No. 04-623

In The
Supreme Court of the United States

October Term, 2005

ALBERTO R. GONZALES,
Attorney General of the United States, *et al.*,
Petitioners,

v.

STATE OF OREGON, *et al.*,
Respondents.

On Writ of Certiorari
To The U.S. Court of Appeals
For The Ninth Circuit

BRIEF AMICUS CURIAE OF THE INTERNATIONAL TASK FORCE ON EUTHANASIA AND ASSISTED SUICIDE In Support of Petitioners

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QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq*., and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

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INTEREST OF AMICUS CURIAE

Amicus curiae, the International Task Force on Euthanasia and Assisted Suicide (ITF),[1] is an international leader in the debate over assisted suicide and euthanasia. ITF is the operating name of the Family Living Council, a non-profit corporation formed in 1976 to provide education related to issues impacting on the family. It addresses legal and public policy issues related to death and dying, health care delivery and pain control, the rights of the terminally ill, the chronically ill, the elderly, persons with disabilities and the impact of such issues on individuals and families.

The ITF has particular expertise in analyzing the practical implications and specific information related to both Attorney General Ashcroft's Directive and the Oregon Death with Dignity Act (ODWDA). This *amicus* brief will be of particular assistance to the Court since it demonstrates that the ODWDA may be carried out without the use of federally controlled substances, which is relevant to the fact that the Ashcroft Directive does not nullify Oregon's law but, instead, affirms the role of the federal government in interpreting its own regulations. Furthermore, it illustrates the fact that prescribing drugs for the purpose of inducing death is not in accordance with a standard of medical practice generally recognized and accepted nationally or internationally. Finally, it clarifies the interstate nature of activities under the ODWDA, which is relevant to maintaining a national standard for dispensing federally controlled substances.

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[1] Letters of consent for the filing of this brief have been filed with the Clerk. Counsel for a party did not author this brief in whole or in part and no person or entity other than *amicus curiae* has made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

This case is not about whether the State of Oregon may permit the practice of assisted suicide within its borders. It is about Oregon's attempt to determine the manner in which a federal registration to prescribe federally controlled substances may be used. The Oregon Death with Dignity Act (ODWDA) gives Oregon physicians the right to "prescribe medication" to induce death. Or. Rev. Stat. §§ 127.800 *et seq.* (2003). However, the ODWDA does not specify the type of drugs for that purpose.

While all federally controlled substances are prescription drugs, not all prescription drugs are federally controlled substances. The Directive issued by Attorney General Ashcroft was an interpretive rule dealing solely with whether using a federal registration to prescribe federally controlled substances to cause drug-induced death serves a "legitimate medical purpose" under DEA regulations. 66 Fed. Reg. 56,607 (2001). Under the Directive, Oregon physicians are still free to prescribe drugs that are not federally controlled.

National standards of medical practice reject the use of drugs for the purpose of inducing death. Likewise, international standards of medical practice reject the use of drugs for the purpose of inducing death. Yet, Oregon seeks to exempt itself from a uniform national standard. It seeks to substitute a state-determined interpretation of "legitimate medical purpose" for the use of federal registrations. Under such an interpretation, each state could determine the use of federally controlled substances, potentially resulting in fifty different sets of accepted purposes.

The use of federally controlled substances for assisted suicide does not affect only the state of Oregon. Distribution of federally controlled substances for assisted suicide cannot be confined within Oregon's borders since prescriptions can be filled through out-of-state mail order prescription services.

ARGUMENT

I. The Ashcroft Directive does not criminalize assisted suicide, nullify Oregon's assisted suicide law or interfere with Oregon's ability to control the practice of medicine.

The Ninth Circuit Court of Appeals erred when its majority asserted, "By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders..." *Oregon v. Ashcroft,* 368 F.3d 1118, 1124 (9th Cir. 2004). The Ashcroft Directive does not criminalize assisted suicide nor does it interfere with Oregon's regulation of medical care within its borders.

Congress granted authority to the Attorney General to carry out the Controlled Substances Act (CSA) and Drug Enforcement Administration (DEA) regulations that implement the CSA, including 21 C.F.R. § 1306.04 (a).

The Ashcroft Directive does not address the matter of whether assisted suicide may be considered a "legitimate medical *practice*" under Oregon law. It deals solely with whether using a federal registration to prescribe federally controlled substances to cause drug-induced death serves a "legitimate medical *purpose*" under DEA regulations.

If the Ashcroft Directive is implemented, and if a physician chooses to prescribe federally controlled substances for assisted suicide, administrative proceedings could be instituted. The outcome of those proceedings would determine whether the physician's federal registration is retained, revoked or suspended. No matter what the outcome of those administrative proceedings, the physician would still be able to lawfully prescribe non-federally controlled drugs and would still be able to practice medicine in Oregon. Furthermore, the physician would still be able to engage in assisted suicide under Oregon's law.

A. Under the Ashcroft Directive assisted suicide would remain legal in Oregon.

The Ninth Circuit's ruling erroneously stated that "Oregon's Death with Dignity Act authorizes physicians to prescribe lethal doses of controlled substances to terminally ill Oregon residents...." *Oregon v. Ashcroft,* 368 F.3d 1118, 1122. The ODWDA permits physicians to "prescribe medication," but does not define "medication." It does not authorize a particular method of inducing death other than precluding the use of a lethal injection, mercy killing or active euthanasia. Or. Rev. Stat. 127.880 (2003). Certainly, it does not specifically authorize physicians to prescribe lethal doses of controlled substances. Passage of the ODWDA approved the act of physician-assisted suicide. However, the ODWDA does not specify the *means* by which the act is to be accomplished. Nothing in the ODWDA limits "medication" to a federally controlled substance.

The Ninth Circuit also misspoke when it stated, "By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders...." *Oregon v. Ashcroft,* 368 F.3d 1118, 1124 (9th Cir. 2004).

