No.: 04-623

IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Writ of Certiorari
To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR THE PATIENT-RESPONDENTS

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QUESTION PRESENTED

Exercising its traditional police powers, Oregon enacted a law that empowers mentally competent, terminally ill Oregonians to request and receive a prescription from their physician for medications to choose the time, place, and manner of their impending deaths. In enacting and amending the Controlled Substances Act (CSA), did Congress clearly authorize the Attorney General to determine that physicians and pharmacists acting in accordance with Oregon law have violated the CSA?

PARTIES TO THE PROCEEDING

Petitioners are Alberto R. Gonzales, Attorney General of the United States; Karen Tandy, Administrator of the Drug Enforcement Administration; Kenneth W. McGee, Assistant Special Agent-in-Charge of the Portland Office of the Drug Enforcement Administration; the United States of America; the United States Department of Justice; and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, John Doe #1 and Don W. James.

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OPINIONS BELOW

The opinion of the Court of Appeals, Pets. App. 1a-63a, is reported at *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004). The opinion of the District Court, Pets. App. 64a-97a, is reported at *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002).

STATEMENT OF JURISDICTION

The judgment of the Court of Appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11, 2004. Pets. App. 98a-99a. The petition for a writ of certiorari was filed on November 9, 2004, and was granted on February 22, 2005. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

Certain provisions of the Controlled Substances Act ("CSA") Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. §§ 801 *et seq.*), and a regulation promulgated thereunder, 21 C.F.R. § 1306.04, are set out in the Petitioners' Appendix at Pets. App. 149a-161a. Certain provisions of the Oregon Death with Dignity Act (the "Dignity Act") are set out in the Petitioners' Appendix at Pets. App. 162a-165a.

STATEMENT OF THE CASE

Congress enacted the CSA as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970. As this Court recently recognized, the CSA was designed "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Gonzales v. Raich*, 545 U.S. ___, 125 S. Ct. 2195, 2203 (2005) (footnote omitted); *see also* H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. (1970) ("HR 91-1444"), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567, 9th Cir. SER at 3[1] (noting that the CSA's principal purpose was "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States"). As the House Committee Report regarding the bill that became the CSA explained:

> The bill provides for control * * * of problems related to drug abuse through registration of manufactur-

[1] Citations to Patient-Respondents' 9th Circuit Supplemental Excerpts of Record are cited hereto as "9th Cir. SER at ___"; citations to Petitioners' Appendix to the Petition for a Writ of Certiorari are cited hereto as "Pets. App. at ___"; citations to Patient-Respondents' Appendix to its Brief in Opposition to Petition for a Writ of Certiorari are cited hereto as "Pet. Opp. App. at ___."

> ers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.

Id. at 4569, 9th Cir. SER at 5 (quoted in *United States v. Moore*, 423 U.S. 122, 135 (1975)).

The provisions of the CSA are overwhelmingly directed toward the registration requirements for individuals engaged in the manufacture, distribution and sale of scheduled drugs and the enforcement provisions for any violation. It is silent as to the regulation of the practice of medicine. Indeed, the CSA manifests Congress' intent to delegate to the States the power to register those who have legitimate dealings with controlled substances, and not any intent for the Attorney General to define how those professionals practice medicine. *See* 21 U.S.C. § 801a(1) (the need to control "illicit trafficking" of psychotropic substances); *id.* § 801(3) (legislation to address "traffic in controlled substances"); *see also Raich*, 125 S. Ct. at 2203 n.20 (citing same). The legislative history similarly confirms that Congress did not intend to regulate medical practices that are legal under state law and that have no relation to drug abuse, trafficking or diversion. *See Moore*, 423 U.S. at 135.[2]

[2] The overwhelming majority of the remarks of various members of Congress highlight that the CSA was intended to address the problems of drug abuse and trafficking of controlled substances, and not the regulation of the practice of medicine. *See, e.g.*, 116 Cong. Rec. 977 (1970), 9th Cir. SER at 27 (Sen. Dodd) (the CSA "is intended to deal with the control of the illicit drug traffic, the diversion of legal drugs into illegal and non-medical channels, and the enforcement of the drug laws by the Justice Department"); *id.* at 1690, 9th Cir. SER at 30 (Sen. Tower) (the CSA addresses "drugs legally produced in this country [that] are diverted through illicit channels to non-medical use" and "reduce the volume of drugs illegally produced, diverted and smug-

Congress amended the CSA in 1984 when it adopted the Dangerous Drug Diversion Control Act (the "DDDCA"). As its title reflects, this legislation was aimed squarely at the diversion of drugs out of the closed medical system:

> [These amendments] are intended to address the severe problem of diversion of drugs of legitimate origin into the illicit market. Diversion of legally produced drugs into illicit channels is a major part of the drug abuse problem in the United States.

S. Rep. No. 98-225, 98th Cong., 2d Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3442, 9th Cir. SER at 80; *see also Trawick v. DEA,* 861 F.2d 72, 75 (4th Cir. 1988) (noting the 1984 Act "specifically targeted dispensing practitioners who abused their registrations by diverting legitimate, prescription drugs to illegitimate uses").[3]

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gled"); *id*. at 33,297, 9th Cir. SER at 31 (Rep. Madden) ("Title II of the bill provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal."); *id*. at 33,311, 9th Cir. SER at 33 (Rep. Clancy) (the CSA is intended to "significantly reduce the widespread diversion of drugs out of legitimate channels into illicit markets"); *id*. at 33,317, 9th Cir. SER at 35 (Rep. Monagan) (Under the CSA, "stringent registration requirements will be imposed upon manufacturers, wholesalers, and retailers in the legitimate drug distribution chain to prevent the diversion of legally produced drugs into the illicit drug traffic.").

[3] The DDDCA was enacted to address limitations in various state laws dealing with the diversion of drugs. *See* S. Rep. No. 98-225, 1984 U.S.C.C.A.N. at 3448, 9th Cir. SER at 86; s*ee also id.* 3448-3449, 9th Cir. SER at 86-87. The remarks of House and Senate members regarding the DDDCA establish that Congress adopted this legislation to prevent the diversion of legitimate drugs into illicit markets. *See, e.g.*, 130 Cong. Rec. 1,586 (1984), 9th Cir. SER at 90 (Sen. Laxalt) ("Current

For the last several decades, and almost entirely without reference to the CSA, the nation has been grappling with complex issues of health policy and individual liberty at the end of life. Modern medicine can now extend the dying process to a point that many terminally ill patients find intolerable. A pair of cases filed in the early 1990s, one in the State of New York and the other in the State of Washington, sought recognition that mentally competent, terminally ill patients have a right protected under the U.S. Constitution's guarantees of liberty and equality to choose to hasten their impending deaths by obtaining medications prescribed by their physicians for this purpose. These cases began to wind their ways through the federal judiciary. *See, e.g., Quill v. Koppell,* 870 F. Supp. 78 (S.D.N.Y. 1994); *Glucksberg v. Washington,* 850 F. Supp. 1454 (W.D. Wa. 1994).

In the legislative arena, in November 1994, Oregon voters approved the Oregon Death With Dignity Act (the "Dignity Act"). However, implementation of the Dignity Act was delayed by litigation until February of 1997. *See Lee v. Oregon*, 107 F.3d 1382, 1386, 1392 (9th Cir. 1997).

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law—the Controlled Substances Act of 1970—provides necessary regulation of manufacturers and distributors, but it does not adequately cover the practitioner level of the distribution chain, the level at which 80 to 90 percent of current diversion of drugs into illicit markets takes place."); *id.* at 25,849, 9th Cir. SER at 91 (Rep. Sawyer) ("Diversion is the connotation for the various means by which legitimate medical controlled substances are diverted from proper use to improper use. Invalid prescriptions and pharmacy robberies are two types of retail level diversion. While much of the drug enforcement focus has been placed on the interdiction of improperly imported substances, the problem of domestic diversion has quietly grown to staggering proportions."). It was the DDDCA that added the "inconsistent with the public interest" revocation provisions of § 824(a)(4); this provision is discussed *infra* at Section II.C of the Argument.

Four months later, on June 27, 1997, this Court issued its decisions in *Washington v. Glucksberg,* 521 U.S. 702 (1997), and *Vacco v. Quill,* 521 U.S. 793 (1997). In *Glucksberg*, the Court concluded:

> Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society.

521 U.S. at 735. Concurring with the Court, Justice O'Connor explained:

> There 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. * * * [T]he * * * 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 (O'Connor, J., concurring) (quotation marks omitted) (quoting *Cruzan v. Director, Mo. Dept. of Health,* 497 U.S. 261, 292 (1990) (O'Connor, J., concurring)).

In November 1997, the citizens of Oregon once again voted on the Dignity Act, with 60% voting in favor of it. *See Official Results State Measure 51*, Nov. 4, 1997 State Wide Special Election *available at*: http://www.sos.state.or.us/elections/nov497/other.info/m51abst.htm; 9th Cir. SER at 103.

In response to requests by members of Congress in late 1997, including then-Senator Ashcroft, Attorney General Reno analyzed the question of whether practitioners acting

in accordance with the Dignity Act contravened the CSA. On June 5, 1998, Reno answered, definitively, "No":

> The Department has reviewed the issue thoroughly and has concluded that 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.

Letter from U.S. Attorney General Janet Reno to Henry J. Hyde (June 5, 1998) ("Reno Letter"), Pet. Opp. App. at 50a. Reno explained that "[t]here 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." *Id.* at 52a.

