No. 04-623

In the Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

OREGON, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 02-35587

STATE OF OREGON, PLAINTIFF-APPELLEE

v.

JOHN ASHCROFT, ATTORNEY GENERAL, 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; UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, DEFENDANTS-APPELLANTS

v.

PETER A. RASMUSSEN; DAVID MALCOLM HOCHHALTER; RICHARD HOLMES; JAMES ROMNEY; MELISSA BUSH; JOHN DOE # 1, PLAINTIFFS-INTERVENORS-APPELLEES

Argued and Submitted May 7, 2003
Filed May 26, 2004

OPINION

Before: LAY,* WALLACE, and TALLMAN, Circuit Judges.

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* Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

TALLMAN, Circuit Judge.

A doctor, a pharmacist, several terminally ill patients, and the State of Oregon challenge an interpretive rule issued by Attorney General John Ashcroft which declares that physician assisted suicide violates the Controlled Substances Act of 1970 ("CSA"), 21 U.S.C. §§ 801-904. This so-called "Ashcroft Directive," published at 66 Fed. Reg. 56,607, criminalizes conduct specifically authorized by Oregon's Death With Dignity Act, Or. Rev. Stat. § 127.800-127.897. We hold that the Ashcroft Directive is unlawful and unenforceable because it violates the plain language of the CSA, contravenes Congress' express legislative intent, and oversteps the bounds of the Attorney General's statutory authority. *See* 5 U.S.C. § 706(2)(C), (D). The petitions for review are granted.

I

We have original jurisdiction over "final determinations, findings, and conclusions of the Attorney General" made under the CSA. 21 U.S.C. § 877. Because the Attorney General maintains that his interpretive rule is a "final determination" and because the Directive orders sanctions for violations of its provisions, we have original jurisdiction pursuant to § 877. *See Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003) (holding that an interpretive rule issued by the Attorney General pursuant to the CSA is a "final determination" for jurisdictional purposes because the rule "impos[es] obligations and sanctions in the event of violation [of its provisions]"); *see also City of Auburn v. Qwest*, 260 F.3d 1160, 1171-73 (9th Cir.

2001). We consider the matter transferred to us from the district court pursuant to 28 U.S.C. § 1631.[1]

This case is ripe for review because, under the Directive, health care practitioners risk criminal prosecution and loss of the privilege to prescribe medication if they choose to assist in the suicide of terminally ill patients pursuant to Oregon's Death With Dignity Act. *See Hemp Indus.*, 333 F.3d at 1086 ("[I]f . . . the challenged regulations present[ ] plaintiffs with the immediate dilemma to choose between complying with newly imposed, disadvantageous restrictions and risking serious penalties for violation, the controversy is ripe.") (citation omitted). "Because standing overlaps substantially with ripeness" in these circumstances, the petitioner health care practitioners have standing to challenge the Ashcroft Directive. *See id.* [2]

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[1] On April 17, 2002, United States District Judge Robert E. Jones entered a permanent injunction against enforcement of the Ashcroft Directive. 192 F. Supp. 2d 1077 (D. Or. 2002). Recognizing that he might lack jurisdiction over the matter, Judge Jones alternatively ordered the petitions for review transferred to us under 28 U.S.C. § 1631 ("Whenever a civil action is filed in a court . . . including a petition for review of administrative action . . . and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or noticed [.]"). 192 F. Supp. 2d at 1086-87. Although we conclude that the district court did not have jurisdiction, Judge Jones' opinion on the merits is well reasoned, and we ultimately adopt many of his conclusions.

[2] We need not decide whether the other plaintiffs also have standing. *See Leonard v. Clark*, 12 F.3d 885, 888 (9th Cir. 1993). However, we do note the argument by the plaintiff patients that the Ashcroft Directive, if followed, will achieve the in terrorem effect intended. Doctors will be afraid to write prescriptions sufficient to painlessly hasten death. Pharmacists will fear filling

II

The Ashcroft Directive purports to interpret and implement the CSA, which Congress enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801-904). The stated purpose of the CSA is "to provide increased research into, and prevention of, drug abuse and drug dependence . . . and to strengthen existing law enforcement authority in the field of drug abuse." *Id.* at 1236 (preamble); *see also* H.R. Rep. No. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567 ("This legislation is designed to deal in comprehensive fashion with the growing menace of drug abuse in the United States[.]"); *United States v. Moore*, 423 U.S. 122, 141, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975); *Raich v. Ashcroft*, 352 F.3d 1222, 1228-29 (9th Cir. 2003); *United States v. Rosenberg*, 515 F.2d 190, 194 (9th Cir. 1975) (noting that the purpose of the CSA is to "counter drug abuse").

Under the CSA, it is unlawful to prescribe or dispense controlled substances without a federal registration. 21 U.S.C. § 841(a)(1); *see also id.* §§ 823(f), 822(a)(2). The CSA originally provided automatic federal registration for state-licensed health-care practitioners. § 303(f), 84 Stat. at 1255. The Attorney General could revoke a practitioner's federal registration only if the practitioner falsified his or her registration application, was convicted of a felony related to

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the prescriptions. Patients will be consigned to continued suffering and, according to the declarations of record, may die slow and agonizing deaths. Should patients attempt suicide without the assistance of their doctors and pharmacists, they may fail or leave loved ones with the trauma of dealing with the aftermath of certain forms of suicide too unpleasant to describe in this opinion.

a controlled substance, or had his or her state license suspended or revoked. *Id.* § 304(a), 84 Stat. at 1255.

In 1971, pursuant to his authority to issue rules regulating controlled substances under the CSA, *see* 21 U.S.C. § 871(b), then Attorney General John Mitchell promulgated the following regulation:

> 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 . . . is not a prescription within the meaning and intent of . . . the Act 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.

21 C.F.R. § 1306.04 (originally designated as 21 C.F.R. § 306.04). This regulation exposed properly licensed and registered physicians to federal prosecution for distributing prescription drugs outside "the usual course of professional practice." *See, e.g.*, *Moore*, 423 U.S. at 143, 96 S. Ct. 335 ("In practical effect, [Dr. Moore] acted as a large-scale 'pusher' not as a physician."); *Rosenberg*, 515 F.2d at 193 ("[A] doctor who acts other than in the course of professional practice is not a practitioner under the [CSA] and is therefore . . . . subject to the criminal provisions of the Act [.]") (citations omitted).

In 1984, Congress amended the CSA to give broader authority to the Attorney General. The Attorney General is now authorized to revoke a physician's pre-

scription privileges upon his determination that the physician has "committed such acts as would render his registration . . . inconsistent with the public interest[.]" 21 U.S.C. § 824(a)(4). When determining which acts are inconsistent with the public interest, the Attorney General must consider the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority;
>
> (2) The applicant's expertise in dispensing . . . controlled substances;
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances;
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f). Although this provision gives the Attorney General new discretion over the registration of health care practitioners, Congress explained that "the amendment would continue to give deference to the opinions of State licencing authorities, since their recommendations are the first of the factors to be considered[.]" S. Rep. No. 98-225, at 267 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449.

Against this backdrop of federal regulation, in 1994, the State of Oregon enacted by ballot measure the country's first law authorizing physician assisted suicide. *See* Or. Rev. Stat. § 127.800-897. Oregon's Death With Dignity Act authorizes physicians to prescribe lethal doses of controlled substances to termi-

nally ill Oregon residents according to procedures designed to protect vulnerable patients and ensure that their decisions are reasoned and voluntary. *See id.*[3] Oregon voters reaffirmed their support for the Death With Dignity Act on November 4, 1997, by defeating a ballot measure that sought to repeal the law.

Soon thereafter, several members of Congress, including then Senator John Ashcroft, urged then-Attorney General Janet Reno to declare that physician assisted suicide violated the CSA. She declined to do so. In a letter dated January 5, 1998, Attorney General Reno explained that the CSA was not "intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice." She concluded that "the CSA does not authorize [the Drug Enforcement Administration ("DEA")] to prosecute, or to revoke DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law."[4]

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[3] Under Oregon's Death With Dignity Act, only adult Oregon residents suffering from an incurable disease likely to result in death within six months are eligible for a lethal prescription. Or. Rev. Stat. 127.800 § 1.01(12); *id.* 127.805 § 2.01(1). A patient's diagnosis must be confirmed by two independent physicians. *Id.* 127.815 § 3.01; 127.820 § 3.02. Patients must sign a written request for the prescription in the presence of two witnesses attesting that the patient is competent and acting voluntarily. *Id.* 127.810 § 2.02.

[4] In response to Attorney General Reno's letter, members of Congress introduced bills to amend the CSA to explicitly authorize the Attorney General to revoke the registration of any practitioner who "intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual." H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998"). The amendments

With a change of administrations came a change of perspectives. On November 9, 2001, newly appointed Attorney General John Ashcroft reversed the position of his predecessor and issued the Directive at issue here. The Ashcroft Directive proclaims that physician assisted suicide serves no "legitimate medical purpose" under 21 C.F.R. § 1306.04 and that specific conduct authorized by Oregon's Death With Dignity Act "may 'render [a practitioner's] registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation." 66 Fed. Reg. at 56,608 (quoting 21 U.S.C. § 824(a)(4)). The Directive specifically targets health care practitioners in Oregon and instructs the DEA to enforce this determination "regardless of whether state law authorizes or permits such conduct by practitioners." *Id.*[5]

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failed. In 1999, Congress again declined to enact a similar proposed amendment. *See* H.R. 2260, 106th Cong. (1999) ("Pain Relief Promotion Act of 1999").

[5] The dissent argues that the Ashcroft Directive does not ban physician assisted suicide outright, but only bars the use of controlled substances for assisting suicide. This argument is wrong for two reasons. First, the Attorney General may revoke physician prescription privileges for any conduct appropriately deemed inconsistent with the public interest; such conduct need not involve controlled substances. *See* 21 U.S.C. § 824(a)(4). Second, it is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives. *See* Gerrit K. Kimsma, *Euthanasia and Euthanizing Drugs in The Netherlands*, in DRUG USE IN ASSISTED SUICIDE AND EUTHANASIA 193, 198-204 (Margaret P. Battin and Arthur G. Lipman eds., 1996); Kathy Farber-Langendoen and Jason H.T. Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, ANNALS INTERNAL MED., Mar. 21, 2000, at 482-87.

III

To be perfectly clear, we take no position on the merits or morality of physician assisted suicide. We express no opinion on whether the practice is inconsistent with the public interest or constitutes illegitimate medical care. This case is simply about who gets to decide. All parties agree that the question before us is whether Congress authorized the Attorney General to determine that physician assisted suicide violates the CSA. We hold that the Attorney General lacked Congress' requisite authorization. The Ashcroft Directive violates the "clear statement" rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress.

A

We begin with instructions from the Supreme Court that the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide" belongs among state lawmakers. *Washington v. Glucksberg*, 521 U.S. 702, 735, 117 S. Ct. 2258 (1997). In *Glucksberg*, Justice O'Connor emphasized that "[s]tates are presently undertaking extensive and serious evaluation of physician-assisted suicide. . . . In such circumstances, the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance." *Id.* at 737, 117 S. Ct. 2258 (O'Connor, J., concurring) (citations and quotation marks omitted); *cf. Cruzan v. Director*, 497 U.S. 261, 293, 110 S. Ct. 2841, 111 L. Ed. 2d 224 (Scalia, J., concurring) ("[W]hen it *is* demonstrated . . . that a patient no longer wishes certain measures to be taken to preserve his or her life, it is up to the citizens[of the

States] to decide, through their elected representatives, whether that wish will be honored."). Here, Oregon voters have twice declared their support for the legalization of physician assisted suicide in their state. We disagree with the dissent's suggestion that this court, rather than the Attorney General, is interfering with the democratic process. *See Glucksberg*, 521 U.S. at 735, 117 S. Ct. 2258 ("Our holding permits this debate [about physician assisted suicide] to continue, as it should in a democratic society.").

The principle that state governments bear the primary responsibility for evaluating physician assisted suicide follows from our concept of federalism, which requires that state lawmakers, not the federal government, are "the primary regulators of professional [medical] conduct." *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002); *see also Glucksberg*, 521 U.S. at 737, 117 S. Ct. 2258 (O'Connor, J., concurring). The Supreme Court has made the constitutional principle clear: "Obviously, direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18, 45 S. Ct. 446, 69 L. Ed. 819 (1925); *see also Barsky v. Bd. of Regents*, 347 U.S. 442, 449, 74 S. Ct. 650, 98 L. Ed. 829 (1954) ("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."). The Attorney General "may not . . . regulate [the doctor-patient] relationship to advance federal policy." *Conant*, 309 F.3d at 647 (Kozinski, J., concurring).[6]

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[6] As noted in *Younger v. Harris*, 401 U.S. 37, 44-45, 91 S. Ct. 746, 27 L. Ed. 2d 669 (1971):

By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders and therefore "alter[s] the 'usual constitutional balance between the States and the Federal Government.'" *Gregory v. Ashcroft*, 501 U.S. 452, 461, 111 S. Ct. 2395, 115 L. Ed. 2d 410 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242, 105 S. Ct. 3142, 87 L. Ed. 2d 171 (1985)). Under these circumstances, "[i]t is incumbent on the federal courts to be certain of Congress' intent" before finding that federal authority supercedes state law. *Gregory*, 501 U.S. at 460, 111 S. Ct. 2395 (quotation marks and citation omitted).

Unless Congress' authorization is "unmistakably clear," the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care. *Id.* at 460-61, 111 S. Ct. 2395 (quoting *Atascadero State Hosp.*, 473 U.S. at 242, 105 S. Ct. 3142); *see also Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173, 121 S. Ct. 675, 148 L. Ed. 2d 576 (2001) ("This concern is heightened where an administrative interpretation alters the federal-state

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> The concept [of federalism] does not mean blind deference to "States' Rights" any more than it means centralization of control over every important issue in our National Government and its courts. The Framers rejected both these courses. What the concept does represent is a system in which there is sensitivity to the legitimate interests of both State and National Governments, and in which the National Government, anxious though it may be to vindicate and protect federal rights and federal interests, always endeavors to do so in ways that will not unduly interfere with the legitimate activities of the States.

framework by permitting federal encroachment upon a traditional state power."); *United States v. Bass*, 404 U.S. 336, 349, 92 S. Ct. 515, 30 L. Ed. 2d 488 (1971) ("[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance."). In divining congressional intent, it is a "cardinal principle" of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems, [federal courts shall] construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575, 108 S. Ct. 1392, 99 L. Ed. 2d 645 (1988).

The Ashcroft Directive is invalid because Congress has provided no indication—much less an "unmistakably clear" indication—that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide. By attempting to regulate physician assisted suicide, the Ashcroft Directive invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice. *See Linder*, 268 U.S. at 18, 45 S. Ct. 446; *Conant*, 309 F.3d at 639. Because Congress has not clearly authorized such an intrusion, the Ashcroft Directive violates the clear statement rule. *See Solid Waste Agency*, 531 U.S. at 172-73, 121 S. Ct. 675; *Yeskey*, 524 U.S. at 208-09, 118 S. Ct. 1952. We need not, and therefore do not, decide whether the Ashcroft Directive actually exceeds Commerce Clause boundaries, but only that it "invokes the outer limits of Congress' power" without explicit authority from Congress. *Solid Waste Agency*, 531 U.S. at 172, 121 S. Ct. 675 (citing *Edward J. DeBartolo*

Corp., 485 U.S. at 575, 108 S. Ct. 1392); *see also Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208-09, 118 S. Ct. 1952, 141 L. Ed. 2d 215 (1998) ("[A]bsent an unmistakably clear expression of intent to alter the usual constitutional balance between the States and the Federal Government, we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers.") (quotation marks and citations omitted).

B

The Ashcroft Directive not only lacks clear congressional authority, it also violates the plain language of the CSA. We hold that the Directive exceeds the scope of federal authority under the CSA, misconstrues the Attorney General's role under the statute, and fails to follow explicit instructions for revoking physician prescription privileges.

The CSA expressly limits federal authority under the Act to the "field of drug abuse." Pub. L. No. 91-513, 84 Stat. 1236; 21 U.S.C. § 801(2)-(6). Contrary to the Attorney General's characterization, physician assisted suicide is not a form of drug "abuse" that Congress intended the CSA to cover.[7]

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[7] The dissent argues that when Congress enacted the CSA it was not solely concerned with "drug abuse," as that term is commonly understood. The dissent suggests that a reference in the legislative record to "suicides and attempted suicides" and "drug-related deaths" indicates that Congress understood "drug abuse" to encompass physician assisted suicide. These excerpts are taken entirely out of context. In the record cited by the dissent, suicide is *distinguished* from "abuse," *see* H.R. Rep. No. 91-1444 (1970), 1970 U.S.C.C.A.N. at 4602, and statements concerning "drug-related deaths" clearly refer to overdoses from abuse of pharmaceutical drugs "diverted from the sick and injured to the black market." 130 Cong. Rec. 25,851 (1984) (statement of Rep. Rodino); 98 Cong.

Physician assisted suicide is an unrelated, general medical practice to be regulated by state lawmakers in the first instance. *Glucksberg*, 521 U.S. at 735, 737, 117 S. Ct. 2258 (O'Connor, J., concurring).

We know that Congress intended to limit federal authority under the CSA to the field of drug abuse because the statute's non-preemption clause provides that the CSA shall be not be construed to preempt state law unless there is a "positive conflict" between the text of the statute and state law. 21 U.S.C. § 903; *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 502, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001) (Stevens, J. concurring) ("[F]ederal courts [must], whenever possible, . . . avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a state have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country.") (citations and quotation marks omitted). No provision of the CSA directly conflicts with Oregon's Death with Dignity Act. However, the Attorney General's expansive interpretation of the CSA clearly conflicts with the Oregon law and therefore cannot be squared with the CSA's non-preemption clause. See 21 U.S.C. § 903; *see also Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325, 117 S. Ct. 832, 136 L. Ed. 2d 791 (1997) ("As is

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Rec. 365 (1984) (statement of Rep. Waxman). The record is voluminous and replete with statements of congressional intent to combat drug abuse and addiction, and particularly the problem of doctors who illicitly funnel prescription drugs into the hands of dealers and addicts. Both the Attorney General and the dissent expand the scope of the CSA in a manner that contravenes and distorts Congress' will.

always the case in our pre-emption jurisprudence, where federal law is said to bar state action in fields of traditional state regulation, . . . we have worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (citation and quotation marks omitted).

To the limited extent that the CSA does authorize federal regulation of medical practice, Congress carefully circumscribed the Attorney General's role. The Attorney General may not define the scope of legitimate medical practice. See Pub. Law No. 91-513, 84 Stat. at 1241 (now codified at 42 U.S.C. § 290bb-2a).[8] In *Moore*, the Supreme Court held that the CSA "requires" the Secretary of Health and Human Services "to determine the appropriate methods of professional practice" under the statute. 423 U.S. at 144, 96 S. Ct. 335 (quoting 42 U.S.C. § 290bb-2a); *see also Rosenberg*, 515 F.2d at 194-95.

The Attorney General, on the other hand, is authorized to revoke prescription privileges from physicians for conduct deemed "inconsistent with the public interest[.]" 21 U.S.C. § 824(a)(4). However, in this case,

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[8] *See also* 21 U.S.C. § 811(b) ("The recommendations of the Secretary to the Attorney General [concerning which substances shall be covered by the CSA] shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug[.]"); 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in . . . regulations or practice guidelines [concerning the treatment of narcotic addicts] 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.").

the Attorney General improperly invokes this authority. When determining what conduct is inconsistent with the public interest under the CSA, the Attorney General is required to consider five factors. *See* 21 U.S.C. § 823(f). The Attorney General reasons that physician assisted suicide is inconsistent with the public interest because the practice threatens public health. *See* Memorandum for the Attorney General from the Office of Legal Counsel, June 27, 2001 ("OLC Memo"), at 3-18.[9] Although threat to public health is one factor the Attorney General is to consider when determining the public interest, in this case he does not consider the other factors required by the statute. *See* 21 U.S.C. § 823(f).

The Attorney General misreads the CSA when he concludes that he may evaluate the public interest "based on *any* of the five factors identified in the statute." OLC Memo at 3 (emphasis added). The CSA clearly provides that all five public interest factors "*shall* be considered." 21 U.S.C. § 823(f) (emphasis added). When the Attorney General declares that his Directive shall apply "regardless of whether state law authorizes or permits such conduct," he ignores the very first factor he is required to consider under the Act—*i.e.* "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority." 21 U.S.C. § 823(f)(1). The Attorney General's categorical prohibition of physician assisted suicide also fails to consider the second and third public interest factors required under the CSA. *See* 21 U.S.C. § 823(f)(2), (3) (listing individual practitioner experience

[9] This memo is attached to the Ashcroft Directive and, according to the Attorney General, "sets forth the legal basis for my decision." 66 Fed. Reg. at 56,608.

and criminal history as the second and third public interest factors).

Thus, we see at least three conflicts between the Ashcroft Directive and the text of the CSA. First, the Directive purports to regulate medical practices outside the field of drug abuse and prevention, despite the statute's limited scope and Congress' stated intent. Second, the Directive makes a unilateral medical determination that may not be made by the Attorney General.[10] Finally, the Directive evaluates public interest under 21 U.S.C. § 823 without considering all five factors required by that subsection. *See* 5 U.S.C. § 706(2)(C), (D) ("The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] without observance of procedure required by law[.]").

C

The CSA's legislative record confirms that the Attorney General has exceeded the scope of his authority. *See SEC v. McCarthy*, 322 F.3d 650, 655 (9th Cir. 2003) ("When the statute is ambiguous or the statutory language does not resolve an interpretive issue, our approach to statutory interpretation is to look to legislative history.") (citation and quotation marks omitted).

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[10] We do not intend to imply that the Secretary of Health and Human Services may determine that physician assisted suicide constitutes an illegitimate medical practice. As noted, by its terms the CSA is limited to "the field of drug abuse," which is not so broad as to include conduct authorized by Oregon's Death With Dignity Act. See Pub. L. No. 91-513, 84 Stat. 1236 (preamble) (1970).

Congress clearly intended to limit the CSA to problems associated with drug abuse and addiction. *See, e.g.*, H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) ("[I]t cannot be overemphasized that the . . . [CSA] is designed to crackdown hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."). As we held in *Rosenberg*, "Congress was concerned with the diversion of drugs out of legitimate channels of distribution" when it enacted the CSA. 515 F.2d at 193. Congress acted to halt "'the widespread diversion of [controlled substances] out of legitimate channels into the illegal market'[.]" *Id.* at 194 (quoting H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4572).

Furthermore, recognizing that this mandate may at times encroach on a state's traditional authority to regulate medical practices, Congress empowered "the principal health agency of the federal government," not the Attorney General, to make medical decisions under the Act. *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4581 ("[T]he committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine. . . . In view of this situation, this section will provide guidelines, determined by the principal health agency of the federal government[.]"). In *Moore*, the Court observed that "Congress pointed out that criminal prosecutions *in the past* had turned on the opinions of federal prosecutors. Under the[CSA], those physicians who comply with the recommendations *made by the Secretary* [of Health and Human Services] will no longer jeopardize their professional careers[.]"

423 U.S. at 144, 96 S. Ct. 335. (emphasis added) (quotation marks and citation omitted).

In 1974, Congress amended the CSA to "cure the present difficulty in [resolving] . . . the intricate and nearly impossible burden of establishing what is beyond the 'course of professional practice' for criminal law purposes." *Moore*, 423 U.S. at 140, n. 16, 96 S. Ct. 335 (citation omitted). Although only tangentially related to this case, the 1974 amendment is noteworthy because it evinces Congress's intent to "preserve[ ] the distinctions found in the Controlled Substances Act between the functions of the Attorney General and the Secretary [of Health and Human Services]. . . . *All decisions of a medical nature are to be made by the Secretary [of Health and Human Services].* Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General." H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034 (emphasis added).

Congress did not intend to expand the scope or general purpose of the CSA when it amended the statute in 1984 to give the Attorney General authority to revoke the federal registrations of physicians and pharmacists. *See* S. Rep. No. 98- 225 at 260, 261-62, 1984 U.S.C.C.A.N. at 3443-44 ("In particular, the amendments . . . are intended to address the severe problem of diversion of drugs of legitimate origin into the illicit market."). Nor did Congress intend to grant the Attorney General any broader authority than he already exercised over the registration of manufacturers and distributers of controlled substances. *See id.* at 3449 ("The broader considerations for registration of practitioners set out in[the amendments] . . . are

similar to those applicable under current law to registration applications on the part of manufacturers and distributors of controlled substances."). By enacting the 1984 amendments, Congress merely intended to close "loop-holes" in the original legislation by authorizing the Attorney General to revoke physician registrations without depending on state licencing boards, which had proven ineffective regulators of physicians who were diverting drugs into the illicit market. *See id.* at 3442- 44.

