CSA as a whole is considered, it becomes apparent that the Attorney General's functions fall into four categories: (1) listing substances on the CSA schedules; (2) registering manufacturers, distributors and dispensers; (3) enforcing the criminal provisions of the CSA; and (4) overseeing the administrative and regulatory provisions of the Act. There was no general delegation of authority to the Attorney General to make law or override a state law defining which practices are "legitimate."

Indeed, the 2000 amendment to the CSA explicitly confirmed the limitation on the scope of delegated authority that was implicit in the original Act, as evidenced by the legislative history of the original Act. That amendment makes it clear that federal officials have no authority "to exercise supervision or control over the practice of medicine or the manner in which medical services are provided."[145] Ashcroft's decision to override Oregon's determination that practices authorized by the Oregon Act are "legitimate" amounts to an exercise of federal supervision or control over medical practices that was not authorized by Congress.

V. If the Ashcroft directive is authorized by the CSA, then the CSA exceeds Congress's constitutional authority to the extent it preempts the Oregon Act{ TC "V. If the Ashcroft directive is authorized by the CSA, then the CSA exceeds Congress's constitutional authority to the extent it preempts the Oregon Act" \f C \l "2" }.

The Ashcroft directive should be invalidated on subconstitutional grounds, for the reasons discussed above. If it is not, then the court will need to decide whether the CSA, as

[143] 21 U.S.C. § 802(5){ TA \l "21 U.S.C. § 802(5)" \s "21 U.S.C. § 802(5)" \c 2 }.

[144] Section 871 gives the Attorney General the authority to "promulgate and enforce any rules, regulations and procedures which he may deem necessary and appropriate for the efficient execution of his functions." 21 U.S.C. § 871{ TA \s "21 U.S.C. § 871" }.

[145] *See* Pub. L. 106-310{ TA \s "106-310, 114 Stat. 1222 (2000)" }, codified at 21 U.S.C. § 823(g)(2)(H)(i){ TA \s "21 U.S.C. § 823(g)(2)(H)(i)" }.

interpreted by the Ashcroft directive, exceeded constitutional limitations on Congress's authority.

A. The Constitution reserves to the States the power to regulate medical practices{ TC "A. The Constitution reserves to the States the power to regulate medical practices" \f C \l "3" }.

The Supreme Court has long recognized that regulation of medical practices is a matter of state, not federal, concern. In *Linder v. United States*,[146] a doctor was convicted of violating the Harrison Anti-Narcotic Act after he prescribed controlled substances to a known addict for nonmedical purposes. The Supreme Court reversed the conviction, holding that (1) the Harrison Act could only be applied as a revenue measure because Congress lacked the constitutional authority to legislate for the general welfare; and (2) the doctor had done nothing to affect the collection of revenue by the federal government. The court explained that "direct control of medical practice in the States is beyond the power of the Federal Government."[147]

While the holding in *Linder*{ TA \s "Linder" } may have been undermined by later Court decisions that expanded federal power under the Commerce and Spending Clauses, the principle that regulation of medical practices is a matter of state concern was reaffirmed by the Court on several occasions over the subsequent decades.[148] In addition, the States' constitutional authority to regulate in the area at issue here—physician assistance in hastening the death of terminally-ill patients—was acknowledged by the Court in two recent cases.

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[146] *Linder v. United States*, 268 U.S. 5, 45 S.Ct. 446 (1925){ TA \l "*Linder v. United States*, 268 U.S. 5, 45 S.Ct. 446 (1925)" \s "Linder" \c 1 }.

[147] 268 U.S. at 18.

[148] *See Graves v. Minnesota*, 272 U.S. 425, 428 (1926){ TA \l "*Graves v. Minnesota*, 272 U.S. 425 (1926)" \s "Graves" \c 1 } (upholding state law regulating the practice of dentistry: "The state is primarily the judge of regulations required in the interest of public safety and welfare"); *Semler v. Oregon State Bd. of Dental Examiners*, 294 U.S. 608, 612-13 (1935){ TA \l "*Semler v. Oregon State Bd. of Dental Examiners*, 294 U.S. 608 (1935)" \s "Semler" \c 1 } (court deferred to state legislature to establish community standards for "the maintenance of professional standards"); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449, 74 S.Ct. 650 (1954){ TA \l "*Barsky v. Bd. of Regents*, 347 U.S. 442, 74 S.Ct. 650 (1954)" \s "Barsky" \c 1 } ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power.").