Later that year the Dignity Act's Congressional opponents, again including then-Senator Ashcroft, introduced the Lethal Drug Abuse Prevention Act of 1998 (the "LDAPA"), *see* S. Rep. No. 105-372, *Lethal Drug Abuse Prevention Act,* 105th Congress, 2d Session (1998), 9th Cir. SER at 120, but it failed to reach the floor of the House or the Senate. *See* H.R. 4006 and S. 2151, 105th Congress (1998). They then introduced the Pain Relief Promotion Act of 1999 (the "PRPA"). *See* S. Rep. No. 106-299, *The Pain Relief Promotion Act*, 106th Congress, 2d Session (2000), 9th Cir. SER at 173. The PRPA passed the House in 1999 and made it out of the Senate Judiciary Committee in 2000, but failed to reach a vote on the floor of the Senate. *See* H.R. 2260 and S. 1272, 106th Congress (1999). Both the LDAPA and the PRPA would have expanded the scope of the CSA to nullify the Dignity Act. Both failed.

Following the election of 2000, President Bush appointed Ashcroft to be U.S. Attorney General. Understandably concerned, Oregon's Attorney General wrote to Ashcroft, asking that Oregon be consulted in the event that the Department of Justice decided to reconsider the relationship between the CSA and the Dignity Act. Letter from Hardy Myers, Oregon Attorney General, to John Ashcroft, United States Attorney General (February 2, 2001), Pet. Opp. App. at 55a. In response, Ashcroft stated that he "would be happy to include [Oregon's] views" if he ever revisited the matter. Letter from Lori Sharpe, Director and Advisor to the U.S. Attorney General, to Hardy Myers, Oregon Attorney General (April 17, 2001), Pet. Opp. App. at 58a.

However, on November 6, 2001, without consulting or even notifying Oregon, Ashcroft announced that he had reversed his predecessor's decision. Under his new interpretation of the CSA—even without passage of the LDAPA or the PRPA—prescribing controlled substances under the Dignity Act would be a violation of the CSA and would result in the revocation of a practitioner's license. *See* 66 Fed. Reg. 56,607 (November 9, 2001), Pets. App. at 100a (the "Directive").

Respondents then filed this action. The District Court found that the Directive violated the CSA and permanently enjoined it. *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002). Pets. App. at 64a. The Court of Appeals, exercising its own jurisdiction to review the challenge to the Directive, held that the 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." *Oregon v. Ashcroft*, 368 F.3d 1118, 1120 (9th Cir. 2004), Pets. App. at 1a. This writ followed.

ARGUMENT

I. Ashcroft's Interpretations of the CSA and Its Regulations Are Not Entitled to Deference.

Petitioners contend that the Court of Appeals erred by failing to accord the Directive proper deference. Yet they provide no support for this assertion of executive power.[4]

An agency's action is subject to distinct standards of review based upon whether it interprets a statute or its own regulation. Some actions, as here, implicate both. Although the Directive states that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)," Pets. App. at 102a, Section 1306.04 does not authorize the Attorney General to suspend a health care provider's DEA registration. Thus, the Directive also relied upon the CSA itself in addition to Section 1306.04: "Such conduct by a physician * * * may render his registration * * * subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4)." *Id.* (quotation marks

[4] The question of the deference due Petitioners' interpretation of the CSA arises only if this Court finds that it cannot divine Congress's intent based upon its own analysis. *See General Dynamics Land Systems, Inc. v. Cline*, 540 U.S. 581, 600 (2004) ("Even for an agency able to claim all of the authority possible under *Chevron*, deference to its statutory interpretation is called for only when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent.") (citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446-48 (1987)); *see also* Resp. Oregon Br. at 30-31. For the reasons set forth by Respondent State of Oregon, Resp. Oregon Br. at 34-42, Patient-Respondents submit that the CSA is unambiguous and does not include the necessary clear statement of intent to displace the states' traditional regulation of medicine. (Patient-Respondents endorse and adopt the positions set forth by the State of Oregon; this brief is intended to complement the State's brief.) That said, the following discussion assumes that this Court does reach the question of deference and must decide whether, between the competing interpretations, the Petitioners' view is entitled to greater deference than that of the Respondents.

omitted). Petitioners therefore must defend Ashcroft's interpretation of both the statutory and regulatory provisions under this Court's separate standards.

A. Ashcroft's Interpretation of the CSA Is Not Entitled to Heightened Deference Under *Chevron.*

An agency's interpretation of a statute is entitled to one of two levels of deference—either the higher level of deference laid out by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or the lower level of respect described in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Until petitioning this Court, Ashcroft did not claim *Chevron* deference; indeed, he expressly relied upon *Skidmore* below. *See, e.g.*, Br. for Appellants, 2002 WL 32157019 at 22 and 38-40 (Sept. 23, 2002). And, while Petitioners now claim *Chevron* deference in Section I.B.2 of their opening brief, they do not explain why it is warranted. *See* Pets. Br. at 21.

As a threshold matter, an agency's interpretation of a statute is entitled to *Chevron* deference only if it "appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). If an agency passes the first test,[5] it still must establish the right to *Chevron* deference rather than *Skidmore* respect. This Court's recent decisions in

[5] Petitioners simply assume that Ashcroft was exercising authority accorded by the CSA when promulgating the Directive. As with the threshold question of whether it is necessary to reach a deference analysis, Respondent State of Oregon's Brief details why this is inaccurate. *See* Resp. Oregon Br. at 21-25. However, for the purposes of this discussion, it may be assumed that Ashcroft did possess such authority.

Barnhart v. Walton, 535 U.S. 212 (2002), and *Mead* identified eight factors to consider in selecting between *Chevron* and *Skidmore*: (1) the formality of interpretation; (2) the interstitial nature of the legal question; (3) the expertise of the agency; (4) the importance of the question to the administration of the statute; (5) the complexity of that administrative scheme; (6) the duration of consideration; (7) the consistency of interpretation; and (8) the care of consideration. *See Barnhart*, 535 U.S. at 222; *Mead*, 533 U.S. at 231-34; *see also James v. Von Zemenszky*, 301 F.3d 1364, 1365-66 (Fed. Cir. 2002) (discussing same). Petitioners neither analyzed these factors nor even cited *Barnhart* or *Mead*.

1. The *Mead* and *Barnhart* factors preclude *Chevron* deference.

a. *Interpretive rules such as the Directive are not entitled to Chevron deference. Chevron* deference is generally withheld from informal agency actions such as interpretive rulings. *Barnhart*, 535 U.S. at 222 ("[W]hether a court should give [*Chevron*] deference depends in significant part upon the interpretive method used * * *."). As this Court explained, interpretive rules

> are not entitled to the same deference as norms that derive from the exercise of [an agency's] delegated lawmaking powers. Instead, interpretations contained in formats such as opinion letters are 'entitled to respect' under [the] decision in *Skidmore v. Swift & Co.*, but only to the extent that those interpretations have the power to persuade.

Christensen v. Harris County, 529 U.S. 576, 587 (2000) (quoting *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991)) (citations and quota-

tion marks omitted); *see also Mead*, 533 U.S. at 232 ("[I]nterpretive rules * * * enjoy no *Chevron* status as a class."). Indeed, *Chevron* itself explained that it applied only to "legislative regulations." *Chevron*, 467 U.S. at 844.

In *Mead*, this Court recognized that "the overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication." *Mead*, 533 U.S. at 230 n.12. The Court then cited to twenty-seven separate examples of its own application of *Chevron* deference to formal agency actions, and only one to an informal rulemaking. *Id*. at 230-31 & nn.12-13.[6] Just last year this Court again refused to apply *Chevron* deference in a situation similar to the one here. *See Alaska Dept. of Environmental Conservation v. EPA*, 540 U.S. 461, 124 S. Ct. 983, 1001 (2004) (ruling an EPA "internal guidance memoranda * * * d[id] not qualify for the dispositive force described in *Chevron*") (citing *Christensen*, 529 U.S. at 587, and *Mead*, 533 U.S. at 234).

As Petitioners admit, the Directive is an "interpretive rule." *See* Pets. Br. at 8 ("On November 9, 2001, the Attorney General published an interpretive rule * * * that adopted the analysis of the OLC Memorandum."). The burden therefore falls to Petitioners to establish that the Directive is entitled to heightened deference under *Chevron*. They have not even attempted to meet this burden.

b. *Physician-assisted dying is not an interstitial gap in the CSA*. This Court, in *Barnhart*, accepted that an agency

[6] The *Barnhart* Court did not find any new examples. The lone case cited by the *Mead* and *Barnhart* Courts wherein an informal agency action received *Chevron* deference was *NationsBank of N.C., N.A. v. Variable Annuity Life Insurance Co.*, 513 U.S. 251 (1995), which hinged upon the extreme deference granted to the Comptroller of the Currency under longstanding precedent. *See Mead*, 533 U.S. at 231 n.13.

might receive *Chevron* deference where it employed informal rulemaking to plug a small hole in a regulatory scheme. *See Barnhart*, 535 U.S. at 214-215, 223-224 (accepting the Social Security Administration's definitions of "inability" and "expected to last," notwithstanding the informal method used to arrive at those definitions). Such is not the case here, as there was no such interstitial gap in the CSA with regard to physician-assisted dying. Indeed, there is no evidence that Congress ever considered the practice of physician-assisted dying when it adopted the CSA.

c. *The Department of Justice is not an expert in the field of medicine*. The Department of Justice is neither the Department of Health and Human Services nor the Surgeon General's Office, two federal agencies concerned with matters of medical policy. *See Oregon v. Ashcroft*, 368 F.3d at 1130 (noting that "that the Attorney General has no specialized expertise in the field of medicine"). In fact, the Attorney General was specifically denied the authority to make medical and scientific decisions under the CSA.