The Ashcroft Directive does not prevent physicians from engaging in the *practice* of physician-assisted suicide under the ODWDA. Physicians may still write prescriptions for medication for the purpose of enabling patients to commit suicide. The Ashcroft Directive only addresses the *means,* by stating that practitioners may not use their federal registrations to prescribe federally controlled substances for the purpose of causing drug-induced deaths.

B. Under the Ashcroft Directive, physicians may still prescribe assisted suicide.

Although all federally controlled substances are prescription drugs, not all prescription medications are federally controlled substances. A federal registration is

only required to dispense prescription medications that are federally controlled substances. The Ashcroft Directive applies only to those prescription drugs for which a federally issued license is necessary and only to those drugs when they are prescribed for the purpose of enabling a patient to commit suicide.

Despite the fact that barbiturates (sleeping pills) taken by mouth account for 204 of the 208 deaths reported in the first seven years during which the ODWDA has been in effect (Oregon Dept. of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act,* March 10, 2005, http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf at 24, Table 4), the ODWDA does not limit the means of assisted-suicide deaths to oral medication.

While it is not the intent of *amicus* to provide "how to" instructions for assisted suicide, the discussion below is necessary to illustrate the full meaning of "medication" and the fact that assisted suicide can be carried out under the ODWDA without using federally controlled substances.

The ODWDA refers to a prescription for "medication" but does not define the term. However, accepted definitions of medication include: "medicinal substance, a drug, and treatment with remedies." TABER'S CYCLOPEDIC MEDICAL DICTIONARY 1017 (19th ed. 2001). "Remedy," which falls within the meaning of "medication" is defined as "anything that relieves or cures a disease." *Id.* at 1776.

Shortly after passage of the ODWDA in 1994, Peter A. Goodwin, MD, of the Oregon Health Sciences University, who was one of the authors of the ODWDA, appeared on ABC's *Nightline* to discuss the ODWDA. He explained that no route of administration of lethal medication would be excluded under the ODWDA "as long as the patient had full responsibility."[2]

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[2] Referring to a device in which a patient pushes a lever that activates the flow of a substance (similar to that which had been used by Jack Kevorkian to deliver carbon monoxide or another substance), Dr.

Thus, a prescription of "medication" as permitted under the ODWDA could encompass routes other than oral and substances other than barbiturates.

The fact that the ODWDA does not preclude varied routes of administration was also noted in a 1997 Oregon State Bar Association publication:

> An attending physician may write a prescription for "medication to enable a qualified patient to end his or her life in a humane and dignified manner." Or. Rev. Stat. §127.815(9) [sic]. The choice of drug, or drugs, is left to the discretion of the physician as a medical practice decision. 2 Oregon Health Law Manual 8-19, §8.23, Oregon CLE 1997.
>
> The *route of administration is also discretionary,* except that the Act expressly prohibits "lethal injection." Or. Rev. Stat. §127.880. It appears that other routes of administration — such as oral ingestion, rectal suppository, or transdermal absorption — would fall within the Act. *Id.* (emphasis added).

The publication goes on to ask and answer a query:

> Would a delivery method such as inhalation be eligible for immunity, since the Act does not expressly mention "devices," and some sort of delivery system would be needed for an inhaled gas? Interpretation may also be needed to clarify whether intravenous equipment, such as might be in place already for the treatment of pain and dehydration, may be used by the patient to deliver a slow infusion of medication. One might reasonably interpret a prescription for an "infusion" as distinct from an "injection," and therefore be within the scope of

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Goodwin stated that "if the patient had a gadget similar to that that Dr. Kevorkian used and wanted to do it that way, it's my belief that that would not be excluded as long as the patient had full responsibility." *Nightline* (ABC television broadcast, Dec. 7, 1994) (transcript No. 3533) available in LEXIS/NEXIS.

> the Act. *Because the goal of the Act is to regulate voluntary self-administration, the critical question is whether the medication, by whatever route, is self-administered. Id.* (emphasis added).

It seems highly probable that devices would be permitted under the ODWDA since a device is a "remedy" and does fall within the definition of "medication." Furthermore, prescriptions are frequently written for devices. For example, it is customary for physicians to write prescriptions for a specific type of dental appliance — known as a Mandibular Protruding Device (MPD) — as a remedy for sleep apnea.

Similarly, a device that could be used to enable a patient to end his or her life could be prescribed under the ODWDA. A physician could write a prescription for the type of assisted suicide appliance made from plastic tubing to be used with substances that are not federally controlled substances. Alternatively, a physician could merely direct the patient about how he or she might obtain the devices that are well known, widely advertised and widely distributed by assisted suicide proponents.

The Ninth Circuit inappropriately ventured into determining what it believed to be the optimal way to induce patients' deaths when the majority opined that "it is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives." *Oregon v. Ashcroft,* 368 F.3d 1118, 1123 (9th Cir. 2004).

It is interesting to note that, among those who have had actual experience in facilitating patients' deaths, there is actually some question about the merits of barbiturates.

For a number of years, the Hemlock Society (now known as Compassion and Choices) has operated a program called "Caring Friends" which provides how-to-commit-suicide information and in-person support to individuals as they die. *See:* International Task Force on Euthanasia

and Assisted Suicide, *Facts about Hemlock and Caring Friends* (2005) at http://www.internationataskforce.org/hemlockcf.htm.

Lawrence D. Egbert, MD, MPH, who acknowledges being present at about fifty deaths as a Caring Friends volunteer, has suggested that "helium is a better way to do a hastened death than barbiturates." Message from Lawrence D. Egbert, MD, MPH, "Perhaps helium better than barbiturates," (July 8, 2004) available at http://www.mailman.efn.org/pipermail/right_to_die/2004-July/000172.html, last accessed April 25, 2005.

An additional method of inducing a patient's death includes the use nitrous oxide. It has been used for suicide,[3] either alone or in combination with tricyclic antidepressants (which cause sedation). Another means could include the infusion of a massive overdose of insulin.