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1 In *Washington v. Glucksberg{* TA \s "Glucksberg" *}*, the Court acknowledged the
2 ongoing public debate on the issue that was occurring in many states: "Public concern and
3 democratic action are thereby sharply focused on how best to protect dignity and independence
4 at the end of life, with the result that there have been many significant changes in state laws and
5 in the attitudes these laws reflect."[149] The Court upheld a Washington law that prohibited
6 physician assistance in hastening death, while acknowledging that Oregon had legalized the
7 practice.[150] This recognizes, at least implicitly, that the subject is a policy issue for each state to
8 decide. This implicit recognition was made explicit by Justice O'Connor, who explained that the
9 decision was "entrusted to the 'laboratory' of the States in the first instance."[151] In a companion
10 case, *Vacco v. Quill*,[152] the Court affirmed the district court's conclusion that, "[u]nder the U.S.
11 Constitution and the federal system it establishes, the resolution of this issue is left to the normal
12 democratic processes within the state."[153] The same is true here.

13 **B. Under Ashcroft's interpretation, the CSA violates the Commerce Clause{ TC**
14 **"**B. Under Ashcroft's interpretation, the CSA violates the Commerce Clause**" \f C \l "3" }.**

15 As interpreted by Ashcroft, regulation under the CSA would depend solely on the intent
16 of an Oregon doctor. A doctor who prescribes a controlled substance to a terminally ill patient
17 with the intent of alleviating pain—but not hastening death—is *not* in violation of the CSA under
18 the directive. A doctor who prescribes the same substance, to the same patient, but with the
19 intent of complying with the patient's request for medication to hasten death as authorized by the
20 Oregon Act, *would* be in violation of the CSA under the Ashcroft directive.
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22 [149] *Glucksberg{* TA \s "Glucksberg" *}*, 521 U.S. at 716.
23 [150] 521 U.S. at 717.
24 [151] 521 U.S. at 737 (O'Connor, J., concurring), *quoting Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 292, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990)**{** TA \l "*Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990)" \s "Cruzan" \c 1 **}** (O'Connor, J., concurring).
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26 [152] *Vacco v. Quill*, 521 U.S. 793, 117 S.Ct. 2293, 138 L.Ed.2d 834 (1997)**{** TA \l "*Vacco v. Quill*, 521 U.S. 793, 117 S.Ct. 2293, 138 L.Ed.2d 834 (1997)" \s "Vacco" \c 1 **}**.
[153] 521{ TA \s "Glucksberg" } U.S. at 798.

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1 Regulating a physician's intent in this context exceeds Congress's authority under the
2 Commerce Clause. In *United States v. Lopez*, the Supreme Court held that the Federal Gun-Free
3 School Zones Act of 1990 exceeded Congress's authority under the Commerce Clause.[154]
4 Congress's power to regulate interstate commerce, the Court explained, only gave Congress the
5 power to: (1) "regulate the use of the channels of interstate commerce";[155] (2) "regulate and
6 protect the instrumentalities of interstate commerce, or persons or things in interstate
7 commerce";[156] or (3) "regulate * * * those activities having a substantial relation to interstate
8 commerce."[157]

9 Regulation that is based solely on the intent of a doctor—or a pharmacist who fills the
10 prescription—fits none of these categories. That conclusion is confirmed by the Court's decision
11 in *United States v. Morrison*.[158] There, the court found that Congress's attempt to regulate
12 gender-based violence exceeded its Commerce Clause power because the regulated conduct was
13 not "economic in nature."[159]

14 The same is true here. In addition, the fact that Ashcroft's interpretation of the CSA
15 would override Oregon's policy decision in areas traditionally left to the States—the practice of
16 medicine and the protection of public health, safety and general welfare—supports the
17 conclusion that Ashcroft's interpretation violates the Commerce Clause. In *Lopez***{** TA \s
18 "Lopez" **}**, the Federal Gun-Free School Zones Act affected two areas traditionally left to the
19 States, education and crime. One of the flaws in the Act was the fact that it displaces state policy
20 choices in these areas. As Justice Kennedy put it in his concurrence, the Act "forecloses the

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22 [154] *United States v. Lopez*, 514 U.S. 549, 567, 115 S.Ct. 1624, 131 L.Ed.2d 626 (1995)**{** TA \l "*United States v. Lopez*, 514 U.S. 549, 115 S.Ct. 1624, 131 L.Ed.2d 626 (1995)" \s "Lopez" \c 1 **}**.