The original draft of the CSA would have given the Attorney General the unchecked authority to make medical and scientific decisions regarding drug control:

> Attorney General * * * may, upon his own motion * * * add, delete, or reschedule a substance as a controlled dangerous substance. Before so doing, the Attorney General shall request the advice in writing from the Secretary of Health, Education, and Welfare and from the Scientific Advisory Committee [appointed by the Attorney General] * * *. After considering the above factors, the Attorney General shall make findings with respect thereto and shall issue an order controlling the substance if he finds that the substance has a potential for abuse or that control is required * * *.

Legislation to Regulate Controlled Dangerous Substances and Amend Narcotics and Drug Laws, H.R. 17463, 91st Cong. § 201 (1970), 9th Cir. SER at 45-46. In other words, under the provision as originally written, the Attorney General had to request advice, but there was no requirement that he follow it.

After the scientific and medical communities expressed concern, and following lengthy testimony from numerous medical professionals and organizations,[7] Congress adopted the present version of the CSA, which places responsibility for such decisions in the Department of Health and Human Service:

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[7] For example, the Chairman of the AMA's Committee on Alcoholism and Drug Dependence testified as follows:

> The bill gives the Attorney General authority to control dangerous substances. This authority includes the scheduling of drugs. * * *
>
> There are several considerations which go into a decision to control a drug, and the bill, in fact, lists nine of them. Many of these considerations are exclusively medical and scientific in nature * * *. Others are exclusively in the area of police power * * * Still others involve both medico-scientific and enforcement aspects * * *.
>
> We believe the Secretary of HEW is in a favorable situation to provide for the necessary basic studies and to evaluate recommendations for classifying drugs. He should have the final decision on the medical and scientific aspects of scheduling, and scheduling should be predicated on his decision.

91st Cong. at 358, 9th Cir. SER at 48 (statement of Dr. Henry Brill, Chairman, Committee on Alcoholism and Drug Dependence of American Medical Association's Council on Mental Health). Similarly, a representative of the Pharmaceutical Manufactures Association testified: "We feel very strongly that determinations and ultimate decision on scientific and medical matters must be made by qualified medical and scientific personnel on the basis of medical and scientific evidence." *Id.*, at 437, 9th Cir. SER at 53 (statement of Mr. Bruce J. Brennan, Vice President and General Counsel, Pharmaceutical Manufacturers Association).

> The Attorney General shall, before initiating proceedings [to Schedule a drug], request from the Secretary [of Health and Human Services] a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled * * *. The recommendations of the Secretary to the Attorney General *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 or other substance.

21 U.S.C. §811(b), Pet. Opp. App. at 1a (emphasis added).

If Congress withheld from the Attorney General the lesser power to make medical and scientific decisions as to the scheduling of drugs, Congress certainly did not intend to grant the Attorney General the greater power to decide—on a national basis—what constitutes a legitimate medical practice.

d. *Federal prohibition of state-regulated physician-assisted dying does not impact the CSA's administration*. As the courts' analyses below make clear, the CSA was not intended to address the situation covered by the Dignity Act. Pets. App. at 13a-14a & n.7; Pets. App. at 89a-92a. Rather, "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Raich*, 125 S. Ct. at 2203 (footnote omitted).

e. *The Dignity Act does not make the CSA's administrative scheme more complex.* The CSA's administrative

scheme is made no more complex by protecting Oregon's medical practitioners from prosecution in the limited circumstances of the Dignity Act. Indeed, the Directive has the opposite effect. If it were implemented, DEA agents would be required to determine a doctor's intent, *post-facto*, whenever a patient died after obtaining a prescription from that patient's doctor.

f. *There is no evidence that the Attorney General considered the Directive for a substantial period of time*. One cannot tell how long Ashcroft considered his position, as the process occurred behind closed doors.

g. *The Directive is inconsistent with another Attorney General's prior interpretation*. The Directive is inconsistent with the Department's prior definitive position. In 1998, Attorney General Reno "concluded 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." Reno Letter, Pet. Opp. App. at 53a. The Ashcroft Directive is an improper reversal of this rule.

h. *The Attorney General did not consider the matter with care*. Ashcroft's involvement with the legal issues implicated at the end of life traces back to his role as the Governor of Missouri during the lead-up to *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990). Upon entering the Senate, he assumed a leading role in congressional efforts to amend the CSA to prohibit the practice of physician-assisted dying. *See Oregon v. Ashcroft*, 368 F.3d at 1123 & n.4.

After being appointed Attorney General in 2000, Ashcroft reversed his predecessor's decision. This process took place under a cloak of secrecy and relied almost exclusively upon

pre-*Glucksberg* materials and analysis. Neither the OLC Memo nor the Directive indicate that Ashcroft considered the available data that Oregon had compiled from three years of experience with the Dignity Act.

By November 6, 2001, teams of epidemiologists from both the federal and Oregon governments had prepared three annual reports based upon the experience of Oregon's doctors and patients.[8] Given the parade-of-horribles the Dignity Act's opponents espoused in opposing its passage—a litany which the OLC Memo repeated, *see* OLC

[8] There are now a total of seven annual reports on Oregon's experience with the Dignity Act: A. E. Chin *et al*., *Oregon's Death with Dignity Act*: *The First Year's Experience*, Department of Human Resources, Oregon Health Division Center for Disease Prevention and Epidemiology, February 18, 1999 ("First Annual Report"), 9th Cir. SER at 281; A. D. Sullivan *et al.*, *Oregon's Death with Dignity Act: The Second Year's Experience*, Department of Human Services, Oregon Health Division Center for Disease Prevention and Epidemiology, February 23, 2000 ("Second Annual Report"), 9th Cir. SER at 329; K. Hedberg, *Oregon's Death with Dignity Act: Three Years of Legalized Physician-Assisted Suicide*, Department of Human Services, Oregon Health Division Center for Disease Prevention and Epidemiology, February 22, 2001 ("Third Annual Report"), 9th Cir. SER at 361; *Fourth Annual Report on Oregon's Death with Dignity Act*, Department of Human Services, Office of Disease Prevention and Epidemiology, February 6, 2002 ("Fourth Annual Report"), 9th Cir. SER at 384; K. Hedberg *et al.*, *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 NEW ENG. J. MED. 961 (March 6, 2003) ("Fifth Annual Report"), Pet. Opp. App. at 46a; *Sixth Annual Report on Oregon's Death with Dignity Act*, Oregon Department of Human Services, March 10, 2004 ("Sixth Annual Report"), Pet. Opp. App. at 11a; *Seventh Annual Report on Oregon's Death with Dignity Act*, Oregon Department of Human Services, March 10, 2005 ("Seventh Annual Report"), *available at* http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf. All of these reports can be accessed in .pdf format on the Oregon Department of Human Services' website, *available at* http://egov.oregon.gov/DHS/ph/pas/ar-index.shtml.

Memo at 10 n.17, Pets. App. at 122a-124a—the most probative evidence on the question of whether physician-assisted dying *actually* poses a threat to the public is the substantive data gathered pursuant to the Dignity Act.[9] Yet this wealth of information was not cited once by the OLC Memorandum nor the Directive, and there are no findings or analyses anywhere that purport to show how these data evidence the alleged threat to the public interest. Such studied ignorance is a failure to consider the matter with care, and by itself grounds for striking the Directive. *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983) ("*MVMA*") ("[A]n agency rule would be arbitrary and capricious if the agency * * * entirely failed to consider an important aspect of the problem.").

The parallels between *MVMA* and the present case are striking. The *MVMA* Court reviewed the National Highway Traffic Safety Administration's ("NHTSA") 1982 rescission of a 1977 regulation, which regulation would have required passive restraints—airbags or automatic seatbelts—in all cars made after 1984. *Id.* at 38-39. The 1982 rescission explained that the NHTSA was no longer able to find, as it had in 1977, that the requirement would produce any significant benefit. In 1977, the agency assumed a 60/40 split of airbags to automatic seatbelts. By 1981, however, it was clear that automobile manufacturers would install automatic seatbelts in 99% of the new cars, and that most automatic seatbelts could easily be detached. Thus, reasoned the NHTSA, there was no rationale for requiring either type of restraint. *Id.*

[9] These data show not only that regulated physician-assisted dying does not pose a threat to the public, they suggest that the practice serves the public interest. *See* Section II.B, *infra*.

This Court disagreed. Given the admitted effectiveness of airbags, the "logical response" to the industry's shift would be to require airbags. *Id.* at 48. "[T]his alternative way of achieving the objectives of the Act should have been addressed and adequate reasons given for its abandonment. But the agency * * * did not even consider the possibility in its 1981 rulemaking. Not one sentence of its rulemaking statement discusses the airbags-only option." *Id.* Continuing, the Court stated:

> There are no findings and no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such * * * practice * * *. Expert discretion is the lifeblood of the administrative process, but unless we make the requirements for administrative action strict and demanding, *expertise,* the strength of modern government, can become a monster which rules with no practical limits on its discretion.

Id. (quoting *Burlington Truck Lines, Inc. v. United States,* 371 U.S. 156, 167 (1962)) (emphasis in original).

Just as in *MVMA*, the Oregon data was not cited once in the OLC Memo, nor is there any evidence that the data were considered behind the Department's closed doors. Neither was Oregon's evidence mentioned in the Directive. There are no findings or analysis anywhere regarding how this data relates to the claimed threat to the public interest. Thus, just as in *MVMA*, this Court should not accord Ashcroft's interpretation deference.