Accordingly, self-administration of "medication" under the ODWDA, can occur orally, by application of a patch, insertion of a suppository, activation of a device and/or inhalation of a substance.

While *amicus* believes that permitting assisted suicide in policy or in law is tragic for patients, dangerous for society and bad public policy, this case is not about overturning Oregon's law permitting assisted suicide. As discussed and illustrated above, implementation of the Ashcroft Directive does not nullify the ODWDA, nor does it prevent assisted suicide deaths under the Act.

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[3] The use of nitrous oxide for suicide has been described in medical literature. *See, e.g.,* A. Chadly, B. Marc, D. Barres, M. Durigon, *Suicide by Nitrous Oxide Poisoning,* 10 Am. J. Forensic Med. & Pathology 330 (1989).

C. The Ashcroft Directive does not affect state control of medical practice in Oregon.

States regulate the practice of medicine. States issue medical licenses. Only states may revoke physicians' licenses to practice medicine.

The Attorney General, under the authority granted by the CSA, controls the dispensing of federally controlled substances. It is the Attorney General who registers physicians to prescribe federally controlled substances and it is the Attorney General who may suspend or revoke such registrations, in accordance with administrative procedures.

Physicians in Oregon are not required to have a federal registration to practice medicine. Without a federal registration, physicians may diagnose and treat patients. They may perform surgery. They may prescribe any of the thousands of medication that are not federally controlled substances.[4]

If the Ashcroft Directive is implemented, the conduct of a physician who prescribes federally controlled substances to assist suicide "*may* render his registration...inconsistent with the public interest and therefore subject to *possible* suspension or revocation under 21 U.S.C. §824(a)(4)." 66 Fed. Reg. 56,607 (2001) (emphasis added). Prescribing or providing medications for assisted suicide that are not controlled substances would not subject a practitioner's registration to any risk of suspension or revocation.

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[4] For qualifications and licensing procedures for physicians, see Or. Rev. Stat. §§ 677.100 – 677.139. Although Oregon law provides that the Board of Medical Examiners *may* suspend or revoke a physician's license to practice medicine if the physician violates the federal CSA Or. Rev. Stat. §677.190 (24), the ODWDA prevents the state from taking such action against a physician for actions in compliance with the ODWDA. Or. Rev. Stat. §127.885 (2).

II. The United States has never considered prescribing drugs to cause death to be a legitimate medical purpose, nor has it ever deemed drug-induced death for any patient to be in the public interest.

A. The federal government has consistently viewed drug-induced death as a threat to public health.

Opponents of the Ashcroft Directive have asserted that, since the CSA does not explicitly state that assisted suicide is not a legitimate medical practice, Congress did not intend to prevent a practitioner from prescribing federally controlled substances for that purpose.

On the contrary. While, in 1984, no one envisioned that any medical professional would seriously claim that assisting suicide was a "legitimate medical practice," there was great concern about the serious threat that drug-induced deaths posed to public health and safety. When Congress amended the CSA in that year, it did so to strengthen the ability of the Attorney General to deny, suspend or revoke registrations of practitioners who dispensed federally controlled substances in a way that threatened public health and safety and to give the Attorney General the authority to act in cases where a state was either unable or unwilling to intervene.

At that time, supporters of amending the CSA based the legal change on the need to expand the Attorney General's authority so that the most serious threat to public health and safety — the frequency with which prescription drugs were involved in drug-induced deaths — could be addressed.

Indeed, common sense dictates that the basis for control of certain drugs is the prevention of threats to health and life. Throughout the history of the nation, intentionally participating in causing or enabling drug-induced death has never been considered a legitimate medical practice.

Furthermore, suicide has never been viewed as a treatment or therapy for any medical condition.

As recently as 1999, David Satcher, MD, then Surgeon General of the United States, declared, "Suicide is a serious public health problem." U.S. Public Health Service, *The Surgeon General's Call to Action to Prevent Suicide* (1999) at 1. He noted that suicide was the ninth leading cause of mortality in the United States, accounting for nearly 31,000 deaths per year, a number that was more than 50 percent higher than the number of homicides for the same year. *Id.*

Surgeon General Satcher urged implementation of a comprehensive national strategy for suicide prevention as an important step in responding to the "the major public health problem of suicide in the United States." *Id.* at 16. He did not urge suicide prevention for all but the terminally ill.

B. The CSA has never provided an exception for individuals with a terminal illness.

When it passed the CSA, Congress found, "Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. §801 (1). Thus, the CSA grants exemptions to the overall prohibition on dispensing controlled substances so that those substances may be dispensed for useful and legitimate medical purposes that are needed to maintain the health and general welfare of the American people.

Suicide — including suicide by intentional overdose of federally controlled substances — has never been considered an act that maintains "health and general welfare."

Those who oppose the Ashcroft Directive would have this Court believe that there is an implied exception to the CSA, permitting prescriptions for federally controlled substances to assist suicides of terminally ill patients. There is, however, no basis for such an exception.

Nowhere is there any evidence that Congress intended protections related to drugs to apply only to persons suffering from curable diseases. In *Rutherford,* the Court noted that "the concept of safety under §201 (p) is not without meaning for terminal patients." *United States v. Rutherford,* 442 U.S. 544, 552, 555 (1970). In its discussion of the Food and Drug Administration's (FDA) approval of drugs for use by the public, this Court declared, "For the terminally ill, *as for anyone else,* a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *Id.* at 555-556 (emphasis added).

If the FDA will not approve a drug for use if its *potential* for inducing death is not offset by the possibility of therapeutic benefit, it is preposterous to think the Attorney General should be compelled to authorize prescribing controlled substances for the specific *purpose* of inducing death.