23 [155] *Lopez***{** TA \s "Lopez" **}**, 514 U.S. at 558.

24 [156] *Id.*

25 [157] *Id*. at 558-59.

26 [158] *United States v. Morrison*, 120 S.Ct. 1740 (2000)**{** TA \l "*United States v. Morrison*, 120 S.Ct. 1740 (2000)" \s "Morrison" \c 1 **}**.

[159] *Id*. at 1751.

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1 States from experimenting and exercising their own judgment in an area to which States lay
2 claim by right of history and expertise, and it does so by regulating an activity beyond the realm
3 of commerce in the ordinary and usual sense of that term."[160] Ashcroft's interpretation of the
4 CSA has the same flaw.

5 Seventy dying Oregonians utilized the Oregon Act during 1997-2000. This is not an
6 activity that "substantially affects" interstate commerce. Congress's scheme to stop illegal
7 trafficking in drugs is not hindered in any way by allowing the Oregon Act to remain in effect.

8 **C. The Ashcroft directive also violates the Tenth Amendment and principles of**
9 **federalism{ TC "**C. The Ashcroft directive also violates the Tenth Amendment and principles of federalism**" \f C \l "3" }.**

10

11 Three recent Supreme Court cases demonstrate the Court's reluctance to allow the federal
12 government to override a state's considered policy decision in areas traditionally reserved to the
13 States. The system of "dual sovereignty" that is reflected in the constitutional structure and
14 confirmed by the Tenth Amendment precludes federal regulation in some instances, even in
15 areas that might fall within the federal Commerce Clause power.[161]

16 In *New York{* TA \s "New York" *} v. United States*, the Court concluded that a state's
17 sovereign's rights protected by the Tenth Amendment could not be superceded by Congress in
18 exercising its Article I powers.[162] In *Printz{* TA \s "Printz" *} v. United States*, the Court
19 explained that a law enacted by Congress under its Commerce Clause power may be invalid if it
20 nonetheless violated "the principle of state sovereignty reflected in * * * various constitutional

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22 [160] *Lopez{* TA \s "Lopez" *}*, 514 U.S. at 583 (Kennedy, J., concurring).

23 [161] *See Gregory{* TA \s "Gregory" *} v. Ashcroft*, 501 U.S. at 457 (Constitution established a system of "dual sovereignty"); *Printz v. United States*, 521 U.S. 898, 918-19, 117 S.Ct. 2365,
24 138 L.Ed.2d 914 (1997){ TA \l "*Printz v. United States*, 521 U.S. 898, 117 S.Ct. 2365, 138 L.Ed.2d 914 (1997)" \s "Printz" \c 1 } (explaining that "[r]esidual state sovereignty was 'reflected throughout the Constitution's text" and "implicit" in the conferral of only enumerated powers to
25 Congress, an implication that "was rendered express by the Tenth Amendment").

26 [162] *New York v. United States*, 505 U.S. 144, 156-57, 112 S.Ct. 2408, 120 L.Ed.2d 120 (1992){ TA \l "*New York v. United States*, 505 U.S. 144, 112 S.Ct. 2408, 120 L.Ed.2d 120 (1992)" \s "New York" \c 1 }.

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1 provisions[.]"[163] And in *Alden{ TA \s "Alden" } v. Maine*, the Court described the "structural"
2 aspect of a state's sovereignty that was "implicit in the constitutional design" and "inheres in the
3 system of federalism established by the Constitution".[164] Under the *Alden{* TA \s "Alden" *}*
4 analysis, "the question is not the primacy of federal law but the implementation of the law in a
5 manner consistent with the constitutional sovereignty of the States."[165]

6 Those cases are somewhat different from the present case, but the principles still apply.[166]
7 The Court has never limited the underlying principle of "dual sovereignty" and its respect for the
8 States' "residuary and inviolable sovereignty"[167] to the situations presented in those cases. The
9 Ashcroft directive effectively overrides a considered policy choice made by Oregon voters on
10 two occasions on a subject that is reserved to the States. Ashcroft's action violates the sovereign
11 right of the people of Oregon to make that choice even if the action falls within the boundaries of
12 the Commerce Clause.

