Hastened Death and the Regulation of the Practice of Medicine

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I. GONZALES V. OREGON: HISTORY AND DECISION

On November 9, 2001, then-Attorney General John Ashcroft issued an interpretive rule (hereinafter “November 2001 Interpretive Rule” or “Interpretive Rule”) stating that “assisting suicide is not a ‘legitimate medical purpose’ within the meaning of 21 CFR
§ 1306.04. The cited regulation requires all prescriptions for controlled substances to “be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” The Attorney General’s directive purported to make the prescribing, dispensing, or administering of a controlled substance to assist in a suicide a violation of the Controlled Substances Act (CSA).

To prescribe controlled substances a physician must be registered with the appropriate federal agency, currently the Drug Enforcement Administration (DEA). Issuing a prescription for an invalid purpose can result in revocation of the physician’s registration and subject the physician to civil and criminal penalties. Based on the wording of the Interpretive Rule itself, Attorney General Ashcroft clearly intended to revoke the registration of any Oregon physician who prescribed a controlled substance under the Oregon Death with Dignity Act (ODWDA)7 for the purpose of assisting a patient in hastening their death. This state statute authorizes a physician to comply with the request of a terminally ill, mentally competent patient for a prescription for a lethal dose of medication, which the patient can ingest if the dying process becomes intolerable. If the Interpretive Rule had been implemented, there is little doubt that it effectively would have nullified the ODWDA, as few, if any, physicians would have risked violating the Attorney General’s rule.

On January 17, 2006, the Supreme Court, in a 6-3 ruling, with the majority opinion authored by Justice Kennedy, concluded that the Interpretive Rule was an invalid exercise of the Attorney General’s

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1. Dispensing of Controlled Substances to Assist Suicide, 66 Fed. Reg. 56,607 (Nov. 9, 2001) (to be codified at 21 C.F.R. pt. 1306). The “Interpretive Rule” issued by Attorney General Ashcroft, which was to take effect immediately, was promulgated in the Federal Register without prior notice to or comments by interested parties.
2. 21 C.F.R. § 1306.04 (2005).
6. See the third and fourth paragraphs of the supplementary information to 66 Fed. Reg. 56,608.
8. Id. § 127.805.
The Supreme Court’s recent decision resolved one of the critical legal issues relating to the controversy over assistance in hastening death. However, other important issues, both legal and moral, remain. First, the decision underscores the fact that there is no consensus among health care professionals about the precise boundaries of the legitimate practice of medicine. While many physicians firmly believe that, under appropriate circumstances, assistance in hastening death is an appropriate means of addressing a patient’s needs, other physicians are emphatic in condemning the practice. Second, there is significant disagreement regarding the appropriate process for determining the boundaries of medical practice. In particular, there is disagreement about the extent to which the government should be involved in drawing these boundaries as well as the proper allocation of regulatory authority between and within state and federal governments.

We begin discussion of these problems with a summary of the controversy over legalized assistance in hastening death and a description of how that controversy led to Gonzales v. Oregon. We then review the Gonzales decision, explaining what it did and did not resolve. Looking to how these issues should be analyzed in the future, we will explain why a fundamental distinction currently embedded in the law is unhelpful in analysis of the legitimacy of assistance in hastening death. We will argue that, correctly

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10. Gonzales, 126 S. Ct. at 925. This article will use the phrase “assistance in hastening death” to describe the practice authorized by the Oregon statute. The authors recognize that “assisted suicide” is the term often used to describe this practice. Our reluctance to use the phrase “assisted suicide” does not stem from any squeamishness or desire to use euphemisms, but rather reflects a desire to be accurate in our description. As discussed in more detail below, not only must the patient in Oregon be terminally ill prior to receiving a prescription for a lethal drug from her physician, but the patient maintains control of the process and may decide to forgo use of the prescription or the drug obtained via the prescription. Many do. Under these circumstances, the term “assisted suicide” can be misleading. No normative conclusion depends on use of our terminology.
understood, assistance in hastening death is properly regarded as a medical practice, or, more broadly stated, that a physician legitimately may assist in various ways in helping to bring about the death of a terminally ill patient who has explicitly and competently requested this assistance from the physician. In making this argument, we suggest how these and other disputes over medicine’s boundaries should be resolved.

A. The Movement Toward Legalization of Assistance in Hastening Death and Oregon’s Death with Dignity Act

Recent decades have witnessed increased public debate over assistance in hastening death. A number of different factors account for the emergence of this debate. Among them are dramatically improved medical care and technology that allow an individual’s life to be prolonged, perhaps beyond the point where the individual wishes. “[W]ith the advance of medical technology capable of sustaining life well past the point where natural forces would have brought certain death in earlier times, cases involving the right to refuse life-sustaining treatment have burgeoned.”12 In addition, patients have demanded, and physicians have given, greater deference to patients’ wishes regarding the scope of medical treatment. Respect for a patient’s autonomy has become an accepted principle in medical ethics.13 This respect for autonomy has grown to encompass a patient’s decisions about life-sustaining treatment.14

The legal basis for recognition of the right to refuse or direct the withdrawal of life-sustaining treatment has its foundations in the common-law right to be free from bodily touchings or invasions absent consent.15 Although there was some initial resistance to extending this right to include refusals of life-sustaining treatment,

14. Id.
15. See, e.g., Schloendorff v. Soc’y of N.Y. Hosps., 105 N.E. 92, 93 (N.Y. 1914), overruled on other grounds by Bing v. Thunig, 143 N.E.2d 3 (1957) (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent, commits an assault, for which he is liable in damages.”).
the patient’s right to refuse such treatment has now become widely accepted, as both a moral and a legal right. Of course, the common law recognized no right to commit suicide. To the contrary, at common law suicide was a criminal offense. To reconcile the traditional rejection of suicide with acceptance of the right to be free of unwanted medical treatment, even when a refusal of treatment would likely result in death, courts have sometimes gone to great lengths to distinguish a refusal of treatment from suicide and assisted suicide. Many courts, including the Supreme Court, have tried to capture this distinction through use of the supposedly contrasting concepts of “letting die” and “killing,” with the former generally regarded as permissible and the latter as impermissible. Withdrawals or withholdings of treatment are classified in the “letting die” category.