Finally, the legislative record demonstrates Congress' clear intent to prevent the Attorney General from revoking health care practitioners' DEA registrations on the sole basis of his decision that certain conduct "may threaten the public health and safety." *See* 21 U.S.C. § 823(f)(5). Congress unmistakably intended the Attorney General to consider all five factors under § 823(f) before determining whether physician conduct contravenes public interest. Congress specifically intended that the Attorney General must "continue to give deference to the opinions of the State licencing authorities," as their recommendations "are the first of the factors to be considered." S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449. It is undisputed that the Attorney General made no effort to solicit input from the State of Oregon before issuing his Directive, notwithstanding an express promise to do so by his subordinates within the United States Department of Justice.

D

The Ashcroft Directive proclaims that physician assisted suicide constitutes an illegitimate medical practice under 21 C.F.R. § 1306.04. Just as the Attorney

General's interpretation of the text of the CSA conflicts with the statute's plain language and the clear intent of Congress, so too does his interpretation of this regulation.

The Attorney General's interpretation of § 1306.04 exceeds the CSA's limited mandate to combat prescription drug abuse and addiction. *See* 21 U.S.C. § 801(2)-(6); Pub. L. No. 91-513, 84 Stat. 1236 (preamble); S. Rep. No. 98-225 at 260-62, 1984 U.S.C.C.A.N. at 3442-44; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; *Rosenberg*, 515 F.2d at 193-95. To the extent that the federal regulation of controlled substances impacts medical care, the Supreme Court in *Moore* articulated no role for the Attorney General in determining the appropriate methods of medical practice under § 1306.04. *See* 423 U.S. at 144, 96 S. Ct. 335. While the 1984 amendments to the CSA do extend the Attorney General's authority over federal registration of practicing physicians, these changes neither impact § 1306.04 nor provide the Attorney General the authority to determine the scope of legitimate medical practice in the manner attempted here.

IV

Given the plain language of the CSA and its legislative record, we are under no obligation to defer to the Attorney General's interpretation of his role under the statute and its implementing regulations. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984); *see also Solid Waste Agency*, 531 U.S. at 172- 74, 121 S. Ct. 675. Agency determinations that squarely conflict with governing statutes are not entitled to deference. *Chevron*, 467 U.S. at 842-43, 104 S. Ct. 2778. We "must, of course,

set aside [agency] decisions which rest on an erroneous legal foundation." *NLRB v. Brown*, 380 U.S. 278, 291-92, 85 S. Ct. 980, 13 L. Ed. 2d 839 (1965) (citation and quotation marks omitted); *cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 120 S. Ct. 1291, 146 L. Ed. 2d 121 (2000).

As already explained, the Ashcroft Directive exceeds the scope of the CSA and ignores the Attorney General's limited role. *See* Pub. L. No. 91-513, 84 Stat. 1236 (preamble); *see also* S. Rep. No. 98-225 at 260-62, 1984 U.S.C.C.A.N. at 3442-44. The Attorney General fails to follow the CSA's clear instructions when he declares that his assessment of the public interest may be based on "any" of the five factors required under § 823(f) and that his determination shall apply "regardless of whether state law authorizes or permits such conduct." *See* 21 U.S.C. § 823(f); *see also* S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449.

We also note that the Attorney General has no specialized expertise in the field of medicine and that he imposes a sweeping and unpersuasive interpretation of the CSA—which directly conflicts with that of his predecessor—without notice or comment. There is no reason to defer to his interpretation of his authority under the CSA. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161, 89 L. Ed. 124 (1994) (holding that an agency's interpretation may merit some deference in a field of its specialized expertise); *see also United States v. Mead Corp.*, 533 U.S. 218, 234-35, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001).

Nor shall we defer to the Attorney General's interpretation of 21 C.F.R. § 1306.04, which conflicts with the Supreme Court's interpretation of the same regulation in *Moore*. *See* 423 U.S. at 144, 96 S. Ct. 335;

see also Alhambra Hosp. v. Thompson, 259 F.3d 1071, 1076 (9th Cir. 2001) (refusing to defer to an agency's interpretation of its own regulation when it conflicted with the "overriding intent" of Congress); *Maislin Indus., U.S., Inc. v. Primary Steel, Inc.*, 497 U.S. 116, 131, 110 S. Ct. 2759, 111 L. Ed. 2d 94 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning.").

Citing federalism concerns, the Supreme Court recently refused to defer to an agency's interpretation of its own regulations without clear authority from Congress. *See Solid Waste Agency*, 531 U.S. at 172-74, 121 S. Ct. 675. As already explained, the Attorney General's interpretation of § 1306.04 permits him to override state regulation of general medical practices *despite* Congress' express intent to limit federal authority under the CSA to the field of drug abuse and addiction. *See* Pub. L. No. 91-513, 84 Stat. 1236 (preamble); 21 U.S.C. § 801. Clearly, "our deference does not extend to agencies' constructions which conflict with statutory directives." *Pacific Coast Med. Enter. v. Harris*, 633 F.2d 123, 131 (9th Cir. 1980).[11]

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[11] The Supreme Court has also refused to extend deference to an agency's interpretation of a regulation when, as here, it conflicts with the agency's previous interpretation of the same regulation. *See Norfolk S. Railway Co. v. Shanklin*, 529 U.S. 344, 356, 120 S. Ct. 1467, 146 L. Ed. 2d 374 (2000) ("[N]o . . . deference is appropriate [because] [n]ot only is the [agency's] interpretation inconsistent with the text of [the regulation], but *it also contradicts the agency's own previous construction* [.]") (emphasis added); *Solid Waste Agency*, 531 U.S. at 168, 121 S. Ct. 675 (noting that the

V

In sum, the CSA was enacted to combat drug abuse. To the extent that it authorizes the federal government to make decisions regarding the practice of medicine, those decisions are delegated to the Secretary of Heath and Human Services, not to the Attorney General. The Attorney General's unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interferes with the democratic debate about physician assisted suicide and far exceeds the scope of his authority under federal law. We therefore hold that the Ashcroft Directive is invalid and may not be enforced.

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agency's new interpretation is unsupported by any "evidence that the [agency] mistook Congress' intent" the first time); see also *Pacific Coast Med. Enter.*, 633 F.2d at 131 ("The [regulation] must be reasonably susceptible to the construction placed upon them by the [agency], both on [its] face and in *light of [its] prior interpretation and application.*") (emphasis added). Nor is deference due when an agency's interpretation of a regulation conflicts with the agency's intent at the time the regulation was promulgated. *See Thomas Jefferson Univ. Hosp. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 129 L. Ed. 2d 405 (1994) (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430, 108 S. Ct. 1306, 99 L. Ed. 2d 515 (1988)). Here, the Attorney General asserts that the CSA and its implementing regulations must reflect a uniform federal standard of practice. But when Attorney General Mitchell promulgated 21 C.F.R. § 1306.04 in 1971, physicians were entitled to distribute controlled substances—as a matter of right—merely by complying with *state* law. *See* Pub. L. No. 91-513, 84 Stat. 1253, 1255 (§§ 303(f), 304(a)). Neither Congress nor Attorney General Mitchell could have intended § 1306.04 to empower the Attorney General to enforce a uniform federal standard of medical care, as contemplated here, when authorization to prescribe drugs under the CSA turned on the decisions of state licensing and law enforcement authorities. *See id.*

The petitions for review are GRANTED. The injunction previously entered by the district court is ORDERED continued in full force and effect as the injunction of this court.

WALLACE, Senior Circuit Judge, dissenting:

As my colleagues in the majority suggest, this case is not about the ethics or public policy implications of physician-assisted suicide. We need not decide whether the federal government or the states is better equipped to regulate physician-assisted suicide. Setting aside the public policy aspects of physician-assisted suicide that evoke passionate feelings, this case involves a single legal question: is the Attorney General's interpretation of 21 C.F.R. § 1306.04(a) entitled to deference? Because our past decisions command deference to the Attorney General's interpretive rule, I would deny the petition for review on the merits.

I.

The Oregon Death with Dignity Act (Oregon Act) provides that a capable adult who "has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified manner." OR. REV. STAT. § 127.805(1). Once various safeguards have been satisfied, the attending physician may "writ[e] a prescription for medication to enable a qualified patient to end his or her life," *id.* § 127.815(1)(k), and the attending physician, the pharmacist, or a third person may dispense the medication to the patient, *id.* § 127.815(1)(L). To date,

Oregon is the only state that has passed legislation expressly legalizing physician-assisted suicide.

By authorizing physicians to prescribe and dispense controlled substances for the purpose of assisting suicide, the Oregon Act arguably draws Oregon law into tension with the federal Controlled Substances Act, 21 U.S.C. §§ 801-971. "Except as authorized by [the Controlled Substances Act]," it is unlawful for any person—including physicians—to "manufacture, distribute, or dispense" a controlled substance. 21 U.S.C. § 841. The Controlled Substances Act permits physicians to dispense controlled substances only if they have previously registered with the Attorney General. *Id.* §§ 822(a)(2), 823(f). Even registered physicians may not distribute controlled substances, however, without first issuing a "prescription," *id.* § 829(a), which, "to be effective[,] must be issued for a legitimate medical purpose," 21 C.F.R. § 1306.04(a). The Attorney General may revoke or suspend a physician's registration if the registrant has been convicted of violating the Controlled Substances Act, 21 U.S.C. § 824(a)(2), or has committed acts "inconsistent with the public interest," *id.* §§ 823(f), 824(a)(4).

Whether physician-assisted suicide is "a legitimate medical purpose" and "consistent with the public interest" has been the subject of considerable public debate. In a letter dated November 5, 1997, Drug Enforcement Administration (DEA) Administrator Thomas A. Constantine opined that assisting suicide is not a "legitimate medical purpose" under the Controlled Substances Act. Letter from Constantine, DEA Administrator, to Henry J. Hyde, Congressman (Nov. 5, 1997), available at http://www.house.gov/judiciary/constantine.htm. Seven months later, however, then-

Attorney General Janet Reno rejected the DEA Administrator's opinion letter, concluding that "the [Controlled Substances Act] does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Statement of Attorney General Reno on Oregon's Death with Dignity Act (June 5, 1998), *available at* http://www.usdoj.gov/opa/pr/1998/June/259ag.htm.html. General Reno's interpretation of the Controlled Substances Act prompted a stern letter from several Senators-including then Missouri Senator John Ashcroft:

> [T]here is agreement among all three branches of the Federal government that assisted suicide is not a legitimate medical practice. The DEA is therefore on solid ground in concluding that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose,'" and that such a misuse of drugs warrants the revocation of a physician's license to dispense controlled substances.

Letter from John Ashcroft et al., U.S. Senators, to Janet Reno, Attorney General (Dec. 19, 1997).

Following his appointment to head the Department of Justice, General Ashcroft issued an interpretive rule on November 9, 2001, reversing his predecessor's earlier position regarding physician-assisted suicide. Dispensing of Controlled Substances To Assist Suicide (Ashcroft Directive), 66 Fed. Reg. 56,607 (Nov. 9, 2001) (to be codified at 21 C.F.R. pt. 1306). The Ashcroft Directive states that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R.

§ 1306.04 (2001)" and that a physician who prescribes controlled substances to assist suicide "may' render his registration . . . inconsistent with the public interest'" and thereby risk suspension or revocation of his registration under 21 U.S.C. § 824(a)(4). *Id.* at 56,608. General Ashcroft directed "the DEA, effective upon publication of this memorandum in the Federal Register, to enforce and apply this determination, notwithstanding anything to the contrary in the June 5, 1998, Attorney General's letter." *Id.*

Before the Department of Justice took action to enforce the Ashcroft Directive, a group of physicians, patients, and the state of Oregon (collectively Petitioners) brought this action in federal district court, seeking declaratory and injunctive relief. Although the district court lacked jurisdiction to consider the petition for review, *see Pac. Power & Light Co. v. Bonneville Power Admin.*, 795 F.2d 810, 814-16 (9th Cir. 1986); *UMC Indus., Inc. v. Seaborg*, 439 F.2d 953, 955 (9th Cir. 1971) (per curiam), this court has jurisdiction pursuant to 28 U.S.C. § 1631 and 21 U.S.C. § 877.

II.

The Petitioners do not dispute that the Controlled Substances Act prohibits physicians from dispensing and prescribing controlled substances except for legitimate medical purposes. *See* 21 C.F.R. § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose. . . ."); *United States v. Moore*, 423 U.S. 122, 124, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975) (holding that physicians violate the Controlled Substances Act "when their activities fall outside the usual course of professional practice"); *United States v. Kaplan*, 895 F.2d 618, 619 (9th Cir.

1990) (stating that the Controlled Substances Act prohibits "prescribing controlled substances for reasons other than legitimate medical purposes"); *United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975) (interpreting the Controlled Substances Act "to mean that a doctor who acts [outside] the course of professional practice is not a practitioner under the Act and is therefore not authorized to prescribe controlled substances"). Instead, they argue that the Ashcroft Directive is not a valid agency rule—and thus is not entitled to deference—for the following four reasons: (1) the Attorney General did not promulgate the Ashcroft Directive pursuant to the Administrative Procedure Act's (APA) notice-and-comment rulemaking procedures; (2) the Ashcroft Directive violates the Controlled Substances Act's non-preemption provision; (3) the Ashcroft Directive exceeds the scope of the Attorney General's authority under the Controlled Substances Act; and (4) the Ashcroft Directive is an arbitrary and capricious agency action. As will be seen, none of these creative challenges to the Ashcroft Directive withstands close scrutiny or justifies the majority's departure from our customary canons of deference to agency action.

A.

Petitioners argue first that deference to the Ashcroft Directive is not warranted because the Attorney General did not satisfy the APA's notice-and-comment rulemaking procedures. *See* 5 U.S.C. § 553 (requiring that agencies give "interested persons" notice of proposed rules and "an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation"). The United States counters that the

APA does not require notice and comment here, because the Ashcroft Directive is an interpretive rule, not a legislative rule. *See id.* § 553(b)(3)(A) (stating the APA's notice-and-comment procedures do not ordinarily apply to interpretive rules). If the Ashcroft Directive is "genuinely an interpretive rule, it is valid despite the absence of notice and comment procedures." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003).

We distinguish interpretive and legislative rules by asking (1) whether, absent the rule, there would be an inadequate legislative basis for an enforcement action; (2) whether the agency "explicitly invoked its general legislative authority"; and (3) whether "the rule effectively amends a prior legislative rule." *Id.* "If the answer to any of these questions is affirmative, we have a legislative, not an interpretive rule." *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000), *quoting Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

The Ashcroft Directive does not bear any of these three hallmarks of a legislative rule. First, even absent the Ashcroft Directive, the Attorney General could bring an enforcement action because the Controlled Substances Act itself prohibits distributing a controlled substance without a prescription, 21 U.S.C. § 829(a), and preexisting Department of Justice regulations declare that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose," 21 C.F.R. § 1306.04(a). Second, the Attorney General did not expressly invoke his statutory authority to "promulgate . . . any [legislative rules] . . . which he may deem necessary and appropriate for the efficient execution of his functions under" the

Controlled Substances Act. 21 U.S.C. § 871(b). Third, although the Ashcroft Directive contradicts former Attorney General Reno's 1998 statement, the Ashcroft Directive is not inconsistent with any *legislative* rule. *See Chief Prob. Officers of Cal. v. Shalala*, 118 F.3d 1327, 1337 (9th Cir. 1997) (holding that an interpretive rule can amend an interpretive rule); Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 ADMIN. L. REV. 547, 566-73 (2000) (discussing this principle).

The Ashcroft Directive does not purport to "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." *Hemp*, 333 F.3d at 1087. Instead, like other interpretive rules, the Ashcroft Directive is "essentially hortatory and instructional," clarifying what the Controlled Substances Act means when applied to a narrowly defined situation. *Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984); *see also Hemp*, 333 F.3d at 1087 (explaining that interpretive rules "explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule"). Thus, General Ashcroft's failure to give Petitioners advance notice and an opportunity to comment does not invalidate the Ashcroft Directive.

B.

The Petitioners next contend that the Ashcroft Directive violates 21 U.S.C. § 903, the Controlled Substances Act's non-preemption clause. Section 903 reads:

> 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

> . . . 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.

21 U.S.C. § 903. The Petitioners argue that the Ashcroft Directive construes the Controlled Substances Act to preempt the Oregon Act and that this result violates 21 U.S.C. § 903 because there is no "positive conflict" between the Controlled Substances Act's text and the Oregon Act.

Petitioners are wrong; the Ashcroft Directive is consistent with section 903 because it does not utterly exclude state regulation of medical practice or even state regulation of physician-assisted suicide. The Ashcroft Directive does not effect a "positive conflict" with state law because it does not make "the federal role . . . so pervasive that no room is left for the states to supplement it." *Sayles Hydro Assocs. v. Maughan*, 985 F.2d 451, 455 (9th Cir. 1993). States may supplement the Ashcroft Directive by expanding the Controlled Substances Act's prohibitions, providing additional civil or criminal sanctions against physicians who assist suicide, or permitting conduct that the Ashcroft Directive does not prohibit.

More relevant for present purposes, the Ashcroft Directive proscribes only one method of assisting suicide: prescription, dispensation, and administration of controlled substances. The majority vastly exaggerates the Ashcroft Directive's scope by intimating that it "ban[s] physician-assisted suicide outright." A closer examination of the Ashcroft Directive's text reveals that "[assisting] suicide is not a 'legitimate medi-

cal purpose'" only "*within the meaning of 21 C.F.R. § 1306.04*" (prescription of controlled substances). Ashcroft Directive, 66 Fed. Reg. at 56,608 (emphasis added). The Ashcroft Directive avoids the sweeping prohibition claimed by the majority by assiduously limiting its reach to controlled substances; under its plain terms, only applications involving *controlled substances* may "render [a physician's] registration . . . inconsistent with the public interest" and therefore subject to revocation. *Id.*, *quoting* 21 U.S.C. § 824(a)(4). Oregon physicians may continue to assist suicide by other means without risking suspension or revocation of their registration to prescribe controlled substances. *See* George J. Annas, *The "Right To Die" in America: Sloganeering from* Quinlan *and* Cruzan *to* Quill *and* Kevorkian, 34 DUQ. L. REV. 875, 891 (1996) (discussing carbon monoxide as an alternative to controlled substances); Jeffrey G. Sherman, *Mercy Killing and the Right To Inherit*, 61 U. Cin. L. Rev. 803, 834 (1993) (same). The Ashcroft Directive does not, therefore, "occupy the field" of physician-assisted suicide in violation of section 903. *See United States v. Leal*, 75 F.3d 219, 227 (6th Cir. 1996) (holding that "there is no such conflict" between 21 C.F.R. § 1306.04 and state law).

C.

Petitioners maintain—and the majority agrees—that the Ashcroft Directive is not entitled to deference because the Attorney General promulgated it "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

1.

The Ashcroft Directive is not entitled to deference, the majority contends, because "Congress intended to

limit federal authority under the [Controlled Substances Act] to the field of drug abuse" while preserving states' discretion to authorize other life-threatening applications of controlled substances. By what authority? True, the Controlled Substances Act's preamble arguably manifests Congress's intent "to strengthen existing law enforcement authority in the field of drug abuse," Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, pmbl., 84 Stat. 1236, 1236, but it does not "expressly limit[ ] federal authority under the Act" to mainstream drug abuse, as the majority argues. Moreover, there is simply no textual support for the majority's conclusory assertion that "the field of drug abuse," as discussed in the Controlled Substances Act, does not encompass drug-induced, physician-assisted suicide.

The Controlled Substances Act's text furnishes ample evidence that Congress was concerned not only with street-variety drug trafficking and abuse but also with any other improper drug use that might have a "detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2). The Act targets all "improper use of controlled substances," *id.*, and gives the Attorney General discretion to decide whether registering a physician to dispense drugs is "consistent with the public health and safety," *id.* § 823(b)(5). Reasonable minds might disagree as to whether physician-assisted suicide constitutes an "improper use" of a controlled substance, but nothing in the Controlled Substances Act's text precludes its application to physician-assisted suicide.

Lacking a textual hook for its position, the majority attempts to patch the holes in its argument with inconclusive fragments of legislative history. Discern-

ing congressional intent from legislative history is a speculative enterprise under the best of circumstances, and the risk of error is compounded in a case such as this when legislators' published statements do not squarely address the question presented-i.e., whether Congress intended to exclude drug-induced, physician-assisted suicide from regulation under the Controlled Substances Act. *See Chisom v. Roemer*, 501 U.S. 380, 406, 111 S. Ct. 2354, 115 L. Ed. 2d 348 (1991) (Scalia, J., dissenting) ("We are here to apply the statute, not legislative history, and certainly not the absence of legislative history.").

The Controlled Substances Act's legislative history suggests that some members of Congress envisioned the physician-registration provisions primarily as a mechanism to stem the flow of controlled substances into illicit channels, *Moore*, 423 U.S. at 135, 96 S. Ct. 335, but the record also specifically identifies "suicides and attempted suicides" as a"[m]isuse of a drug." H.R. REP. NO. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572; *see also Dangerous Drug Diversion Control Act of 1984: Hearing on H.R. 5656 Before the House Subcomm. on Health and the Env't*, 98th Cong. 365 (1984) (statement of Rep. Henry A. Waxman, Chairman, House Subcomm. on Health and the Env't) (expressing concern that "[d]rugs legally manufactured for use in medicine are responsible for a substantial majority of drug-related deaths"); 130 CONG. REC. 25,851 (statement of Rep. Rodino) (1984) (reporting that "diversion" of prescription drugs "is responsible for 70 percent of the deaths and injuries due to all drug abuse"). Viewed holistically, the record "does not demonstrate a clear and certain congressional intent" to preclude physician-assisted suicide from

regulation under sections 823 and 824. *Rust v. Sullivan*, 500 U.S. 173, 190, 111 S. Ct. 1759, 114 L. Ed. 2d 233 (1991). Controlling precedent thus compels the conclusion that the Controlled Substances Act's "legislative history . . . cannot form the basis for enjoining [the Attorney General's] regulation[ ]." *Id.*; *see also Student Loan Fund of Idaho, Inc. v. U.S. Dept. of Educ.*, 272 F.3d 1155, 1165 (9th Cir. 2001) (applying this principle in an analogous setting).

2.

The majority asserts that the Attorney General lacks authority to decide whether physician-assisted suicide is consistent with "the public interest" and a "legitimate medical practice" under the Controlled Substances Act and its implementing regulations because Congress intended to preserve the states' traditional authority to make these determinations. This argument ignores the Controlled Substances Act's text and controlling Supreme Court decisions.

It is axiomatic that the meaning of federal law is a federal question. *See Reconstr. Fin. Corp. v. Beaver County*, 328 U.S. 204, 208, 66 S. Ct. 992, 90 L. Ed. 1172 (1946) ("What meaning Congress intended is a federal question we must determine."). Although federal law occasionally incorporates state-law definitions by reference, *see, e.g.*, *De Sylva v. Ballentine*, 351 U.S. 570, 580-82, 76 S. Ct. 974, 100 L. Ed. 1415 (1956) (defining the word "children" in a federal statute according to state law), recourse to state law is the exception rather than the norm. "[I]n the absence of a plain indication to the contrary, . . . Congress when it enacts a statute [does] not mak[e] the application of the federal act dependent on state law." *Miss. Band of Choctaw Indians v.*

Holyfield, 490 U.S. 30, 43, 109 S. Ct. 1597, 104 L. Ed. 2d 29 (1989) (quoting *Jerome v. United States*, 318 U.S. 101, 104, 63 S. Ct. 483, 87 L. Ed. 640 (1943)); *Kahn v. INS*, 36 F.3d 1412, 1414 (9th Cir. 1994) (per curiam) (same).

State law may be *relevant* to certain provisions of the Controlled Substances Act, *see, e.g.*, 21 U.S.C. § 823(f) (instructing the Attorney General to consider state-law violations when deciding whether a physician's registration would be contrary to the public interest), but nothing in the Controlled Substances Act plainly evinces a congressional intent to define "the public interest" solely according to state law. On the contrary, section 823 instructs the Attorney General to identify acts "inconsistent with the public interest" by reference to a variety of sources, including a physician's federal conviction record, compliance with "Federal . . . laws relating to controlled substances," and "other conduct which may threaten public health and safety." *Id.* The majority's contention that the Attorney General cannot suspend or revoke a physician's registration without state authorization ignores *Mississippi Band's* "plain indication" rule and contravenes Congress's clearly expressed intent.