Just as the legislative history and consistent administrative interpretation of the Federal Food, Drug, and Cosmetic Act (FDCA), (21 U.S.C. 355 *et seq.*) gave no implicit exception to the terms "safe" and "effective" for drugs used by the terminally ill, the CSA does not imply any exception to the meaning of "public health and safety" for those who are terminally ill.

The concept of "safety" applies equally to all patients under the FDCA, including terminally ill patients. So, also, the meaning of "public health and safety" is equally applicable to all patients – young and old, rich and poor, temporarily ill, chronically ill, and terminally ill – under the CSA.

Moreover, if prescribing federally controlled substances for the purpose of causing drug-induced death for terminally ill patients were to be considered a legitimate medical purpose, the Attorney General would be compelled to consider such prescribing a legitimate medical purpose for

any and all other patients if a state so decides since the exception to the CSA would be based on a state's right to decide how a federal registration may be used.

C. Maintaining national standards pertaining to federally controlled substances is vital to prevent chaos and to protect public health and safety.

The Ninth Circuit's decision radically undermines the Federal Government's ability to enforce a uniform national standard related to federal registrations and federally controlled substances. It renders the federal government powerless to interpret its own regulations.

This has broad implications. Indeed, if Oregon has the right to unilaterally determine what constitutes a legitimate medical purpose under federal regulations promulgated under the CSA, then each and every state has similar authority. Absent uniform enforcement of the CSA, chaos will ensue.

The use of a federal registration to prescribe controlled substances would be subject to widely varied and constantly changing state determinations. One state could choose to permit physicians to use their federal registrations to prescribe federally controlled substances to terminally ill people for the purpose of suicide. Another could decide that such registrations could be used to prescribe federally controlled substances for recreational purposes. Yet another may choose to do both of the preceding while another may choose to do neither. Essentially, any state could prevent federal officials from enforcing the CSA within its borders. Although the CSA and its relevant regulations are federal, enforcement of federally controlled substances would be virtually impossible.

Unless the Ninth Circuit's decision is overturned, the power to regulate the medical uses of federally controlled substances will rest with each state, potentially leading to fifty different interpretations of what constitutes a proper

medical purpose for prescribing federally controlled substances. This would compel the federal government to cede all authority for interpreting and regulating controlled substances to the individual states and would result in total disintegration of a national drug policy as it relates to prescriptions for narcotics.

III. National and international standards of medical practice reject the use of drugs for the purpose of inducing a patient's death.

A. Prescribing drugs for the purpose of inducing a patient's death does not reflect national medical standards.

As this Court has previously noted, the American Medical Association, in its Code of Ethics, condemns physician-assisted suicide as an act that is incompatible with the physician's role as a healer. *Washington v. Glucksberg,* 521 U.S. 702, 731 (1997).

That position, explicitly stating that "allowing physicians to participate in assisted suicide would cause more harm than good" and that "physician assisted suicide is fundamentally incompatible with the physician's role as healer" remains unchanged. American Medical Association, *E-2.211 Physician-Assisted Suicide* (June 1994), based on the reports *Decisions Near the End of Life* (adopted June 1991) and *Physician-Assisted Suicide* (adopted December 1993), (JAMA 1992:267:2229-2233); updated June 1996, July 22, 2002.

The American College of Physicians-American Society of Internal Medicine opposes physician-assisted suicide, stating that it "raises serious ethical and other concerns" and that it would "endanger the value our society places on life, especially the lives of disabled, incompetent, and vulnerable individuals." Lois Snyder and Daniel P. Sulmasy, *Position Paper: Physician-Assisted Suicide,* 135 Annals of Internal Medicine 209 (2001).

The American Geriatrics Society has noted that limits on physician-assisted suicide would be difficult to maintain, that problems in carrying it out would be legion and that, "by collaborating in causing early deaths, when continuing to live has been made so difficult, geriatricians would become complicit in a social policy which effectively conserves community resources by eliminating those who need services." Joanne Lynn *et al, Public Policy: American Geriatrics Society on Physician-Assisted Suicide,* 45 Journal of the American Geriatrics Society, 489, 490-491 (1997).

Furthermore, in November 1996, 46 national specialty and state medical societies filed a brief with this Court stating that, although it might appear compassionate to intentionally cause death, "institutionalizing physician-assisted suicide as a medical treatment would put many more patients at serious risk for unwanted and unnecessary death." Brief of *Amici Curiae* American Medical Association, the American Nurses Association, and the American Psychiatric Association, *et al* Supporting Petitioners at 3, *Vacco v. Quill* (No. 95-1858) (1996).

Clearly, prescribing federally controlled substances for the purpose of inducing death does not reflect national medical standards.

Even in Oregon, physicians are reluctant to become involved in assisted suicide. This has led one managed care corporation to solicit physicians to become assisted-suicide providers.

On August 6, 2002, Robert Richardson, MD, Administrator of Oregon's Kaiser Permanente, sent an e-mail to doctors affiliated with Kaiser, asking them to contact him if they were willing to act as the "attending physician" for patients requesting assisted suicide. According to the message, the HMO needed more physicians because, "Recently our ethics service had a situation where no attending MD could be found to assist an eligible member in implementing the law for three weeks...." Andis Robeznieks,

HMO query reignites assisted-suicide controversy, American Medical News, Sept. 9, 2002.

The lack of willing physicians has resulted in assisted-suicide advocacy groups such as the Hemlock Society and Compassion in Dying, (now combined under the name "Compassion and Choices") and physician activists being the main facilitators of assisted suicide in Oregon. According to Compassion in Dying, the group was involved in 79 percent of Oregon assisted-suicide deaths in 2003. Compassion in Dying of Oregon, *Summary of Hastened Deaths,* attachment to IRS Form 990 for 2003, available at http://www.guidestar.org.Documents/2003/931/230/2003-931230393-1-9-pdf.