Along with recognition of a patient’s right to refuse treatment has come acceptance by the medical profession of alternative forms of care, designed not to cure, but, insofar as possible, to make the patient comfortable and maintain the quality of her life throughout her final illness. Palliative and hospice care were at first controversial, precisely because in providing such care a physician

16. In re Quinlan, 70 N.J. 10 (1976), was the seminal decision on this issue, being the first state court decision to authorize the withdrawal of life-sustaining treatment under certain conditions. Id. at 54. For a discussion of the legal regulation of withdrawal of life-sustaining treatment, see Lawrence O. Gostin, Drawing a Line Between Killing and Letting Die: The Law, and Law Reform, on Medically Assisted Dying, 21 J.L. MED. & ETHICS 94 (1993).


19. The Supreme Court utilized and endorsed the distinction between “killing” and “letting die” in Vacco v. Quill, 521 U.S. 793, 800–07 (1997), stating that withdrawals of life-sustaining treatment merely allow the patient to die from the underlying disease. But see Cruzan v. Dir., Mo. Dep’t of Health, 497 U.S. 261, 295–97 (1990) (Scalia, J., concurring) (refusal of life-sustaining treatment can constitute a “suicide”). We regard the distinction between “killing” and “letting die,” when used as a basis for distinguishing impermissible from permissible acts, as unsatisfactory for a number of reasons, not least because it tends to inhibit, rather than promote, consideration of relevant factors. See discussion infra note 113 (addressing this distinction and the role it plays in the debate over the boundaries of medical practice).

chooses to forgo further efforts at a cure. For those who believe that medical practice is limited to “healing,” palliative care appears to fall outside the boundaries of medicine. Nonetheless, palliative and hospice care are now nearly universally approved. Physicians and other health care professionals are today intimately involved in patient-directed withdrawal or withholding of life-sustaining treatment, not only with respect to advising patients about their condition and overseeing the withdrawal or withholding of treatment, but also with respect to providing alternative forms of care, including palliative care.

Withdrawal or withholding of treatment will hasten death only for those individuals who are being sustained by such treatment. Many other individuals, including cancer patients, may face a protracted period of dying even when respirators and other life-preserving technology are not being utilized. For some of these patients, palliative care and the ability to refuse treatment do not adequately address their concerns. During their prolonged period of dying, they may endure a loss of functional capacity, unremitting pain and suffering, an inability to experience the simplest of pleasures, and long hours aware of the hopelessness of their condition. Some patients find this prospect unbearable. They desire a means to hasten their deaths.

Most states have statutes in place that prohibit assisting a suicide, and, at least arguably, these statutes could be applied to any form of hastening death that is not classified by the courts as a withdrawal or withholding of treatment. Moreover, even in jurisdictions in which assisting a suicide is not expressly prohibited by statute, persons who assist in hastening death might be convicted of a common-law felony.

21. See generally Jill Rhymes, Hospice Care in America, 264 J. AM. MED. ASS’N 369 (1990) (discussing the history and modern day perception of hospice care as well as impediments to it).


23. Washington v. Glucksberg, 521 U.S. 702, 725–26 (1997) (discussing the assisted suicide laws of various states and observing that the right to refuse unwanted medical treatment was not “transmuted into a right to assistance in committing suicide” by prior case law).
Recognition of the plight of patients who find themselves trapped in a lengthy and agonizing process of dying has resulted in efforts to overcome legal barriers that might prevent assistance in hastening death when there is no life-sustaining treatment to forgo. Proponents of assistance in hastening death have tried to enact statutes that would make the requested assistance for terminally ill patients explicitly lawful under specified conditions, and have brought suits alleging that statutes prohibiting such assistance are unconstitutional, at least as applied to terminally ill individuals.

Significantly, the vast majority of proposed statutes have envisaged an important role for physicians providing assistance in hastening death. Physician participation in the process is viewed as critical for several reasons. To begin, the patient’s decision to request assistance in hastening death should be fully informed. Many patients do not have the capacity to evaluate their own health condition accurately and objectively. Furthermore, they may be unaware of all the alternatives available to them, especially with respect to palliative care. In addition, of course, a patient should be competent to make a decision regarding treatment at the time of the request for assistance in hastening death, as well as free from inappropriate influences. Examination by and consultation with one or more physicians are


25. This, of course, was the gravamen of the complaint in Glucksberg. In that case, four physicians, three terminally ill patients, and a nonprofit organization that counsels individuals about end-of-life options, Compassion in Dying (now known as Compassion and Choices), brought suit alleging that Washington’s assisted suicide ban placed a constitutionally impermissible undue burden on the patients’ liberty interest in controlling the time and manner of their deaths. Id. at 708. In a unanimous decision, the Supreme Court disagreed. Id. at 735. Although some of the Justices indicated that in certain circumstances a statute banning assisted suicide might impose an intolerable burden on a patient’s freedom, id. at 752 (Stevens, J., concurring), it is safe to conclude, based on the Glucksberg precedent, that all or almost all of the existing state statutes prohibiting assisted suicide would withstand a constitutional challenge. Accordingly, most proponents of assistance in dying agree that legislation is now the only reliable method for ensuring that assistance in hastening death will not be subject to criminal prosecution.

effective means of ensuring that the patient is competent and is making a truly voluntary choice. Ideally, the patient’s physician will also be sufficiently acquainted with the patient’s history, condition, and character to be able to engage the patient in a constructive dialogue regarding her decision. Finally, the person providing assistance should have the ability to provide a means of hastening death that is quick and painless. Only physicians can prescribe drugs with the appropriate efficacy.