The majority also cites *Washington v. Glucksberg*, 521 U.S. 702, 735, 737, 117 S. Ct. 2258, 138 L. Ed. 2d 772 (1997) (O'Connor, J., concurring), for the position that the Attorney General must defer to the Oregon Act because "[p]hysician-assisted suicide is an unrelated, general medical practice to be regulated by the States in the first instance." *Glucksberg*, however, addressed states' authority to *prohibit* physician-assisted suicide *in the absence of federal regulation*; the case did not answer the question whether Congress may exercise its

Commerce Clause power to deny physicians access to controlled substances for physician-assisted suicide. Rather than place federalism limitations on the federal government's authority to restrict physician-assisted suicide, Justice O'Connor's concurring opinion stressed that "[t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill . . . individuals . . . and the State's interests in protecting those who might seek to end life mistakenly or under pressure." *Id.* at 737, 117 S. Ct. 2258. Simply put, courts should defer to the political process instead of interposing hasty constitutional constraints.

Glucksberg does not require the Attorney General to interpret the Controlled Substances Act and its implementing regulations according to state standards of professional conduct. Rather, the Supreme Court's decision stands for the broader proposition that federal courts generally should keep their distance, allowing the political process to decide whether and how to regulate physician-assisted suicide. The majority's shortsighted decision to declare the Ashcroft Directive invalid has precisely the opposite effect.

3.

As an alternative, the majority contends that the Secretary of Health and Human Services (Secretary)—not the Attorney General—should decide whether medical practices are "legitimate" and consistent with the "public interest" under the Controlled Substances Act and its implementing regulations. The Controlled Substances Act's text directly contradicts this argument: "*The Attorney General* may deny an application for . . . registration [of a practitioner to dispense

drugs] if *he determines* that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. § 823(f) (emphasis added). Congress could not have stated more plainly that the Attorney General, not the Secretary, has authority to determine whether a physician's registration is consistent with the public interest.

The majority's reading of section 823 is a particularly astonishing exercise in statutory construction because the Controlled Substances Act specifically provides for the Secretary's participation in other discretionary judgments. *See, e.g.*, 21 U.S.C. § 811(b) (providing that the Secretary's determination with respect to the classification of controlled substances "shall be binding on the Attorney General"); *id.* § 823(f) (authorizing the Secretary to evaluate a practitioner's "qualifications and competency" to perform "research with controlled substances"); *id.* (stating that the Secretary "shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of . . . controlled substances from legitimate medical or scientific use"); *id.* § 823(g)(2)(H)(i) (empowering the Secretary to "issue regulations . . . or issue practice guidelines" for the approval of "additional credentialing bodies"). When Congress wished to entrust a discretionary judgment to the Secretary it said so explicitly. The Controlled Substances Act conspicuously omits any reference to the Secretary, however, when discussing the Attorney General's authority to assess "the public interest" for purposes of ordinary physician registrations. *Id.* § 823(f). The explanation for this omission is perfectly clear: section 823 authorizes the Attorney General—not the Secretary—to decide whether a

physician's registration is consistent with the public interest.

The majority asserts that under the Controlled Substance Act all standards of legitimate professional conduct are set by the Secretary, not by the Attorney General. The majority's argument relies on a section of the Act entitled "Medical Treatment of Narcotic Addiction," which is located in a different title of the legislation. This section provides that the Secretary, "after consultation with the Attorney General . . ., shall determine the appropriate methods of professional practice in the medical treatment of . . . *narcotic addiction*." 42 U.S.C. § 290bb 2a (emphasis added). Obviously, this is irrelevant to the issue before us. Yet from this narrow provision, the majority draws the sweeping, untenable conclusion that the Attorney General cannot enforce the Controlled Substances Act against a physician unless the Secretary first concludes that the prescription did not issue for a "legitimate medical purpose."

The Supreme Court rejected a similar challenge to the Attorney General's interpretive authority in *Moore*. The Court explained that Congress designed subsection 290bb 2a to function only as a limited safe-harbor for physicians who prescribe controlled substances to drug addicts; as long as physicians employ the treatment methods outlined in the Secretary's published standards of professional practice, the Attorney General may not prosecute them under the Controlled Substances Act. *Moore*, 423 U.S. at 144, 96 S. Ct. 335. The Court recognized, however, that "[t]he negative implication [of this provision] is that physicians who go beyond approved practice remain subject to serious criminal penalties." *Id.* In other words, section 290bb-

2a prevents the Attorney General from enforcing the Controlled Substances Act and its implementing regulations only when the Secretary declares that a specific *narcotic addiction treatment* serves a "legitimate medical purpose."

We confirmed *Moore's* reading of subsection 290bb 2a in *Rosenberg*, holding that the Attorney General may enforce the Controlled Substances Act against physicians whose practices do not qualify for protection under the Secretary's specific safe-harbor guidelines. We explained that the Secretary's authority to

> determine the appropriate method of professional practice in the medical treatment of narcotic addiction . . . was adopted in light of Congress' awareness that there had been criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of Federal prosecutors. *The committee evidenced no intention to restrict such prosecutions.* Indeed[,] *they seemed to think [these prosecutions] would continue*, but that some standards of professional practice should be established so that . . . physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers by accepting narcotic addicts as patients.

515 F.2d at 194-95 (emphasis added) (internal quotations omitted), *citing* H.R. REP. NO. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. at 4581 (observing that "for the last 50 years" federal officials have "determine[d] the appropriate method of the practice of medicine . . . through . . . criminal prosecution[s]" and suggesting that these prosecutions should continue subject to the Secretary's limited guidelines for treatment of narcotic

addiction); *see also* H.R. REP. NO. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034 (recognizing that "[t]he registration required under [the section of the Controlled Substances governing treatment of narcotic addiction] is *separate and distinct* from regular registration under the Controlled Substances Act," which is administered by the Attorney General (emphasis added)).

Here the Petitioners have not shown and do not contend that the Secretary's guidelines approve physician-assisted suicide as an "appropriate method[ ] of professional practice in the medical treatment of . . . *narcotic addiction*." 42 U.S.C. § 290bb 2a (emphasis added). As such, subsection 290bb 2a's safe-harbor rule does not apply, and the Attorney General was not required to consult the Secretary prior to issuing his determination that physician-assisted suicide does not constitute a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a).

4.

The majority maintains that even if the Controlled Substances Act authorizes the Attorney General to ascertain whether physician-assisted suicide is "inconsistent with the public interest," General Ashcroft abused his discretion in this case by failing to consider all five factors outlined in 21 U.S.C. § 823(f). Subsection (f) provides in part that "[i]n determining the public interest, the following factors shall be considered":

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

28 U.S.C. § 823(f). The Ashcroft Directive is invalid, the majority argues, because General Ashcroft "made no effort to solicit input from the State of Oregon before issuing" the interpretive rule.

Contrary to the majority's assertion, the Ashcroft Directive does not sidestep subsection 823(f)'s five-factor inquiry. The Justice Department has yet to initiate an enforcement action against any individual physician pursuant to section 824, so the hour has not arrived for the Attorney General to consider subsections 823(f)(1)-(4) (i.e., the state licensing board's recommendation and physicians' relevant experience and criminal record). The Ashcroft Directive merely cautions that a physician who prescribes controlled substances to assist suicide "*may* 'render his registration . . . inconsistent with the public interest,'" Ashcroft Directive, 66 Fed. Reg. at 56,608 (emphasis added); it does not declare that assisting suicide *shall* render a physician's registration inconsistent with the public interest. This word choice is significant, because it conclusively refutes the majority's contention that assisting suicide *automatically* renders a physician's registration "inconsistent with the public interest"

under the Ashcroft Directive. Even if "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)," the Attorney General remains free to consult all of section 823's five factors—including the recommendation of Oregon's licensing board or disciplinary authority—before making a final decision whether to suspend or revoke a particular physician's registration.

Significantly, the Ashcroft Directive's warning that assisting suicide could prompt Controlled Substances Act enforcement actions comports with fundamental administrative law principles:

> When a governmental official is given the power to make discretionary decisions under a broad statutory standard [e.g., "the public interest"], case-by-case decisionmaking may not be the best way to assure fairness. Here the [Attorney General] . . . sought to define the statutory standard . . . by the use of his rulemaking authority. The decision to use objective rules in this case provides [physicians] with more precise notice of what conduct will be sanctioned and promotes equality of treatment among similarly situated [individuals].

Dixon v. Love, 431 U.S. 105, 115, 97 S. Ct. 1723, 52 L. Ed. 2d 172 (1977). The Controlled Substances Act facilitates adherence to these principles by expressly authorizing the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871. Thus, General Ashcroft acted well within the scope of his statutory authority in declaring that assisting suicide does not serve a "legitimate medical

purpose" under 21 C.F.R. § 1306.04(a) and that this practice "may 'render [a physician's] registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation under [section] 824." Ashcroft Directive, 66 Fed. Reg. at 56,608.

5.

Finally, the majority argues that the Ashcroft Directive exceeds the Attorney General's statutory authority because Congress has not clearly authorized the Attorney General to upset the delicate balance between federal regulation of controlled substances and state control of medical practices. As support for this conclusion, the majority invokes the Supreme Court's recent analysis in *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 121 S. Ct. 675, 148 L. Ed. 2d 576 (2001):

> 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.

Id. at 172-73, 121 S. Ct. 675 (internal citations omitted), *citing Edward J. DeBartalo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575, 108 S. Ct. 1392, 99 L. Ed. 2d 645 (1988). *See generally id.* at

172-74, 108 S. Ct. 1392 (refusing to afford deference to an agency regulation that raised a serious constitutional issue where there was no indication in the statute that Congress intended to encroach on traditional state powers over land and water use). Although the Court addressed the validity of "an administrative interpretation of a *statute*," *id.* at 172, 121 S. Ct. 675 (emphasis added), its reasoning should apply equally to an administrative interpretation of an agency regulation.

Solid Waste's clear statement rule is based upon understandable and significant federalism concerns, the importance of which I do not doubt. The question we must ask ourselves, however, is whether this canon of statutory interpretation applies to the case before us.

Not every colorable constitutional question triggers *Solid Waste's* clear statement rule. Our past decisions dictate that we must "scrutinize constitutional objections to[the] agency interpretation skeptically. Only if the agency's proffered interpretation raises *serious* constitutional concerns may [we] refuse to defer. . . ." *Williams v. Babbitt*, 115 F.3d 657, 662 (9th Cir. 1997), *citing Republican Nat'l Comm. v. Fed. Election Comm'n*, 76 F.3d 400, 409 (D.C. Cir. 1996). As such, the proper approach here is to proceed directly to the merits of Petitioners' constitutional challenge, deciding whether the agency interpretation "raise[s] the sort of grave and doubtful constitutional questions" that could lead us to "invalidate the regulations in order to save the statute from unconstitutionality." *Rust*, 500 U.S. at 191, 111 S. Ct. 1759 (internal quotation marks omitted); *see also United States v. Deaton*, 332 F.3d 698, 704-08 (4th Cir. 2003) (construing the *Solid Waste* canon in light of *Rust* and deciding the disputed constitutional question to determine if it is serious enough to warrant

requiring a clear statement). Only if the Attorney General's proposed interpretation would likely render the statute unconstitutional do we apply *Solid Waste's* clear statement canon. *See Williams*, 115 F.3d at 663 ("*Rust* . . . limits this intrusion on agency power to situations where it's absolutely necessary."). Applying these principles, we should not require a clear statement in this case because controlling precedent compels the conclusion that the Attorney General's interpretation did not invoke "the outer limits" of Congress's Commerce Clause power. *Solid Waste*, 531 U.S. at 172, 121 S. Ct. 675; *see also Republican Nat'l Comm.*, 76 F.3d at 409 ("Because we can easily resolve the [constitutional] challenges through the application of controlling precedent . . ., we do not face the sort of serious constitutional questions 'that would lead us to assume Congress did not intend to authorize the [regulation's] issuance.'" (quoting *Rust*, 500 U.S. at 191, 111 S. Ct. 1759)).

The Commerce Clause empowers Congress to regulate (1) "the use of the channels of interstate commerce"; (2) "the instrumentalities of interstate commerce, or persons or things in interstate commerce"; and (3) "those activities that substantially affect interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-59, 115 S. Ct. 1624, 131 L. Ed. 2d 626 (1995). Our court has long recognized that "the Commerce Clause empowers the federal government to regulate prescription drugs," *In re Grand Jury Proceedings*, 801 F.2d 1164, 1169 (9th Cir. 1986) (per curiam); accord *Rosenberg*, 515 F.2d at 198. We have steadfastly upheld the Controlled Substances Act against Commerce Clause challenges, even in cases involving wholly intrastate activity. *See, e.g., United States v. Tisor*, 96 F.3d 370,

375 (9th Cir. 1996); *United States v. Kim*, 94 F.3d 1247, 1250 (9th Cir. 1996). *But see Raich v. Ashcroft*, 352 F.3d 1222, 1227-28 (9th Cir. 2003) (stating that the Controlled Substances Act, as applied to "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to a valid California state law," likely exceeded Congress's Commerce Clause power).

Turning to the specific issue raised here—whether the prescription or dispensation of controlled substances to assist suicide substantially affects interstate commerce—we base our assessment on four factors:

> 1) whether the statute in question regulates commerce or any sort of economic enterprise; 2) whether the statute contains any express jurisdictional element which might limit its reach to a discrete set of cases; 3) whether the statute or its legislative history contains express congressional findings that the regulated activity affects interstate commerce; and 4) whether the link between the regulated activity and a substantial effect on interstate commerce is attenuated.

United States v. McCoy, 323 F.3d 1114, 1119 (9th Cir. 2003) (internal quotation marks omitted). Of these four factors, the first and last are most important. *Id.*

The Ashcroft Directive clearly satisfies *McCoy's* first and the last criteria. The Ashcroft Directive regulates economic transactions: physicians generally prescribe and dispense controlled substances for a fee. There is no indication here, as there was in *Raich* with regards to medicinal marijuana, that drug-induced physician-

assisted suicide "does not involve [the] sale, exchange, or distribution" of controlled substances. *Raich*, 352 F.3d at 1229. The link between these transactions and their effect on interstate commerce is not attenuated simply because relatively few Oregonians use controlled substances for assisted suicide. We evaluate whether an activity's link to interstate commerce is attenuated by assessing whether its effect on interstate commerce is sufficiently *direct*, *Solid Waste*, 531 U.S. at 195, 121 S. Ct. 675; *McCoy*, 323 F.3d at 1123-24, and we assess individual provisions as "part[s] of a wider regulatory scheme" (i.e., the Controlled Substances Act), which regulates a field of drug-related activity that has "a 'substantial affect' on interstate commerce," *Tisor*, 96 F.3d at 375. Here Congress naturally and directly reduces the amount of a controlled substance that flows through the interstate channels when it prohibits the substance's distribution for a particular use. Thus, the link between drug prescriptions and interstate commerce is sufficiently direct and substantial even if the drugs ultimately are used in intrastate activities such as physician-assisted suicide and the activities' disaggregated effect on interstate commerce is small.

Because the Ashcroft Directive satisfies *McCoy's* first and last factors, we need not consider whether it meets the other, less important ones. See *McCoy*, 323 F.3d at 1119 (explaining that the second and third factors may "aid" the court's analysis, but "are ordinarily not, in themselves, dispositive"); *id.* at 1126-27 (observing that legislative history is "neither necessary nor conclusive" in Commerce Clause analysis). Under *McCoy*, Congress' Commerce Clause power to prohibit physicians from prescribing controlled substances to

assist suicide is not open to serious question. That ends the matter in this circuit and, of course, for this case.

The majority cannot have it otherwise. Their argument that "*direct* control of medical practice in the states is beyond the power of the federal government" misses the point. *Linder v. United States*, 268 U.S. 5, 18, 45 S. Ct. 446, 69 L. Ed. 819 (1925) (emphasis added). Unless and until the Supreme Court directs us differently, our opinions and other binding precedent compel the conclusion that Congress acts comfortably within its Commerce Clause power when it regulates the prescription and dispensation of controlled substances. *See Minor v. United States*, 396 U.S. 87, 98 n. 13, 90 S. Ct. 284, 24 L. Ed. 2d 283 (1969) (stating that "a flat ban on certain [drug transactions] . . . is sustainable under the powers granted Congress" by the Commerce Clause); *Reina v. United States*, 364 U.S. 507, 511, 81 S. Ct. 260, 5 L. Ed. 2d 249 (1960) (referring to Congress's "undoubted power to enact the narcotics laws"); *Tisor*, 96 F.3d at 375 ("[D]rug trafficking is a commercial activity which substantially affects interstate commerce."); *Kim*, 94 F.3d at 1250 n. 4 (recognizing that Congress may regulate controlled substances pursuant to the Commerce Clause even when legislation "intrudes into an area traditionally regulated by states"); *Rosenberg*, 515 F.2d at 198 (dubbing an analogous constitutional challenge "singularly unpersuasive"). General Ashcroft's interpretation of 21 C.F.R. § 1306.04(a) does not, therefore, "invoke[ ] the outer limits of Congress' power," *Solid Waste*, 531 U.S. at 172, 121 S. Ct. 675, the clear statement rule does not apply, and we must evaluate the Ashcroft Directive according to ordinary standards of deference.

D.

The Petitioners contend that the Ashcroft Directive constitutes an arbitrary and capricious interpretation of section 1306.04(a)'s "legitimate medical practice" requirement. General Ashcroft's determination is arbitrary and capricious, they argue, because he failed to examine the "wealth" of substantive data documenting the Oregon Act's effect on public health and safety. They point to a collection of studies which indicate that the Oregon Act's procedures have not been used disproportionately by the poor, uneducated, or uninsured. "Normally, an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L. Ed. 2d 443 (1983).

Although these empirical studies might be socially important, their findings were not an "important aspect of the problem" confronted by the Attorney General. General Ashcroft had before him a single question: whether physician-assisted suicide is a "legitimate medical purpose" as defined in existing case law, federal policy, general state law, and medical opinion. Evidence that Oregon physicians used the Oregon Act's procedures disproportionally against the poor, uneducated, or uninsured could have strengthened his conclusion that physician-assisted suicide is not a "legitimate medical purpose," but it does not follow that the absence of such evidence means physician-assisted suicide is a "legitimate medical practice." Thus, whether the Oregon Act provided adequate safeguards for vulnerable groups was not a sufficiently important aspect of the Attorney General's inquiry to render the

Ashcroft Directive an arbitrary and capricious agency action.

Furthermore, Petitioners' assertion that General Ashcroft "entirely failed to consider" Oregon's position on the social benefits of physician-assisted suicide is plainly false. The Attorney General based his decision on a memorandum from the Office of Legal Counsel, which considered, but rejected, Oregon's position in favor of existing case law, federal policies and practices, the majority state position, and the dominant views of the American medical and nursing professions. *See* Memorandum from Shelden Bradshaw, Deputy Assistant Attorney General, and Robert J. Delahunty, Special Counsel, *Memorandum for the Attorney General: Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under the Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act* (Memorandum) 5-14 (June 27, 2001). Thus, Petitioners have not shown that General Ashcroft's decision to reject the Oregon Act's permissive approach to physician-assisted suicide was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(a).

III.

Having demonstrated the fallacies of the foregoing challenges to the Ashcroft Directive, I now consider what standard of review this court should apply when assessing the Ashcroft Directive's validity. The degree of deference we accord an interpretive rule depends upon whether the rule construes a statute or an agency regulation.

If the Ashcroft Directive represents a statutory interpretation, it enjoys deference as defined in *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124 (1944). *Omohundro v. United States*, 300 F.3d 1065, 1067-68 (9th Cir. 2002). Under *Skidmore*, "[t]he weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140, 65 S. Ct. 161. Especially relevant under *Skidmore* is the fact that the Ashcroft Directive reverses the agency's earlier interpretation. *See Cmty. Hosp. of the Monterey Peninsula v. Thompson*, 323 F.3d 782, 792 (9th Cir. 2003) ("An agency interpretation . . . which conflicts with the agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view." (internal brackets, quotation marks, and citation omitted)). The agency "is not disqualified from changing its mind," however, "and when it does, the courts still sit in review of the administrative decision and should not approach the statutory construction issue *de novo* and without regard to the administrative understanding of the statutes." *NLRB v. Local Union No. 103, Int'l Ass'n of Bridge, Structural & Ornamental Iron Workers*, 434 U.S. 335, 351, 98 S. Ct. 651, 54 L. Ed. 2d 586 (1978).

If the Ashcroft Directive interprets an agency regulation, rather than the Controlled Substances Act itself, we must accord it "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 129 L. Ed. 2d 405 (1994). Under this highly deferential standard,

> [o]ur task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation. In other words, we must defer to the Secretary's interpretation unless an alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation.

Id. (internal citations and quotation marks omitted). Agency interpretations of regulations enjoy substantial deference even if they are inconsistent with the agency's prior interpretations. As the Supreme Court explained in *Thomas Jefferson*, an agency "is not estopped from changing a view[it] believes to have been grounded upon a mistaken legal interpretation." *Id.* at 517, 114 S. Ct. 2381 (internal quotation marks and citation omitted). "[W]here the agency's interpretation of [its regulation] is at least as plausible as competing ones, there is little, if any, reason not to defer to its construction." *Id.* (internal quotation marks and citation omitted) (second brackets in original).

In my view, the Ashcroft Directive constitutes an interpretation of a regulation rather than a statutory interpretation. The Ashcroft Directive's single interpretive act is to "determine that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)." Ashcroft Directive, 66 Fed. Reg. at 56,608. The Petitioners point to General Ashcroft's warning that prescribing a controlled substance to assist suicide may render a physician's registration subject to suspension or revocation under section 824(a)(4). This statement was not an *interpretation* of

the Controlled Substances Act, however, but an explanation of the logical consequences flowing from General Ashcroft's interpretation of 21 C.F.R. § 1306.04. If assisting suicide is not a "legitimate medical purpose," the direct result is that a physician cannot prescribe controlled substances for this purpose without violating Controlled Substances Act section 829 and thereby risking suspension or revocation of their registration under sections 823 and 824. *See* 21 U.S.C. § 823(f)(4) (stating that a physician's violation of federal law is relevant to determine if his registration is inconsistent with the public interest); *id.* § 824(a)(4) (providing that a physician's registration may be revoked for acts inconsistent with the public interest under section 823). Petitioners' contention that General Ashcroft was interpreting the word "practitioner" under 21 U.S.C. § 829 is likewise wrong. Nothing in the Ashcroft Directive turns upon the definition of "practitioner." Thus, the Ashcroft Directive qualifies for *Thomas Jefferson's* highly deferential standard of review.

Applying the *Thomas Jefferson* standard, I have no trouble upholding the Ashcroft Directive from Petitioners' attack. As the Office of Legal Counsel concluded:

> [T]he overwhelming weight of authority in judicial decisions, the past and present policies of nearly all of the States and of the Federal Government, and the clear, firm and unequivocal views of the leading associations within the American medical and nursing professions, establish that assisting in suicide is not an activity undertaken in the course of professional medical practice and is not a legitimate medical purpose. Indeed, we think it fair to say that

> physician-assisted suicide should not be considered a *medical* procedure at all. . . . It is plainly a fallacy to assume that a procedure must be "medical" because it is performed by a physician rather than, say, by a family member, or because it involves the use of a drug that a physician has prescribed.

Memorandum at 13-14; *see also* Ashcroft Directive, 66 Fed. Reg. at 56,608 (stating that the Memorandum "sets forth the legal basis for my decision"). In *Glucksberg*, the Supreme Court offered a similar assessment: "opposition to and condemnation of suicide—and, therefore, of assisting suicide—are consistent and enduring themes of our philosophical, legal, and cultural heritages. More specifically, for over 700 years, the Anglo American common-law tradition has punished or otherwise disapproved of both suicide and assisting suicide." *Glucksberg*, 521 U.S. at 711, 117 S. Ct. 2258 (internal citations omitted). Given this overwhelming historical, legal, and medical consensus that physician-assisted suicide is not a legitimate medical purpose, the Ashcroft Directive clearly satisfies *Thomas Jefferson*. Therefore, I would defer to the Ashcroft Directive's conclusion that physician-assisted suicide is not a "legitimate medical practice" under 21 C.F.R. § 1306.04(a).

IV.

Although I concur with the majority's brief discussion on justiciability and its conclusion as to our jurisdiction, I write separately to address the latter, as it is contested by the parties and resolved improperly by the district court, yet given scant attention by the majority. The majority suggests that *Hemp Industries Association v. DEA*, 333 F.3d 1082 (9th Cir. 2003), is

dispositive, but *Hemp Industries* declined to answer the precise question at issue here; that is, we left open "whether we would have original jurisdiction over an interpretive rule." *Id.* at 1085. A more thorough analysis is therefore needed to determine whether the Ashcroft Directive, which by its terms is an interpretive rule, is a "final determination" within the meaning of 21 U.S.C. § 877 over which we would have jurisdiction.