In sum, all of the factors laid out in *Barnhart* and *Mead* indicate that the Directive is not entitled to *Chevron* deference. At most it warrants only *Skidmore* respect.

2. Ashcroft's interpretation is entitled to little respect under *Skidmore*.

Under *Skidmore*, an agency's interpretation of a statute may be entitled to respect, but the value thereof "depend[s] 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 * * * ." *Skidmore*, 323 U.S. at 140; *see also Christensen*, 529 U.S. at 587 (noting that, under *Skidmore*, interpretations are due respect "only to the extent that those interpretations have the power to persuade") (quotes and citation omitted). Ashcroft's interpretation fails the *Skidmore* criteria—which Petitioners did not analyze—and, as such, was given the proper amount of respect by the courts below.

a. *Ashcroft did not thoroughly consider the matter.* Although Ashcroft told Oregon's Attorney General that Ashcroft "would be happy to include [Oregon's] views" if he ever revisited the CSA and physician assisted-dying, he neither informed Oregon of the reconsideration nor included its views. Letter from Sharpe to Myers (April 17, 2001), Pet. Opp. App. at 58a. Neither did he consider any of the data gathered during the first four years of the Dignity Act's existence. As the District Court below observed, by "ignor[ing] his earlier promise to the Oregon Attorney General to ascertain Oregon's views," Ashcroft "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 [Respondents] in these proceedings." *Oregon v. Ashcroft*, 192 F. Supp. 2d at 1083.

b. *Ashcroft's legal reasoning lacks merit.* The only legal precedent cited in the Ashcroft Directive is *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). Pets. App. at 101a (citing same). Yet Petitioners abandoned this authority in the district court and mentioned it only in passing in the Court of Appeals. *See Oregon v. Ashcroft*, 192 F. Supp. 2d at 1092 n.20 (noting Petitioner "abandoned the notion, espoused in the Ashcroft directive, that the Supreme Court's decision in [*Oakland Cannabis*] is somehow controlling on the issues presented here") (citation omitted), Pets. App. at 94a. Petitioners' inconsistent reliance upon *Oakland Cannabis* is not surprising, as the sole holding therein was that "medical necessity is not a defense to manufacturing and distributing marijuana." 532 U.S. at 494. The doctrine of medical necessity is not at issue here, nor are Schedule I substances. Schedule I substances are those which have been determined to have "no currently accepted medical use," whereas those prescribed in accordance with the Dignity Act are Schedule II substances which do. *See* 21 U.S.C. §§ 812 (b)(1) and (2); *see generally*, *Raich*, 125 S. Ct. at 2203-04. Thus, *Oakland Cannabis* provides no support for the Directive.

c. *Ashcroft's interpretation is inconsistent with previous interpretations.* Lastly, as noted above, Ashcroft's interpretation conflicts with that of his predecessor, Attorney General Reno, who "concluded 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." Reno Letter, Pet. Opp.

App. at 53a; *see, Hall v. EPA*, 273 F.3d 1146, 1156 (9th Cir. 2001) (refusing to defer to an "interpretation advanced [by the E.P.A. that] does not fit with prior interpretations").

Based upon these factors, Ashcroft's interpretation of the CSA should receive no more respect than an ordinary party's.

B. Ashcroft's Interpretation of Section 1306.04 Is Not Entitled to *Seminole Rock* Deference.

Just as with its power to interpret statutes, an agency's power to interpret its regulations is neither unbounded nor unchecked. Courts "are not obliged to stand aside and rubberstamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *NLRB v. Brown*, 380 U.S. 278, 291 (1965). Instead, under *Seminole Rock*, such interpretations must be struck if "plainly erroneous or inconsistent with the regulation." *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *see Norfolk Southern Railway, Co. v. Shanklin*, 529 U.S. 344, 356 (2000) ("Although generally an agency's construction of its own regulations is entitled to substantial deference, no such deference is appropriate here. Not only is the [agency's] interpretation inconsistent with the text of [the rule], but it also contradicts the agency's own previous construction * * *.") (citations omitted). Although Petitioners cite certain cases from the *Seminole Rock* line of precedent, they again simply assume deference without analysis. *See* Pets. Br. at 21.

1. The Ashcroft Directive brings Section 1306.04 too close to the constitutional line.

Ashcroft's interpretation of Section 1306.04 effectively federalizes the practice of medicine, and thus pushes the CSA too close to a constitutional line over which Congress was careful not to step. *See, e.g., Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless construction is plainly contrary to the intent of Congress.").[10] The issue here is not whether Congress *could* federalize control of the practice of medicine. Rather, it is whether Congress *did* federalize control of the practice of medicine, and in doing so gave a *clear statement* of its intent to do so. *See Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173-74 (2001) ("*SWANCC*") (refusing to analyze several constitutional questions where there was no clear statement from Congress that Congress intended to

[10] Section 1306.04 is a regulation rather than a statute. However, the canon of constitutional avoidance still applies. The "judiciary is the final authority on issues of statutory construction," *Chevron*, 467 U.S. at 843, and, of course, an agency may not assume powers by regulation that were not granted to it by statute. *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988) (an "agency's power to promulgate legislative regulations is limited to the authority delegated by Congress"); *accord La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act * * * unless and until Congress confers power upon it."). Thus, the judiciary is also the final authority on whether an agency's interpretation of a regulation has stretched it beyond its permissible scope, particularly where the agency's interpretation raises constitutional issues.

alter "the federal-state framework by permitting federal encroachment upon a traditional state power").[11] As is explained more fully in the brief of Respondent State of Oregon, there is no such clear statement in the CSA. In the absence of a clear statement from Congress authorizing the Attorney General to assume control over the practice of medicine, Ashcroft's interpretation is "plainly erroneous." *Seminole Rock*, 325 U.S. at 414.

2. The Ashcroft Directive pushes Section 1306.04 beyond the boundaries of the CSA.

Ashcroft's interpretation of Section 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, 9th Cir. SER at 80; H.R. Rep No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 9th

[11] This Court and others have long recognized "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *see also, e.g., Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975) ("We recognize that the States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions."); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (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 state's discretion in that field extends naturally to the regulation of all professions concerned with health."); *cf. Cruzan*, 497 U.S. at 284 (recognizing the States' right to govern end-of-life decisions); *Bristol Myers Squibb v. Shalala*, 91 F.3d 1493 (D.C. Cir. 1996) (noting that the Food Drug and Cosmetic Act does not allow the FDA to regulate how a physician prescribes a medication once approved); *see generally* Resp. Oregon Br. at 27-47.

Cir. SER at 2. To the extent that federal regulation of controlled substances does impact medical care, this Court has, when addressing the matter, seen no role for the Attorney General in determining the appropriate methods of medical practice under Section 1306.04. *See United States v. Moore*, 423 U.S. at 144 (recognizing decisions regarding "the appropriate methods of professional practice" are entrusted to what is now the Secretary of Health and Human Services) (citation omitted). While the 1984 amendments to the CSA extended the Attorney General's authority over federal registration of practicing physicians, the DDDCA neither impacted Section 1306.04 nor provided the Attorney General the authority to determine the scope of legitimate medical practice. Indeed, Section 1306.4 long *preceded* these amendments and thus clearly was not adopted to implement them.

3. Section 1306.04 was not intended to federalize the practice of medicine.

An agency must have some regulatory scheme in mind when it promulgates a rule and may not later depart from such scheme without promulgating new rules. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (holding a court should not defer to an agency's interpretation where 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") (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430 (1988)); *see also Caruso v. Blockbuster-Sony Music Entertainment Centre*, 193 F.3d 730, 737 (3d Cir. 1999) ("An agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning.") (citation

omitted). Yet this is exactly what Ashcroft attempted to do by reinterpreting a thirty-year-old regulation to preempt the states' traditional role as the regulators of the medical profession within their borders.

In 1971, the Bureau of Narcotics and Dangerous Drugs published notice of the "Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970." *Purpose of Issue of Prescription*, 36 Fed. Reg. 4948 (1971), Pet. Opp. App. at 3a-4a. The proposed regulation included no official commentary and almost went unnoticed. The only public comment was summarized as follows: "The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § [1306.04] to determine the legitimacy of a prescription. The language has been revised to require knowledge." *Comments and Objections to Part 306*, 36 Fed. Reg. 7777 (1971), Pet. Opp. App. at 5a-7a. The regulation was adopted substantially unchanged and has since remained untouched and largely unconstrued. *Purpose of Issue of Prescription*, 36 Fed. Reg. 7799 (1971), Pet. Opp. App. at 8a-9a.

Neither the regulation itself nor its lone public comment even hinted at Ashcroft's expansive interpretation. If it was intended as Ashcroft later interpreted it—*i.e.*, to usurp the states' traditional role as the regulators of the medical profession[12]—the proposed regulation should have been accompanied by agency commentaries and would have prompted untold hundreds of public comments from medical groups and the states. Moreover, it is unlikely that a shift of this magnitude in the role of the states within our federal system would have been achieved by means of a

[12] *See* n.11, *supra*.

single regulation, routinely promulgated amidst many others. The obvious conclusion is that the Bureau did not intend to federalize the field of medicine. *Thomas Jefferson Univ.*, 512 U.S. at 512.