Efforts to enact legislation that would legalize assistance in hastening death have met determined resistance. Much of this resistance stems from religious objections to the practice.27 Other objections, however, reflect concerns that assistance in hastening death could not be effectively regulated and would have serious adverse consequences for many, including for those who do not desire such assistance. Moreover, opponents of legalization have maintained that the practice inevitably would be expanded to include euthanasia (including non-voluntary euthanasia), the quality of palliative care for all patients would deteriorate, patients would be manipulated or coerced into requesting assistance in hastening death, patients whose judgment was impaired would be allowed to request such assistance, and members of allegedly vulnerable groups (such as the elderly, women, members of racial and ethnic minorities) would be adversely affected in disproportionate numbers.28 Proponents of


legal assistance in hastening death have tried to meet these objections by incorporating various procedural safeguards into their proposed legislation.29

In 1994 the voters of Oregon, by referendum, adopted the ODWDA, the first and still the only statute in the United States expressly to permit assistance in hastening death.30 It authorized Oregon physicians to prescribe drugs for certain terminally ill patients requesting assistance in hastening their death.31 However, under the ODWDA, patients may seek, and physicians may provide, assistance in hastening death only after compliance with extensive procedural requirements.32 Eligibility is limited to patients who have received a diagnosis from their attending physician that they have a terminal illness that will cause their death within six months.33 Patients must manifest a durable, verifiable desire for assistance: the patient must make two oral requests, separated by at least fifteen days, and one written request, signed in the presence of two witnesses.34 There are various procedural safeguards to ensure that the patient’s request is informed and truly voluntary, including consultation with and a confirming diagnosis by a second physician.35 A patient must be referred to counseling if either the prescribing or the consulting physician believes he might be suffering from a psychological disorder that causes impaired judgment.36 The patient must ingest the prescribed drug—the physician may not administer it.37 Physicians must maintain detailed records of the process leading to the prescription, and these records must be shared with the Oregon Department of Human Services.38 The records also provide the basis for an annual public report.39

29. E.g., Baron et al., supra note 26.
31. See id. § 127.815.
32. See id. §§ 127.805–127.897.
33. Id. § 127.800(12).
34. Id. § 127.840.
35. Id. § 127.800(8).
36. Id. §§ 127.815(e), 127.825.
37. Id. §§ 127.815(L), 127.880.
38. Id. § 127.865.
39. Id. § 127.865(3).
Whether because of these safeguards or because some of the concerns about the supposedly dire consequences of legalizing assistance in hastening death are simply unwarranted, none of the abuses predicted by some have materialized. The statute’s restrictions have been neither loosened nor broadened. There is no evidence that any patient has died other than in accordance with his or her own wishes. The number of patients seeking prescriptions under the statute has been both low and stable (sixty in 2004\textsuperscript{40}), and hastened death has not been used primarily by individuals who might be thought vulnerable to intimidation or abuse.\textsuperscript{41} Indeed, those choosing assisted death had, on average, a higher level of education and better medical coverage than terminally ill Oregonians who did not obtain assistance in dying.\textsuperscript{42} Women and members of disadvantaged racial minorities have not been adversely affected in disproportionate numbers.\textsuperscript{43} Rather, the overwhelming number of persons requesting assistance in hastening death are white and the gender of these patients reflects that of the general population.\textsuperscript{44} In addition, there is evidence that the quality of palliative care has actually improved in Oregon,\textsuperscript{45} possibly because of the increased attention the statute brings to end-of-life care. Perhaps most significantly, about one-third of the patients requesting assistance in dying ultimately decide not to use the prescribed drug.\textsuperscript{46} Under the statute, mentally competent, terminally ill patients remain securely in control of decision-making about their lives.

In providing assistance in hastening death under the ODWDA, a physician is to exercise his or her professional judgment in prescribing the most effective drug.\textsuperscript{47} The drug prescribed in almost

\begin{enumerate}
\item OR. DEP’T OF HUMAN SERVS., SEVENTH ANNUAL REPORT ON OREGON’S DEATH WITH DIGNITY ACT 4 (2005).
\item See id. at 13–14 (describing characteristics of those who utilized Oregon’s Death with Dignity Act).
\item Id. at 13.
\item Id. at 13, 20 tbl.1.
\item Id. at 20 tbl.1.
\item OR. DEP’T OF HUMAN SERVS., supra note 40, at 4.
\item See OR. REV. STAT. § 127.815 (2003).
\end{enumerate}
all instances in Oregon is a form of barbiturate, the use of which is regulated by the CSA.\textsuperscript{48} Use of barbiturates as a means of hastening death, which otherwise is of virtually no consequence for the ethical and legal debate over assistance in dying, assumed critical significance in the Gonzales v. Oregon litigation.\textsuperscript{49} The fact that substances controlled under the CSA are used to hasten death allowed those opposed to legalized assistance in hastening death to attempt to utilize the CSA as a means of thwarting the ODWDA.

\textbf{B. The Controlled Substances Act and the Gonzales v. Oregon Litigation}

The federal government has regulated certain aspects of the distribution of drugs deemed susceptible to abuse since the Pure Food and Drug Act of 1906.\textsuperscript{50} The primary contemporary vehicle for federal regulation is the Comprehensive Drug Abuse Prevention and Control Act, enacted in 1970; the CSA is Title II of that Act.\textsuperscript{51} A “controlled” substance is one that is regulated under the CSA.\textsuperscript{52} The CSA classifies controlled substances in five categories or schedules based on their potential for abuse, their accepted medical use, and the risks associated with their use under medical supervision.\textsuperscript{53} Schedule I substances have a high potential for abuse and have no currently accepted use in medical treatment.\textsuperscript{54} Schedule II through Schedule V substances are approved for medical use but are subject to a descending hierarchy of restrictions on their use, reflecting the likelihood of abuse and the likely degree of harm if abuse occurs.\textsuperscript{55}