Assisted-suicide activist Peter Rasmussen, MD, has acknowledged writing assisted-suicide prescriptions numbering in the double digits. Public Radio International and KCRW (Santa Monica, CA) *To the Point: Challenge to Oregon's Assisted Suicide Law* (Feb. 23, 2005), transcript of Tape 1, p. 5. In addition, Dr. Rasmussen admits that he prescribes assisted suicide for patients he has not treated and with whom he has spent as little as three hours, either in person or by phone, before writing the prescription. Andis Robeznieks, *Oregon sees fewer numbers of physician-assisted suicides,* American Medical News, Apr, 4, 2005.

In states where laws similar to Oregon's assisted-suicide law have been proposed, state medical organizations have failed to support the measures. Most recently, during an April 2005 Assembly Judiciary Committee hearing regarding the proposed California "Compassionate Choice Act" (A.B. 654), a measure virtually identical to Oregon's assisted-suicide law, Michael Sexton, MD, president of the California Medical Association (CMA), spoke on behalf of the organization. Explaining that a doctor is responsible "to, at all times, act in the best interests of the patient," Dr. Sexton said the assisted-suicide bill "puts physicians in a position where they're not acting in the patient's best interest." Kate

Folmar, *Senate panel endorses assisted-suicide bill,* Contra Costa Times, Apr. 12, 2005.

The CMA's opposition to A.B. 654 is consistent with the group's strong position against 1992 and 1999 attempts to legalize assisted suicide in California. California Medical Association press release, *California Medical Association Opposes Physician-Assisted Suicide: Legalization Will Abuse Dying Patients' Rights and Dignity,* Apr. 21, 1999, available at http://www.cmanet.org/ publicdoc.cfm. That policy was reaffirmed at the CMA's annual meeting in March 2005. Kerry Benefield, *State to weigh assisted suicide bill,* Press Democrat (Santa Rosa, CA), Apr.11, 2005.

Assisted suicide is a violation of acceptable national medical standards in the United States, and it is also considered unethical in most of the world.

B. International standards of medical practice reject the provision of drugs for the purpose of induced death.

Throughout most of the world, assisted suicide and euthanasia are considered profound violations of medical ethics.

The World Medical Association (WMA), with members representing medical associations (including the American Medical Association) from eighty-two countries, has adopted strong resolutions condemning both euthanasia and assisted suicide and urging all national medical associations and physicians to refrain from participating even if national law allows or decriminalizes the practices:

> Euthanasia, that is the act of deliberately ending the life of a patient, even at the patient's own request or at the request of close relatives, is unethical. This does not prevent the physician from respecting the desire of a patient to allow the natural process of death to follow its course in the terminal phase of sickness. World Medical Association, *The World Medical Association Resolution*

> *on Euthanasia,* (adopted by the 38th WMA Assembly, Madrid, Spain, October 1987, reaffirmed by WMA General Assembly, Washington, 2002, May 2001, 20.3/2001) available at http://www.wma.net/e/policy/e13b.htm (last accessed March 15, 2005).
>
> Physician-assisted suicide, like euthanasia is unethical and must be condemned by the medical profession. Where the assistance of the physician is intentionally and deliberately directed at enabling an individual to end his or her own life, the physician acts unethically. However, the right to decline medical treatment is a basic right of the patient and the physician does not act unethically even if respecting such a wish results in the death of the patient. World Medical Association, *The World Medical Association Resolution on Euthanasia* (adopted by the 44th WMA Assembly, Marbella, Spain, September 1992, reaffirmed by WMA General Assembly, Washington, 2002, May 2001, 20.3/2001) available at http://www.wma.net/e/policy/e13b.htm (last accessed March 15, 2005).

When it decided an assisted-suicide case, the European Court of Human Rights found that its policies "did not confer any claim on an individual to require a State to permit or facilitate his or her death." *Pretty v. United Kingdom,* No. 2346/02, Eur. Ct. H.R. available at http://www. eher.coe.Int. / Eng/ Judgments.htm.

In addition to the state of Oregon and in spite of the nearly universal rejection of assisted suicide and euthanasia, only three countries (Australia, which later repealed its law, the Netherlands and Belgium), have passed laws permitting assisted suicide and euthanasia.

1) *Assisted suicide and euthanasia are not considered legitimate medical practices in Australia where international standards of medical ethics are observed.*

In 1995, with the passage of the "Rights of the Terminally Ill (ROTI) Act," Australia's Northern Territory

became the only jurisdiction in the world with both legalized assisted suicide and euthanasia. Northern Territory Government (1995), *Rights of the Terminally Ill Act 1995,* Northern Territory of Australia, Darwin: Government Publisher. The law went into effect in July 1996, but was repealed on March 25, 1997. The Australian Medical Association opposed the Northern Territory legislation while it was in effect and continues to oppose both euthanasia and assisted suicide. *See, e.g.,* Belinda Hickman, Katherine Glascott and Jody Scott, *Ethical dilemma,* The Australian, Sept. 27, 1996; *Doctor aids first legal euthanasia act,* 313 Brit. Med. J. 835 (1996); Adrian Bradley, *Majority of doctors oppose euthanasia,* The Australian, Nov. 18, 1996; and Lisa Allison, *Nitschke to pick recruits for "suicide school,"* The Advertiser (Australia), Nov. 30, 2004 at 25.

During the eight months the law was in effect, four deaths occurred under its assisted-suicide provision. Dr. Philip Nitschke, a long-time activist and campaigner for assisted suicide and euthanasia, was listed as a certifying physician under the law and facilitated all four deaths. Annette Street and David W. Kissane, *Dispensing Death, Desiring Death: An Exploration of Medical Roles and Patient Motivation during the Period of Legalized Euthanasia in Australia,* 40 OMEGA 234, 237 (Table 1) (1999-2000). Before his involvement with assisted suicide, Nitschke had not been involved in caring for terminally ill people nor had he been a part of any medical or palliative care network in the Northern Territory. *Id.* at 238.