Moreover, under the CSA in 1971, physicians were entitled to distribute controlled substances so long as they complied with state law, and *only* state law. *See* Pub. L. No. 91-513, 84 Stat. 1253, 1255 (§§ 303(f), 304(a)). Authorization to prescribe drugs under the CSA at that time turned on the decisions of state licensing and law enforcement authorities. *See id.* Given the statutory boundaries of the CSA as it existed in 1971, neither Congress nor the Attorney General could have intended Section 1306.04 to give the Attorney General the power to impose a uniform federal standard of medical practice. If Section 1306.04 could not have been read to federalize the practice of medicine in 1971, it cannot be interpreted to go so far in 2001. *Thomas Jefferson Univ.*, 512 U.S. at 512.

4. The Ashcroft Directive is inconsistent with the Department of Justice's prior interpretation.

Lastly, the Ashcroft Directive warrants no deference because it is contrary to Attorney General Reno's 1998 interpretation of the same regulation. *See Norfolk S. Railway Co.*, 529 U.S. at 356 (striking agency's interpretation where it was inconsistent with prior construction). As this Court recently wrote in an analogous situation, "[a]lthough generally an agency's construction of its own regulations is entitled to substantial deference, no such deference is appropriate here. Not only is the [agency's] interpretation inconsistent with the text of [the regulation], but it also contradicts the agency's own previous construction * * * ."

Id. (citation omitted); *see also SWANCC,* 531 U.S. at 168 (noting that the agency interpretation before the Court reversed the agency's prior interpretation of the same rule, yet the agency had "put forward no persuasive evidence that the [agency] mistook Congress' intent" the first time); *Hall*, 273 F.3d at 1156.

Given these faults, the Directive is "plainly erroneous [and] inconsistent with the regulation." *Seminole Rock*, 325 U.S. at 414. Ashcroft's interpretation of Section 1306.04 is therefore entitled to no deference.

II. Petitioners' Contention that the Directive Sets Forth the "Prevailing View" of Physician-Assisted Dying is Unsupported and Unsupportable.

Ashcroft purported to justify his conclusion that practice comporting with the Dignity Act is not a "legitimate medical purpose" by disregarding the most salient and authoritative information on the practice, and by positing the existence of supposedly monolithic opposition to it.[13] Yet both the size and the uniformity of this opposition is chimerical. Ashcroft ignored copious evidence of wide-ranging and growing support for legalization of physician-assisted dying. For at least the last two decades, a majority of the public has *favored* permitting physician-assisted dying under certain circumstances, and the proportion of the public supporting such legalization now dwarfs that of the opposition. Evidence readily available to Ashcroft in 2001 also revealed that, far from forming a consensus, the medical community is divided on the question of legalizing physician-assisted dying. Ashcroft's determination that

[13] Pets. App. at 102a (OLC Memo sets forth legal basis for the Ashcroft directive); *id*. at 113a-130a (OLC Memo's discussion of whether physician-assisted dying serves a "legitimate medical purpose").

physician-assisted dying threatened the public health and safety, even if stringently regulated by state law, is unsupported. Ashcroft did not so much as acknowledge the data in the three official reports that Oregon had published regarding its experience with physician-assisted dying since 1998.[14] These reports established that the risks forecast by opponents of the Dignity Act—such as involuntary administration of life-ending drugs, exploitation of vulnerable individuals, and the substitution of physician-assisted dying for effective pain management—had not come to pass.

Ashcroft's disregard of the Oregon data is significant not only for its arbitrariness and capriciousness; it goes to the heart of the Directive's violation of the CSA. The Directive decreed that a practitioner prescribing controlled substances for physician-assisted dying might have his or her license to prescribe controlled substances revoked under 21 U.S.C. § 824(a)(4). Pets. App. at 102a. Yet, as the Court of Appeals noted below, the Attorney General may revoke a practitioner's license as inconsistent with the public interest only if he considers *all five factors* specified in § 823(f). The Directive violates § 823(f) because it authorizes revocation without the required consideration of several of these factors and, as to the last factor, incorrectly assumes that physician-assisted dying is "conduct which may threaten the public health and safety."

As more fully discussed below, these flaws in logic and the law are fundamental and insurmountable. The permanent injunction of the Directive should be upheld.

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[14] *See* Third Annual Report; Second Annual Report; First Annual Report.

A. The Public, the Medical Community, and the States Are Divided on the Question of Physician-Assisted Dying.

The OLC Memo, on which Ashcroft relied, asserted the existence of uniform opposition to the legalization of physician-assisted dying by selectively quoting this Court's *Glucksberg* decision and *amici* briefs and law review articles opposing physician-assisted dying, and by exploring the official positions of but two medical associations. Pets. App. at 113a-130a.[15] Ashcroft adopted the OLC Memo's analysis wholesale while ignoring the abundance of data that refuted the notion of unvariegated opposition. For example, a Harris poll published just two months after the Directive found that, by 65% to 29%, a substantial majority of American adults favored legalization of physician-assisted dying for a terminally ill patient who so chooses.[16] Another group of studies published in 1996 found that between 63% and 90% of people with a terminal illness

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[15] Cobbling together snippets of federal enactments other than the CSA and pronouncements of political appointees, the OLC Memo also contended that federal policy opposed legalization of physician-assisted dying. *See id.* at 119a-123a. None of these authorities, however, indicate that in enacting the CSA Congress intended to address the practice of physician-assisted dying, let alone to forbid a state from legalizing the practice. Moreover, that the federal government may not endorse physician-assisted dying does not mean that federal policy seeks to ban it.

[16] H. Taylor, *The Harris Poll #2, 2-to-1 Majorities Continue to Support Rights to Both Euthanasia and Doctor-Assisted Suicide*, Jan. 9, 2002, *available at* http://www.harrisinteractive.com/harris_poll/index.asp?PID=278. The report also noted that ever since Harris began asking this question in 1982, a majority of respondents had expressed their support for legalization of physician-assisted dying under these circumstances. *Id.*

supported a right to physician-assisted dying and wished to have the option available to them.[17]

Like Ashcroft, Petitioners fail to acknowledge these studies and more recent data that confirm the continued and growing public support for the legalization of physician-assisted dying. For example, a Gallup poll conducted in May 2003 found that approximately three-quarters of Americans supported physician-assisted dying for terminally ill patients,[18] and a Harris poll published in April 2005 found that 70% of Americans favor legalization of physician-assisted dying for a terminally ill patient who chooses this course.[19]

Ashcroft also ignored, and Petitioners presently ignore, evidence of the substantial and growing support for the legalization of physician-assisted dying by large segments of the medical, hospice, bioethics, health policy, and legal communities. This support was detailed in the *amici* briefs filed in support of the respondents in the *Quill* and *Glucksberg* cases in 1996.[20] Inexplicably, the OLC Memo did not

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[17] A. Batavia, *The Relevance of Data on Physicians and Disability on the Right to Assisted Suicide*, 6 PSYCH. PUB. POL'Y & L., at 552-53 (2000) (citing W. Breibart et al., *Interest in Physician Assisted Suicide Among Ambulatory HIV Infected Patients*, 153 AM. J. PSYCHIATRY, 238-42 (1996), B. Trindell et al., *Attitudes to Euthanasia and Assisted Suicide in a Group of Homosexual Men with Advanced HIV Disease*, 6 J. OF ACQUIRED IMMUNE DEFICIENCY SYNDROME 1069 (1993)).

[18] K. Jost, *Right To Die*, 15 CQ RESEARCHER 423, 428 (2005).

[19] *The Harris Poll #32, Majorities of U.S. Adults Favor Euthanasia and Physician-Assisted Suicide by More than Two-to-One*, Apr. 27, 2005, *available at* http://www.harrisinteractive.com/harris_poll/index.asp?PID=561.

[20] *See, e.g.*, Brief of the Coalition of Hospice Professionals as Amicus Curiae for Affirmance of the Judgments Below, *Glucksberg*, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 709342; Brief of Amicus Curiae Bioethicists Supporting Respondents, *Glucks-*

mention these *amici* briefs, even as it relied heavily on *amici* briefs filed in support of the petitioners in *Quill* and *Glucksberg*.

Ashcroft also ignored other, more timely evidence of support for the legalization of physician-assisted dying in the medical community. A 2001 survey published by the *Journal of the American Medical Association* found that 51% of responding physicians in Oregon supported the Dignity Act and legalization of physician-assisted dying.[21] A nationwide survey published in 2001 in the *Journal of General Internal Medicine* found that 45% of responding physicians believed that physician-assisted dying should be legal, whereas only 34% expressed views to the contrary.[22] The American Medical Women's Association has, since 1997, supported "the right of physicians to engage in practice wherein they may provide a patient with, but not administer, a lethal dose of medication and/or medical knowledge, so that the patient can, without further assistance, end her/his life."[23] None of these views were con-

berg, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 709337; Brief for Ronald Dworkin, Thomas Nagel, Robert Nozick, John Rawls, Thomas Scanlon, and Judith Jarvis Thomson as Amici Curiae in Support of Respondents, *Glucksberg*, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 708956; Brief Amicus Curiae of the American College of Legal Medicine, *Glucksberg*, 521 U.S. 702, and *Quill*, 521 U.S. 793, *available at* 1996 WL 668827.

[21] L. Ganzini, MD, *et al.*, *Oregon Physicians' Attitudes About and Experiences with End-of-Life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363, 2365 (May 9, 2001).

[22] S. N. Whitney, MD, JD, *et al.*, *Views of United States Physicians and Members of American Medical Association House of Delegates on Physician-assisted Suicide*, 16 J. GEN. INTERNAL MED. 290, 292-93 (2001).

[23] Am. Med. Women's Ass'n, *Position Statement on Physician-Assisted Suicide*, *available at* http://www.amwa-doc.org/index.cfm?objectid=242FFEF5-D567-0B25-585DC5662AB71DF9.

sidered by Ashcroft nor addressed in the underlying OLC memo.