\textsuperscript{48} OR DEP’T OF HUMAN SERVS., supra note 40, at 24.
\textsuperscript{49} See Gonzales v. Oregon, 126 S. Ct. 904, 913 (2006).
\textsuperscript{50} Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, repealed by Food, Drug and Cosmetic Act, ch. 627, 52 Stat. 1040–1059, 1059. Among other things, the Act prohibited the shipment in interstate commerce of mislabeled or adulterated drugs. Indirectly, the Act affected the sale of over-the-counter narcotics, as many consumers became aware for the first time that their elixirs contained opium, which was a common ingredient in patent medicines of the time. See R OY P ORTER, T HE G REATEST B ENEFIT TO  M ANKIND 663–64 (1998).
\textsuperscript{52} Id. § 802(6).
\textsuperscript{53} Id. § 812.
\textsuperscript{54} Id. § 812(1)(A)-(B).
\textsuperscript{55} See id. § 812(b)(2)-(5).
Barbiturates are listed on Schedule II. 56 To give a lawful prescription for a controlled substance, a physician must be registered with the DEA, 57 and to be valid under the CSA, such a prescription must be issued for “a legitimate medical purpose.” 58

There is little dispute that the primary purposes of the CSA are to control drug abuse and to eliminate illicit trafficking in drugs. In accomplishing these objectives there is a division of responsibility among various federal agencies, in particular the Department of Health and Human Services and the Department of Justice. Of particular relevance to the controversy in Gonzales v. Oregon is the Attorney General’s authority to revoke a physician’s registration for prescribing controlled substances if the registration would be inconsistent with the public interest. 59 In making this determination the Attorney General is directed by the CSA to consider five factors:

(1) The recommendations 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. 60

Despite federal laws deterring drug abuse and prohibiting drug trafficking, the states have remained the primary, although by no means the exclusive, source of most regulation of medical practice. Prior to Gonzales the Supreme Court observed that establishing “standards of reasonable medical care” is a “quintessential[] state-law” function. 61 States license physicians, establish boards and

56. See id. § 812(c).
57. See id. § 822(a)(c), § 823; see also 28 C.F.R. § 0.100(b)(2) (2003) (oversight of physician registration delegated to the DEA).
59. Id. § 824(a)(4).
60. Id. § 823(f).

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agencies to regulate the actions of physicians, and promulgate rules and guidelines to which physicians are required to adhere. Indeed, as part of their complex regulatory frameworks, all fifty states have their own statutes and regulations addressing various aspects of the distribution and administration of controlled substances. Many of these provisions are more detailed or restrictive than the CSA and its accompanying regulations.

The CSA expressly preserves the primary role of the states in regulating most aspects of medical practice; it does not preempt state law except where there is a direct conflict between federal and state law. Under the CSA, however, a state cannot excuse within its borders practices that the CSA prohibits.

In 1997 various members of Congress voiced their opposition to the ODWDA, including then-Senator John Ashcroft of Missouri. Some members of Congress who opposed assistance in hastening death asked the DEA to revoke the registration of physicians who prescribed drugs under the ODWDA. They contended that the use of controlled substances to hasten death is not a legitimate medical practice, so prescribing controlled substances for that purpose violated the CSA. Then-Attorney General Janet Reno rejected this request, reasoning that Oregon had the right to determine what constitutes legitimate medical practice within its boundaries. Undeterred, some members introduced the Lethal Drug Abuse

newborns constitute exercise of federal authority in “what would otherwise be the domain of state power”); Linder v. United States, 268 U.S. 5, 18 (1925) (“Direct control of medical practice in the States is beyond the power of the Federal Government.”).

62. 21 U.S.C. § 903. This section reads:

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

Id.

63. In Gonzales v. Raich the Supreme Court held that the CSA overrides a California state law that permits limited growth and use of marijuana for specific medical purposes. 125 S. Ct. 2195, 2201, 2212–13 (2005). Marijuana is a Schedule I substance under the CSA, and hence banned from medical use; 21 U.S.C. § 812(c).

64. 143 CONG. REC. 5589–92 (1997).

Prevention Act\textsuperscript{66} and later the Pain Relief Promotion Act,\textsuperscript{67} legislation that would expressly have prohibited the use of controlled substances in connection with assistance in hastening death. Both proposals failed.

In 2001 John Ashcroft assumed the top position at the Department of Justice. He did not hesitate long in using his new position to attempt to nullify the same Oregon statute he had criticized as a senator. After obtaining a sympathetic analysis from the Justice Department’s Office of Legal Counsel, he issued the November 2001 Interpretive Rule. However, ultimately his efforts as Attorney General were no more successful than his efforts as a legislator. The Interpretive Rule never took effect.

The state of Oregon and individual named plaintiffs, including physicians and terminally ill patients, obtained from the district court an injunction against implementation of the Interpretive Rule, and the Ninth Circuit affirmed.\textsuperscript{68} In upholding the Ninth Circuit, the Supreme Court held that the November 2001 Interpretive Rule was an invalid exercise of the Attorney General’s authority under the CSA.\textsuperscript{69} The Court reasoned that the CSA gives the Attorney General limited powers and there is no indication, explicit or implicit, in the language of the statute that the Attorney General has the authority to define what constitutes a legitimate medical practice as long as the practice does not implicate drug trafficking or drug abuse as regulated by the CSA.\textsuperscript{70}

The Supreme Court acknowledged that the Attorney General has authority to issue regulations for the “control” of drugs,\textsuperscript{71} but concluded that the Interpretive Rule could not be characterized as an exercise of this authority.\textsuperscript{72} “Control” is expressly defined under the statute to mean adding a drug or other substance to one of the CSA’s

\textsuperscript{68. Oregon v. Ashcroft, 192 F. Supp. 2d 1077 (D. Or. 2002), aff’d, 368 F.3d 1118 (9th Cir. 2004).}
\textsuperscript{69. Gonzales v. Oregon, 126 S. Ct. 904, 925 (2006).}
\textsuperscript{70. Id.}
\textsuperscript{71. See 21 U.S.C. § 821 (2000).}
\textsuperscript{72. Gonzales, 126 S. Ct. at 925.}
five schedules. Moreover, prior to exercising this authority, the Attorney General must follow a specified set of procedures, including soliciting scientific and medical evidence. As the Court observed, the Interpretive Rule “does not concern the scheduling of substances and was not issued after the required procedures for rules regarding scheduling, so it cannot fall under the Attorney General’s ‘control’ authority.”