Section 877 provides that "[a]ll final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved." 21 U.S.C. § 871. The section provides us original jurisdiction where "any person aggrieved by a final decision of the Attorney General" seeks "review of the decision." *Id.* Significantly, the Ashcroft Directive echoes the language of this provision by "advis[ing] . . . that the original DEA *determination* is reinstated and should be implemented." Ashcroft Directive, 66 Fed. Reg. 56,608 (emphasis added); *see also*, *e.g.*, *id.* ("I hereby *determine* that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001). . . ." (emphasis added)); *id.* ("I hereby direct the DEA . . . to enforce and apply this *determination*. . . ." (emphasis added)). Although helpful, the Attorney General's choice of words does not necessarily mean his "determination" is "final."

The district court held that the Ashcroft Directive is not "final" because General Ashcroft kept his own counsel, gave no notice or opportunity for comment, took no evidence, and did not produce an administrative record. As the district court observed, there is a paucity of appellate court decisions analyzing section

877's requirements for review. In order to respond to the district court's argument, therefore, I must reason by analogy and look to general principles of administrative law formulated under the APA. *See U.S. West Communications, Inc. v. Hamilton*, 224 F.3d 1049, 1054-55 (9th Cir. 2000) (using the APA's definition of "final" to interpret "final orders" under the Hobbs Act). For an agency action to be final under the APA, the agency need not obtain outside advice. It need not give notice and an opportunity to comment. *Guadamuz v. Bowen*, 859 F.2d 762, 771 (9th Cir. 1988). Absent a contrary command under the governing statute, the agency need not produce an administrative record, especially for review of purely legal questions such as those in the case before us.

As the Supreme Court held in *Bennett v. Spear*, 520 U.S. 154, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997), an agency action is "final" under the APA if it satisfies two criteria: (1) "the action must mark the consummation of the agency's decision making process—it must not be of a merely tentative or interlocutory nature"; and (2) "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 177-78, 117 S. Ct. 1154 (internal citations and quotation marks omitted). In evaluating whether an agency action meets these conditions, relevant considerations include: (a) whether the action is a "definitive statement of an agency's position," (b) whether it has a "direct and immediate effect on the complaining parties," (c) whether it "has the status of law," and (d) whether it "requires immediate compliance." *Assn. of Am. Med. Colls. v. United States*, 217 F.3d 770, 780 (9th Cir. 2000).

As an interpretive rule, the Ashcroft Directive does not have the "force of law." *Hemp Indus. Ass'n*, 333 F.3d at 1087. Nevertheless, this does not necessarily preclude the Ashcroft Directive from constituting a "final determination." In *Abbott Laboratories v. Gardner*, 387 U.S. 136, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99, 97 S. Ct. 980, 51 L. Ed. 2d 192 (1977), the Supreme Court announced that finality is to be interpreted "in a pragmatic way," meaning that even pre-enforcement regulations that merely state an agency's intentions may be final for review. *Id.* at 149-50, 87 S. Ct. 1507; *see also Alaska v. EPA*, 244 F.3d 748, 750 (9th Cir. 2001) (order) (holding that the EPA's pre-enforcement order to invalidate a permit was final). Because an interpretive rule can be a final order, and because "final orders" are analytically equivalent to "final agency actions," *U.S. West Communications*, 224 F.3d at 1055, it follows that interpretive rules can constitute final agency actions under the APA. Thus, the Ashcroft Directive may qualify as a final agency action notwithstanding the fact that it has not been enforced and does not have the force of law.

Turning to the first *Bennett* requirement, the Ashcroft Directive clearly marks the consummation of the Attorney General's decision making process even though it is a nonbinding, pre-enforcement, interpretive rule. The Ashcroft Directive reflects internal agency deliberation, on a matter of public importance, and commands immediate implementation. Eschewing tentative or equivocal words, it speaks in the immediate and imperative language of final agency action. *See* Ashcroft Directive, 66 Fed. Reg. at 56,608 ("I hereby direct the DEA . . . to enforce and apply this

determination. . . ."); *accord Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 702 (D.C. Cir. 1971) (holding that "when [an agency's] interpretation is not labeled as tentative or otherwise qualified by arrangement for reconsideration" there is "no basis" for concluding that the "'agency action' is 'not final' for purposes of the APA and judicial review"). The Ashcroft Directive purports to be the Attorney General's interpretation, not the interpretation of an underling whose view may be overruled. *Accord Nat'l Automatic Laundry*, 443 F.2d at 701 (reasoning that "with the authoritative interpretative ruling by the [agency head,] the agency's interpretative action has come to an end, and there is no fair basis for saying this process will be disrupted by judicial review"). In addition, the Attorney General's decision to publish the Ashcroft Directive in the Federal Register, rather than simply issue a press release or send an opinion letter to a private party, indicates that the Ashcroft Directive represents the consummation of his decision-making process. For these reasons, the Ashcroft Directive clearly satisfies the first *Bennett* inquiry.

The next question under *Bennett* is whether legal consequences flow from the agency action. 520 U.S. at 178, 117 S. Ct. 1154. Relevant factors include whether the agency action has a "direct and immediate effect" on the complaining parties and requires their "immediate compliance." *Am. Med. Colls.*, 217 F.3d at 780. As explained previously, an interpretive rule may be a final agency action even though it is not legally binding.

The Ashcroft Directive satisfies this second requirement as well. Although it may not have the force of law, the Ashcroft Directive significantly and immedi-

ately alters the legal landscape for Oregon physicians. *See Bennett*, 520 U.S. at 178, 117 S. Ct. 1154 (holding that an agency action met this requirement because it had similar "direct and appreciable legal consequences"); *Abbott Labs.*, 387 U.S. at 152-53, 87 S. Ct. 1507 (holding that where plaintiffs must either comply with unfavorable regulations immediately or "risk serious criminal and civil penalties," the agency action satisfies this requirement). The Ashcroft Directive "direct[s] the DEA, effective upon publication of this memorandum in the Federal Register, to enforce and apply" the Attorney General's interpretation of 21 C.F.R. § 1306.04(a). This instruction created direct and immediate consequences for physicians who wish to prescribe controlled substances for assisted suicide.

It is of no moment that physicians will not experience the Ashcroft Directive's concrete legal effects unless they actually choose to prescribe controlled substances for assisted suicide. An agency action can be final even if its concrete legal effects are contingent upon a future event. *City of Fremont v. FERC*, 336 F.3d 910, 914 (9th Cir. 2003) (concluding that agency orders that attach legal consequences to future proceedings are final for judicial review). The Ashcroft Directive requires the physicians' immediate compliance. Thus, it satisfies *Bennett's* second requirement for finality.

Because the Ashcroft Directive constitutes a final agency action under *Bennett*, the instant petition for review falls squarely within this court's original jurisdiction. I therefore concur in the majority's assessment that the district court was without jurisdiction and the petition should be considered transferred to this court under 28 U.S.C. § 1631.

V.

Although I am convinced of the merits of my legal argument, I admit that even if I persuaded one of my colleagues to join me, my opinion would not be a final chapter. Those who are uneasy with my position (as I assume Petitioners will be) should see its limited grasp. The Ashcroft Directive constitutes a final agency action, but it surely will not be the last word on physician-assisted suicide. The Ashcroft Directive does not spell the end of the public's "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," *Glucksberg*, 521 U.S. at 735, 117 S. Ct. 2258, nor does it halt states' "extensive and serious evaluation of physician-assisted suicide and other related issues," *Glucksberg*, 521 U.S. at 736, 737, 117 S. Ct. 2258 (O'Connor, J., concurring). State legislators may supplement the Ashcroft Directive's sanctions, and they may authorize alternative methods for assisting suicide that do not involve the prescription of controlled substances.

More to my point, the Ashcroft Directive is not even an immutable expression of *federal* policy. A change in presidential administrations or a shift in the current President or Attorney General's perspective might precipitate the Ashcroft Directive's rescission. Certainly, Congress is free to enact legislation limiting or counteracting the Ashcroft Directive's effects. Although opinions differ over the propriety of assisted suicide, I fully subscribe to Justice O'Connor's canny observation that there is simply "no reason to think that the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the [government]'s interests in protecting

those who might seek to end life mistakenly or under pressure." *Id.* In short, we should trust the democratic process.

Thus, the discrete question before this court is a narrow one: is the Attorney General's interpretation of 21 C.F.R. § 1306.04 entitled to deference? Nothing in the Controlled Substances Act's text or legislative history authorizes the majority to deny deference to the Ashcroft Directive. As an interpretive rule, the Ashcroft Directive is not subject to the APA's notice-and-comment rulemaking procedures. It does not violate the Controlled Substances Act's nonpreemption provision. It neither exceeds the Attorney General's statutory authority under the Controlled Substances Act nor "push[es] the limit of congressional authority" under the Commerce Clause. *Solid Waste*, 531 U.S. at 173, 121 S. Ct. 675. Petitioners have not demonstrated that the Ashcroft Directive's interpretation of section 1306.04 is arbitrary and capricious. For these reasons, firmly established principles of administrative law formulated by the Supreme Court and our court command us to defer to the Attorney General's interpretation of section 1306.04.

Therefore, I dissent.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

No. 01-1647-JO

STATE OF OREGON, PLAINTIFF

AND

PETER A. RASMUSSEN; ET AL.,
PLAINTIFF-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-APPELLANTS

April 17, 2002

OPINION AND ORDER

Before: ROBERT E. JONES, District Judge.

INTRODUCTION

After surviving voter and legal challenges, the 1994 Oregon Death with Dignity Act ("Oregon Act"), O.R.S. 127.800 *et seq*, finally went into effect in October 1997.

On November 6, 2001, with no advance warning to Oregon representatives, Attorney General John Ashcroft (herein referred to as "Ashcroft") fired the first shot in the battle between the state of Oregon and the federal government over which government has the ultimate authority to decide what constitutes the legitimate practice of medicine, at least when schedule II substances regulated under the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*, are involved. Ashcroft began the battle by issuing the so-called "Ashcroft directive,"—a few paragraphs published in the Federal Register on November 9, 2001, in which Ashcroft declares, in relevant part, that

- controlled substances may not be dispensed to assist suicide, thus reversing the position taken by his predecessor, Attorney General Janet Reno, in June 1998.

- assisting suicide is not a "legitimate medical purpose" and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA.

- prescribing, dispensing, or administering federally controlled substances to assist suicide may "render [a physician's] registration * * * inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4).

66 FR 56608 (Nov. 9, 2001).

Through his directive, Ashcroft evidently sought to stifle an ongoing "earnest and profound debate" in the various states concerning physician-assisted suicide.

Washington v. Glucksberg, 521 U.S. 702, 735, 117 S. Ct. 2258, 138 L. Ed. 2d 772 (1997). In *Glucksberg*, the Supreme Court was called upon to decide whether the state of Washington's statutory ban on assisted suicide violated the Due Process Clause. In a thoughtful opinion, the Court acknowledged that "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality and practicality of physician-assisted suicide." The Court recounted the various states' "serious, thoughtful examinations" of the issues in this difficult debate, including Oregon's 1994 enactment of the Oregon Act. *See* 521 U.S. at 716-19, 117 S. Ct. 2258. The Court declined to "strike down the considered policy choice" of the State of Washington, deferring instead to that state's resolution of the debate. 521 U.S. at 719, 724, 735, 117 S. Ct. 2258.

In her concurring opinion in *Glucksberg*, Justice O'Connor further elaborated that

> [t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure. * * * States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. * * * In such circumstances, "the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance."

Glucksberg, 521 U.S. at 737, 117 S. Ct. 2258 (O'Connor, J., concurring) (citations omitted).

As the Court acknowledged in *Glucksberg*, the citizens of Oregon, through their democratic initiative process, have chosen to resolve the moral, legal, and ethical debate on physician-assisted suicide for themselves by voting—not once, but twice—in favor of the Oregon Act. The Oregon Act attempts to resolve this "earnest and profound debate" by "strik[ing] the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure." *Glucksberg*, 521 U.S. at 737, 117 S. Ct. 2258 (O'Connor, J., concurring).

With publication of the Ashcroft directive, Ashcroft essentially nullified the Oregon Act and four years of Oregon experience in implementing it. In response to what it perceived as an unwarranted and unauthorized intrusion into the sovereign interests of Oregon, the medical practices of Oregon physicians, and the end-of-life decisions made by terminally-ill Oregonians, plaintiff state of Oregon ("plaintiff") immediately commenced this lawsuit to, among other things, enjoin Ashcroft and the other defendants[1] from giving the Ashcroft directive any legal effect. A temporary

[1] The defendants are John Ashcroft, Asa Hutchinson in his official capacity as Administrator of the Drug Enforcement Agency ("DEA"), Kenneth Magee in his official capacity as Director of the DEA in Portland, Oregon, the United States, the United States Department of Justice, and the DEA.

restraining order, issued on November 8, 2001, remains in effect.[2]

Despite the enormity of the debate over physician-assisted suicide, the issues in this case are legal ones and, as pertain to my disposition, are fairly narrowly drawn. My resolution of the legal issues does not require any delving into the complex religious, moral, ethical, medical, emotional or psychological controversies that surround physician-assisted suicide or "hastened death" (as the parties sometimes describe it), because in Oregon, those controversies have been—for now—put to rest.

The case presently is before me on several motions: (1) plaintiff's motion for summary judgment (# 111); (2) intervenors' motions for summary judgment or partial summary judgment (## 85, 101); and (3) defendants' motion to dismiss and alternative motion for summary judgment (# 133). For the reasons stated below, I grant plaintiff's and intervenors' motions for summary judgment in part and today enter a permanent injunction enjoining defendants from enforcing, applying, or otherwise giving any legal effect to the Ashcroft directive at issue in this case. Those portions of plaintiff's and intervenors' motions not addressed in this opinion are denied as moot.[3] Defendants' motion to dismiss and alternative motion for summary judgment are denied.

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[2] The procedural history of this case is discussed more fully below.

[3] The patient intervenors also filed a motion for class certification (# 41). During the hearing on March 22, 2002, defendants agreed not to object to the addition or substitution of new patient plaintiffs as needed to continue the viability of patient-plaintiffs' claims in this action. Patient-plaintiffs remain concerned, however, so I have included in the injunction language prohibiting defen-

FACTUAL AND PROCEDURAL BACKGROUND

1. *The Controlled Substances Act*

Congress enacted the CSA, 21 U.S.C. §§ 801-950, as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides a comprehensive federal scheme for regulation and control of certain drugs and other substances. The congressional findings supporting Title II reveal that Congress' overarching concern in enacting the CSA was the problem of drug abuse and illegal trafficking in drugs. *See* 21 U.S.C. § 801.

The CSA establishes five schedules of controlled substances, ranging from schedule I substances, which have no accepted medical use and can be utilized only in very limited contexts, to schedules II, III, IV, and V substances, which have recognized uses and can be manufactured, distributed, possessed and used, subject to the restrictions of the CSA. *See* 21 U.S.C. §§ 812, 841. The CSA sets forth initial schedules, 21 U.S.C. § 812(c), and specifies procedures by which the Attorney General may add, remove, or transfer substances to or between schedules. 21 U.S.C. § 811.

The CSA makes it unlawful for any person to manufacture, distribute, or dispense any controlled substance "[e]xcept as authorized by [the CSA]." 21 U.S.C. § 841(a)(1). As pertinent in this case, physicians who prescribe controlled substances and pharmacists who fill the prescriptions are considered "practitioners" who

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dants from objecting to additions or substitutions of patients during the pendency of this case. In view of defendants' agreement and the injunction, the motion for class certification is denied.

"dispense" controlled substances. 21 U.S.C. § 802(10) and (21). To obtain authorization to do so, practitioners must register with the Attorney General and obtain a Drug Enforcement Agency ("DEA") certificate of registration. 21 U.S.C. § 822.

Under the CSA as originally enacted, state-licensed practitioners were entitled to be registered with the DEA as a matter of right. *See* 21 U.S.C. § 823(f)(1983) ("Practitioners shall be registered to dispense * * * controlled substances in schedule II, III, IV, or V if they are authorized to dispense * * * under the law of the State in which they practice"); *see also United States v. Moore*, 423 U.S. 122, 140-41, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975) (registration mandatory if applicant authorized under state law). The Attorney General could suspend or revoke a practitioner's registration only if the registrant (1) materially falsified an application; (2) was convicted of a felony relating to controlled substances; or (3) had his or her state license or registration suspended or revoked. *See* 21 U.S.C. § 824(a) (1983).

Congress has amended the CSA many times since 1970. *See* Oregon's Memorandum in Support of Motion for Summary Judgment, p. 4 n. 22 (amendments cited). With each amendment, Congress further attempted to address the problems of drug abuse and illegal trafficking in drugs. In 1984, apparently concerned with the domestic diversion of otherwise legitimate medical controlled substances into the illegal market by registered practitioners, Congress again amended the CSA. As pertinent here, the 1984 amendment empowered the Attorney General to deny, suspend, or revoke a practitioner's DEA registration if the Attorney General "determines that the issuance of such registration

would be inconsistent with the public interest." 21 U.S.C. § 823(f); *see also* 21 U.S.C. § 824(1)(4).

In 1971, under authority delegated by the Attorney General pursuant to 21 U.S.C. § 871(a), the predecessor to the Administrator of the DEA[4] adopted formal regulations implementing the CSA. One of the regulations, now codified at 21 C.F.R. § 1306.04, provides, in relevant part:

> 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. § 829) 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.

21 C.F.R. § 1306.04(a)(emphasis added).

2. *The Oregon Death with Dignity Act*

In November 1994, Oregon voters enacted the Oregon Act through the initiative process. Having survived legal challenges, *see Lee v. State of Or.*, 891 F. Supp. 1429 (D. Or. 1995) (Oregon Act does not provide sufficient safeguards for terminally ill persons and therefore violates the Equal Protection Clause), *va-*

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[4] The predecessor agency was the Bureau of Narcotics and Dangerous Drugs.

cated 107 F.3d 1382 (9th Cir. 1997), and an initiative that would have repealed it, the Oregon Act went into effect in October 1997.

The Oregon Act provides a detailed procedure by which a mentally competent, terminally ill patient may make a written request for medication "for the purpose of ending his or her life in a humane and dignified manner * * *." O.R.S. 127.805(1). Once a valid request has been properly documented and all waiting periods have expired, the attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. Physicians and pharmacists are immune from civil and criminal liability and any adverse disciplinary action for participating in good faith compliance with the Oregon Act. *See generally* O.R.S. 127.805-.885; *see also* Affidavit of Stephen Bushong ("Bushong Aff."), Exh. 5, pp. 1-2.

Since 1997, the Oregon Act has been utilized by approximately 70 terminally ill Oregonians. Although defendants quibble somewhat with the data,[5] the parties appear to agree that these patients all utilized medications that are listed as schedule II controlled substances under the CSA.

3. *Events Giving Rise to This Action*

On July 27, 1997, Senator Orrin Hatch and Representative Henry Hyde sent a letter to the Administrator of the DEA advocating an interpretation of the CSA that would, in effect, permit the DEA to revoke the

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[5] Defendants state that they have not been provided data from which they can verify whether controlled substances were utilized by all patients. *See* Defts.' Response to Plaintiff State of Oregon's Concise Statement of Material Facts, ¶ 2.

registrations of physicians and pharmacists who take actions authorized by the Oregon Act. *See* Bushong Aff., Exh. 1. In late October 1997, Hatch and Hyde sent a second letter to the DEA, expressing "heightened * * * urgency" resulting from the United States Supreme Court's decision to deny certiorari in *Lee v. State of Or.*, *supra*, which had, until then, kept the Oregon Act from going into effect. Bushong Aff., Exhibit 2. The second letter included a memorandum that purported to provide a legal basis for a proposed interpretation of the CSA that would make it illegal to prescribe controlled substances for the purpose of assisted suicide. Bushong Aff., Exh. 2, pp. 4-7.

On November 5, 1997, then-DEA Administrator Thomas Constantine wrote Hyde a letter in which he expressed the opinion that

> delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a "legitimate medical purpose." As a result, the activities that you described in you[r] letter to us would be, in our opinion, a violation of the CSA.
>
> * * *
>
> DEA must examine the facts on a case-by-case basis to determine whether a physician's actions conflict with the CSA. If the facts indicate that a physician has acted as set forth in your letter, however, then DEA would have a statutory basis to initiate revocation proceedings.

Bushong Aff., Exh. 3.

By letter dated December 3, 1997, Oregon Deputy Attorney General David Schuman, Ph.D., J.D., a noted constitutional scholar and former Professor of Law, University of Oregon, wrote to Jonathan Schwartz of the United States Department of Justice ("USDOJ") urging USDOJ to reconsider the DEA's position. Bushong Aff., Exh. 4. After considering Oregon's response and making her own evaluation, on June 5, 1998, then-Attorney General Janet Reno responded to Hyde's "request concerning the question whether the Department of Justice, through the [DEA], may invoke the [CSA] * * * to take adverse action against any physicians who assist patients in ending their lives by prescribing controlled substances." Bushong Aff., Exh. 5. Reno stated that the USDOJ "has reviewed the issue thoroughly" and has concluded that "the federal government's pursuit of adverse actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA." Bushong Aff., Exh. 5, pp. 1, 4. USDOJ's opinion was confirmed by letter to Oregon Attorney General Hardy Myers the same day. *See* Bushong Aff., Exh. 6.

Between 1998 and 2000, two separate federal legislative attempts to preempt the Oregon Act failed to pass.[6] On February 2, 2001, Hardy Myers wrote to newly-appointed Attorney General John Ashcroft asking that "[i]f the current interpretation of the CSA in relation to [the Oregon Act] is to be reexamined,"

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[6] The Lethal Drug Abuse and Prevention Act of 1998, which was introduced in Congress in 1998 and which would have preempted the Oregon Act, failed to reach the floor of either the House or the Senate. The Pain Relief Promotion Act of 1999 passed the House in 1999, but failed to reach the Senate floor for a vote. *See* Bushong Aff., ¶ 8.

Oregon representatives be given an opportunity to meet with USDOJ representatives to discuss the issue. Bushong Aff., Exh. 7. Two months later, on April 17, 2001, a representative of USDOJ wrote Myers on behalf of Ashcroft, stating that

> I am aware of no pending legislation in Congress that would prompt a review of the Department's interpretation of the CSA as it relates to physician-assisted suicide. *Should such a review be commenced in the future, we would be happy to include your views in that review.*

Bushong Aff., Exh. 8 (emphasis added).

On June 27, 2001, two USDOJ attorneys, Sheldon Bradshaw and Robert Delahunty, sent a "Memorandum for the Attorney General" that reexamined, in great detail, the then-existing USDOJ interpretation of the CSA in relation to the Oregon Act. Bushong Aff., Exh. 9. Notwithstanding the assurances made on Ashcroft's behalf in April 2001, that "we would be happy to include [Oregon's] views in that review," the 24-page memorandum evidently was researched and written without any request for or consideration of Oregon data or comments of Oregon representatives. The memorandum was not disclosed to Oregon Attorney General Myers until November 6, 2001. Bushong Aff., ¶ 10. Thus, the Attorney General of the United States completely ignored his earlier promise to the Oregon Attorney General to ascertain Oregon's views. In doing so, he lost the opportunity to evaluate carefully the scientifically conducted epidemiological studies of the Oregon Act, and the excellent analysis of the multiple issues as set forth in the briefs submitted by plaintiff and intervenors in these proceedings.

On November 6, 2001, Ashcroft issued a memorandum to DEA Administrator Asa Hutchinson. This memorandum, the so-called "Ashcroft directive," relies on the June 27, 2001, Bradshaw/Delahunty memorandum as "the legal basis for my [Ashcroft's] decision." Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, Exhibit 1, p. 1. The Ashcroft directive reinstates the "original DEA determination," and directs the DEA to "enforce and apply this determination" upon publication in the Federal Register. *Id.* at p. 2. Significantly for purposes of the present proceeding, the Ashcroft directive states:

> I hereby determine that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. § 1306.04 (2001), and that the prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA.

Id. at p. 1.

The Ashcroft directive was published in the Federal Register on November 9, 2001. *See* Bushong Aff., Exhibit 10. Before publication, defendants did not consult with Oregon public officials, provide any notice to them or to the Oregon general public, or provide any opportunity for any public comment anywhere.