13 **D. Prior constitutional challenges to the CSA are distinguishable{ TC "**D.
14 Prior constitutional challenges to the CSA are distinguishable**" \f C \l "3" }.**

15 Prior challenges to the CSA under the Commerce Clause and/or the Tenth Amendment
16 have been uniformly rejected by the courts.[168] However, all of those challenges were raised by
17 practitioners who were either prosecuted for criminal violations, or had their DEA registrations
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19 [163] *Printz{* TA \s "Printz" *}*, 521 U.S. at 924.

20 [164] *Alden v. Maine*, 527 U.S. 706, 730, 119 S.Ct. 2240, 144 L.Ed.2d 636 (1999){ TA \l "*Alden v. Maine*, 527 U.S. 706, 119 S.Ct. 2240, 144 L.Ed.2d 636 (1999)" \s "Alden" \c 1 }.

21 [165] *Alden{* TA \s "Alden" *}*, 527 U.S. at 732.

22 [166] *Alden{ TA \s "Alden" } v. Maine* dealt with state sovereign immunity from suit; *New York{* TA \s "New York" *}* and *Printz{* TA \s "Printz" *}* dealt with efforts by the federal government to
23 compel states or state officials to enact policies or administer federal programs.

[167] *Alden{ TA \s "Alden" }*, 527 U.S. at 715, *quoting The Federalist* No. 39, at 245.

24 [168] *See, e.g., United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 446 L.Ed.2d 333 (1975){ TA \s
25 "Moore" }; *United States v. Lerebours*, 87 F.3d 582 (1st Cir. 1996), *cert. denied*, 117 S.Ct. 694 (1997){ TA \l "*United States v. Lerebours*, 87 F.3d 582 (1st Cir. 1996), *cert. denied*, 117 S.Ct.
26 694 (1997)" \s "Lerebours" \c 1 }; *United States v. Rosenberg*, 515 F.2d 190 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975){ TA \l "*United States v. Rosenberg*, 515 F.2d 190 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975)" \s "Rosenberg" \c 1 }.

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1 revoked, after they engaged in practices that were prohibited by the CSA and were not
2 authorized by state law. None of those cases involves practices that were expressly authorized
3 by state law.

4 That issue was mentioned in the *Oakland Cannabis{* TA \s "Cannabis" *}* case, but the
5 Supreme Court declined to decide it because it had not been preserved on appeal.[169] If this court
6 finds it necessary to reach the constitutional issues presented here, the court should recognize
7 that *United States v. Moore{* TA \s "Moore" *}* and other cases presenting constitutional
8 challenges to the CSA are distinguishable. This case would thus present the issue that was left
9 open in *Oakland Cannabis{* TA \s "Cannabis" *}*—whether Congress exceeded its constitutional
10 authority in this context. As explained above, the court should conclude, in deciding this issue of
11 first impression, that Congress's constitutional authority does not extend this far.

12 **VI. Oregon has standing to bring these claims{ TC "**VI. Oregon has standing to bring
13 these claims**" \f C \l "2" }.**

14 Oregon briefed the issue of standing in its supplemental memorandum in support of
15 motion for preliminary injunction. Oregon relies primarily on the authorities cited in that brief to
16 demonstrate that it has standing here. Oregon has also submitted affidavits from its Department
17 of Human Services, Board of Medical Examiners, and Board of Pharmacy to further demonstrate
18 how its regulatory interests are affected by the Ashcroft directive.[170] Finally, as explained above,
19 Oregon contends that the Ashcroft directive intrudes upon sovereign interests that are properly
20 asserted by Oregon.

21 **CONCLUSION{ TC "**CONCLUSION**" \f C \l "1" }**

22 The Ashcroft directive is an unprecedented federal intrusion into an area that is properly
23 reserved to the States. Ashcroft took this action without complying with federal procedural
24

25 [169] *United States v. Oakland Cannabis Buyers Coop.*, 532 U.S. 483, 121 S.Ct. 1711, 1719
(2001){ TA \l "*United States v. Oakland Cannabis Buyers Coop.*, 532 U.S. 483, 121 S.Ct. 1711
26 (2001)" \s "Cannabis" \c 1 }.

[170] *See* Affidavits of Katrina Hedberg, M.D.; Kathleen Haley; and Gary A. Schnabel.

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requirements, and without any clear statement of authority from Congress. His directive is invalid as a matter of law.

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1 Accordingly, Oregon's motion for summary judgment should be granted.

2 DATED this ____ day of January, 2002.

3 Respectfully submitted,

4 HARDY MYERS
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5

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