The Court also considered the federal government’s contention that the Interpretive Rule represented a valid exercise of authority because amendments to the CSA in 1984 broadened the Attorney General’s authority to allow him to deny or revoke the registration of a physician after concluding that the registration was inconsistent with the public interest. The Court found multiple flaws in this argument. The 1984 amendments required the Attorney General to consider the five different factors described above before determining that a physician’s registration was inconsistent with the public interest. The Court found that the Attorney General did “not undertake the five-factor analysis” prior to issuing his Interpretive Rule. The Attorney General’s Interpretive Rule did not even purport to be an application of the registration provisions of the CSA. Instead, it explicitly stated that it represented “an interpretation of the substantive federal law requirements for a valid prescription.”

Effectively, the Attorney General’s rule “work[ed] in the opposite direction” from that contemplated in the statute. He declared the issuance of a prescription to assist in hastening death to be criminally unlawful under the CSA, thereby automatically “placing in jeopardy the registration of any physician” writing a prescription under the ODWDA, whereas the CSA requires the Attorney General to consider the five specified factors before determining whether a

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73. 21 U.S.C. § 802(5).
75. Gonzales, 126 S. Ct. at 917.
76. Id. at 917–18 (citing 21 U.S.C. § 823(f)).
77. Id.
78. Id. at 918.
79. Id.
80. Id.
physician’s registration should be revoked.\textsuperscript{81} Only after weighing these factors is the Attorney General authorized by the CSA to revoke the physician’s registration.\textsuperscript{82} If the deregistered physician then writes an additional prescription for a controlled substance, this is a criminal violation of the CSA. The Court reasoned that the Attorney General could not utilize the “public interest” factor listed in the CSA’s registration provisions to impose his own views about what does and does not violate that statute.\textsuperscript{83}

Finally, the Court addressed the federal government’s argument that the CSA’s mandate that prescriptions be issued only for “a legitimate medical purpose” necessarily implies that prescriptions under the ODWDA are unlawful.\textsuperscript{84} The government contended that intentionally hastening death cannot be part of accepted medical practice, which is “a healing or curative art.”\textsuperscript{85} In response, the Court acknowledged that limiting medical care to treatment designed to cure a patient is one understanding of “medicine’s boundaries.”\textsuperscript{86} However, the Court also pointed out that there are alternative understandings of the scope of medicine.\textsuperscript{87} The CSA does not authorize the Attorney General to impose on physicians his particular understanding of the practice of medicine.\textsuperscript{88}

The Court both noted the absence of any statutory warrant for the government’s position and emphasized that the implications of that position are dangerous.\textsuperscript{89} It stated that were this interpretation of the CSA accepted, the Attorney General’s authority to make medical judgments would not be limited to the issue of physician assistance in hastening death.\textsuperscript{90} The Attorney General would have the authority to interfere with any medical practice he deemed inappropriate if it involved use of controlled substances: “Were [the government’s] argument accepted, [the Attorney General] could decide whether any

\begin{itemize}
\item \textsuperscript{81} \textit{Id.}
\item \textsuperscript{82} \textit{Id.}
\item \textsuperscript{83} \textit{Id.}
\item \textsuperscript{84} \textit{Id. at 924.}
\item \textsuperscript{85} \textit{Id.}
\item \textsuperscript{86} \textit{Id.}
\item \textsuperscript{87} \textit{Id. at 924–25.}
\item \textsuperscript{88} \textit{Id. at 925.}
\item \textsuperscript{89} \textit{Id. at 921.}
\item \textsuperscript{90} \textit{Id. at 921–22.}
\end{itemize}
particular drug may be used for any particular purpose, or indeed whether a physician who administers any controversial treatment could be deregistered.”91 Accordingly, the Court concluded that the CSA does not allow the Attorney General to prohibit physicians from prescribing drugs for use in assistance in dying, provided state law permits the procedure.92

II. ASSISTANCE IN DYING AND DEFINING MEDICINE’S BOUNDARIES

As a result of the Supreme Court’s decision, physician assistance in hastening death remains a legal option in Oregon. Obviously, this is an important consequence for those who favor laws permitting assistance in hastening death. Although obtaining a barbiturate or similar drug via a physician’s prescription is not the only way to hasten death, it is considered a humane method, is preferred by many physicians, and is the one contemplated under the ODWDA. For a variety of reasons, including the views of many that physician involvement is critical to a patient’s informed decision-making about whether to hasten death, it is unlikely that Oregon or any other state would have legalized other methods had there been an adverse Supreme Court ruling.

Notably, the Supreme Court decision does not preclude congressional action to prohibit at the national level assistance in hastening death on the ground that it does not comport with legitimate medical practice. Such federal legislation probably would be deemed constitutional under the Commerce Clause.93 Although it now seems unlikely that such legislation will be considered or enacted in the near future, there is the possibility that, given the shifting tides of political fortune, such a measure could eventually garner support. In the balance of this article we argue that any legislation that would prohibit physician assistance in hastening death on the ground that it does not fall within the scope of legitimate

91. Id. at 921.
92. Id.
93. See Gonzales v. Raich, 125 S. Ct. 2195, 2207 (2005) (declaring the CSA’s categorical prohibition of manufacture and possession of marijuana, a Schedule I substance, is a valid exercise of Congress’ authority under the Commerce Clause, even as applied to intrastate manufacture and possession of marijuana for medical purposes).
medical practice should be rejected. For reasons set forth below, we
conclude that physician assistance in hastening death is a legitimate
form of medical care. We also present a principled basis for
permitting physician assistance in hastening death in states where it
has not yet been legalized, based on larger principles already
established in the laws regulating medical practice today.

A. Assistance in Hastening Death as a Legitimate Form of
Medical Practice

We start with the premise that physician assistance in hastening
depth is best viewed as part of a continuum of medical care. A
physician who encounters a sick patient should initially seek, if
possible, to rid the patient’s body of injuries, diseases, or related
infirmities. Restoration of health is morally mandatory as a goal as
long as there is a reasonable prospect of success and the patient
supports the means necessary to this end. However, to direct the
physician to stop at this point and confine the practice of medicine to
those measures designed to cure diseases or heal injuries is an unduly
narrow way of thinking about what the physician has to offer the
patient. The value of physicians is broader.