The method used to end the four patients' lives was a far cry from what would be considered an accepted medical procedure. It was appropriately described as "death-by-laptop." *First legal suicide reignites Australia euthanasia debate,* American Medical News, Oct.14, 1996. To facilitate the deaths, Dr. Nitschke made house calls, carrying a suitcase that held his laptop computer, plastic tubing, and a pump-driven syringe filled with barbiturates. Seth Mydans,

Assisted Suicide: Australia Faces a Grim Reality, N. Y. Times, Feb. 2, 1997, at A3.

The computer was equipped with an interactive suicide software program. After the patient was hooked up to an intravenous line connected to the computer and the program was turned on, a series of three questions appeared on the computer screen to test the person's intent to commit suicide.

If the patient clicked "yes" in response to each question, a syringe driver and a sequential delivery of death-inducing drugs were activated. *Id.* The method meant that the doctor did not directly administer the fatal dose.

Even while the Northern Territory law was in effect, Dr. Nitschke was designing another death-inducing machine that would use carbon monoxide and an oxygen mask, thus eliminating the need for drugs. He said such a device would enable people to end their lives without needing someone to insert intravenous tubes and would be better for older people. "When people get too old and frail it can be very difficult to get access to veins and gas is a much easier way to go," he explained. *Suicide kit goes on the Internet,* The Mercury (Hobart, Australia), Oct. 21, 1996 at 12.

After repeal of the Northern Territory law, he stepped up his efforts to design the perfect assisted-suicide method. The Hemlock Society (now known as Compassion and Choices) provided tens of thousands of dollars for his various projects. Brett Foley, *Euthanasia groups cool on suicide pill,* The Age (Australia), Aug. 3, 2001. Also see: International Task Force, *Assisted Suicide: Not for Adults Only,* (2002) available at: http://www.international taskforce.org/noa.htm.

In December 2002, Dr. Nitschke unveiled the "COGen" machine, a more elaborate model of his earlier carbon monoxide and face mask method. *Id.* The device generates carbon monoxide delivered to the recipient through nasal

prongs. As the celebrity speaker at Hemlock's 13th Biennial Conference held in San Diego, he told a cheering audience, "You don't need a doctor! You can die without one! You can do it! You can do it yourself!" *Cheers Welcome Australia's "Dr Death,"* Chicago Tribune, Jan. 13, 2003.

The activities of Dr. Philip Nitschke highlight the non-medical nature of death by assisted suicide. His acknowledgment that a doctor is not needed underscores the fact that, although a physician may carry it out, assisted suicide is not a medical act. And, although drugs may be used in some assisted-suicide deaths, their use for assisted suicide constitutes a life-ending, not a medical, purpose.

2) *In the Netherlands, where international standards of medical ethics are not observed, assisted suicide and euthanasia expanded to include drug-induced death for infants, children, and the mentally ill, followed by advocacy of the practices for healthy patients.*

Euthanasia and assisted suicide have been widely practiced in the Netherlands for a number of years. However, they were against the law until 2002. Penal Code of the Netherlands, §§ 293 and 294. The Dutch situation between 1973 and 2002 stemmed from a series of court decisions and medical association guidelines that began with a 1973 District Court case. In that case, Dutch physician Geertruida Postma was convicted of the crime of euthanasia after she ended the life of her seriously ill mother. *Nederlandse Jurisprudentie* 1973, no. 183, District Court of Leeuwarden, 21 (Feb. 21, 1973); See translation in Walter Lagerway, 3 Issues in Law and Medicine 429, 439-42 (1988). The conditions under which the elderly woman died might have never come to the attention of authorities had it not been for Dr. Postma's insistence that her actions be made public. *Implications of Mercy,* Time, March 5, 1973, at 70.

The highly visible case became a rallying point for those seeking to change the law. Doctors in the province signed an

open letter to the Netherlands Minister of Justice stating that euthanasia was commonly practiced. *Id.*

Although it found Dr. Postma guilty of the crime of mercy killing that was punishable by imprisonment for a maximum of 12 years, the court imposed only a one-week suspended sentence and a one-week probation. The Dutch court relied heavily on expert testimony by the District's medical inspector who set forth certain conditions under which the average physician thought euthanasia should be considered acceptable. Those conditions[5] formed the basis for subsequent acceptance of euthanasia and assisted suicide in the Netherlands.

Other cases followed, initiated by physicians with the support of the Dutch Medical Association.[6] Each widened the boundaries and further liberalized the conditions under which euthanasia and assisted suicide would remain illegal, but not punishable. If the guidelines were followed, prosecution would not take place.

Dutch physicians have expressed certainty that there is no need for any real oversight of their activities. At a 1990

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[5] The guidelines required that the patient must be considered incurable (not necessarily terminal) and experiencing subjectively unbearable suffering, the request for termination of life should be in writing and there should be adequate consultation with other physicians before death could be induced. CARLOS GOMEZ, REGULATING DEATH, 30 (1991).

[6] Among the cases was one in which a woman died after requesting death due to advancing age and a physical condition that caused her to be dependent on others, thus leading to psychological suffering. (Alkmaar) *Nederlandse Jurisprudentie* 1985, no. 106. The case gave rise to the 1986 decision by the Hague Court of Appeals recognizing "psychic suffering" and "potential disfigurement of personality" as grounds for induced death. The court exonerated physicians who assisted in the suicide of a young woman with *anorexia nervosa.* (Amelo) *Tijdschrift voor Gezondheidsrecht* 1992, no. 19. Another exoneration took place in the case of a woman who was depressed over the death of her two children and the failure of her marriage. (Assen) *Nederlandse Jurisprudentie* 1994, no. 656.

right-to-die conference held in the Netherlands, Dr. H. S. Cohen, a Dutch general practitioner who has often carried out euthanasia, was asked if there was ever any abuse related to the practice of euthanasia. Cohen dismissed the possibility, saying that the Dutch medical establishment is of such high integrity that it is "not corruptible." RITA MARKER, DEADLY COMPASSION 142-143 (2003).