PROCEDURAL BACKGROUND

On November 7, 2001, plaintiff state of Oregon commenced this action by filing a complaint for declaratory and injunctive relief together with a motion for a temporary restraining order ("TRO") or a preliminary injunction to enjoin defendants from enforcing, applying, or otherwise giving any legal effect to the Ashcroft directive pending further order of the court. Following

a hearing on November 8, 2001, I granted plaintiff's motion and entered a TRO. I also granted motions to intervene filed by Peter Rasmussen, M.D., and David Hochhalter, Rph, and by certain terminally-ill patients[7] (together, the "intervenors").

On November 20, 2001, I held a full hearing on plaintiff's and intervenors' motions for preliminary injunction. Following the hearing, I continued the TRO and established a briefing schedule for the parties' dispositive motions. In mid-January 2002, a second group of patients sought and were granted leave to intervene.

On March 22, 2002, I held a full hearing on the merits of the pending motions. Following the hearing, I took the motions under advisement. I have reviewed and thoroughly considered the parties' arguments and submissions, as well as the submissions of the numerous amici curiae.[8]

As I suggested to the parties during the March hearing, the resolution of this case turns on the CSA and does not require constitutional analysis. As did former Attorney General Reno almost four years ago, I conclude that Congress did not intend the CSA to override

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[7] Although I granted the individual patients' motion to intervene, I denied intervenor status to the organization, Compassion in Dying of Oregon.

[8] Amici curiae briefs have been filed on behalf of the following: New York Physicians, ACLU Foundation of Oregon, Inc., Association of the Bar of the City of New York, Surviving Family Members, Autonomy, Inc., et al, American Academy of Pain Management, et al, Coalition of Mental Health Professionals, Not Dead Yet, et al, National Right to Life Committee and Oregon Right to Life, and the Family Research Council. The court thanks all amici for their valuable and insightful submissions.

a state's decisions concerning what constitutes legitimate medical practice, at least in the absence of an express federal law prohibiting that practice. Similarly, I conclude that Congress never intended, through the CSA or through any other current federal law, to grant blanket authority to the Attorney General or the DEA to define, as a matter of federal policy, what constitutes the legitimate practice of medicine.

Moreover, while I tend to agree with plaintiff and intervenors that the Ashcroft directive fails to pass muster as a matter of administrative law,[9] I decline to resolve this case on that basis. Whether characterized as a substantive or an interpretative rule, the fact remains that the Ashcroft directive exceeds the authority delegated to the defendants under the CSA.

DISCUSSION

I. *Defendants' Motion to Dismiss*

For the first time in this proceeding, defendants challenge this court's subject matter jurisdiction over plaintiff's and intervenors' claims. Defendants maintain that under 21 U.S.C. § 877, exclusive jurisdiction to review the Ashcroft directive rests with the courts of appeals. Section 877 provides:

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[9] The Ashcroft directive bears little similarity to another alleged "interpretive rule" recently issued under the CSA. That rule, which was brought to the court's attention as supplemental authority by defendants, serves to underscore how hastily the Ashcroft directive appears to have been crafted and published. *See* Notice of Filing Supplemental Authority in Support of Defendants' Motion to Dismiss (Order in *Hemp Industries Associationl v. DEA*, No. 01-71662 (9th Cir. March 7, 2002)); *see also* 66 FR 51530, 51535, and 51539 (Oct. 9, 2001).

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within 30 days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

According to defendants, the Ashcroft directive is a "final determination" within the meaning of that provision.

There is little pertinent authority to inform my decision on this issue. Two matters, however, are certain. First, defendants do not contend and could not maintain any argument that plaintiff did not initiate this action within 30 days after notice of Ashcroft's decision. *See* Transcript of Proceedings ("TR") (March 22, 2002), pp. 51-52.[10] Second, although in their motion, defendants insist that this action must be dismissed, they now agree that if this court should decide that section 877 divests jurisdiction, transfer to the Ninth

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[10] *See Nutt v. Drug Enforcement Admin.*, 916 F.2d 202, 204 n. 2 (5th Cir. 1990) (district court could cure jurisdictional defect caused by petitioner's failure to timely file petition for review of agency decision in court of appeals by transferring the petition pursuant to 28 U.S.C. § 1631).

Circuit Court of Appeals pursuant to 28 U.S.C. § 1631 would be appropriate.[11] *Id.* at p. 50.

After careful consideration of this question, I conclude that the Ashcroft directive, however it is characterized, is not a final determination, finding, or conclusion within the meaning of section 877. Although the correct answer to this question is by no means clear, in the balance I am persuaded that section 877 applies in situations where the Attorney General makes a quasi-judicial determination that resolves disputed facts in a specific case after some level of administrative proceedings; for example, in classifying a substance under section 811, or in denying, suspending, or revoking a DEA registration under sections 823 or 824, and the like. *See, e.g.*, *Humphreys v. Drug Enforcement Admin.*, 96 F.3d 658 (3rd Cir. 1996) (appellate court review of DEA revocation of physician's registration); *Nutt v. Drug Enforcement Admin.*, 916 F.2d 202 (5th Cir. 1990) (appellate court had jurisdiction to review DEA revocation of physician's registration). Section 877 may also, at least theoretically, apply where the Attorney General undertakes formal rulemaking, which

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[11] 28 U.S.C. § 1631 provides:

> Whenever a civil action is filed in a court * * * or an appeal, including a petition for review of administrative action, is noticed for or filed with such a court and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or noticed, and the action or appeal shall proceed as if it had been filed in or noticed for the court to which it is transferred on the date upon which it was actually filed in or noticed for the court from which it is transferred.

he did not do in this case.[12] Those types of proceedings "under this subchapter" produce administrative records susceptible to review by an appellate court.

In this present case, in contrast, the Attorney General essentially kept his own counsel, did not provide notice or an opportunity for comment, did not take any vidence, did not decide disputed facts, and more importantly, did not produce an administrative record. Instead, the only record with respect to the Ashcroft directive is the one currently being created in this court.

Moreover, even defendants appear to concede that section 877 is not exclusive, recognizing that "plaintiffs can obtain district court review only one way, by demonstrating that the review provision is inapplicable to their particular claim." Memorandum in Support of Defendants' Motion ("Defendants' Memorandum"), p. 10. In *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 111 S. Ct. 888, 112 L. Ed. 2d 1005 (1991), the Supreme Court examined an Immigration and Nationality Act provision that, similar to section 877, provided for only a single level of review in the courts of appeals. In ruling that the district court retained jurisdiction to

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[12] In this regard, I acknowledge defendants' submission of supplemental authority, *Hemp Industries Association v. DEA*, No. 01- 71662 (9th Cir.), which consists of a Ninth Circuit order staying operation of a DEA "Interpretive Rule" pending a hearing of the appeal on the merits. There is nothing before this court to suggest that the issues in that case and this one are in any respect similar. Moreover, defendants have themselves raised in *Hemp* the question of whether a DEA interpretive rule is subject to review under section 877. *See* Oregon Response to Notice of Filing of Supplemental Authority, Exh. 1, p. 5. Finally, it does not appear that the Ninth Circuit has determined that it in fact has jurisdiction to review the DEA interpretive rule under section 877.

hear constitutional and statutory challenges to INS procedures, the Court explained:

> [I]t is unlikely that a court of appeals would be in a position to provide meaningful review of the types of claims raised in this litigation. * * * Not only would a court of appeals * * * most likely not have an adequate record * * * but it also would lack the factfinding and record-developing capabilities of a federal district court. * * * [S]tatutes that provide for only a single level of judicial review in the court of appeals "are traditionally viewed as warranted only in circumstances where district court fact-finding would unnecessarily duplicate an adequate administrate record—circumstances that are not present * * * where district court factfinding is essential given the inadequate administrative record."

McNary, 498 U.S. at 497, 111 S. Ct. 888 (citation omitted).

In summary, I conclude that this court has subject matter jurisdiction over plaintiff's and intervenors' broad statutory, procedural, and constitutional challenges to the Ashcroft directive. Because, however, in the inevitable appeal that will follow this decision the Ninth Circuit might decide otherwise, I hereby find that if there is a "want of jurisdiction" in this court, then in the interests of justice transfer to the Ninth Circuit Court of Appeals would be appropriate under 28 U.S.C. § 1631. *See Intern. Broth. of Teamsters v. Dept. of Transp.*, 932 F.2d 1292, 1298 (9th Cir. 1991) ("Jurisdictional substance, rather than procedural niceties or magic words, governs the propriety of transfers under section 1631").

II. *The Issue of Oregon's Standing*

Earlier in this case, defendants moved to dismiss the state of Oregon for lack of standing. The parties briefed the issue and I heard argument on it during the November 20, 2001, hearing. I then entered an order denying the motion "at this juncture."

Defendants have not again raised the issue of Oregon's standing and, despite an invitation to do so (TR at 23), failed to argue or even mention standing during the March 22, 2002, hearing. Although defendants' silence on this issue suggests that they now concede standing, to put this matter firmly to rest, I hereby find that the state of Oregon meets the statutory requirements for standing under the Declaratory Judgment Act, 28 U.S.C. § 2201, the Administrative Procedures Act, 5 U.S.C. § 702, as well as under any prudential principles that might apply. Oregon also meets the constitutional requirements for standing under Article III of the United States Constitution. Oregon has alleged and proved a sufficient injury to its sovereign and legitimate interest in the continued enforceability of its own statutes. See, *e.g.*, *Maine v. Taylor*, 477 U.S. 131, 137, 106 S. Ct. 2440, 91 L. Ed. 2d 110 (1986) ("a State clearly has a legitimate interest in the continued enforceability of its own statutes"); *Bowen v. Public Agencies Opposed to Social Sec.*, 477 U.S. 41, 50 n. 17, 106 S. Ct. 2390, 91 L. Ed. 2d 35 (1986) (state had "judicially cognizable interest in the preservation of its own sovereignty"); see also *State of Alaska v. U.S. Dept. of Transp.*, 868 F.2d 441, 443 n. 1 (D.C. Cir. 1989) ("Inasmuch as the States' sovereign interest in law enforce-

ment is sufficient to support standing, we need not delve into the issue of *parens patriae* standing").[13]

III. *Cross-Motions for Summary Judgment*

I now turn to the central substantive issue in this case, whether the Ashcroft directive, which declares that prescribing controlled substances to assist patient suicide is not a "legitimate medical purpose," is authorized under the CSA and its implementing regulations. Having carefully considered this matter, I conclude that nothing in the plain language of the CSA or its legislative history demonstrates Congress' intent to grant defendants the authority under the CSA to determine that prescribing controlled substances for purposes of physician-assisted suicide in compliance with Oregon law is not a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a).

I begin with the axiom that an administrative agency's power is limited to the authority delegated by Congress. *In re Altabon Foods, Inc.*, 998 F.2d 718, 719 (9th Cir. 1993), (*citing Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208, 109 S. Ct. 468, 102 L. Ed. 2d 493 (1988) ("agency's power to promulgate legislative regulations is limited to the authority delegated by Congress")). In defining the bounds of its regulatory authority, "'an agency may appropriately look to the

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[13] As did the D.C. Circuit, I, too, decline to "delve into the issue of *parens patriae* standing." *State of Alaska v. U.S. Dept. of Transp.*, 868 F.2d 441, 443 n. 1 (D.C. Cir. 1989). I also note that defendants do not challenge the patient-intervenors' standing, and, recognizing that five of the initial nine patients in this case have died, have agreed to permit additional patients to join as plaintiff-intervenors to "keep the case alive" and get "this issue resolved." Transcript of Proceedings (March 22, 2002), pp. 90-91.

legislative history and underlying policies of its statutory grants of authority.'" *Altabon Foods*, 998 F.2d at 719 (quoting *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 132, 106 S. Ct. 455, 88 L. Ed. 2d 419 (1985)). This court's concomitant inquiry must "'focus on the language, structure, and legislative history of the CSA, with the primary goal of determin[ing] the intent of Congress.'" *Altabon Foods*, 998 F.2d at 719-20 (*quoting California v. Block*, 663 F.2d 855, 860 (9th Cir. 1981)).

1. *The Plain Language of the CSA Does Not Support the Ashcroft Directive.*

Defendants contend that the CSA authorizes the Ashcroft directive because provisions of the statute "plainly contemplate the existence of federal standards." Defendants' Memorandum, p. 20. According to defendants, certain provisions are "directly controlling here":

> that a "practitioner" must dispense controlled substances "in the course of professional practice" [§ 802(21)], that a controlled substance cannot be distributed "other than for a medical purpose" [§ 829(c)], and that a prescription "must be issued for a legitimate medical purpose" (21 C.F.R. § 1306.04) * * *.

Defendants' Memorandum, p. 20. Defendants also point to the rulemaking authority set forth in sections 821 and 871(b), the reference to "federal" control of drug trafficking in section 801(6), the reference to "this subchapter" in section 841(a), and the language that limits registered persons to dispensing controlled substances only "to the extent authorized by their registration and in conformity with the other provisions of this sub-

chapter." 21 U.S.C. § 822(b); *see* Defendants' Memorandum, pp. 20-21. Defendants find further significance in the CSA scheduling provisions, specifically sections 811(a)(1) (Attorney General may by rule assign controlled substances to schedules), and 812(b) (required findings for schedules I V include consideration of any "currently accepted medical use in treatment in the United States"). Defendants' Memorandum, p. 21.

Defendants urge the court to conclude that taken together, these gleaned bits and pieces of statutory language demonstrate Congress' intent that federal, rather than state, standards control the determination of what medical practices are authorized under the CSA with respect to controlled substances. In this regard, I agree with plaintiff that defendants' analysis, which focuses on "isolated words or sentences" to discern Congress' intent, is contrary to accepted principles of statutory construction. *U.S. Nat. Bank of Or. v. Independent Ins. Agents*, 508 U.S. 439, 455, 113 S. Ct. 2173, 124 L. Ed. 2d 402 (1993).

In *U.S. Nat. Bank*, the Supreme Court emphasized that it has "over and over * * * stressed that '[i]n expounding a statute, [the court] must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'" *Id.* at 455, 113 S. Ct. 2173 (*quoting United States v. Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122, 12 L. Ed. 1009 (1849) and noting that *Boisdore's* has been quoted in more than a dozen cases). Indeed, it is a "'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 120 S. Ct. 1291, 146 L. Ed. 2d 121

(2000); *see also Lexecon Inc. v. Milberg Weiss Bershad Hynes*, 523 U.S. 26, 36, 118 S. Ct. 956, 140 L. Ed. 2d 62 (1998) (central tenet of interpretation is that statute is to be considered in all its parts when construing any one of them).

Thus,

> [a] court must * * * interpret the statute "as a symmetrical and coherent scheme," * * * and "fit, if possible, all parts into an harmonious whole" * * *. In addition, [a court] must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such * * * political magnitude to an administrative agency.

FDA v. Brown & Williamson, 529 U.S. at 133, 120 S. Ct. 1291 (citations omitted).

It is undisputed that under the CSA, the Attorney General and the DEA have broad authority to regulate controlled substances. No provision of the CSA, however, alone (as defendants urge) or viewed as a "symmetrical and coherent scheme" demonstrates or even suggests that Congress intended to delegate to the Attorney General or the DEA the authority to decide, as a matter of national policy, a question of such magnitude as whether physician-assisted suicide constitutes a legitimate medical purpose or practice.

Nor, as defendants propose, did the 1984 amendments to the CSA delegate such authority. As amended, section 823(f) permits the Attorney General to deny an application for registration as "inconsistent with the public interest" after consideration of the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) such other conduct which may threaten the public health and safety.

The revocation section, § 824(a)(4), as amended, includes as a ground for revocation or suspension "such acts as would render his registration under section 823 * * * inconsistent with the public interest as determined under such section." Defendants read these amendments, together with 21 C.F.R. § 1306.04, as supplying evidence that Congress intended to expand the Attorney General's and the DEA's authority to include the power to define the parameters of legitimate medical practices. I do not, however, read the CSA or the 1984 amendments as containing—either explicitly or implicitly—such a remarkable grant of power.

2. *The Legislative History of the CSA Does Not Support the Ashcroft Directive.*

As observed by Professor William Funk of the Lewis and Clark Law School in his review of Justice Scalia's essay[14] on legislative interpretation:

> The legitimacy of legislative history as a means of interpreting statutes, at least when they are unclear, is, rightly or wrongly, well established. Other than Justice Thomas, no Justice seems interested in adopting Justice Scalia's rejection of legislative history or his rejection of the notion of legislative intent.

William Funk, *Review Essay Faith in Texts—Justice Scalia's Interpretation of Statutes and the Constitution: Apostasy for the Rest of Us?* 49 Admin. L. Rev. 825 (1997). Both sides in this controversy resort to certain congressional comments and reports to buttress their views of what Congress intended in enacting and amending the CSA. Nothing in the legislative history suggests, however, that anyone in Congress intended the CSA to restrict or proscribe prescriptions for controlled substances that might be used legitimately under state law to assist suicide or hasten death. To the contrary, the legislative history of both the 1970 enactment and the 1984 amendments overwhelming support a conclusion that Congress' intent was to address problems of drug abuse, drug trafficking, and diversion of drugs from legitimate channels to illegiti-

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[14] A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW. An Essay by Antonin Scalia with Commentary by Amy Gutmann, editor, Gordon S. Wood, Laurence H. Tribe, Mary Ann Glendon, and Ronald Dworkin. Princeton: Princeton University Press, 1997.

mate channels. *See United States v. Moore*, 423 U.S. 122, 134-35, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975) ("Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant").

The best defendants can produce in the way of supportive legislative history is a vague comment by one congressman, Representative Gillman, to the effect that by amending the CSA, Congress wanted to "make it easier" for the DEA to suspend or revoke the authority of physicians who write or dispense prescriptions in a way that is threatening to public health or safety, and an equally curious reference from the House Committee report, which states:

> Although the Committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of federal prosecutors of what constitutes appropriate methods of professional practice.

Defendants' Memorandum, pp. 16-17.

What does this add to the issue at hand? I have already explained that the core objective of the CSA was to permit federal prosecution of drug dealers, drug abusers, and "practitioners" who engage in the illegal diversion and distribution of drugs. Defendants cannot seriously conclude from the above-quoted language that Congress delegated to federal prosecutors the authority to define what constitutes legitimate *medical* prac-

tices.[15] To state the proposition is to refute it. Federal prosecutors have never possessed such powers, and the vagueness of the reference would render any alleged violation based on a prosecutor's subjective views about medical practice patently unenforceable.

Having served in the state legislature, I do not give much credence to floor speeches or even committee reports as representing the intent of a legislative body. As many have observed in watching Congress at work, members of Congress often speak about legislative intent to an empty room, or place material prepared by staff, lobbyists and the like into the congressional record. To construe this as revealing legislative intent defies reality and more often than not ignores the plain meaning of the statute in favor of the subjective beliefs of individual members of Congress, an extremely unreliable approach to statutory interpretation.[16] As Justice Scalia observed in his essay[17] and in his concurring opinion in *Conroy v. Aniskoff*, 507 U.S. 511, 519, 113 S. Ct. 1562, 123 L. Ed. 2d 229 (1993):

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[15] The case law defendants cite belies this conclusion. As discussed in the next portion of this decision, even in cases where a doctor or pharmacist is a "drug pusher" or blatantly operates a "pill mill," the issue of whether the conduct is outside the normal course of professional or medical practice is entrusted to a jury, to decide the issue as mixed subjective-objective question of fact under instructions based on community standards, not on some national standard adopted as a federal regulation.

[16] In contrast, carefully prepared advisory committee notes, when officially adopted by a legislative body, can be exceedingly helpful in interpreting statutes and rules. *E.g.*, Federal Rules of Civil Procedure; Federal Rules of Evidence.

[17] *See* footnote 14, *supra*.

> Judge Harold Leventhal used to describe the use of legislative history as the equivalent of entering a crowded cocktail party and looking over the heads of the guests for one's friends.

Here, neither side has presented any convincing relevant comment from friend or foe to reliably demonstrate that Congress ever considered assisted suicide in enacting or amending the CSA. Moreover, no legislative history supports defendants' theory that Congress intended the 1984 amendments to "alter[ ] the federal-state framework by permitting federal encroachment upon a traditional state power." *Solid Waste Agency v. Army Corps of Engineers*, 531 U.S. 159, 173, 121 S. Ct. 675, 148 L. Ed. 2d 576 (2001) (citation omitted). Thus, I need not determine the merit or lack of merit of the legislative history, simply because there is none on point.

3. *The Case Law Does Not Support the Ashcroft Directive.*

The cases defendants cite as "equally clear that federal law determines what medical practices are authorized by the CSA,"[18] *United States v. Moore*, *supra*, *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975), *United States v. Hayes*, 794 F.2d 1348 (9th Cir. 1986), *United States v. Boettjer*, 569 F.2d 1078 (9th Cir. 1978), and *U.S. v. Leal*, 75 F.3d 219 (6th Cir. 1996), do not advance their position. All involved criminal proceedings against DEA registered physicians or pharmacists whose activities fell far outside any definition of the usual or accepted course of professional medical practice. In none of the cases was a doctor or

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[18] Defendants' Memorandum, p. 21.

pharmacist prosecuted and convicted under the CSA for legal medical actions taken in compliance with state law, which is precisely what the Ashcroft directive would permit if allowed to stand.

In *Moore*, for example, the defendant doctor "acted as a large-scale 'pusher' not as a physician," and admitted that he did not observe generally accepted medical practices. 423 U.S. at 126, 143. In *Rosenberg*, the evidence established that "[w]hen a doctor acts as Dr. Rosenberg did in this case, he can appropriately be called a trafficker in drugs." 515 F.2d at 196. The *Rosenberg* court was careful to note, however, that the phrase "in the course of professional medical practice" as used in the CSA "clearly means that a doctor is not exempt from the statute when he takes actions *that he does not in good faith believe are for legitimate medical purposes*," plainly a subjective standard. 515 F.2d at 197 (emphasis added).[19]

In both *Hayes* and *Boettjer*, the quoted language on which defendants rely for a "federal" standard of medicine actually was part of the trial courts' jury instructions. *Hayes*, 794 F.2d at 1351; *Boettjer*, 569 F.2d at

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[19] Defendants' reliance on *Rosenberg* for the proposition that federal law determines what medical practices are authorized by the CSA is misleading. In the portion of the opinion that defendants quote, the Ninth Circuit's comments were directed to the doctor's constitutional argument that whether he was acting in the course of his professional practice must be determined by the state court, because " 'direct control of medical practice in the states is beyond the power of the federal government.' " *Rosenberg*, 515 F.2d at 198 (citation omitted). The Ninth Circuit did not hold that the CSA authorizes direct agency determination of what constitutes the ordinary course of professional practice, instead, the court held only that the CSA is constitutional under the Tenth Amendment.

1081. Nothing in either opinion suggests that the Ninth Circuit approved or adopted a federal test for "legitimate medical purpose" or "usual course." The last case defendants cite, *United States v. Leal*, concerned a "pill mill" operated by a physician and a pharmacy. The *Leal* court rejected defendant pharmacist's argument that he was entitled to a jury instruction concerning his duties as a pharmacist under state law, because as a DEA registrant, the CSA imposed a "federal duty on *Leal* to be vigilant in filling prescriptions, so as to avoid filling those that were issued for a non-medical purpose. Whether state law imposes an equivalent civil or criminal duty is irrelevant." *Leal*, 75 F.3d at 227. The *Leal* court did not, as defendants would like this court to infer, hold that the federal law gives content to what is or is not a "medical purpose."[20]

IV. *Summary*

The determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. State statutes, state medical boards, and state regulations control the practice of medicine. The CSA was never intended, and the USDOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board. To allow an attorney general—an appointed executive whose tenure depends entirely on whatever administration occupies the White House—to determine the legitimacy of a particular medical practice

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[20] I note that defendants seem to have abandoned the notion, espoused in the Ashcroft directive, that the Supreme Court's decision in *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 121 S. Ct. 1711, 149 L. Ed. 2d 722 (2001), is somehow controlling on the issues presented here.

without a specific congressional grant of such authority would be unprecedented and extraordinary. As stated, the practice of medicine is based on state standards, recognizing, of course, national enactments that, within constitutional limits, specifically and clearly define what is lawful and what is not.[21] Without doubt there is tremendous disagreement among highly respected medical practitioners as to whether assisted suicide or hastened death is a legitimate medical practice, but opponents have been heard and, absent a specific prohibitive federal statute, the Oregon voters have made the legal, albeit controversial, decision that such a practice is legitimate in this sovereign state.