When in the patient’s eyes the burdens of continued attempts at a
cure outweigh their probable benefits, the caring physician, in
consultation with the patient, should redirect the course of treatment
so that its primary focus is the relief of pain and suffering. For many
patients, palliative care with aggressive use of analgesics will prove
sufficient to accomplish this goal. For other patients, relief of
intolerable distress or suffering will come only with death, which
some patients will therefore seek to hasten.94

To prevent a physician from using her skills to bring comfort and
relief to a patient on the ground that the measures available are not
curative is to prevent the physician from meeting what both the
physician and the patient may consider the physician’s commitment

94. Again, under the ODWDA, many patients never ingest the drug provided via
the physician’s prescription. Fear of pain and the loss of bodily functions and autonomy is one of
the principal causes of distress for many. OR. DEP’T OF HUMAN SERVS., supra note 40, at 15.
Knowledge that one can readily escape these dreaded conditions if they become intolerable
may, by itself, provide sufficient comfort.
to and responsibility for her incurably ill patients. This narrow view of the practice of medicine is analogous to the clearly incorrect claim that the practice of law is confined to measures designed to obtain an outright victory in litigation. To the contrary, lawyers often serve their clients best by reconciling them to the inevitable, securing a negotiated outcome and working with them to ease their passage through legal woes. It would be incongruous to claim that a physician cannot attend to a patient in analogous caring ways. In both professions the goal is the best possible outcome for the client or patient, whatever that may be in the informed view of the patient or client.

Many, if not most, contemporary physicians view their practice as encompassing assistance in hastening death. A recent survey finds that 57% of physicians practicing in the United States today consider it ethically permissible to assist a terminally ill, mentally competent patient who has made a considered choice to terminate life in order to avoid unbearable suffering.95 Other studies find similar support among a plurality of physicians.96 The pages of respected medical journals also demonstrate that a significant number of physicians today consider assistance in hastening death to be squarely within the bounds of legitimate medical practice, whether the patient’s motivation is the alleviation of physical pain or relief from profound suffering.97 This support by physicians themselves for inclusion of assistance in hastening death within the scope of their practice, while not dispositive of this issue, demonstrates that claims that assistance in hastening death is fundamentally incompatible with the physician’s

role are based on the speaker’s own viewpoint rather than on most contemporary physicians’ self-perception. 98

There are prudential reasons for permitting physicians to provide such assistance legally and publicly. First, if physicians are barred from providing assistance lawfully, some patients will resort to self-help in causing their own deaths, with adverse consequences. A few, being concerned about waiting until it is “too late” (that is, until they lack the physical or mental ability to hasten their own deaths), will end their lives prematurely. If they had access to the security of a lethal drug, they might find their situation bearable and continue to live until a natural death arrives. As one perceptive commentator has observed: “If the only choice is suicide now and suffering later, individuals will frequently choose suicide now. . . . The possibility of physician-assisted suicide enables them to wait until they have more information before deciding whether to live or die.”99

Alternatively, some patients will seek and obtain covert assistance from physicians. Although statistics regarding covert assistance are elusive given the illegality of the practice, available evidence indicates that a substantial number of physicians provide such assistance in secret at least once in their careers. 100 This assistance, which takes place with the involvement of as few individuals as possible, is more susceptible to abuse than a practice that is open and regulated. A regulatory scheme that minimizes the chance that patients will be manipulated or coerced into dying also diminishes the risk that they will make an ill-advised choice while cognitively impaired or experiencing depression, and it encourages them to live as long as they find their lives worthwhile. For this reason alone, a

100. See, e.g., Ezekiel Emanuel et al., Euthanasia and Physician-Assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public, 347 LANCET 1805, 1808 (1996) (in one study half of oncologists surveyed had received a request for assisted death, and 13.6% had complied); Diane E. Meier et al., A National Survey of Physician-Assisted Suicide and Euthanasia in the United States, 338 NEW ENG. J. MED. 1193, 1195 (1998) (11% of physicians polled reported that, even under current legal constraints, there are circumstances in which they would prescribe a medication for a competent patient to use with the primary intention of ending his or her life); Lee R. Slome et al., Physician-Assisted Suicide and Patients with Human Immunodeficiency Virus Disease, 336 NEW ENG. J. MED. 417, 419 (1997) (53% of 117 Bay-area physicians specializing in the care of patients with AIDS indicated that they had acceded at least once to a request to hasten death).
scheme that allows physicians to provide legal assistance in hastening death is preferable to a total ban on that assistance.

Some who contend that assistance in hastening death lies outside the boundaries of medical practice rely on a mechanical and telescoped concept of the physician’s role. Under this view, assisting a patient to die does not make use of medical skills or judgment, but rather consists only of utilizing technical knowledge about how to cause a patient’s death.\(^\text{101}\) These arguments treat assistance in hastening death as if it begins and ends with a doctor’s prescription of a lethal dose of medication. This view of the physician’s role is again too narrow.

A physician who assists a patient in hastening his or her death is not a mere technician, nor does this physician provide services that could be provided, just as easily and competently, by a layperson. Sensitive physicians use the full extent of their professional training and experience when they assess the patient’s condition and determine whether the patient is terminally ill; they assess the prospects for effective palliative care for the patient through a meaningful dialogue with the patient; they evaluate what alternatives may be feasible and acceptable to the patient; they determine whether the patient is competent to make a decision regarding the course of treatment; they ensure that the patient’s judgment is not impaired by depression or other factors; and they consult with other physicians to confirm the accuracy of the diagnosis, the exhaustion of other alternatives, and the competence of the patient. To be performed well, these activities all require the experience, knowledge, and skills of the physician.