On April 10, 2001, the Dutch Parliament approved the "Termination of Life on Request and Assisted Suicide (Review Procedures) Act." It amended sections of the criminal code, specifically stating that the offenses of euthanasia and assisted suicide are not punishable if they have been "committed by a physician who has met the requirements of due care" that are described in the act and if they have informed the municipal "autopsist" in accordance with the Burial and Cremation Act. The Termination of Life on Request and Assisted Suicide (Review Procedure) Act, at http://www.minbuza.nl/default.asp?CMS_TCP=tcpAsset&id=CA83D9494B444D268938017F2330E54E.

The inclusion of "due care" requirements transformed the crimes of euthanasia and assisted suicide into medical treatments, just as physicians had advocated. Under the new law, minors between sixteen and eighteen may request that their lives be terminated and, although parents or guardians must be consulted, they have no authority to prevent the requested death. *Id.* Chapter II, Due Care Criterian, Section 2 (3). Children between the ages of twelve and sixteen may request euthanasia or assisted suicide but a parent or guardian must agree with the decision. *Id.* Section 2 (4).

The law recognizes the right of a physician to carry out euthanasia based on a written advance request for death of a currently incapacitated patient who is 16-years-old or older. *Id.* Section 2 (2). Although the person must be at least 16-years-old to be euthanized there is no requirement that one be at least that age when the request is put in writing.

Within days of the new law's passage, Dutch Health Minister Els Borst, who had guided the bill through parliament, said the government should consider introducing a suicide pill for patients who are healthy but are ready to die. Borst said this would be carefully regulated. Margaret Oostveen, *Ik kan me goed voorstellen dat artsen stervenshulp niet melden,* NRL Handelsblad, Apr. 14, 2001, available at: http://www.nrc.nl/W2/Nieuws/2001/ 04/14/Vp/ 01a.html (English translation available at http://www. international task force.org/holbors.htm). Three years later, the Royal Dutch Medical Association (KNMG) issued a report, known as the "Dijkhuis Commission Report."[7] It argued that the criteria in place for euthanasia under the current law were unhelpful in defining the limits of medical practice. Toby Sterling, *Lifelong suffering can be valid reason for euthanasia, Dutch study finds,* Associated Press, Dec.16, 2004, available in LEXIS/NEXIS. The report stated that the guidelines were "an illusion." Tony Sheldon, *Dutch euthanasia law should apply to patients 'suffering through living,' report says,* 330 Brit. Med.J. 61 (2005). It concluded that euthanasia should be allowed for virtually anyone who didn't want to live.

According to Dr. Rob Jonquiere of the Dutch Voluntary Euthanasia Society, the proposal addresses an "existential problem" outside of the medical domain but should, nevertheless, be adopted since it is within the context of ending unbearable suffering. Amsterdam Forum, *Boundaries of euthanasia: Does unbearable suffering have to be linked to terminal illness?* Jan. 21, 2005, available at http://www2.rnw.nl/rnw/en/features/amsterdam forum/ 050122af. The KNMG said it would "take the lead" in discussing how the issue confronts doctors in practice. Sterling, *supra.*

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[7] The full report of the Dijkhuis Commission is available, in Dutch, at http://knmg.artsennet.nl/uri/?uri=AMGATE_6059_100_TICH_ R144638358841695.

Three months later, the University Medical Centre Groningen, acknowledged that it had been euthananizing infants, not only in the case of terminally ill newborns but also in cases of children who had spina bifida and other disabilities. Tony Sheldon, *Killing or caring?* 330 Brit. Med. J. 560 (2005). In publishing its procedures for pediatric euthanasia, the medical center explained that the "approach suits our legal and social culture," although it acknowledged that it was "unclear to what extent it would be transferable to other countries." Eduard Verhagen and Pieter J. J. Sauer, *The Groningen Protocol — Euthanasia in Severely Ill Newborns,* 352 New Eng. J. Med. 959-962 (2005).

The Dutch experience clearly illustrates how rapidly assisted suicide and euthanasia can engulf a nation when the provision of drugs to induce death is viewed as a legitimate medical purpose.

3) *In Belgium, which ignores international standards of medical ethics, legalization of euthanasia has rapidly led to infanticide and disregard for guidelines.*

The Belgian act legalizing euthanasia was passed on May 28, 2002 and went into effect on September 23, 2002.[8] The law limits euthanasia to competent adults and emancipated minors. The Belgian Act on Euthanasia of May 28, 2002, Chap. II, Sec. 3, §1. However, only two years later, lawmakers introduced a proposal to extend euthanasia to children and individuals suffering from dementia. Sénat de Belgique, "Proposition de loi modifiant la loi du 28 mai 2002 relative à l'euthanasie," July 7, 2004, available at http://www.senate.be/wwwcgi/get_pdf?50332915.

According to ruling Flemish Liberal party Senators Jeannine Leduc and Paul Wille who introduced the bill, terminally ill children and teenagers had as much right to

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[8] For text of law, *see The Belgian Act on Euthanasia of May, 28, 2002,* 10 Eur. J. of Health L. 329-335. (2003).

choose when they want to die as anyone else. Allan Hall, *Bill backs euthanasia for children,* The Scotsman, Sept. 9, 2004. The bill did not pass. However, a recent report indicated that physicians in Belgium are, nonetheless, administering lethal drugs to newborns and older infants. Veerle Provoost, *et al, Medical end-of-life decisions in neonates and infants in Flanders,* 365 Lancet 1315 (2005). This has led to new calls to expand the scope of euthanasia.