The Ashcroft directive attempts to define the term "legitimate medical purpose" to exclude use of controlled substances for otherwise legal physician-assisted suicide where Congress failed to do so despite multiple opportunities. Obviously, Congress knows how to do so, as manifested in its abandoned attempts to restrict assisted suicide nationwide. Because former Attorney General Reno concluded that the CSA has no application to the Oregon Act, Representative Hyde introduced two bills in the House of Representatives to specifically address the Oregon Act. The first bill, the Lethal Drug Use Prevention Act of 1998, would have amended the CSA to directly authorize the suspension or revocation of a practitioner's DEA registration if the

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[21] For example, in section 4 of Title I of the 1970 CSA, 42 U.S.C. § 257a, Congress expressly required the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction. . . ." *United States v. Moore*, 423 U.S. 122, 144, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975).

registrant intentionally dispensed or distributed a controlled substance for the purpose of assisting the suicide or euthanasia of another individual. The second bill, the Pain Relief Promotion Act, attempted to clarify the CSA to provide that the alleviation of pain is a legitimate medical purpose, but that the CSA did not permit the use of controlled substances to cause death or assist in a suicide. While the second bill passed the House, neither bill passed the Senate, and neither was signed into law.

Even though both acts failed in Congress, certain congressional leaders made a good faith effort to get through the administrative door that which they could not get through the congressional door, seeking refuge with the newly-appointed Attorney General whose ideology matched their views, and this is precisely what occurred. The Executive Branch immediately began its efforts to re-write the law to achieve its goal of abolishing assisted suicide anywhere. Although congressional action attempting to control matters traditionally left to the state may raise constitutional issues for any future legislation in this field, suffice it to say that at this juncture, neither the U.S. Constitution nor the Bill of Rights speaks to assisted suicide, neither providing for it as a personal right nor prohibiting it.

I again emphasize that I resolve this case as a matter of statutory interpretation, and my interpretation of the statutory text and meaning is that the CSA does not prohibit practitioners from prescribing and dispensing controlled substances in compliance with a carefully-worded state legislative act. Thus, the Ashcroft directive is not entitled to deference under any

standard[22] and is invalid. I also emphasize that my task is not to criticize those who oppose the concept of assisted suicide for any reason. Many of our citizens, including the highest respected leaders of this country, oppose assisted suicide. But the fact that opposition to assisted suicide may be fully justified, morally, ethically, religiously or otherwise, does not permit a federal statute to be manipulated from its true meaning to satisfy even a worthy goal. As the Supreme Court has warned, courts should be "out of the business of reviewing the wisdom of statutes," *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15, 96 S. Ct. 2882, 49 L. Ed. 2d 752 (1976), a proposition not to be taken "cum grano salis" (with a grain of salt). *Barrick Gold Exploration, Inc. v. Hudson*, 47 F.3d 832, 836 (6th Cir. 1995) (commenting on Easterbrook, *The Constitution of Business*, 11 Geo. Mason U.L. Rev. 53 (1988)).

CONCLUSION

For the reasons stated, plaintiff's motion for summary judgment (# 111) and intervenors' motions for summary judgment or partial summary judgment (## 85, 101) are granted in part and moot in part; patients-intervenors' motion for class certification (# 41) is denied; and defendants' motion to dismiss and alternative motion for summary judgment (# 133) is denied. The Permanent Injunction entered concurrently with this Opinion and Order shall be effective immediately upon filing. Any other pending motions are denied as moot.

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[22] *See* Oregon's Memorandum in Support, pp. 16-18, for a discussion of the various levels of deference, none of which governs here.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 02-35587

STATE OF OREGON, PLAINTIFF-APPELLEE

v.

JOHN ASHCROFT, ATTORNEY GENERAL, IN HIS OFFICIAL CAPACITY AS UNITED STATES ATTORNEY GENERAL, ET AL., DEFENDANTS-APPELLANTS

v.

PETER A. RASMUSSEN, ET AL.,
PLAINTIFF-INTERVENORS-APPELLEES

[Filed August 11, 2004]

ORDER

Before: Lay[*] , Wallace, and Tallman, Circuit Judges.

Judges Lay and Tallman have voted to deny the petition for panel rehearing; Judge Tallman has voted to deny the petition for rehearing en banc and Judge Lay so recommends. Judge Wallace has voted to grant the petition for panel rehearing and the petition for rehearing en banc.

[*] Honorable Donald P. Lay, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for panel rehearing and the petition for rehearing en banc are denied.

APPENDIX D

RULES and REGULATIONS

DEPARTMENT OF JUSTICE

Office of the Attorney General

21 CFR Part 1306

[AG Order No. 2534-2001]

Dispensing of Controlled Substances To Assist Suicide

Friday, November 9, 2001

AGENCY: Department of Justice.

ACTION: Interpretive rule.

SUMMARY: For the reasons provided in the memorandum set forth below, the Attorney General has determined that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 CFR 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act. Such conduct by a physician registered to dispense controlled substances may "render his registration . . . inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4). The Attorney General's conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless

of the condition of the person whose suicide is assisted. The Attorney General recognizes, however, that pain management is a legitimate medical purpose justifying a physician's dispensing of controlled substances. Finally, the Attorney General's determination makes no change in the current standards and practices of the DEA in any State other than Oregon.

EFFECTIVE DATE: November 9, 2001.

FOR FURTHER INFORMATION CONTACT: Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, telephone 202-307-7297.

SUPPLEMENTARY INFORMATION: The text of the Attorney General's memorandum follows:

Memorandum for Asa Hutchinson,
Administrator, The Drug Enforcement Administration

From: John Ashcroft, Attorney General

Subject: *Dispensing of Controlled Substances to Assist Suicide*

As you are aware, the Supreme Court reaffirmed last term that the application of federal law regulating controlled substances is uniform throughout the United States and may not be nullified by the legislative decisions of individual States. See *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001). In light of this decision, questions have been raised about the validity of an Attorney General letter dated June 5, 1998, which overruled an earlier Drug Enforcement Administration (DEA) determination that narcotics and other dangerous drugs controlled by federal law may not be dispensed consistently with the Con-

trolled Substances Act, 21 U.S.C. 801-971 (1994 & Supp. II 1996) (CSA), to assist suicide in the United States. Upon review of the *Oakland Cannabis* decision and other relevant authorities, I have concluded that the DEA's original reading of the CSA—that controlled substances may not be dispensed to assist suicide—was correct. I therefore advise you that the original DEA determination is reinstated and should be implemented as set forth in greater detail below.

The attached Office of Legal Counsel opinion, entitled "*Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under The Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act*" (June 27, 2001) ("OLC Opinion") (attached) sets forth the legal basis for my decision.

1. *Determination on Use of Federally Controlled Substances to Assist Suicide.* For the reasons set forth in the OLC Opinion, I hereby determine that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 CFR § 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA. Such conduct by a physician registered to dispense controlled substances may "render his registration * * * inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4). This conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted.

I hereby direct the DEA, effective upon publication of this memorandum in the **Federal Register**, to enforce and apply this determination, notwithstanding anything

to the contrary in the June 5, 1998, Attorney General's letter.

2. *Use of Controlled Substances to Manage Pain Promoted.* Pain management, rather than assisted suicide, has long been recognized as a legitimate medical purpose justifying physicians' dispensing of controlled substances. There are important medical, ethical, and legal distinctions between intentionally causing a patient's death and providing sufficient dosages of pain medication necessary to eliminate or alleviate pain.

3. *No Change in Current DEA Policies and Enforcement Practices Outside Oregon.* The reinstated determination makes no change in the current standards and practices of the DEA in any State other than Oregon. Former Attorney General Janet Reno's June 5, 1998, letter relating to this matter emphasized that action to revoke the DEA registration of a physician who uses federally controlled substances to assist a suicide "may well be warranted * * * where a physician assists in a suicide in a state that has not authorized the practice under any conditions." The reinstated determination does not portend any increase in investigative activity or other change from the manner in which the DEA presently enforces this policy outside of Oregon.

4. *Enforcement in Oregon.* Under 3 Oregon Revised Statutes (O.R.S.) § 127.855 (1999), an attending physician who writes a prescription for medication to end the life of a qualified patient must document the medication prescribed. Under 3 O.R.S. § 127.865(1)(b) (1999), the State of Oregon's Health Division must require any health care provider upon dispensing medication pursuant to the Death with Dignity Act to file a copy of the

dispensing record with the Division. Those records should contain the information necessary to determine whether those holding DEA registrations who assist suicides in accordance with Oregon law are prescribing federally controlled substances for that purpose in violation of the CSA as construed by this Memorandum and the attached OLC Opinion.

The Department has the authority to take appropriate measures to obtain copies of any such reports or records sent to the Oregon State Registrar. See 21 U.S.C. 876. When inspection of these documents discloses prohibited prescription of controlled substances to assist suicide following the effective date of this memorandum, then appropriate administrative action may be taken in accordance with 21 CFR §§ 1316.41 to 1316.68 (2001).

Thus, it should be possible to identify the cases in which federally controlled substances are used to assist suicide in Oregon in compliance with Oregon law by obtaining reports from the Oregon State Registrar without having to review patient medical records or otherwise investigate doctors. Accordingly, implementation of this directive in Oregon should not change the DEA's current practices with regard to enforcing the CSA so as materially to increase monitoring or investigation of physicians or other health care providers or to increase review of physicians' prescribing patterns of controlled substances used for pain relief.

5. *Distribution.* Please ensure that this Memorandum and the OLC opinion on which it is based are promptly distributed to appropriate DEA personnel, especially those with authority over the enforcement of the CSA in Oregon.

Attachment

Note: The attachment containing the Office of Legal Counsel opinion dated June 27, 2001, does not appear in the **Federal Register**. It is available from the Drug Enforcement Administration at the address listed in **FOR FURTHER INFORMATION CONTACT.**

Dated: November 6, 2001.

John Ashcroft,
Attorney General.

APPENDIX E

SEAL

U.S. Department of Justice
Office of Legal Counsel

Office of the Deputy Assistant Attorney General *Washington, D.C. 20530*

June 27, 2001

MEMORANDUM FOR THE ATTORNEY GENERAL

FROM: Sheldon Bradshaw
Deputy Assistant Attorney General

Robert J. Delahunty
Special Counsel

RE: *Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under The Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act*

You have asked for our opinion whether a physician who assists in a patient's suicide by prescribing a controlled substance has a "legitimate medical purpose" within the meaning of a regulation of the Drug Enforcement Administration (DEA), 21 C.F.R. § 1306.04(a) (2000),[1] if the physician is immune from liability under a

[1] The DEA regulation was promulgated pursuant to a delegation of the Attorney General's broad authorities under the Controlled Substances Act, 21 U.S.C. §§ 801-971 (1994 & Supp. II 1996) (the CSA or Act), to "promulgate rules and regulations . . .

state law such as the Oregon "Death with Dignity Act" for assisting in a suicide in such a manner.[2] In our view, assisting in suicide, even in a manner permitted by state law, is not a "legitimate medical purpose" under the DEA regulation, and accordingly dispensing controlled substances for this purpose violates the Controlled Substances Act, which the DEA regulation implements.

Background

The Oregon "Death with Dignity Act," which legalized physician-assisted suicide under certain circumstances, was originally approved by Oregon voters on November 8, 1994, and went into effect on October 27, 1997.[3] Prior to the effective date of the Oregon law, Representative Henry J. Hyde, Chairman of the House Judiciary Committee, and Senator Orrin G. Hatch,

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relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions," 21 U.S.C. § 821, and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this [title]." *Id.*, § 871(b). *See also id.*, § 871(a) (authority of Attorney General to delegate CSA functions); 28 C.F.R. § 0.100 (2000) (delegation to DEA); *Touby v. United States*, 500 U.S. 160, 169 (1991) (upholding Attorney General's authority to delegate CSA function to DEA).

[2] The "Death with Dignity Act" is codified at 3 Oregon Revised Statutes (O.R.S.) §§ 127.800-127.995 (1999).

[3] On the circumstances surrounding the adoption of the Oregon "Death with Dignity Act" and a description of its provisions, *see generally* Mark C. Siegel, *Lethal Pity: The Oregon Death With Dignity Act, Its Implications for the Disabled, and the Struggle for Equality in an Able-Bodied World*, 16 Law & Ineq. 259, 270-76 (1998).

Chairman of the Senate Judiciary Committee, wrote to the Administrator of the DEA, Thomas A. Constantine, requesting a determination whether the CSA prohibits the use of controlled substances for the purpose of assisting in a suicide.[4]

Administrator Constantine replied on November 5, 1997, concluding "that delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose'" and thus would violate the CSA.[5]

Within a month, the Oregon Deputy Attorney General, David Schuman, wrote to the United States Department of Justice on December 3, 1997, arguing that "the CSA is addressed to the problems of the abuse and trafficking of controlled substances. In enacting and later amending the CSA, Congress had no intention of regulating medical practices that are legal under state law and that have no relation to drug abuse

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[4] Letter for The Honorable Thomas A. Constantine, Administrator of the Drug Enforcement Administration, from Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives, and Chairman Orrin G. Hatch, Committee on the Judiciary, U.S. Senate, July 29, 1997 ("In our view, assisting in a suicide by prescribing or filling a prescription for a controlled substance cannot be a 'legitimate medical purpose' under DEA regulations, especially when the practice is not reasonable and necessary to the diagnosis and treatment of disease and injury, legitimate health care, or compatible with the physician's role as healer.") (Hyde Letter).

[5] Letter for Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives, from The Honorable Thomas A. Constantine, Administrator of the Drug Enforcement Administration of the United States, Nov. 5, 1997, at 1-2 (Constantine Letter).

or trafficking."[6] Deputy Attorney General Schuman concluded that the DEA had no authority to regulate medical practices authorized by state law and unrelated to drug abuse or trafficking.

On June 5, 1998, Attorney General Janet Reno reversed the interpretation of DEA Administrator Constantine, concluding that "the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Specifically, Attorney General Reno stated: "There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice."[7]

I. *Physicians Are Regulated Under the Controlled Substances Act*

The basic domestic drug trafficking provision of the CSA, 21 U.S.C. § 841, governs physicians' prescriptions of controlled substances. Section 841(a)(1) makes it unlawful for "any person knowingly or intentionally . . . to . . . dispense, a controlled substance." The term

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[6] Letter for Mr. Jonathan Schwartz, [Principal Associate Deputy] Attorney General, U.S. Department of Justice, Office of the [Deputy] Attorney General, from Mr. David Schuman, Oregon Deputy Attorney General, Dec. 3, 1997, at 7 (Oregon Deputy Attorney General Letter).

[7] Letter for The Honorable Henry J. Hyde, Chairman, Committee on the Judiciary, U.S. House of Representatives, from The Honorable Janet Reno, Attorney General of the United States, June 5, 1998, at 1 ("Adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the [CSA]") (1998 Letter).

"dispense" is defined to "mean[] to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner . . . ." 21 U.S.C. § 802(10). A "practitioner" includes a "physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . a controlled substance in the course of professional practice." *Id.*, § 804(21).

Although section 841(a)(1) generally prohibits the dispensing of controlled substances, the statute does permit such action if "authorized by this subchapter." 21 U.S.C. § 841(a). One such form of authorization is found in the CSA's provisions dealing with physician "registration." *See id.*, § 822(b) ("Persons registered by the Attorney General . . . to . . . dispense controlled substances . . . are authorized to . . . dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter."). Physicians may apply to the DEA (which acts here as the Attorney General's delegate) for registration permitting them to prescribe and administer controlled substances. Section 823(b) provides that the DEA shall register qualified applicants unless it "determines that . . . such registration is inconsistent with the public interest." This determination is to be based on any of five factors identified in the statute, including "such other factors as may be relevant to and consistent with the public health and safety." *Id.*, § 823(b)(5).

"[T]he scheme of the [CSA], viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.' . . . Implicit in the registration of a physician is the understanding that

he is authorized only to act 'as a physician.' . . . [R]egistration is limited to the dispensing and use of drugs 'in the course of professional practice or research.' Other provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits." *United States v. Moore*, 423 U.S. 122, 140-42 (1975). Although section 841(a) does not, in terms, state that a physician is authorized to dispense controlled substances only for a legitimate medical purpose, that limitation appears to be implicit in the statute, *see Moore*, 423 U.S. at 137, n.13, and has been made explicit by DEA regulation.[8] The relevant regulation reads:

> A prescription issued 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. 829) 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.

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[8] The courts have found no distinction between the statutory phrase "in the course of professional practice" and the regulatory phrase, "legitimate medical purpose." *See United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975), *cert. denied*, 423 U.S. 1031 (1975); *cf. United States v. Kirk*, 584 F.2d 773, 784 (6th Cir. 1978), *cert. denied*, 439 U.S. 1048 (1978); *United States v. Plesons*, 560 F.2d 890, 897, n.6 (8th Cir. 1977), *cert. denied*, 434 U.S. 966 (1977).

21 C.F.R. § 1306.04(a) (emphasis added).

Where a physician dispenses controlled substances without a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a), the physician violates several provisions of the CSA, including §§ 829 and 841(a)(1). If such dispensing without a legitimate medical purpose is proven in a criminal case, the physician may be subject to criminal penalties under 21 U.S.C. §§ 841(a)(1) (felony) and 842(a)(1) (misdemeanor). *See Moore* (holding that registered physician can be prosecuted and convicted under § 841(a)(1) for dispensing controlled substances outside the usual course of professional practice). Even without a criminal prosecution or conviction, the DEA may initiate administrative proceedings to suspend or revoke the registration of a physician based on evidence that the physician dispensed controlled substances without a legitimate medical purpose under 21 C.F.R. § 1306.04(a). In an administrative proceeding, the Government must prove, by a preponderance of the evidence, that the physician dispensed in violation of § 1306.04(a), and that, as a result, the physician's continued registration would be inconsistent with the public interest. *See* 21 U.S.C. § 824(a)(4) (applying public interest standard of § 823(f) to administrative proceedings for suspension or revocation of registration granted under § 823); *see generally Robert G. Hallermeier, M.D., Continuation of Registration with Restrictions*, 62 Fed. Reg. 26,818 (1997) (administrative proceeding in which DEA sought revocation of physician's federal registration).[9] Nothing in the language of the

[9] We note that practitioners have lost or been denied Federal registrations necessary to prescribe controlled substances because they have prescribed controlled substances used in suicides and other lethal overdoses. *See, e.g., Hugh I. Schade, M.D., Denial of*

CSA or of the relevant DEA regulations requires that the physician be shown to have violated state law in order to be subject to criminal sanctions under §§ 829 or 841(a), or to suspension or revocation of federal registration under § 824(a)(4). Indeed, of the five separate grounds listed in § 824(a)(4) for adverse administration action, only two directly concern state law sanctions.[10] Further, as we shall discuss in detail below, *see infra* at 17-19, Congress added the "public interest" standard in § 824(a)(4) in order to permit the Attorney General to take adverse administrative action against a registrant in cases in which the registrant's wrongful conduct might not have been sanctioned or sanctionable under state law.

II. *Dispensing Controlled Substances to Assist in Suicide Does Not Serve a "Legitimate Medical Purpose"*

We understand that physician-assisted suicide typically involves the use of a lethal dose of a combination

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Application, 60 Fed. Reg. 56,354 (1995); *José R. Castro, M.D., Denial of Application*, 62 Fed. Reg. 16,189 (1997); *Samuel Fertig, M.D., Denial of Application*, 49 Fed. Reg. 6,577 (1984); *Murray J. Walker, M.D., Revocation of Registration*, 55 Fed. Reg. 5,306 (1990); *see also Townwood Pharmacy, Revocation of Registration*, 63 Fed. Reg. 8,477 (1998).

[10] Section 824(a)(2) authorizes the Attorney General to suspend or revoke a registration upon a finding that the registrant "has been convicted of a felony under . . . any . . . law . . . of any State, relating to any . . . controlled substance," while section 824(a)(3) authorizes such action if the registrant "has had his State license or registration suspended, revoked, or denied . . . and is no longer authorized by State law to engage in . . . dispensing . . . controlled substances . . . or has had the suspension, revocation, or denial of his registration recommended by competent State authority."

of drugs, including controlled substances. First, the patient is sedated using either a barbiturate (*e.g.*, sodium pentothal), or an opiate (*e.g.*, morphine). Then, one or more drugs are used to paralyze the muscles and/or to stop the heart. The sedatives involved in these procedures are controlled substances under the CSA. Most lawfully available opiates and barbiturates are in Schedule II of the CSA, the most strictly regulated category of substances available for non-research purposes. *See* 21 C.F.R. § 1308.12(b), (c), (e) (2000).

In our opinion, assisting in suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. § 1306.04(a) that would justify a physician's dispensing controlled substances. That interpretation, which the DEA itself originally adopted before being overruled by Attorney General Reno, is the best reading of the regulatory language: it is firmly supported by the case law, by the traditional and current policies and practices of the Federal government and of the overwhelming majority of the States, and by the dominant views of the American medical and nursing professions.

A. *Case Law*

The case law demonstrates that the CSA forbids dispensing controlled substances except in the course of accepted medical practice, and that physician-assisted suicide is outside the boundaries of such practice.

In *Moore*, the Supreme Court in effect approved a jury instruction under which a physician would be held criminally liable for dispensing controlled substances in violation of 21 U.S.C. § 841(a) unless the physician was acting "in the usual course of professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States."

Moore, 423 U.S. at 139. The lower courts have followed *Moore* in requiring that a physician's actions conform to standards "generally recognized and accepted" throughout the nation. For example, in *United States v. Vamos*, 797 F.2d 1146, 1153 (2d Cir. 1986), the court stated that:

> To permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area. As the Supreme Court noted in *Moore*, "Congress intended the CSA to strengthen rather than weaken the prior drug laws."

As the courts have found, physician-assisted suicide has never been, and is not now, a generally recognized and accepted medical practice in the United States. On the contrary, the American legal system and the American medical profession alike have consistently condemned the practice in the past and continue to do so.

In *Washington v. Glucksberg*, 521 U.S. 702 (1997), the Supreme Court upheld a state prohibition against causing or aiding a suicide against a challenge that, as applied to physicians assisting terminally ill, mentally competent patients, the prohibition offended the requirements of substantive due process. *See id.* at 709, n.6 (describing holding). The Court began its analysis by examining "our Nation's history, legal traditions, and practices," *id.* at 710. The Court found that "[i]n almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide. The States' assisted-suicide bans are not innovations. Rather, they

are longstanding expressions of the States' commitment to the protection and preservation of all human life" (footnote omitted). *Id.*[11] After tracing "the Anglo-American common law tradition" that "for over 700 years" "has punished or otherwise disapproved of both suicide and assisted suicide," *id.* at 711, the Court referred to the Oregon "Death With Dignity Act," which legalized physician-assisted suicide for competent, terminally ill adults. The Court's discussion made plain that the Oregon statute represented an exceptional case, contrary both to longstanding historical practices and to contemporary trends in the law:

> Since the Oregon vote, many proposals to legalize assisted-suicide laws have been and continue to be introduced in the States' legislatures, but none has been enacted. And just last year [*i.e.*, 1996], Iowa and Rhode Island joined the overwhelming majority of States explicitly prohibiting assisted suicide. . . . Also, on April 30, 1997, President Clinton signed the Federal Assisted Suicide Funding Restriction Act of 1997, which prohibits the use of federal funds in support of physician-assisted suicide.

Id. at 717-18 (citations and footnotes omitted). Further, the Court discussed the "serious, thoughtful examinations of physician-assisted suicide and other similar issues" now going on in the States. *Id.* at 719. It referred in particular to the work of New York State's

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[11] *Accord Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 280 (1990) ("As a general matter, the States—indeed, all civilized nations—demonstrate their commitment to life by treating homicide as a serious crime. Moreover, the majority of States in this country have laws imposing criminal penalties on one who assists another to commit suicide.").

Task Force on Life and the Law, a commission composed of doctors, ethicists, lawyers, religious leaders and interested laymen charged with recommending public policy on issues raised by medical advances. The Court noted that after studying physician-assisted suicide, the Task Force had unanimously concluded that "[l]egalizing assisted suicide and euthanasia would pose profound risks to many individuals who are ill and vulnerable. . . . [T]he potential dangers of this dramatic change in public policy would outweigh any benefit that might be achieved." *Id.* (internal quotation marks and citation omitted; ellipses in original).

Summarizing its review of the American legal tradition's view of assisted suicide, the Court said:

> Attitudes toward suicide itself have changed since Bracton, but our laws have consistently condemned, and continue to prohibit, assisting suicide. Despite changes in medical technology and notwithstanding an increased emphasis on the importance of end-of-life decisionmaking, we have not retreated from this prohibition.

Id.