Although physician assistance in hastening death is not universally accepted as a legitimate medical practice, neither is its acceptance an eccentric or novel view. Because the Hippocratic Oath

\(^{101}\) See, e.g., DANIEL CALLAHAN, THE TROUBLED DREAM OF LIFE: IN SEARCH OF A PEACEFUL DEATH 110 (Georgetown Univ. Press 2000) (stating that a doctor does not use medical standards in deciding whether to provide assistance in hastening death); Leon R. Kass, I WILL GIVE NO DEADLY DRUG: WHY DOCTORS MUST NOT KILL, 77 AM. C. SURGEONS BULL. 6 (1992) (noting that “killing” is not part of the physician’s art); see also AM. MED. ASS’N, CODE OF MED. ETHICS R. 2.211 (1998) (declaring that physician-assisted suicide is incompatible with the physician’s role).
instructs physicians not to provide a “deadly drug,”102 some have concluded that physicians, by their training and moral commitment, must necessarily reject assistance in hastening death.103 This is not so. The provision in the Hippocratic Oath that prohibits providing a deadly drug did not even reflect accepted medical practice in ancient Greek city-states where, upon request, a physician could provide a lethal drug for a suffering patient.104 In some sense, physicians who provide assistance in hastening death are adhering to a longstanding understanding of the scope of medical practice: to care for and meet the needs and desires of a patient in all stages of the patient’s life.

Significantly, the activities a physician undertakes in providing assistance in hastening death are the same as those often carried out by a physician who oversees a withdrawal of treatment.105 As a purely medical matter, there is little to distinguish a physician’s activities in withdrawing treatment from activities in hastening death through other means.

B. The Inadequacy of the Distinction Between “Letting Die” and “Killing”

Those who reject physician assistance in hastening death often attempt to distinguish between overseeing a refusal of treatment and what they characterize as assisting in a suicide.106 They attempt further to ground this distinction in what they describe as the

102. LUDWIG EDELSTEIN, ANCIENT MEDICINE 6 (Owsei Temkin & C. Lilian Temkin eds., 1967).
105. We say “often carried out” because given the widespread acceptance of withdrawal of treatment, there is relatively little scrutiny of what most physicians actually do in such situations.
difference between “letting die” and “killing.” This distinction between letting die and killing is applied to distinguish between practices considered permissible under certain conditions from practices that should always be condemned. Withdrawals or withholdings of treatment have often been classified in the “letting die” category, depending on the nature of the illness and the intent of the physician although not always depending on the wishes of the patient. This distinction between killing and letting die has long been the most critical one in attempts in law and moral philosophy to distinguish appropriate from inappropriate means to death.

However, the distinction between “killing” and “letting die” is not a reliable way to distinguish impermissible from permissible acts. It is unsatisfactory for a number of reasons, not least because it tends to mask, rather than promote, consideration of the relevant factors that ought to be considered in determining permissible conduct. For example, we believe that withdrawing treatment from a competent patient is not morally justifiable unless the patient has made an informed decision authorizing this withdrawal. If a physician removes a respirator from a patient who needs it and wants to continue to use it, the action is wrong, even though the physician has only removed artificial life support and let nature take its course. Absent the patient’s authorization, such “letting die” is simply killing. The lack of authorization by the patient is the relevant consideration in assessing the act as unacceptable. Focusing on the distinction between letting die and killing obscures what should be the determinative factor in evaluating the physician’s conduct: the patient’s decision.

A physician’s validly authorized nonintervention in circumstances in which the patient dies as a result is appropriate where the physician is following the patient’s instruction. The physician is not the relevant cause of death and does not act wrongly if he or she has valid authorization for withholding or withdrawing treatment. By contrast, comparable action or inaction is inappropriate in medicine if a physician has a duty to treat but the physician withholds or withdraws, without patient authorization, a life-sustaining technology, and the patient

subsequently dies for lack of the technology. A physician is the relevant cause of death, and thereby acts wrongly, if he or she has no valid authorization from the patient to withhold or withdraw treatment.

Of course, physicians also may use a so-called “active” means to bring about death. Some would argue that use of any “active” means necessarily results in an inappropriate “killing.” But there are several problems inherent in the idea that we can determine appropriate and inappropriate conduct by considering whether an active means to death was involved. This is especially true in the context of the ODWDA, where the distinction between “letting die” and “killing” is not helpful in determining appropriate and inappropriate physician conduct. Physicians who act under the ODWDA do not “kill” patients in any meaningful sense. A physician who prescribes a lethal medication at a patient's request is simply writing a prescription. That act no more “kills” a person than does the writing of a prescription for sedatives or analgesics for a patient who is undergoing withdrawal of treatment. Under the ODWDA, the patient must make a conscious decision to use the drug. About one-third of the patients who seek a prescription under the ODWDA never ingest the lethal drug; others ingest it months after it has been prescribed. For those who do take the drug, the physician’s writing of the prescription is a necessary step in the process that leads to the patient’s death, but it is not the determinative or even the final step. Under any reasonable interpretation of the term, the Oregon physician does not “kill” the patient. Nor, however, does this physician “let the patient die.” Use of the terms “letting die” and “killing” is simply not an illuminating way to view what happens when a physician provides a patient who so requests with the means to escape the ravages of a fatal illness.

One can understand the initial appeal of the letting die/killing distinction. It has deep roots in English tort law, which made unwanted touchings actionable. Moreover, killings are rarely authorized by the victim, and cases of letting-die generally are validly authorized. But the frequency with which one kind of act is justified, by contrast to the other kind of act, should not determine whether either kind of act can ever be legally or morally justified.

C. Resolving Disputes Between Different Models of Medical Practice

It is undeniable that the physician-as-healer model of medical practice derives from a resilient tradition that retains considerable support today, both in the medical community and among the public at large. The reasons it enjoys such support are understandable: it is in some ways a comfortable view and it avoids confrontation of some difficult issues. However, this model no longer appears to be the dominant view, either in the medical community or among the public. We have supported a very different model, the continuum-of-care model, that takes a broader view of the range of activities legitimate for physicians. It is likely that both models will continue to enjoy significant support in the years to come. How, then, should we resolve disputes between these inherently contestable models? Is there any way other than sheer political muscle? Can the models co-exist?