Embrace of euthanasia by medical professionals has led to the formulation of more convenient ways to euthanize patients. Home "euthanasia kits" will be available soon in more than two hundred Belgian pharmacies so that doctors can carry out in-home deaths with greater ease. The kits, which will contain a barbiturate, a paralyzing agent, an anesthetic, and instructions for use, will cost approximately 45 Euros. Annick Hovine, *La mort à domicile, en kit spécial,* LaLibre, Apr. 15, 2005, available at http://www. lalibre.be/ article.phtml?id= 10&subid=90&art_id=215636.

As in the Netherlands, the Belgian experience indicates the danger of disregarding international standards of medical ethics.

IV. Commercial distribution of federally controlled substances that are prescribed under the Oregon Death with Dignity Act is not wholly intrastate in nature.

Providing federally controlled substances for the purpose of assisted suicide under the ODWDA is widely portrayed as solely an intrastate activity. However, the facts regarding the manner in which prescriptions may be filled and where they may be used shatter this image.

Under the ODWDA, the prescribing process for medication that enables patients to end their lives must take place in Oregon. After that, there are no controls on where the prescription may be filled, nor are there any requirements that the patient or the patient's agent personally pick up a filled prescription from a pharmacy.

Controlled substances, like other prescriptions may be filled by mail order.[9] Those prescriptions are convenient, particularly for patients who are severely debilitated or who live in rural areas. Medications are delivered to one's doorstep. This process permits patients to maintain personal privacy. In addition, costs for mail-order prescriptions are less than those filled by local pharmacies. That cost factor has led 22 percent of large employers to require mail-order prescriptions for their employees in 2004. Maria M. Perotin, *Requirements for drugs via mail pits large companies against drugstore chains,* Fort Worth Star-Telegram, Feb. 27, 2005.

The percentage of prescriptions filled by mail-order pharmacies is growing each year. In 1999, mail-order pharmacies accounted for an estimated 10 to 15 percent of the prescription market. Bob Tedeschi, *Want to Be an Online Drugstore? Take a Number,* N.Y. Times, Feb. 2, 1999 and Eric M. Peterson, *Notes & Comments: Doctoring Prescriptions: Federal Barriers to Combating Prescription Drug Fraud against On-Line Pharmacies,* 75 Wash. L. Rev. 1331, 1343 (2000). By 2001, that percentage had reached 17.9 percent. *Mail-Order Prescriptions Again Show Strongest Growth,* 15 Drug Benefit Trends (3) 4 (2003), at http:www.medscape.com/viewarticle/452209 (last accessed Apr. 19, 2005). By the following year it had risen to 18.4 percent. Christopher Rowland, *The Pharmacist is In: Chains Promote Personal Touch to Keep Edge over Mail-order Firms,* Boston Globe, Nov. 10, 2003 at D1. Given the growth trend, it is reasonable to assume that prescriptions for controlled substances, issued under the ODWDA, have been or will be obtained by mail order.

In 1994, during the campaign to legalize assisted suicide in Oregon, the American Association of Retired Persons

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[9] For U.S. Postal Mailing requirements for controlled substances, *see* U.S. Dept. of Justice Drug Enforcement Administration, *Pharmacist's Manual* at 37, available at http://www.deadiversion. usdoj.gov/pubs/manuals/pharm2/phar_content.htm (last accessed April 20, 2005).

(AARP) mail-order pharmacy service confirmed that it could fill a prescription written in Oregon for two hundred 100-mg. capsules of barbiturates, and mail the drugs to the patient either in Oregon or in care of a third party in another state. Diane Gianelli, *Oregon pharmacists wary of assisted-suicide measure,* Am. Med. News, Oct. 24/31, 1994.

When a mail-order pharmacy service is used, drugs prescribed in Oregon pass through interstate channels after the prescription is written.

Currently, AARP pharmacy services will fill any prescription that could be filled at any pharmacy in the United States. The prescription is mailed to AARP's Pennsylvania location, and the prescribed drugs are mailed from there to the patient.[10] In addition, CVS operates a large mail-order pharmacy service.[11] All mail order prescriptions are filled and transported from its Indianapolis location.

Reporting procedures under the Oregon law do not require physicians to know when or where a prescription is filled. Official report forms to be filled out by physicians who write prescriptions request information only up to and including the date on which the lethal dose is prescribed. Oregon Health Services, Center for Health Statistics, *Attending Physician's Compliance Form,* available at http://egov.oregon.gov/DHS/ph/pas/docs/at1form.pdf. The official interview form for follow-up information from prescribing physicians, asking for the date on which the lethal medications were dispensed to the patient, permits "unknown" as a response. Oregon Health Services, Center for Health Statistics, *Oregon Death with Dignity Act*

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[10] Information about AARP's prescription by mail service can be obtained at http://www.aarppharmacy.com/aarpNet/ or by calling 800-289-6031.

[11] Information about the CVS online pharmacy service can be obtained at http://www.cvs.com or by calling 888-607-4287.

Attending Physician Interview Form at 1, available at http://egov.oregon.gov/DHS/ph/pas/docs/mdintdat.pdf.

As indicated above, prescriptions for assisted suicide under the ODWDA can be, and may currently be, filled in other states and transported through other states. Thus, participation in providing federally controlled substances under Oregon's assisted-suicide law currently impacts the federal government's ability to regulate the distribution of federally controlled substances on a national basis. Furthermore, the distribution of federally controlled substances under the ODWDA from outside the state of Oregon violates the laws of other states where filling prescriptions for assisted suicide takes place.

It is unconscionable that a state law would render both the implementing regulations under the Controlled Substances Act and the laws of other states unenforceable. However, if the Ninth Circuit's decision is allowed to stand, that is the effect.

CONCLUSION

The Ashcroft Directive is an appropriate interpretation of a regulation. By barring the use of a federal registration to prescribe federally controlled substances for assisted suicide, the Directive maintains a necessary uniform national standard for dispensing federally controlled drugs. It prevents balkanization in the application of federal regulations related to federally controlled substances, and it does not nullify a law enacted by the state of Oregon. The decision of the Ninth Circuit should be reversed.

Respectfully submitted,

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