B. *State and Federal Policy*

As detailed in *Washington v. Glucksberg*, state law and policy, with the sole exception of Oregon's, emphatically oppose assisted suicide. Assisted suicide has long been prohibited at common law, *see Glucksberg*, 521 U.S. at 711,[12] and at least forty States and terri-

[12] *See generally* Thomas J. Marzen, Mary K. O'Dowd, Daniel Crone & Thomas J. Balch, *Suicide: A Constitutional Right?*, 24 Duq. L. Rev. 1, 71-75 (1985).

tories have laws explicitly prohibiting the practice.[13] "In the two hundred and five years of our [national] existence no constitutional right to aid in killing oneself has ever been asserted and upheld by a court of final jurisdiction." *Compassion in Dying v. Washington*, 49 F.3d 586, 591 (9th Cir. 1995) (Noonan, J.), *rehearing en banc granted*, 62 F.3d 299 (9th Cir. 1995); *vacated*, 79 F.3d 790 (9th Cir. 1996) (en banc) (Reinhardt, J.) (State could not constitutionally prohibit physician-assisted suicide in cases of terminally ill competent adults), *rev'd sub nom. Washington v. Glucksberg*, 521 U.S. 702 (1997). The only state supreme court to decide the matter has rejected recognition of an enforceable right to assisted suicide under that State's constitution. *Krischer v. McIver*, 697 So. 2d 97 (Fla. 1997).

State statutes banning assisted suicide trace back a century or more in many cases. They have not been kept on the books through oversight or neglect:

> Many jurisdictions have expressly reconsidered these laws in recent years and reaffirmed them. In 1980, the American Law Institute conducted a thorough review of state laws on assist[ed] suicide in the United States and acknowledged the continuing widespread support for criminalization. Accordingly, it endorsed two criminal provisions of its own. In the 1990s, both New York and Michigan convened blue-ribbon commissions to consider the possibility of legalizing assisted suicide and euthanasia. The New York commission issued a thoughtful and detailed report unanimously recommending

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[13] *See* Christine Neylon O'Brien & Gerald A. Madek, *Physician-Assisted Suicide: New Protocol for a Rightful Death*, 77 Neb. L. Rev. 229, 275, n.314 (1998).

> the retention of existing laws against assisting suicide and euthanasia. The Michigan panel divided on the issue, but the state legislature subsequently chose to enact a statute strengthening its existing common law ban against assisted suicide. . . . Meanwhile, repeated efforts to legalize the practice —in state legislatures and by popular referenda —have met with near-total failure.

Neil M. Gorsuch, *The Right to Assisted Suicide and Euthanasia*, 23 Harv. J. L. & Pub. Pol'y 599, 639-41 (2000) (footnotes omitted).

Federal policy fully accords with the views that prevail in every State except Oregon. As noted in *Glucksberg*, the Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12, 111 Stat. 23, was signed into law on April 30, 1997. The Act was approved in the House of Representatives by a 398-to-16 vote and in the Senate by a 99-0 vote. The Act bans Federal funding of assisted suicide, euthanasia, or mercy killing through Medicaid, Medicare, military and Federal employee health plans, the veterans health care system, or other Federally funded programs. In the "Findings" preceding the Act's substantive restrictions, Congress stated that "[a]ssisted suicide, euthanasia, and mercy killing have been criminal offenses throughout the United States and, under current law, it would be unlawful to provide services in support of such illegal activities." *Id.* at § 2(a)(2). Then, after taking note that the Oregon "Death With Dignity Act" might soon become operative, *see id.* at § 2(a)(3), Congress determined that it would "not provid[e] Federal financial assistance in support of assisted suicide, euthanasia, and mercy killing and intends that Federal funds not be used to promote such activities." *Id.* at § 2(a)(4). In

general, Congress stated that its purpose was "to continue current Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual." *Id.* at § 2(b).

Even before the enactment of the Assisted Suicide Funding Restriction Act of 1997, it was the policy of the Federal Government not to recognize physician-assisted suicide as a legitimate medical practice. As Acting Solicitor General Walter Dellinger noted in 1996 in the United States Brief in *Glucksberg*:

> The United States owns and operates numerous health care facilities which . . . do not permit physicians to assist patients in committing suicide by providing lethal dosages of medication. The Department of Veterans Affairs (VA), which operates 173 medical centers, 126 nursing homes, and 55 in-patient hospices, has a policy manual that . . . forbids "the active hastening of the moment of death." . . . The military services, which operate 124 centers, the Indian Health service, which operates 43 hospitals, and the National Institutes of Health, which operate a clinical center, follow a similar practice. . . . No federal law . . . either authorizes or accommodates physician assisted suicide.[14]

Other Federal agencies have taken similar views in the past. The Hyde Letter noted that "[t]he Health Care Financing Administration has stated that

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[14] Brief for the United States as *Amicus Curiae* Supporting Petitioners at 1-2, *Washington v. Glucksberg*, 521 U.S. 702 (1997) (No. 96-110) (United States Brief in *Glucksberg*).

physician-assisted suicide is not 'reasonable and necessary' to the diagnosis and treatment of disease or injury and is therefore barred from reimbursement under Medicare." Hyde Letter, *supra* note 4, at 1. Administrator Constantine's reply stated that a review of "a number of cases, briefs, law review articles and state laws relating to physician-assisted suicide" and "a thorough review of prior administrative cases in which physicians have dispensed controlled substances for other than a 'legitimate medical purpose'" demonstrated "that delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose.'"[15]

Finally, Federal medical policy *since* the enactment of the Assisted Suicide Funding Restriction Act also supports the conclusion that physician-assisted suicide is not a legitimate medical practice. In 1999, the Surgeon General sought to classify suicide as a serious public health problem and to intensify suicide prevention efforts, especially among high risk groups such as the sick and elderly, who often suffer from un-

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[15] Constantine Letter, *supra* note 5, at 1-2. Also relevant to the past practice of Federal agencies is *United States v. Rutherford*, 442 U.S. 544 (1979), which involved a challenge by terminally ill cancer patients to the determination of the Food and Drug Administration (FDA) that Leatrile constituted a "new drug" for purposes of the Federal Food, Drug and Cosmetic Act because it was not generally regarded as safe or effective. In upholding the FDA's determination, the Court rejected the plaintiffs' argument that an implied exception from the Act was justified because the safety and effectiveness standards could have no reasonable application to terminally ill patients. It pointed out that "the FDA has never made exception [from the FDA's safety standards] for drugs used by the terminally ill." *Id.* at 553.

diagnosed depression and inadequately treated pain.[16] Dispensing controlled substances to assist the suicides of some of the most vulnerable members of American society is manifestly inconsistent with the Surgeon General's policy.[17]

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[16] *See generally The Surgeon General's Call To Action To Prevent Suicide (1999)*, Dep't of Health and Human Services, U. S. Public Health Service, http://www.surgeongeneral.gov/library/calltoaction/calltoaction.htm; *see also* Kathleen M. Foley & Hellen Gelbard (eds.), *Improving Palliative Care for Cancer: Summary and Recommendations* (2001) (finding depression common among terminally ill cancer patients, and recommending greater emphasis on palliative care).

[17] *See* United States Brief in *Glucksberg* at 19. Medical evidence suggests that many terminally ill patients who seek death do so not as a result of rational deliberation, but rather because of depression or mental illness. Moreover, given modern palliative care techniques, pain-avoidance cannot justify the general practice of assisted suicide. *See* Susan R. Martyn and Henry J. Bourguignon, *Now Is The Moment to Reflect: Two Years of Experience With Oregon's Physician-Assisted Suicide Law*, 8 Elder L. J. 1, 14-16 (2000) (footnotes omitted) ("First, the rate of depression among terminally ill patients appears to be 'much higher than would be expected in the general population.' Recent studies indicate that fully two-thirds of those requesting assisted suicide suffer from depression. Second, seriously ill patients often require powerful medications which can distort the patient's thoughts and feelings. 'For many patients, the progression of disease will result in the impairment of decisionmaking capacity, either from the effects of the disease itself or those of drug treatment.' Third, seriously ill patients may also suffer physical and mental disability, have short attention spans, or find it difficult to concentrate. They may have difficulty hearing or thinking through complex subjects. . . . Physicians, psychiatrists, and psychologists, like anyone else who deals with a seriously ill, mentally or physically disabled patient can all too easily conclude that the patient's request for assisted suicide is reasonable and therefore competent. The greatest threat is that persons with mental or physical disabilities or depression,

especially those who burden others, will readily be found competent to request assistance in suicide. . . . Depression, the major precursor of suicidal intent, often worms its way into serious illnesses and, especially among the elderly, can remain undiagnosed and untreated. In fact, clinical studies now indicate that depression is the only factor that predicts suicidal intent or ideation. Indeed, Oregon physicians report that they recognized symptoms of depression in twenty percent of patients who sought suicide assistance."); *id.* at 38-43 (describing significant recent innovations in palliative care, noting that States are increasingly enacting intractable pain legislation to assure physicians that adequate pain control is legally and medically required, and suggesting that legalizing physician-assisted suicide may inhibit advances in such care); New York State Task Force on Life and the Law, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* 11, 13 (1994) ("Studies that examine the psychological background of individuals who kill themselves show that 95 percent have a diagnosable mental disorder at the time of death. Depression, accompanied by symptoms of hopelessness and helplessness, is the most prevalent condition among individuals who commit suicide. . . . In one study of terminally ill patients, of those who expressed a wish to die, all met diagnostic criteria for major depression."); Brief of *Amici Curiae* American Geriatrics Soc. Urging Reversal of the Judgments Below in *Vacco v. Quill*, 521 U.S. 793 (1997) and *Washington v. Glucksberg*, 521 U.S. 702 (1997) (Nos. 95-1858 & 96-100) (1996) (hospice and palliative care programs relieve pain and other severe symptoms for those near death and should be preferred treatment options; also noting high correlation between cognitive or emotional dysfunctioning such as depression and suicide inquiries); Leon R. Kass and Nelson Lund, *Physician-Assisted Suicide, Medical Ethics and the Future of the Medical Profession*, 35 Duq. L. Rev. 395, 406 (1996) ("Because the quick-fix of suicide is easy and cheap, it will in many cases replace the use of hospice and other humanly-engaged forms of palliative care, for there will be much less economic incentive to continue building and supporting social and institutional arrangements for giving humane care to the dying."); Yale Kamisar, *Against Assisted Suicide—Even a Very Limited Form*, 72 U. Detroit Mercy L. Rev. 735, 744 (1995) ("Although pain is notoriously

C. *Views of the Medical and Nursing Professions*

The leading organizations of the American medical profession have repeatedly, and recently, expressed the profession's condemnation of physician-assisted suicide. The American Medical Association (AMA), joined by the American Nurses Association (ANA), the American Psychiatric Association, and 43 other national medical organizations, filed a brief in the *Glucksberg* case declaring that "[t]he ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics" and that physician-assisted suicide is "'fundamentally incompatible with the physician's role as healer.'"[18] More specifically, the AMA's Brief said:

> The power to assist in intentionally taking the life of a patient is antithetical to the central mission of healing that guides both medicine and nursing. It is a power that most physicians and nurses do not want and could not control. Once established, the right to physician-assisted suicide would create profound danger for many ill persons with undiagnosed depression and inadequately treated pain, for whom physician-assisted suicide rather than good palliative care could become the norm. At greatest risk would be those with the least access to palliative care—the poor, the elderly, and members of minority groups.

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undertreated in this country, 'according to experts in the field of pain control, almost all terminally ill patients can experience adequate relief with currently available treatments.' ") (footnotes omitted); Gorsuch, *supra*, at 691.

[18] Brief of *Amici Curiae* American Medical Association et al. at 5, *Washington v. Glucksberg*, 521 U.S. 702 (1997) (No. 96-110) (1996).

> *Amici* acknowledge that many patients today do not receive proper treatment for their pain, depression, and psychological distress. Nevertheless, physician-assisted suicide is not the right answer to the problem of inadequate care. Although for some patients it might appear compassionate intentionally to cause death, institutionalizing physician-assisted suicide as a medical treatment would put many more patients at serious risk for unwanted and unnecessary death.
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> . . .
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> The ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics. Its roots are as ancient as the Hippocratic oath that a physician "will neither give a deadly drug to anybody if asked for it, nor . . . make a suggestion to this effect," and the merits of the ban have been debated repeatedly in this nation since the late nineteenth century. Most recently, the AMA has reexamined and reaffirmed the ethical prohibition against physician-assisted suicide in 1977, 1988, 1991, 1993, and 1996.[19]

As the Court noted in *Glucksberg*, 521 U.S. at 731, the AMA's Code of Ethics condemns physician-assisted suicide as fundamentally incompatible with the physician's role as a healer. AMA, *Code of Ethics* § 2.211 (1994); *see also* Council on Ethical and Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229, 2233 (1992). Largely on the basis of the AMA's position, the Court found that the State of Washington had "an interest in protecting the integrity and ethics of the

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[19] *Id.* at 2-5.

medical profession" when it prohibited physician-assisted suicide. *Glucksberg*, 521 U.S. at 731; *see also Compassion in Dying*, 49 F.3d at 592 (citation omitted) ("From the Hippocratic Oath with its promise 'to do no harm,' . . . to the AMA's code, the ethics of the medical profession have proscribed killing.").

The AMA took the same unequivocal position in hearings before Congress on the subject of assisted suicide. *See Assisted Suicide in the United States*: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, United States House of Representatives, 104th Cong., 309-11 (1996) (statement of Lonnie L. Bristow, M.D., Pres., AMA) (1996 Hearing). Dr. Bristow testified:

> The AMA believes that physician-assisted suicide is unethical and fundamentally inconsistent with the pledge physicians make to devote themselves to healing and to life. . . . AMA takes seriously its role as a leader in issues of medical and professional ethics. The AMA's "code of ethics" serves as the profession's defining document as to what is right versus what is wrong in medical practice, and such issues are critical to our professionalism and our role as healers. My primary obligation as a physician is to first be an advocate for my patient. If my patient in understandably apprehensive or afraid of his or her own mortality, I need to provide information, support, and comfort, not help them avoid the issues of death.

Id. at 310.

The ANA, a national organization representing 2.2 million registered nurses, submitted written testimony to Congress at the same hearing. *See id.* at 438-50.

Included in the ANA's submission was the organization's *Position Statement on Assisted Suicide* (1994). The *Position Statement* succinctly summarizes the ANA's view of nurse-assisted suicide as follows:

> The American Nurses Association (ANA) believes that the nurse should not participate in assisted suicide. Such an act is in violation of the *Code for Nurses with Interpretive Statements (Code for Nurses)* and the ethical traditions of the profession.

Id. at 443. The "Rationale" in the *Position Statement* sets forth comprehensively the basis of the ANA's view. It states in part:

> • The profession of nursing is built upon the Hippocratic tradition "do no harm" and an ethic of moral opposition to killing another human being. The ethical framework of the profession as articulated through the *Code for Nurses* explicitly prohibits deliberately terminating the life of any human being.
>
> • Nursing has a social contract with society that is based on trust and therefore patients must be able to trust that nurses will not actively take human life. . . . Nurse participation in assisted suicide is incongruent with the accepted norms and fundamental attributes of the profession. . . .
>
> • While there may be individual patient cases that are compelling, there is high potential for abuses with assisted suicide, particularly with vulnerable populations such as the elderly, poor and disabled. These conceivable abuses are even more

> probable in a time of declining resources. The availability of assisted suicide could forseeably weaken the goal of providing quality care for the dying.

Id. at 445.

Scholars have observed that the norms of the medical and nursing professions with respect to physician-assisted suicide, which reflect the experience and the reflection of centuries, are more compelling now than ever. *See* Kass & Lund, *supra* note 17, at 423 ("Given the great pressures threatening medical ethics today —including, among other factors, a more impersonal practice of medicine, the absence of a lifelong relationship with a physician, the push toward managed care, and the financially-based limitation of services—a bright line rule regarding medically-assisted suicide is a bulwark against disaster."); *see also* Seth F. Kreimer, *Does Pro-Choice Mean Pro-Kevorkian? An Essay on Roe, Casey, and the Right to Die*, 44 Am. U. L. Rev. 803, 841 (1995) ("Particularly with the emergence of cost controls and managed care in the United States, the danger of tempting health care providers to persuade chronic patients to minimize costs by ending it all painlessly is no fantasy.").

To be sure, it has been claimed that physician-assisted suicide has become a common, if also usually clandestine, practice.[20] But the claim is questionable. The American Geriatrics Society, for example, has stated that the Society's leadership "is unfamiliar with situations in which this is true, and it seems unlikely. Three-quarters of all deaths happen in institutions where a regularized endeavor would require the collusion of a large number of persons, which seems implau-

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[20] *See, e.g., Compassion in Dying*, 79 F.3d at 811.

sible. Little reliable evidence characterizes the rate and nature of actual instances of [physician-assisted suicide]." Brief of *Amici Curiae* the American Geriatrics Soc., in *Glucksberg*, *supra* note 17, at 10. Moreover, even if there were reliable evidence that unacknowledged physician-assisted suicide was not infrequent, that fact would hardly invalidate the *normative* judgments of the AMA and other medical groups that emphatically condemn the practice. By parity of reasoning, if it could be shown that physicians violated traditional medical canons of ethics more often that is usually supposed, *e.g.*, by engaging in sexual relations with their patients or disclosing patient confidences, it would follow that the evidence of such deviations overturned the professional standards prohibiting such misconduct.

Thus, the overwhelming weight of authority in judicial decisions, the past and present policies of nearly all of the States and of the Federal Government, and the clear, firm and unequivocal views of the leading associations within the American medical and nursing professions, establish that assisting in suicide is not an activity undertaken in the course of professional medical practice and is not a legitimate medical purpose. Indeed, we think it fair to say that physician-assisted suicide should not be considered a *medical* procedure at all. Here we follow an *amicus* brief filed in *Glucksberg* by a group of fifty bioethics professors, who declared that physician-assisted suicide "is not a medical procedure, and medicalizing an act runs the risk of making an otherwise unacceptable act appear acceptable." Brief for Bioethics Professors, *Amici Curiae* Supporting Petitioners, *Vacco v. Quill* & *Washington v. Glucksberg* (Nos. 95-1858 & 96-100) (1996), at 15. As

this brief points out, assisted suicide does not require any medical knowledge whatever, nor does it necessarily depend on access to any prescribed drugs or to medical services. Indeed, the country's most prominent partisan of assisted suicide, Jack Kevorkian, has often used the entirely non-medical method of carbon monoxide poisoning. *See* George J. Annas, *Physician Assisted Suicide—Michigan's Temporary Solution*, 20 Ohio N.U.L. Rev. 561, 568 (1994). It is plainly a fallacy to assume that a procedure must be "medical" because it is performed by a physician rather than, say, by a family member, or because it involves the use of a drug that a physician has prescribed.[21]

Accordingly, we conclude that assisting in suicide is not a "legitimate medical purpose" that would justify a physician's dispensing controlled substances consistent with the CSA.

III. *The Existence of a State Law Permitting Physician-Assisted Suicide Does Not Immunize a Physician from the General Requirements of the CSA*

The CSA establishes a uniform, nation-wide statutory scheme for regulating the distribution of controlled substances. Notwithstanding the traditional role of the

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[21] The Oregon Deputy Attorney General's Letter assumes, uncritically, that physician-assisted suicide, if authorized by state law, *must* be considered a "medical" practice that serves a "medical" purpose. *See* Oregon Deputy Attorney General Letter, *supra* note 6, at 7 ("[T]he CSA is addressed to the problems of the abuse and trafficking of controlled substances, [not to] regulating medical practices that are legal under state law and that have no relation to drug abuse or trafficking"). As we have argued above, it is far from obvious (to say no more) that assisting an individual to kill himself or herself *must* be considered a "medical" procedure.

States in regulating the practice of medicine,[22] state law cannot abrogate the CSA or supersede its provisions in the event of conflict.[23] Thus, the fact that assisting in suicide may be permitted in some cases for Oregon physicians under local law does not entail that they should be held immune from criminal prosecution or adverse administrative action under the CSA if they dispense a controlled substance when rendering that assistance. It is simply wrong to suggest, as the Deputy Attorney General of Oregon did, that the CSA does not reach "practices that are engaged in by physicians in accordance with state law."[24]

The Supreme Court's very recent decision in the so-called "medical marijuana" case, *United States v. Oakland Cannabis Buyers' Coop.*, 121 S. Ct. 1711(2001), demonstrates the fallacy of attempting to read an implied immunity into the CSA for physicians who dispense controlled substances to assist suicides in a State in which such conduct is consistent with local law. In *Oakland Cannabis Buyers'*, the Supreme Court addressed the question whether there was an implied "medical necessity" exception to the CSA's general prohibition in 21 U.S.C. § 841(a)(1) on manufacturing and distributing marijuana. Marijuana is a "schedule I" controlled substance. For drugs on that schedule, there is but one express statutory exception, and that exception is available only for Government-approved research projects. *See* 21 U.S.C. § 823(f); *Oakland*

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[22] *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S. Ct. 1012, 1017 (2001); *Gade v. Nat'l Solid Wastes Management Ass'n*, 505 U.S. 88, 108 (1992).

[23] *See, e.g.*, *Rosenberg*, 515 F.2d at 198, n.14.

[24] *See* Oregon Deputy Attorney General Letter, *supra* note 6, at 6.

Cannabis Buyers', 121 S. Ct. at 1714.[25] Notwithstanding the fact that it did not fall within the sole express statutory exception, the defendant Cooperative argued that the statute should be read to include another, implied exception for "medical necessity." The Supreme Court refused to read such an exception into the CSA.

Because of the passage in a 1996 voter initiative of the Compassionate Use Act of 1996, Cal. Health & Safety Code Ann. § 11362.5 (West Supp. 2001), California laws prohibiting the possession and cultivation of marijuana now include an exception for a patient or primary caregiver who possesses or cultivates marijuana for the patient's medical purposes upon the recommendation or approval of a physician. In the wake of the voter initiative, "medical cannabis dispensaries" were organized to meet the needs of qualified patients. The defendant was one such organization, and distributed marijuana to those it accepted as members. The United States sued the defendant in 1998, arguing that, "whether or not the Cooperative's activities are legal under California law, they violate" § 841(a) of the CSA. *Oakland Cannabis Buyers'*, 121 S. Ct. at 1716. Despite being enjoined from distributing marijuana, the defendant continued to do so, and the United States accordingly initiated contempt proceedings. In defense,

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[25] The controlled substances usually used in physician-assisted suicide are, as we have noted, schedule II substances, and accordingly are governed by a different regulatory régime from schedule I substances. In particular, registered practitioners may "dispense" schedule II, but not schedule I, substances. *See* 21 U.S.C. § 824(f). This distinction does not, however, affect the relevance of *Oakland Cannabis Buyers'* to the questions considered in this memorandum.

it was "contended that any distributions were medically necessary. Marijuana is the only drug, according to the Cooperative, that can alleviate the severe pain and other debilitating symptoms of the Cooperative's patients." *Id.* (citation omitted). The district court found the defendant in contempt, and declined to modify its injunction so as to permit marijuana distributions that were asserted to be medically necessary. Although the defendant's appeal of the contempt order was mooted, its motion to modify the injunction presented a live controversy, and the court of appeals accepted the defendant's argument that medical necessity was a legally cognizable defense under the CSA. The United States sought certiorari to review the court of appeals' decision, and the Supreme Court granted the petition because the appellate decision below "raise[d] significant questions as to the ability of the United States to enforce the Nation's drug laws." *Id.* at 1717.

The Supreme Court flatly rejected the defendant's claim of an implied medical necessity exception. "[T]o resolve the question presented, we need only recognize that a medical necessity exception for marijuana is at odds with the terms of the Controlled Substances Act. The statute, to be sure, does not explicitly abrogate the defense. But its provisions leave no doubt that the defense is unavailable." *Id.* at 1718 (footnote omitted).