The key issue is how to determine the goals of regulation. Fortunately, the historical record may provide useful direction. Regulatory questions regarding whether a particular action serves a legitimate medical purpose are not new. Historically these disputes have focused on whether a proposed treatment is safe and effective. These disputes continue today, as the controversies over various forms of alternative medicine illustrate. In resolving such disputes, regulatory bodies, be they federal or state, have not only looked at the implications for patients receiving the disputed drug, device, or treatment, but also at implications for society as a whole. Two of the principal motivations for the Pure Food and Drug Act of 1906, the first federal law addressing health care, were to ensure that drugs were not adulterated and that consumers received important information about the contents of available drugs.109 This measure reduced the risk to consumers from impure, unsafe drugs and had the effect of improving confidence in manufactured drugs and medications, thereby creating a market for responsible drug manufacturers. Similarly, in evaluating disputed practices today, from

xenotransplantation\textsuperscript{110} to genetic therapies, a critical question is the effect the practice will have not only on patients receiving the care but on society as a whole. Will the welfare of many be adversely affected by tolerance of the benefits afforded others by the practice?

We urge that similar considerations of public health and safety be utilized for adjudicating normative disputes about appropriate restrictions on a physician’s actions in caring for terminally ill patients. Protection of the health and safety of both patients and the public is a presumptively legitimate goal and well-established in the laws regulating medicine. The question we should ask is this: Is the proposed restriction necessary to protect the public from consequences that are regarded as serious and adverse by all or almost all? In the context of assistance in hastening death, the question becomes, is prohibition necessary to ensure that those who wish to die naturally are not tricked, maneuvered, or otherwise manipulated into ending their lives earlier? Might legalization reduce opportunities for effective palliative care, to the detriment of many?

Concerns that legalizing assistance in hastening death might result in serious harms, especially for those \textit{not} seeking such assistance, have been raised by many opposed to assistance in hastening death. If legalization were to bring about unwarranted, involuntary deaths, reduce the quality of palliative care, result in deep-seated and widespread mistrust of physicians, and so on, then we agree that these consequences would support arguments against legalizing physician assistance in hastening death. However, none of these consequences has come to pass in the only state that has legalized physician assistance in dying.\textsuperscript{111} Moreover, it appears that the quality of palliative care has improved more quickly in Oregon than

\textsuperscript{110} “Xenotransplantation” is the transplantation of cells, tissues, or organs from nonhumans to humans. See F.H. Bach et al., \textit{Uncertainty in Xenotransplantation: Individual Benefit Versus Collective Risk, in ETHICAL ISSUES IN BIOTECHNOLOGY} 341 (Richard Sherlock & John D. Morrey eds., 2002).

\textsuperscript{111} See supra notes 40–44 and accompanying text. Although Oregon’s experience strongly suggests that other jurisdictions could legalize assistance in hastening death without significant adverse consequences, it certainly provides no guarantee this would be the case. This, of course, is one argument in favor of adopting a state-by-state approach to assistance in hastening death. Only through experiences with various states will we be able to determine whether opponents’ concerns about legalization have any empirical basis anywhere.
Accordingly, there is currently no empirical basis for concluding that prohibiting physician assistance in hastening death would protect the public health and safety.

Clearly, some terminally ill patients, those who seek prescriptions under the ODWDA, are enabled by the statute to exercise control over the time and manner of death. The public health and safety of these patients is served by legalization and the strict procedural safeguards contained in the Oregon statute. There is no countervailing harm to others in the state. The only effect of the statute on them seems to have been a benefit: increased attention to end-of-life care, with a resulting improvement in palliative care. Thus, the public health and safety of the community as a whole is served by legalization of physician assistance in hastening death accompanied by procedural safeguards.

Neither those who are convinced for moral, religious, or medical-traditional reasons that medical practice must be confined to some model of “healing,” nor those who are convinced, for distinct moral, religious, or other reasons, that there should be no restrictions on patient autonomy, especially in the context of end-of-life care, will likely be persuaded by our proposal. However, focusing on public health and safety is the only way that we see to define the limits of medical care without turning this issue into a political football. One does not have to be a moral skeptic to know that there is no popularly accepted decision-making procedure for determining whether one well-defended moral argument is more rationally persuasive than another. Uncertainty about different normative conclusions is only exacerbated when the dispute encompasses the regulation of an important, respected, and influential profession and restrictions on patients’ rights.

We recommend the following general principle for regulation of medical practice: neither the states nor the federal government should limit the type of care physicians provide their patients in the absence

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112. See supra note 45.
113. Both before and after the decision in Gonzales v. Oregon, much attention has been given to the allocation of regulatory authority between federal and state governments with respect to the regulation of medical practice. This is an important issue, but, in our view, a secondary one. Certainly, no invocation either of states’ rights or of the need for uniform federal regulation will resolve debates over the limits that should be placed on medical practice.
of evidence that the practice at issue poses a significant threat to the health and safety of the public. Utilizing this standard avoids unresolvable disputes about the goals or ends of medicine while ensuring that legitimate public concerns are taken into account. Under this standard, there is no sound basis for state or federal legislation that would prevent physicians from assisting patients in hastening their deaths pursuant to the provisions like those of the ODWDA.

CONCLUSION

Assistance in hastening death is controversial and is likely to remain so for the foreseeable future. The debate is particularly difficult to resolve because the two sides argue from sharply divergent views about the appropriate role of physicians. Attempts to end the debate over, and the experiments with, legalized assistance in hastening death by imposing a restrictive model of medical practice, either through executive fiat or legislation, would needlessly sacrifice the benefits derived from legal assistance in hastening death. The touchstone for decisions over legalization should not be whether assistance in hastening death can be characterized as “healing” or “letting die,” but whether legalization causes significant harm to the public health and safety. The Oregon experience demonstrates that the health and safety of the citizens of that state have been protected, and even promoted, by legalization of physician assistance in dying.

114. Note that our proposed standard is similar to one of the five factors that the Attorney General is required to consider under the CSA prior to revoking the registration of a physician. 21 U.S.C. § 823(f) (2000) (stating that the Attorney General must consider threats to public health and safety). Thus, it finds a firm foundation in the established statutory scheme regulating medical practice.