Petitioners maintain Ashcroft's blinkered approach by ignoring recent evidence of growing support for legalization among the medical community and other professional communities. A national survey conducted in February 2005 found that 57% of physicians believe it is ethical for a physician to assist a competent, dying patient in hastening death.[24] Medical organizations increasingly are adopting a neutral stance on the legalization of physician-assisted dying.[25] These organizations include mainstream leaders in the medical community, such as the American Academy of Hospice and Palliative Medicine, the American Pharmaceutical Association, and the Oncology Nursing Society.[26] Petitioners' refusal even to acknowledge the positions of these organizations and the views of medical professionals nationwide, while repeatedly referring to the position of the American Medical Association (AMA), *see* Pets. Br. at 23-24, reveals how narrow is their focus.[27]

[24] Louis Finkelstein Institute for Social and Religious Research, poll conducted last week of February 2005 of 1,000 physicians. Reuters, Business Wire, March 3, 2005.

[25] *See, e.g.*, T. E. Quill, MD & C. K. Cassel, MD, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, 138 ANNALS OF INTERNAL MEDICINE 208, 208-11 (2003) (attaching appendix listing Medical Organizations with Neutral Stance on Physician-Assisted Suicide).

[26] *Id*. at 210.

[27] It bears mention that only 30% of physicians in this country belong to the AMA, *see* http://www.ama-assn.org/ama/pub/category/5105.html, and there is a well-established gulf between the views of the AMA's leadership on this issue and those of its rank-and-file. *See, e.g*., T. Ackerman, *Poll: Many Doctors Back Assisted Suicide*, Houston Chronicle, May 3, 2001, *available at* http://www.dwd.org/fss/news/houston.asp.

Simply put, Petitioners are flat wrong when they declare that the Directive is "consistent with the prevailing legal and medical views regarding medical practice." Pets. Br. at 24.[28]

Much of the discussion concerning physician-assisted dying that is occurring within the medical and academic communities has been informed by and focused upon Oregon's experience with the Dignity Act.[29] The ethical, philosophical and medical literature has swelled with studies on physician-assisted dying. For instance, various surveys have been published documenting the experiences not only of the terminally ill, but also of doctors, psychiatrists, social workers and nurses who have had first-hand experience with physician-assisted

[28] Support for the legalization of physician-assisted dying also continues to grow outside of the United States. Physician-assisted dying has been legal in the Netherlands since 1994, and is legal now in Belgium and Switzerland as well. *See generally* R. Cohen-Almagor, *Euthanasia and Physician-Assisted Suicide in the Democratic World: A Legal Overview*, 16 N.Y. INT'L L. REV. 1 at nn.157-166 (Winter 2003); *Comparative Reflections on the Belgian Euthanasia Act 2002*, 11 MEDICAL L. REV. 353-376 (Autumn 2003). Great Britain is now considering legalizing physician-assisted dying for the terminally ill**,** and in June the British Medical Association dropped its opposition to legalization of the practice. C. Hall, *'Historic' Change as Opposition to Euthanasia Ends***,** The Telegraph, July 1, 2005, *available at* http://www.telegraph.co.uk/news/mainjhtml?xml=/news/2005/07/01/neut01.xml&sSheet=/news/2005/07/01/ixhome.html. A recent poll found that strong public support exists in Spain for legalizing physician-assisted dying, with 60% of Spanish doctors favoring legalization. P. Ford, *World Divided on Ethics of Terri Schiavo Case*, Christian Science Monitor, Mar. 25, 2005, *available at* http://www.csmonitor.com/2005/0325/p01s04wogi.html.

[29] For an overview of the literature, *see, e.g.*, J. L. Werth & H. Wineberg, *A Critical Analysis of Criticisms of the Oregon Death With Dignity Act*, 29 DEATH STUDIES 1, 2 (2005).

dying.[30] This literature confirms that Oregon's experience has informed the debate, and actual data have debunked many of the shibboleths erected by opponents of physician-assisted dying.

B. The Data Regarding Oregon's Experience with the Dignity Act Demonstrate that Legal, Physician-Assisted Dying Poses No Threat to the Public Health and Safety.

Perhaps the Directive's most glaring omission was its complete disregard of the data set forth in the three annual reports that the Oregon Department of Human Services had issued regarding Oregon's experience with the Dignity Act. Published pursuant to state law, and written by public health experts, these reports provided a wealth of unvarnished empirical information on the practice of physician-assisted dying under the Dignity Act.[31] Their significance cannot be understated: at the time Ashcroft issued the Directive, they presented the only data regard-

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[30] *See, e.g.*, L. Ganzini *et al.*, *Oregon Physicians' Attitudes About and Experiences with End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363 (May 9, 2001); L. Ganzini *et al.*, *Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEW. ENG. J. MED. 557 (2000), 9th Cir. SER at 322; L. Ganzini *et al.*, *Oregon Physicians' Perceptions of Patients Who Request Assisted Suicide and Their Families*, 6 J. PALLIATIVE MED. 381 (2003); L. Ganzini *et al.*, *Attitudes of Oregon Psychiatrists Toward Physician-assisted Suicide*, 153 AM. J. PSYCHIATRY 1469 (1996); L. Ganzini *et al.*, *Experiences of Oregon Nurses and Social Workers with Hospice Patients Who Requested Assistance with Suicide*, 347 NEW. ENG. J. MED 582 (2002); D. Fenn & L. Ganzini, *Attitudes of Oregon Psychologists Toward Physician-Assisted Suicide and the Oregon Death with Dignity Act*, 30 PROF. PSYCH.: RES. & PRACTICE 235 (1999).

[31] Or. Rev. Stat. § 127.865, Pet. Opp. App. at 10a.

ing the experience of legal, regulated physician-assisted dying in the United States.

The Oregon reports established that legalization of physician-assisted dying, administered under the strictures of the Dignity Act, did not threaten the public health and safety. Physician-assisted dying was not being forced upon those who were uneducated, uninsured, or otherwise disadvantaged, which opponents of the Dignity Act had speculated would materialize. The Third Annual Report, published in 2001, found that college-educated patients were far more likely to choose physician-assisted dying than patients with less than a high-school degree.[32] The report also determined that all patients who availed themselves of physician-assisted dying under the Dignity Act had some form of health insurance, and almost all of them died at home; no patient died in an acute-care hospital.[33] The report further found that there was no evidence that pressure from others was a primary motivating influence among the patients who had chosen physician-assisted dying over the previous three years.[34]

The three reports also demonstrated that use of physician-assisted dying under the Dignity Act was quite limited. From 1998 through 2000, only 70 individuals in Oregon had availed themselves of physician-assisted dying, representing less than one-tenth of one percent of all deaths in the state.[35] Nor did every patient who obtained a prescription for life-ending medication use that medication: only

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[32] Third Annual Report at 10, 17, 9th Cir. SER at 370, 377.

[33] *Id*. at 11, 22, 9th Cir. SER at 371, 381-382

[34] *Id*. at 14, 9th Cir. SER at 374.

[35] *Id*. at 13, 9th Cir. SER at 373.

two-thirds of the patients who had obtained such prescriptions in 2000 died from ingesting the medication.[36]

Petitioners likewise ignore the three annual reports published before issuance of the Directive, as well as the four annual reports published since. The four post-Directive reports confirm that the Dignity Act has been utilized sparingly and responsibly.[37] In the seven years since the Death with Dignity Act was implemented, only 208 persons have chosen physician-assisted dying, reflecting approximately 1 physician-assisted death in every 800 deaths in Oregon in 2004.[38] After an initial increase following the enactment of the Dignity Act, the number of persons who die annually utilizing physician-assisted dying has leveled off; in fact, the number of such deaths in 2004 actually declined from the previous year.[39] A 2003 study concluded that the number of Oregonians who died having chosen physician-assisted dying was less than half the number of Oregonians who hastened their death by refusing nutrition.[40]

In addition to there being relatively few deaths under the Dignity Act, the data indicates that the Act has been utilized responsibly. The overwhelming majority of persons

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[36] *Id*. at 10, 9th Cir. SER at 370.

[37] Seventh Annual Report; Sixth Annual Report, Pet. Opp. App. at 15a; Fifth Annual Report, Pet. Opp. App. at 46a; Fourth Annual Report, 9th Cir. SER at 384.

[38] Seventh Annual Report at 12-16.

[39] *See id.*

[40] *See, e.g.*, L. Ganzini *et al.*, *Experiences of Oregon Nurses and Social Workers with Hospice Patients Who Requested Assistance with Suicide*, 347 NEW. ENG. J. MED. 582 (2002); D. Colburn, *Terminally Ill Opting to Starve*, The Oregonian, July 24, 2003, *available at* http://www.oregonlive.com/special/assisted_suicide/index.ssf?/special/oregonian/suicide/072403.html.

dying via physician-assisted dying are white (97%), and tend to be younger, more affluent, and better educated than the average Oregon decedent.[41] In 2004, Oregonians with a baccalaureate degree or higher were 8.3 times more likely to use physician-assisted dying than those without a high school diploma.[42] In 2004, as in 2000, all patients who elected physician-assisted dying had some form of health insurance, and all but one of them died at home.[43] These data dispel the notions that legalization will result in large numbers of physician-assisted deaths or that the practice will be imposed disproportionately on the disadvantaged.[44]

Similarly, recent studies conducted on terminally ill patients belie the notion that the decision to choose physi-

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[41] *See, e.g.*, Seventh Annual Report; S. Tolle *et al.*, *Characteristics and Proportion of Dying Oregonians Who Personally Consider Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS 111 (2004).