The question whether Oregon physicians may dispense controlled substances to assist in a suicide without violating the CSA is similar to (although it is of course not the same as) the question decided in *Oakland Cannabis Buyers'*. In effect, the argument that such physicians do *not* violate the CSA depends on the assumption that because assisting suicide in that manner is permissible under state law, the CSA must

be interpreted so that such dispensing is done "in the course of professional practice," 21 U.S.C. § 802(21), and the DEA's regulations must be read so that such actions serve "a legitimate medical purpose," 21 C.F.R. § 1306.04(a). But a State cannot, by its unilateral action, take its physicians' conduct out of the scope of otherwise nationally applicable prohibitions on the dispensing of controlled substances. The CSA contains no express immunity for such conduct in States in which physicians may assist suicides compatibly with local law, and it should not be construed in a manner that implies such an immunity.[26]

IV. *The CSA Contemplates Concurrent Federal and State Regulation of Medical Practices Involving Controlled Substances*

Like the Court in *Oakland Cannabis Buyers'*, we share the concern for "'showing respect for the sovereign States that comprise our Federal Union.'" *Oakland Cannabis Buyers'*, 121 S. Ct. at 1720, n.7 (quoting Stevens, J., concurring in judgment). But we think it shows no disrespect for the principles of federalism to conclude that the States cannot, by their unilateral

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[26] We note that the 1998 Letter, *see supra* note 7, at 3-4, expressly recognized that its conclusion was "limited to these particular circumstances" in Oregon (and, should any other State follow Oregon, such a State), and affirmed that "[a]dverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions." Construing the CSA and its regulations as Attorney General Reno did would accordingly cause the Act's prohibitions to apply differently from one State to another, and would in effect grant the States the power to immunize their physicians from liability under otherwise generally applicable Federal law.

actions, shelter their physicians from the Federal narcotics code. Although the States are the *primary* regulators of the practice of medicine, they are not its *exclusive* regulators: since the Harrison Narcotics Act of 1914, the Federal Government has regulated the practice of medicine insofar as it involved the dispensing of controlled drugs.[27] Physicians were often prosecuted under the Harrison Act for prescribing drugs in a manner that did not comport with Federal statutory requirements or that fell outside the course of professional practice as determined by the Federal courts.[28] Further, the Supreme Court repeatedly upheld the authority of Federal prosecutors to bring such cases against physicians over the objection that the Harrison Act impermissibly encroached on a regulatory

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[27] *See Moore*, 423 U.S. at 132 ("Physicians who stepped outside the bounds of professional practice could be prosecuted under the Harrison Act (Narcotics) of 1914, 38 Stat. 785, the predecessor of the CSA."); *id.* at 139 ("Under the Harrison Act physicians who departed from the usual course of medical practice were subject to the same penalties as street pushers with no claim to legitimacy.").

[28] *See, e.g., United States v. Behrman*, 258 U.S. 280 (1922) (sustaining conviction of physician over dissent's argument that defendant should have been assumed to have given drugs in the regular course of his practice and in good faith); *Jin Fuey Moy v. United States*, 254 U.S. 189, 194 (1920) (sustaining conviction; Court states that "[m]anifestly the phrases 'to a patient' and 'in the course of his professional practice only' are intended to confine the immunity of a registered physician, in dispensing the narcotic drugs mentioned in the act, strictly within the appropriate bounds of a physician's . . . practice."); *Webb v. United States*, 249 U.S. 96, 99-100 (1919) (holding that to call the defendant's order for the use of morphine a "physician's prescription" would "be so plain a perversion of meaning that no discussion of the subject is required.").

power exclusively reserved to the States.[29] The CSA was intended "to strengthen rather than to weaken the prior drug laws."[30] Consequently, dispensing controlled substances has been an aspect of medical practice that the Federal Government has regulated concurrently with the States for some eighty-seven years.[31]

Both in enacting the CSA in 1970 and in amending it in 1984, Congress was well aware that enforcement of the Federal law would unavoidably necessitate Federal regulation of medicine concurrent with, and in some circumstances designedly superseding, state regulation. In the House Report on what is now 42 U.S.C. § 257a,[32] the Committee on Interstate and Foreign Commerce noted the difficulty but found it inescapable:

> Although the committee is concerned about the appropriateness of having Federal officials determine the appropriate method of the practice of

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[29] *See Nigro v. United States*, 276 U.S. 332, 353-54 (1928) (upholding constitutionality of Harrison Act as revenue measure despite claim that it infringed on States' police power to regulate intrastate purchases of commodities); *Linder v. United States*, 268 U.S. 5, 18 (1925) (prosecution of physician under Harrison Act; Court states that while "direct control of medical practice in the States is beyond the power of the Federal Government," "[i]ncidental regulation of such practice by Congress through a taxing act" may be permitted); *United States v. Doremus*, 249 U.S. 86, 93-94 (1919).

[30] *Moore*, 423 U.S. at 139.

[31] *Cf. Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41 (1921) (state law regulating physicians' furnishing or prescribing narcotic drugs held compatible with Harrison Act).

[32] This provision was originally enacted as § 4 of title I of the Comprehensive Drug Abuse and Control Act of 1970, 84 Stat. 1236, 1241 (1970); title II comprised the CSA. Hence the legislative history of the provision is highly relevant to the CSA.

> medicine, *it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinion of Federal prosecutors of what constitutes appropriate methods of professional practice.*

H.R. Rep. No. 91-1444, pt. 1, 91st Cong. at 15 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4581 (emphasis added).

Further, Congress revisited the CSA in 1984 in order to add amendments that expanded Federal authority at the expense of the States and were specifically directed against the misuse of Federally regulated prescription drugs (that otherwise have legitimate medical uses) in a manner that did not violate state law. The expanded Federal authority was accomplished by adding "inconsistency with the public interest" as a ground for denying, suspending, or revoking Federal registration. *See* 21 U.S.C. § 823(f) ("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.") and *id.* § 824(a)(4) (DEA may revoke registration of any physician who has committed acts "inconsistent with the public interest."). Previously, the Federal Government lacked the authority under the CSA to deny a physician's registration application when the physician possessed a license from the State to practice medicine and had no felony drug conviction. *See* S. Rep. No. 98-225, at 262 (1984) (footnote omitted) ("the Attorney General must presently grant a practitioner's registration application unless his State license has been revoked or he has been convicted of a felony drug

offense, even though such action may clearly be contrary to the public interest").[33]

Supporters of the 1984 amendments explained that the most serious threat to "public health and safety" prompting this legal change was the frequency with which prescription drugs were involved in "drug-related deaths" and overdoses that threatened life.[34] Representative Hamilton Fish, a sponsor of the 1984 amendments, said that giving flexibility to the Federal Government was necessary because States often did not respond adequately to abuses: "State policing of these activities . . . have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate." 130 Cong. Rec. at 25,849. At a hearing before the House Commerce Subcomm. on Health and the Environment, the DEA called the expanded Federal authority to revoke practitioner registrations "one of the most important sections of the bill," not only because States were often ill-equipped to enforce their own drug laws but also

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[33] *See also* 130 Cong. Rec. 25,852 (1984) (statement of Rep. Rangel); *see generally Moore*, 423 U.S. at 140-41 ("In the case of a physician th[e] scheme [of the registration provision of the then-existing CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice. The federal registration . . . follows automatically.").

[34] *Dangerous Drug Diversion Act of 1984:* Hearing on H.R. 5656 Before House Comm. on Health and the Environment, 98th Cong., 365 (1984) (testimony of Rep. Waxman) ("[d]rugs legally manufactured for use in medicine are responsible for a substantial majority of drug-related deaths and injuries"); *see also* 130 Cong. Rec. 25,851 (statement of Rep. Rodino) ("prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse").

because "[m]any controlled drug violations involving prescription drugs are not felonies under state law and therefore cannot be used in a DEA revocation action" under then-existing law.[35] Members of Congress also explained that the 1984 amendments were intended to "expand[] the standards for practitioner registration beyond the current exclusive reliance upon authorization by the practitioner's own jurisdiction."[36]

Congress intended, therefore, that the "inconsistent with the public interest" standard be more demanding than the standard of a physician's licensing State. The 1984 amendments authorized the DEA to enforce the CSA against medical practitioners who prescribed controlled substances in a manner that "endangers public health or safety" contrary to the "public interest," notwithstanding the nature or content of state law or regulation. Consistent with Congress' purpose, the public interest standard incorporated in § 824(f) is best understood to authorize suspension or revocation of the Federal registration of a practitioner who dispenses controlled substances to assist in a suicide, even if such conduct is permitted under state law.

V. *The CSA's Preemption Provision Is Consistent With This Interpretation*

The CSA itself includes a provision designed to narrow possible Federal preemption of state law. The

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[35] *Dangerous Drug Diversion Control Act of 1984*: Hearing on H.R. 5656 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 403-04 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration).

[36] 130 Cong. Rec. 1,586 (1984) (statement of Sen. Laxalt); *see also* 130 Cong. Rec. at 25,851-52 (statement of Rep. Rangel).

provision is found at 21 U.S.C. § 903. Section 903 plainly does not require the Department of Justice to accept Oregon's determination of what is a "legitimate medical purpose."

Section 903 reads as follows:

> **Application of State law**
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> 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.

21 U.S.C. § 903.

For at least two reasons, we do not think that § 903 affects the conclusion that assisting in a suicide is not a legitimate medical purpose that would justify a physician's dispensing a controlled substance.

First, if § 841(a) and other pertinent parts of the CSA are read and applied in accordance with the DEA's regulation, 21 C.F.R. § 1306.04(a), and the interpretation of it here, it would certainly not follow that the CSA was being understood to "occupy the field" of regulating the medical profession to the "exclusion of any State law."[37] On the contrary, as we have just

[37] Congress' intent to preempt all state law in a particular area may be inferred "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation" or "where the field is one in which 'the federal interest is so dominant

shown, the States remain free to regulate that profession *concurrently* with the Federal government, as they have done since 1914. Federal regulation of the profession under the CSA would reach only the dispensing of controlled substances, which is hardly the whole field of medical practice. Moreover, States would remain free to regulate that activity as well, as long as such regulation did not conflict with Federal law.

Second, even if our interpretation would make it harder as a practical matter for Oregon physicians to assist in suicides, the CSA and its regulations as we read them do not *preempt* Oregon's Death With Dignity Act.[38] Oregon physicians remain free under that law to assist in suicides, provided of course that they follow the procedures that Oregon imposes. All that our interpretation does is to affirm that *dispensing controlled substances in connection with such an assisted suicide* will cause an Oregon physician to be in violation of the CSA. Any method of assisting in suicides in which an Oregon physician does *not* dispense a controlled substance entails *no* violation of the CSA. The Attorney General's interpretation forecloses one, but

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that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 713 (1985) (citations omitted). Interpreting the CSA and its regulations to reach the conduct of physicians who dispense drugs to assist suicide does not require the assumption that Congress intended to occupy the field of regulation of the medical profession.

[38] *Cf. Dalton v. Little Rock Family Planning Servs.*, 516 U.S. 474, 476 (1996) (per curiam) (state law preempted only to the extent that it "'actually conflicts'" with federal law) (citation omitted); *Pharmaceutical Society of State of New York v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (no preemption because no actual conflict).

only one, method of assisting suicide in a manner consistent with Oregon law.

We respectfully disagree with the contrary opinion of the Oregon Deputy Attorney General. *See* Oregon Deputy Attorney General Letter, *supra* note 6, at 7-8. That Letter argues, in part, that the CSA should not be construed to enable the Attorney General to regulate the practice of medicine, which is said to be an area traditionally reserved to the States. We consider that argument to be mistaken.

First, as we have shown, the Federal Government has regulated the dispensing of controlled substances by physicians continuously since the Harrison Act of 1914, and in enacting the CSA in 1970, Congress clearly intended that the Attorney General continue to do so.[39]

Second, as we have also shown, the legislative history of the 1984 amendments to the CSA demonstrates that Congress intended the Attorney General to have regulatory authority with respect to the conduct of physicians even in circumstances in which that conduct was not sanctionable under state law.

Third, the activity of assisting in suicide should not, in our view, be considered a "medical" practice solely because it is undertaken by a physician: as we have shown, physician-assisted suicide has been condemned by the overwhelming majority of the States and by the leading professional associations of medical and nursing practitioners. On the theory of the Oregon Deputy Attorney General's Letter, an act that was performed by doctors, despite being forbidden by ordinary professional standards or even punishable elsewhere as a

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[39] *See Moore*, 423 U.S. at 132-33.

crime, could be transformed into a "medical" practice if a single State were to decide to deem it so; and that State's unilateral decision would presumptively place the act beyond the reach of Federal regulation. It would follow that if a State authorized physicians to perform involuntary euthanasia on severely handicapped or mentally retarded persons, and thus "medicalized" that procedure, it could place it beyond Federal regulatory power pursuant to the CSA even if controlled substances were used. Equally, it would follow that if a State authorized physicians to prescribe controlled substances to addicts in order to enable them to maintain their customary use and so avoid discomfort, the Federal Government would be unable to prosecute those physicians or to revoke their registrations under the CSA. We cannot accept these consequences of the theory: no State has the power to determine unilaterally what practices count as "medical" for purposes of the CSA.

VI. *The DEA Had the Authority to Promulgate and Interpret A Regulation Concerning Whether Dispensing a Controlled Substance Has a "Legitimate Medical Purpose"*

Finally, we consider the basis of the Attorney General's authority to determine that dispensing a controlled substance to assist in a suicide in a State permits such conduct on the part of a physician does not serve a "legitimate medical purpose" under 21 C.F.R. §1306.04 (a).

We address this question because of an apparent ambiguity in the 1998 Letter. The Letter could be understood, not as controverting DEA's interpretation of the CSA and the DEA's own regulations, but rather

as making the *jurisdictional* claim that DEA lacked statutory authority to find that a physician's prescription of controlled substances to assist a suicide in Oregon went beyond "the course of professional practice," 21 U.S.C. § 802(21), and did not serve a "legitimate medical purpose," 21 C.F.R. § 1306.04(a). *See* 1998 Letter, *supra* note 7, at 3 ("[T]here is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving 'the earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide.' *Washington v. Glucksberg*, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances."). We do not understand the 1998 Letter to be making a jurisdictional point, but rather to be offering its own interpretation of the CSA and the DEA's regulations. If, however, the Letter were understood to be putting forward a jurisdictional claim, we think that it would be both misleading and mistaken.

First, it is misleading to raise the question whether Congress assigned responsibility for interpreting and enforcing the CSA to *the DEA*. It is clear that Congress assigned that responsibility to *the Attorney General*, not to the DEA. *See* 21 U.S.C. § 821 ("*The Attorney General* is authorized to promulgate rules and regulations . . . relating to the . . . dispensing of controlled substances . . . and control of regulated persons and of regulated transactions") (emphasis added); *id.*, § 871(b) ("*The Attorney General* may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.") (emphasis added). The Attorney General is authorized to delegate his or her CSA responsibilities

to "any officer or employee of the Department of Justice," *id.*, § 871(a), and the Attorney General determined to delegate those functions to the DEA. *See Touby*, 500 U.S. at 169. Thus, if the 1998 Letter were construed to be questioning the DEA's authority to interpret, *e.g.*, what the CSA means by "the course of professional practice," 21 U.S.C. § 802(21), it would necessarily be questioning the authority of *the Attorney General* to interpret that provision. Such a conclusion would plainly be at odds with the broad language of the CSA's authorizing provisions, *id.*, §§ 821, 871(b).

Second, it is also misleading to say that Congress did not intend to assign to the DEA the role of resolving the national debate over physician-assisted suicide. Of course Congress did not intend to do that. What Congress plainly *did* intend to do was to give the Attorney General (and, accordingly, his or her delegate, the DEA) the authority to "promulgate rules and regulations . . . relating to the . . . dispensing of controlled substances and control of regulated persons." *Id.*, § 821. That is precisely what the DEA did when it promulgated a regulation such as 21 C.F.R. § 1306.04(a); and it was well within the scope of DEA's authority to determine how that regulation was to be applied to the use of controlled substances in physician-assisted suicides.

Third, the DEA did not undertake to "*resolve*" the national debate over physician-assisted suicide, and should not be faulted for having attempted to do so. The DEA acts pursuant to delegated authority under an Act of Congress. Congress remains free to alter the terms on which the DEA acts: it could, *e.g.*, carve out an exception for the use of controlled substances by physicians to assist suicide. Moreover, the DEA has no

power to control the ability of the States to enact laws permitting (or forbidding) physician-assisted suicide. What DEA could, and did, properly resolve was that the dispensing of controlled substances by a physician to assist a suicide did not have a "legitimate medical purpose" within the meaning of its own regulation, notwithstanding the fact that a single State chose to legalize physician-assisted suicide. In *no* way did the DEA preclude open and vigorous debate in the legislative process on the merits of physician-assisted suicide.

Fourth, the 1998 Letter suggests that the DEA—and, by necessary implication, the Attorney General—had no authority to adopt an interpretation that addressed "fundamental questions of morality and public policy." 1998 Letter at 3. If that were so, it would follow that the Attorney General had no authority to decide whether dispensing controlled substances to assist in suicide served a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a), because in deciding that question—one way or the other—the Attorney General would unavoidably be addressing such moral and policy questions.[40] Indeed, it seem to would follow that that regulation was itself *ultra vires*—which is clearly a mistaken view.

The truth is that, far from being outside the Attorney General's mission under the CSA, addressing such questions is inherent in that mission. *See Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984) ("The power of an administrative agency to administer a congressionally created program neces-

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[40] We note that the 1998 Letter was *itself* an administrative interpretation that assumed a particular view of public policy.

sarily requires the formulation of policy . . .") (internal quotation marks, internal ellipses and citation omitted). If the CSA is to be administered effectively, the Attorney General *must* interpret its provisions so as to decide, *e.g.*, whether prescribing of controlled substances in a particular class of cases takes place within the "course of professional practice," 21 U.S.C. § 802(21), whether a physician's conduct involving such substances "may threaten the public health and safety," *id.*, § 823(f)(5), and whether issuing a registration to an applicant would be "inconsistent with the public interest," *id.*, § 823(f). Of course such administrative determinations will require a judgment about public policy.[41] So do, *e.g.*, administrative determinations as to what constitute "excessive profits" on government contracts, *see Lichter v. United States*, 334 U.S. 742, 778-86 (1948), when commodity prices are "fair and equitable," *see Yakus v. United States*, 321 U.S. 414, 426-27 (1944), when rates for the sale of a commodity are "just and reasonable," *see Federal Power Comm'n v. Hope Gas Co.*, 320 U.S. 591, 600-02 (1944), when voting power has been "unfairly or inequitably" distributed among security holders, *see American Power & Light Co. v. SEC*, 329 U.S. 90, 104 (1946), when broadcast licensing is in the "public interest," *see National Broadcasting Co. v. United States*, 319 U.S. 190, 225-26 (1943), or when a new drug poses an "imminent hazard to the public safety," *see Touby*, 500 U.S. at 165. *See generally Whitman v. American Trucking Ass'n, Inc.*, 121

[41] Indeed, one of the primary reasons why an agency's construction of a statute it administers may be entitled to judicial deference is that it is more appropriate for an agency to make "policy choices" than it is for the courts. *Chevron*, 467 U.S. at 865.

S. Ct. 903, 912 (2001).[42] As a matter of administrative practice, there was nothing unusual or unauthorized in the fact that the DEA's interpretation implicated questions of public policy or morality.

Accordingly, if the 1998 Letter were construed as denying the Attorney General (or the DEA) the statutory authority to reach the question whether prescribing controlled substances to assist suicide is consistent with the CSA and its implementing regulations in a State that had legalized physician-assisted suicide, the Letter would be clearly mistaken as a matter of law.

Conclusion

Based on the foregoing considerations, the conclusion that a physician's assisting suicide through the dispensing of a controlled substance does not serve a "legitimate medical purpose" within the meaning of 21 CFR § 1306.04 is the best reading of that regulation.

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[42] The Department of Justice may also be required to interpret statutes implicating judgments about policy or morality when bringing criminal prosecutions or when instituting deportation proceedings. *See, e.g., Jordan v. DeGeorge*, 341 U.S. 223, 231 & n.15 (1951) (deportation proceeding based on alien's commission of asserted "crime involving moral turpitude;" Court finds that phrase "presents no greater uncertainty or difficulty than language found in many other statutes repeatedly sanctioned by the Court"); *see also Kay v. United States*, 303 U.S. 1, 3, n.1, 7 (1938) (rejecting argument that statute making it criminal in some contexts willfully to "overvalue[] any security" was unconstitutionally vague).

APPENDIX F

UNITED STATES CODE

TITLE 21—FOOD AND DRUGS

Sec. 801. Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

* * * * *

Sec. 802. Definitions

As used in this subchapter:

* * * * *

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

* * * * *

Sec. 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

* * * * *

Sec. 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. * * *

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United

States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

* * * * *

Sec. 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions.

Sec. 822. Persons required to register

(a) Period of registration

* * * * *

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized

to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

* * * * *

Sec. 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded there from into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

* * * * *

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

* * * * *

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the

State in which he practices. 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. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of

such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheuled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

* * * * *

Sec. 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State

authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) 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; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of title 42.

* * * * *

Sec. 829. Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

* * * * *

Sec. 830. Regulation of listed chemicals and certain machines

* * * * *

(b) Reports to Attorney General

* * * * *

(3) MAIL ORDER REPORTING.—(A) As used in this paragraph:

* * * * *

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by

law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

Sec. 841. Prohibited acts A

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance;

* * * * *

Sec. 871. Attorney General

* * * * *

(b) Rules and regulations

The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.

* * * * *

Sec. 903. Application of State law

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.

APPENDIX G

CODE OF FEDERAL REGULATIONS

TITLE 21-FOOD AND DRUGS

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

Sec. 1306.04 Purpose of issue of prescription.

(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. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. 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. 829) 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.

* * * * *

APPENDIX H

OREGON REVISED STATUTES

127.800. Definitions.

The following words and phrases, whenever used in ORS 127.800 to 127.897, have the following meanings:

* * * * *

(7) "Informed decision" means a decision by a qualified patient, to request and obtain a prescription to end his or her life in a humane and dignified manner, that is based on an appreciation of the relevant facts and after being fully informed by the attending physician of:

(a) His or her medical diagnosis;

(b) His or her prognosis;

(c) The potential risks associated with taking the medication to be prescribed;

(d) The probable result of taking the medication to be prescribed; and

(e) The feasible alternatives, including, but not limited to, comfort care, hospice care and pain control.

(8) "Medically confirmed" means the medical opinion of the attending physician has been confirmed by a consulting physician who has examined the patient and the patient's relevant medical records.

* * * * *

127.805. Who may initiate a written request for medication.

(1) An adult who is capable, is a resident of Oregon, and has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified manner in accordance with ORS 127.800 to 127.897.

* * * * *

127.815. Attending physician responsibilities.

(1) The attending physician shall:

(a) Make the initial determination of whether a patient has a terminal disease, is capable, and has made the request voluntarily;

(b) Request that the patient demonstrate Oregon residency pursuant to ORS 127.860;

(c) To ensure that the patient is making an informed decision, inform the patient of:

(A) His or her medical diagnosis;

(B) His or her prognosis;

(C) The potential risks associated with taking the medication to be prescribed;

(D) The probable result of taking the medication to be prescribed; and

(E) The feasible alternatives, including, but not limited to, comfort care, hospice care and pain control;

(d) Refer the patient to a consulting physician for medical confirmation of the diagnosis, and for a determination that the patient is capable and acting voluntarily;

(e) Refer the patient for counseling if appropriate pursuant to ORS 127.825;

(f) Recommend that the patient notify next of kin;

(g) Counsel the patient about the importance of having another person present when the patient takes the medication prescribed pursuant to ORS 127.800 to 127.897 and of not taking the medication in a public place;

(h) Inform the patient that he or she has an opportunity to rescind the request at any time and in any manner, and offer the patient an opportunity to rescind at the end of the 15 day waiting period pursuant to ORS 127.840;

(i) Verify, immediately prior to writing the prescription for medication under ORS 127.800 to 127.897, that the patient is making an informed decision;

(j) Fulfill the medical record documentation requirements of ORS 127.855;

(k) Ensure that all appropriate steps are carried out in accordance with ORS 127.800 to 127.897 prior to writing a prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner; and

(L)(A) Dispense medications directly, including ancillary medications intended to facilitate the desired effect to minimize the patient's discomfort, provided the attending physician is registered as a dispensing physician with the Board of Medical Examiners, has a

current Drug Enforcement Administration certificate and complies with any applicable administrative rule; or

(B) With the patient's written consent:

(i) Contact a pharmacist and inform the pharmacist of the prescription; and

(ii) Deliver the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, the attending physician or an expressly identified agent of the patient.

(2) Notwithstanding any other provision of law, the attending physician may sign the patient's death certificate.

127.820. Consulting physician confirmation. Before a patient is qualified under ORS 127.800 to 127.897, a consulting physician shall examine the patient and his or her relevant medical records and confirm, in writing, the attending physician's diagnosis that the patient is suffering from a terminal disease, and verify that the patient is capable, is acting voluntarily and has made an informed decision.

* * * * *

127.885. Immunities; basis for prohibiting health care provider from participation; notification; permissible sanctions. Except as provided in ORS 127.890:

(1) No person shall be subject to civil or criminal liability or professional disciplinary action for participating in good faith compliance with ORS 127.800 to 127.897. This includes being present when a qualified patient takes the prescribed medication to end his or her life in a humane and dignified manner.

* * * * *