

## **WHETHER PHYSICIAN-ASSISTED SUICIDE SERVES A “LEGITIMATE MEDICAL PURPOSE” UNDER DEA REGULATIONS**

*A physician’s assisting in a patient’s suicide, even in a manner permitted by State law, is not a “legitimate medical purpose” within the meaning of a Drug Enforcement Agency regulation, and accordingly dispensing controlled substances for this purpose violates the Controlled Substances Act, which the DEA regulation implements.*

June 27, 2001

### **MEMORANDUM OPINION FOR THE ATTORNEY GENERAL**

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),<sup>1</sup> if the physician is immune from liability under a state law such as the Oregon “Death with Dignity Act” for assisting in a suicide in such a manner.<sup>2</sup> 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

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<sup>1</sup> 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 . . . 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).

<sup>2</sup> The “Death with Dignity Act” is codified at 3 Oregon Revised Statutes (O.R.S.) §§ 127.800-127.995 (1999).

\* Editor’s Note: Relying upon the analysis set forth in this memorandum opinion, the Attorney General subsequently promulgated an interpretive rule, which provided that “assisting suicide is not a ‘legitimate medical purpose’ within the meaning of 21 C.F.R. § 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act.” 66 Fed. Reg. 56,608 (Nov. 9, 2001). In *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Supreme Court held that the Attorney General was not statutorily authorized to issue the interpretive rule. *See id.* at 274-75.

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went into effect on October 27, 1997.<sup>3</sup> Prior to the effective date of the Oregon law, Representative Henry J. Hyde, Chairman of the House Judiciary Committee, and Senator Orrin G. Hatch, 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.<sup>4</sup>

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.<sup>5</sup>

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 or trafficking.”<sup>6</sup> 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

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<sup>3</sup> 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).

<sup>4</sup> 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).

<sup>5</sup> 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).

<sup>6</sup> 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).

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to override a state’s determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice.”<sup>7</sup>

### *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 “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

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<sup>7</sup> 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).

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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.<sup>8</sup> 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.

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).<sup>9</sup> Nothing in the language of the CSA or of the

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<sup>8</sup> 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).

<sup>9</sup> 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 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);

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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.<sup>10</sup> 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 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.

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*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).

<sup>10</sup> 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.”

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.*<sup>11</sup> 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-

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<sup>11</sup> 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.”).

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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 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

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common law, *see Glucksberg*, 521 U.S. at 711,<sup>12</sup> and at least forty States and territories have laws explicitly prohibiting the practice.<sup>13</sup> “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 (9<sup>th</sup> 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 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

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<sup>12</sup> 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).

<sup>13</sup> 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).

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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.<sup>[14]</sup>

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

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<sup>14</sup> 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*).

substance with the intent of assisting a suicide would not be under any current definition a ‘legitimate medical purpose.’<sup>15</sup>

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 undiagnosed depression and inadequately treated pain.<sup>16</sup> 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.<sup>17</sup>

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<sup>15</sup> 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 Leatire 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.

<sup>16</sup> 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).

<sup>17</sup> 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

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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.””<sup>18</sup> 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.

*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

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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 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.

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

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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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.<sup>[19]</sup>

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 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 is understandably apprehensive or afraid of his or her own

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<sup>19</sup> *Id.* at 2-5.

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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 foreseeably 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.<sup>20</sup> 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 implausible. 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 than 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”

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<sup>20</sup> *See, e.g.*, *Compassion in Dying*, 79 F.3d at 811.

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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.<sup>21</sup>

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 States in regulating the practice of medicine,<sup>22</sup> state law cannot abrogate the CSA or supersede its provisions in the event of conflict.<sup>23</sup> 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.”<sup>24</sup>

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);

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<sup>21</sup> 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.

<sup>22</sup> 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).

<sup>23</sup> See, e.g., *Rosenberg*, 515 F.2d at 198, n.14.

<sup>24</sup> See Oregon Deputy Attorney General Letter, *supra* note 6, at 6.

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*Oakland Cannabis Buyers'*, 121 S. Ct. at 1714.<sup>25</sup> 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, 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

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<sup>25</sup> 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.

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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.<sup>26</sup>

## *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 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.<sup>27</sup> 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.<sup>28</sup> Further, the Supreme Court repeatedly upheld the authority of Federal

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<sup>26</sup> 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.

<sup>27</sup> 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.”).

<sup>28</sup> 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

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prosecutors to bring such cases against physicians over the objection that the Harrison Act impermissibly encroached on a regulatory power exclusively reserved to the States.<sup>29</sup> The CSA was intended “to strengthen rather than to weaken the prior drug laws.”<sup>30</sup> 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.<sup>31</sup>

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,<sup>32</sup> 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 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, 91<sup>st</sup> 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

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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.”).

<sup>29</sup> 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).

<sup>30</sup> *Moore*, 423 U.S. at 139.

<sup>31</sup> 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).

<sup>32</sup> 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.

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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”).<sup>33</sup>

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.<sup>34</sup> 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 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.<sup>35</sup> Members of Congress also explained that the 1984 amendments were intended to

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<sup>33</sup> *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.”).

<sup>34</sup> *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”).

<sup>35</sup> *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).

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“expand[] the standards for practitioner registration beyond the current exclusive reliance upon authorization by the practitioner’s own jurisdiction.”<sup>36</sup>

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 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**

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

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

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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.”<sup>37</sup> On the contrary, as we have just 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.<sup>38</sup> 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 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.<sup>39</sup>

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<sup>37</sup> 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 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.

<sup>38</sup> 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).

<sup>39</sup> See *Moore*, 423 U.S. at 132-33.

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 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 contorting 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

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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.<sup>40</sup> Indeed, it seems to 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 necessarily 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.<sup>41</sup> So do, *e.g.*, administrative determinations as to what constitute “excessive profits” on government contracts, *see Lchter 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 S. Ct. 903, 912 (2001).<sup>42</sup> As a matter of administrative practice, there was nothing

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<sup>40</sup> We note that the 1998 Letter was *itself* an administrative interpretation that assumed a particular view of public policy.

<sup>41</sup> 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.

<sup>42</sup> 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).

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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.

/s/  
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