[42] Seventh Annual Report at 13, 22.

[43] *Id*. at 14, 24.

[44] *See, e.g.*, L. Ganzini & S. K. Dobscha, *Clarifying Distinctions between Contemplating and Completing Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS 119, 121 (2004) (concluding that "these data do not support a slippery slope of increasing death-hastening acts"). These concerns partly underlay this Court's opinion in *Glucksberg*, which preceded the promulgation of data pursuant to the Dignity Act. *See, e.g.*, 521 U.S. at 729-31 (state's interest in protecting life, especially among vulnerable groups, including the poor, the elderly, the disabled, and those who have mental disorders such as depression, justifies its banning assisted dying); *id*. at 732 (risk of harm greatest for those who suffer from poverty, lack of medical care, advanced age, or membership in a stigmatized group, and many of these might resort to physician-assisted dying to spare their families health care costs); *see also id*. at 787 (Souter, J., concurring) (capacity of state to protect incompetent patients subject to genuine question, creating a factual controversy not susceptible to judicial resolution).

cian-assisted dying is vulnerable to undue influence or coercion because it is motivated by mental disorders such as depression, or by a fear of pain or a wish alleviate the burden on family members. For instance, recent studies suggest that the decision to choose physician-assisted dying is consistently motivated by well-considered concerns of autonomy, identity and independence.[45] Interestingly, up to 40% of persons who requested and were prescribed lethal dosages did not actually take the medications,[46] suggesting that their decisions to request or to take the medication were not susceptible to undue influence, and that this option gives comfort to many more than those who actually make use of it.

The data from the Oregon experiment also suggest that physician-assisted dying and other, non-terminal end-of-life options, such as palliative care, are not mutually antagonistic. Rather, they form a continuous spectrum of end-of-life care alternatives available to terminally ill Oregonians.[47]

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[45] *See, e.g.*, Seventh Annual Report at 16 (citing, *inter alia*, A. Sullivan *et al.*, *Legalized Physician-Assisted Suicide in Oregon—The Second Year*, 342 NEW. ENG. J. MED. 598 (2000)); *see also* L. Ganzini *et al., Oregon Physicians' Perceptions of Patients Who Request Assisted Suicide and Their Families*, 6 J. PALLIATIVE MED. 381 (2003); L. Ganzini *et al., Physicians' Experiences with the Oregon Death with Dignity Act*, 342 NEW ENG. J. MED. 557 (2000), 9th Cir. SER at 322); (patients choosing physician-assisted dying are generally "independent, determined and inflexible," most frequently cited reasons for choosing physician-assisted dying include loss of independence (57%); current or future concern of poor quality of life (55%), and desire to control the circumstances of death (53%)).

[46] *See* Seventh Annual Report at 12.

[47] *See, e.g.*, V. P. Tilden *et al.*, *Oregon's Physician-Assisted Suicide Vote: Its Effect on Palliative Care*, 44 NURSING OUTLOOK 80 (1996); J. L. Werth, *"Assisted Suicide" versus Improved End-of-Life Care: Mutually Exclusive Decisions Or Artificial Dichotomy*? 27

Almost 90% of patients who took lethal prescriptions pursuant to the Dignity Act were enrolled in hospice care.[48] Significantly, the Seventh Annual Report noted that "[t]he availability of [physician-assisted dying] as an option in Oregon also may have spurred Oregon doctors to address other end-of life care options more effectively."[49] It has promoted increased awareness of palliative care both amongst Oregon's physicians and general public; over three quarters of physicians reported that the legislation had prompted them to improve their knowledge of pain medication and their ability to diagnose psychiatric disorders such as depression.[50] Other studies indicate that, due to the presence of cumulative safeguards in the Dignity Act, Oregon's levels of legalized physician-assisted dying fall short of the levels of covert, illegal physician-assisted dying and outright euthanasia that occur in other states, and that legalization may actually be lowering the occurrence of such illegal practices.[51]

DEATH STUDIES 748 (2003) (reviewing THE CASE AGAINST ASSISTED SUICIDE: FOR THE RIGHT TO END-OF LIFE CARE).

[48] Seventh Annual Report at 14.

[49] *Id*. at 17.

[50] *See* L. Ganzini *et al.*, *Oregon Physicians' Attitudes About and Experiences with End-of-life Care Since Passage of the Oregon Death with Dignity Act*, 285 JAMA 2363 (2001).

[51] *See, e.g.*, L. Ganzini & S. K. Dobscha, *Clarifying Distinctions between Contemplating and Completing Physician-Assisted Suicide*, 15 J. CLINICAL ETHICS at 121 (legalization may be causing a decrease in the rate of physician-assisted dying, possibly because its safeguards provide "substantial hurdles" and because it promotes physician intervention intervene once patients reveal their fears and concerns); R. S. Magnusson, *"Underground Euthanasia" and the Harm Minimization Debate*, 32 J. L. MED. & ETHICS 486 (2004) (legalization may prevent covert and inappropriate practice of physician-assisted dying and euthanasia, which occurs frequently in other states); D. E. Meier *et al.*,

The Oregon data, both in 2001 and the present day, demonstrate that the practice of physician-assisted dying, when conducted under a responsible regulatory framework such as that of the Dignity Act, poses no threat to the public health and safety. Ashcroft's failure to consider this most probative evidence on the question of whether a threat to the public health is present suggests ideology overriding reasoned analysis.

C. Physician-Assisted Dying Comports with the Five Statutory Factors Required by § 823(f).

Ashcroft determined that prescribing, administering, or dispensing controlled substances under the Dignity Act might "'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)." Pets. App. at 102a. The Directive further declared that "[t]his 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." *Id.*

Section 824(a)(4) provides that the Attorney General may suspend or revoke a physician's registration to dispense controlled substances upon a finding that the physi-

A National Survey of Physician-Assisted Suicide and Euthanasia in the United States, 338 NEW ENG. J. MED. 1193 (1998), 9th Cir. SER at 272 (survey showing that over 3% of American physicians had written at least one lethal prescription, while almost 5% have ministered a legal injection); E. J. Emanuel *et al.*, *Attitudes and Practices of U.S. Oncologists Regarding Euthanasia and Physician-Assisted Suicide*, 133 ANNALS INTERNAL MED. 527 (2000) (Over 10% of American oncologists have assisted suicide); R. J. Kohlwes *et al.*, *Physicians' Responses to Patients' Requests for Physician-Assisted Suicide*, 161 ARCHIVES INTERNAL MED. 657 (2001) (more physicians favor assisted suicide than not).

cian "has committed such acts as would render his registration under section 823 of [title 21] inconsistent with the public interest as determined under such section * * *." 21 U.S.C. § 824(a)(4). Section 824(a)(4) thus expressly incorporates by reference § 823's standard for determining whether a physician's registration is "inconsistent with the public interest."

Subsection (f) of § 823 provides that standard. It lists five factors that the Attorney General "shall" consider in determining the public interest:

> (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.

Id. § 823(f). The Court of Appeals correctly noted below that consideration of *all five of these factors* is mandatory because § 823(f) provides that the five factors *"shall* be considered." *Oregon v. Ashcroft*, 368 F.3d at 1127 (quoting 21 U.S.C. § 823(f)) (emphasis in original). The OLC Memo's advice that Ashcroft could revoke or suspend a physician's registration based on "any" of these five factors contravened the plain language of the statute. *Id.* (quoting OLC Memo, Pets. App. at 110a).

Ashcroft impermissibly applied this erroneous advice. As the Court of Appeals correctly concluded, this core aspect of the directive represents a clear-cut violation of the CSA that cannot be cured.[52]

Ashcroft's decision to avoid consideration of all five factors was surely no accident. A review of the practice of lawful, regulated physician-assisted dying demonstrates that it comports with the five factors—both those Ashcroft purported to consider and those he ignored—and, thus, cannot be the basis for revoking a physician's license to prescribe controlled substances. The first factor is satisfied if a physician complies with the regulations of the law of

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[52] Petitioners contend that the Directive does not implicate § 823(f) because that section "applies only to actions by the Attorney General to deny or revoke a CSA registration" and the Directive "is not such a denial or revocation" but "an interpretation of the *substantive* provisions of the [CSA] * * *." Pets. Br. at 49 (emphasis in original). Petitioners' argument does not square with the plain language of the Directive. Ashcroft declared that dispensing controlled substances pursuant to the Dignity Act would furnish a basis for a revocation or suspension proceeding pursuant to 21 U.S.C. § 824(a)(4). Pets. App. at 102a. This means that Ashcroft pre-determined that, solely on the basis of such conduct's purported inconsistency with federal law, he could revoke or suspend a practitioner's registration pursuant to § 824(a)(4)—a result at odds with § 823(f), which requires consideration of all five factors therein. Unless the Attorney General is willing to rescind this aspect of the Directive, it must comply with § 823(f).

Petitioners also argue that affirmance of the Court of Appeals' ruling would violate the CSA "by requiring the Attorney General to make one factor—compliance with state law—determinative of" whether a physician's registration is consistent with the public interest. Pets. Br. at 49-50. This is a straw man. Enjoining enforcement of the Directive would not render compliance with state law exclusively determinative; rather, it would simply preclude revocation or suspension based solely on a physician's having prescribed controlled substances in accordance with state law to facilitate physician-assisted dying.

the state in which he or she is licensed in dispensing controlled substances for physician-assisted dying. The second and third factors are not necessarily implicated by participation in physician-assisted dying. The fourth factor is satisfied with respect to state and local laws provided that the physician complies with them. Ashcroft thus expressly dismissed the first and fourth factors' references to state law when he determined that the Directive's "conclusion applies regardless of whether state law authorizes or permits" physician-assisted dying. Pets. App. at 102a. As for the federal law element of the fourth factor, Respondents' briefs elsewhere make plain that federal law does not authorize the Attorney General to prohibit physician-assisted dying. As for the fifth factor, the Oregon data make clear that prescribing controlled substances in accordance with responsible state laws like the Dignity Act does not threaten the public health and safety. For these reasons and others, Ashcroft violated the CSA when he ruled that dispensing controlled substances in connection with physician-assisted dying, even when consistent with state law, is by itself a sufficient basis for revocation or suspension of a practitioner's license under 21 U.S.C. § 824(a)(4).

III. In Grappling with the Issue of Assisted Dying, Oregon Is Fulfilling its Intended Role as a Laboratory of Social Experimentation.

Justice O'Connor provided the critical fifth vote in *Glucksberg*, and supported it with a call for the issue of physician-assisted dying to be "entrusted to the laboratory of the states." *Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring) (quoting *Cruzan*, 497 U.S. at 292) (quotes omitted). The idea of the "laboratory of the states" as engines of social experimentation has a deeply rooted his-

tory in the fabric of constitutional doctrine. Justice Brandeis first brought the analogy to life over seventy years ago, emphasizing the power of the states to amend their practices and institutions to meet changing social and economic needs. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (one of the "happy incidents" of federalism is that "a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country"; denial of the "right to experiment" may create "serious consequences for the nation"); *id*. at 280 (it is not necessary to challenge the authority of the states to indulge in experimental legislation as long as they adhere to limitations imposed by the Federal Constitution).

Since Justice Brandeis's *New State Ice Co.* opinion, this Court's opinions have repeatedly emphasized the benefits of social experimentation by the states.[53] Members of this Court have frequently relied on the principles articulated

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[53] *See, e.g., United States v. Lopez*, 514 U.S. 549, 575 (1995) (Kennedy, J., concurring) (When "considerable disagreement" exists about how best to accomplish a desired goal, "the theory and utility of our federalism are revealed, for the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear"); *Arizona v. Evans*, 514 U.S. 1, 26 (1995) (Ginsburg, J., dissenting) (to encourage experimentation and promote solution of empirical questions, Court should encourage state exploration of different modes of protecting individual rights); *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 546 (1985), *overruled on other grounds* ("The science of government * * * is the science of experiment"); *EEOC v. Wyoming*, 460 U.S. 226, 265 (1983) (Burger, C.J., dissenting), *overruled on other grounds* ("Flexibility for experimentation not only permits each state to find the best solutions to its own problems, it is the means by which each state may profit from the experiences and activities of all the rest."); *Santosky v. Kramer*, 455 U.S. 745, 771 (1982) (Rehnquist, C.J., dissenting) (leaving the States

by Justice Brandeis to analyze some of the most profound and relevant social issues of the day.[54]

Indeed, several Justices in addition to Justice O'Connor invoked the doctrine when this Court addressed similar confluxes of medical policy and individual liberty at the end of life in *Cruzan* and *Glucksberg*. In the first of these, Justice Scalia stated the issue succinctly: "The States have begun to grapple with" the "difficult, indeed agonizing, questions that are presented by the constantly increasing power of science to keep the human body alive for longer than any reasonable person would want to inhabit it."

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free to experiment with various remedies to a difficult social problem produces novel approaches and promising progress.); *San Antonio Independent School Dist. v. Rodriguez*, 411 U.S. 1, 50 (1973) (experimentation allows social policy to benefit from a "multiplicity of viewpoints and from a diversity of approaches").

[54] *See, e.g., Raich*, 125 S. Ct at 2220 (O'Connor, J., dissenting) ('medical marijuana' statute should not be restricted, in part because Court should protect states' role as laboratories); *Oakland Cannabis Buyers' Cooperative*, 532 U.S. at 502 (Stevens, J., concurring) ('medical marijuana' statute should be upheld; Court should minimize legal conflict between the federal and state governments when state's citizens have chosen to serve as a laboratory without risk to the rest of the country); *Atkins v. Virginia*, 536 U.S. 304, 326 (2002) (Rehnquist, C.J., dissenting) (Court should uphold state statute permitting execution of mentally retarded, which is developed "through the workings of normal democratic processes in the laboratories of the States"); *Boy Scouts of America v. Dale*, 530 U.S. 640, 664 (2000) (Stevens, J., dissenting) (state anti-discrimination statute should be upheld as permissible and necessary social experimentation); *Zelman v. Simmons-Harris*, 536 U.S. 639, 680 (2002) (Thomas, J., concurring) (state funding to religious schools is proper; Fourteenth Amendment should not "handcuff the State's ability to experiment with education"); *id.* at 685 (Stevens, J., dissenting) (Court should not accept state funding of religious education before permitting recent state experimentation with alternative public schools to take effect).

Cruzan, 497 U.S. at 292 (Scalia, J., concurring). Similarly, Justice Souter wrote in *Glucksberg* that, "Legislatures, on the other hand, have superior opportunities to obtain the facts necessary for a judgment about the present controversy * * *. [T]heir mechanisms include the power to experiment, moving forward and pulling back as facts emerge within their own jurisdictions." 521 U.S. at 788 (Souter, J., concurring). The *Glucksberg* majority implicitly endorsed experimentation in the context of physician-assisted dying when it acknowledged that Oregon's policy was not arrived at on a whim but rather was the result of serious democratic debate. *See id.* at 719 (describing various state policies, including Oregon's, on physician-assisted dying and concluding that "the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues"). Indeed, the Court recognized the "earnest and profound debate" occurring across the nation on the issue of physician-assisted dying, and concluded with the declaration that "[o]ur holding permits this debate to continue, as it should in a democratic society." *Id.* at 736.

Oregon's experience with physician-assisted dying illustrates the concrete benefits of state-based experimentation with the profound issues of death and autonomy and confirms the wisdom of promoting the states' role as engines of social change. One of the most important benefits arising from Oregon's experience is the generation of scientifically validated, objective empirical data regarding physician-assisted dying—information that was lacking in the debate prior to the Dignity Act's enactment.[55] The annual reports

[55] *Cf. Globe Newspaper Co. v. Superior Court for Norfolk County* 457 U.S. 596, 617 (1982) ("It makes no sense to criticize the [State] for its failure to offer empirical data in support of its rule; only by

generated pursuant to the Dignity Act have provided other states confronting the issues of end of life care with immense insights into physician-assisted dying. For example, Vermont is currently considering a bill very similar to Oregon's Death with Dignity Act.[56] When last it considered such a bill,[57] it commissioned a study examining end of life issues that drew heavily on Oregon's experience.[58] California is presently considering the issue as well.[59] The legislatures of both Hawaii[60] and Arizona also recently considered the enactment of similar statutes.

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allowing state experimentation may such empirical evidence be produced."). As noted above, *see* n.44, *supra*, these data were not available to this Court when last it addressed this issue in *Glucksberg*.

[56] *See* H.R. 168, 2005 Leg., 2005-06 Sess. (Vt. 2005); text *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/bills/intro/H-168.HTM.

[57] *See* H.R. 318, 2003 Leg., 2003-04 Sess. (Vt. 2004), *available at* http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2004/bills/intro/H-318.HTM

[58] *See* R. Lunge *et al.*, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands*: *Factual Disputes* (2004) (survey requested by Vermont legislators), *available at* http://www.leg.state.vt.us/reports/04Death/Death_With_Dignity_Report.htm. This study concluded that "it is apparent from credible sources in and out of Oregon that the Death with Dignity Act has not had an adverse impact on end-of-life care and in all probability has enhanced the other options." *Id.* at 30.

[59] *See* A.B. 654, 2005 Sess. (Cal. 2005), *available at* http://www.aroundthecapitol.com/billtrack/billview.html?bill=AB_654. For a description of the legislation, see http://democrats.assembly.ca.gov/members/a01/articles/an012005016.htm

[60] During Hawaii's 2002 legislative session, a bill modeled on Oregon's Death With Dignity Act passed through the house and came within two votes of passage in the Senate. This bill was reintroduced in 2004 and likely will be reintroduced again.

The advances in understanding and awareness that have resulted from Oregon's earnest and informed debates are not an accident, but rather exactly the sort of wisdom that our federal system was designed to foster. Since *Glucksberg* was decided, Oregon's experience with physician-assisted dying has provided the nation with its only source of scientific and objective data on the practice of physician-assisted dying and social attitudes towards it. Such data amply demonstrate the benefits of Oregon's experiment with dignified dying, and the wisdom of leaving the responsibility for its outcome with its citizens. Oregon's experience with the Dignity Act has proven beneficial to Oregonians, and its social experiment has proven beneficial to the nation as a whole. It is precisely these kinds of benefits that this Court's jurisprudence is intended to foster.

As noted above and explained in greater detail in the briefs of the other Respondents, the CSA does not interfere with the "historic primacy of state regulation of matters of health and safety."[61] Thus, both the intent of Congress as evidenced by the plain language of the CSA and this Court's approach to the profound issues of health policy and individual liberty that underlie this case require that the Directive be enjoined as an act of overstepping by the U.S. Attorney General.

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[61] *Medtronic, Inc*, 518 U.S. at 485; *see also* n.11, *supra*.

CONCLUSION

For the foregoing reasons, the Patient-Respondents respectfully submit that the judgment by the Court of Appeals should be affirmed.

Respectfully submitted,

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