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"Assisted
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(includes cover page)



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

April 16, 1997
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

H.R. 1003 - Assisted Suicide Funding Restriction Act of 1997 (Rep Hall (D) TX and 118 cosponsors)

The President has made it clear that he does not support assisted suicides. The Administration, therefore, does not oppose enactment of H.R. 1003, insofar as it would reaffirm current Federal policy prohibiting the use of Federal funds to pay for assisted suicides and euthanasia.

However, the Department of Justice advises (in the attached letter) that section 5 of the bill, which would prohibit the use of any federal funds to support an activity that has a purpose of "asserting or advocating a legal right to cause, or to assist in...the suicide...of any individual," exceeds the intent of the legislation and raises concerns regarding freedom of speech. Therefore, the Administration urges the Senate to address this concern as the legislation moves forward, in order to avoid potential constitutional challenges and implementation problems.



U. S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

April 16, 1997

The Honorable Trent Lott
Majority Leader
United States Senate
Washington, DC 20510

Dear Mr. Leader:

This presents the views of the Department of Justice on H.R. 1003, the "Assisted Suicide Funding Restriction Act of 1997." As you know, the President has made it clear that he does not support assisted suicides. The Administration therefore does not oppose enactment of H.R. 1003. We do, however, have a concern that we would like to bring to your attention.

Section 5 of H.R. 1003 provides that "no funds appropriated by Congress may be used to assist in, to support, or to fund any activity or service which has a purpose of assisting in, or to bring suit or provide any other form of legal assistance for the purpose of . . . asserting or advocating a legal right to cause, or to assist in causing, the suicide, euthanasia, or mercy killing of any individual." This restriction, by its plain terms, would apply without limitation to all federal funding. As a result, we believe that the proposed bill would constitute a constitutionally suspect extension of the type of speech restriction upheld in Rust v. Sullivan, 500 U.S. 173 (1991).

In Rust, the Supreme Court upheld a program-specific funding restriction on the use of federal family planning counseling funds to provide abortion-related advice. It explained that the restriction constituted a permissible means of furthering the government's legitimate interests in ensuring program integrity and facilitating the government's own speech. See id. at 187-194. The Court stressed, however, that its holding was not intended "to suggest that funding by the Government, even when coupled with the freedom of the fund recipients to speak outside the scope of a Government-funded project, is invariably sufficient to justify Government control over the content of expression." Id. at 199. For example, the Court emphasized that the First Amendment analysis might differ for restrictions on federally funded services that were "more all encompassing" than the limited pre-natal counselling program at issue in Rust. Id.

at 200. In addition, the Court explained that the government's authority to place speech restrictions on the use of governmental funds in "a traditional sphere of free expression," such as a forum created with governmental funds or a government-funded university, was far more limited. Id. at 200.

The Court affirmed the limited nature of Rust in Rosenberger v. Rectors and Visitors of the University of Virginia, 115 S.Ct. 2510 (1995). There, the Court explained that Rust applies where the government itself acts as the speaker. "When the government disburses public funds to private entities to convey a governmental message," the Court explained, "it may take legitimate and appropriate steps to ensure that its message is neither garbled nor distorted by the grantee." Id. at 2519. The government may not, however, impose viewpoint-based restrictions when it "does not itself speak or subsidize transmittal of a message it favors, but instead expends funds to encourage a diversity of views from private speakers." Id.

Here, the bill places a speech restriction on all uses of federal funds. It would move beyond speech restrictions on the use of federal funds in specific, limited programs, such as the one identified in Rust, to establish a viewpoint-based restriction on the use of federal funds generally. As a result, the bill's restriction on speech could apply to an unknown number of programs that are designed to "encourage a diversity of views from private speakers," Rosenberger, 115 S.Ct. at 2519, and to which the Court has held application of a viewpoint-based funding limitation unconstitutional. The bill could also apply to a number of services that are "more all encompassing" than the counselling program at issue in Rust, see 500 U.S. at 200, and to which application of a viewpoint-based funding restriction would be subject to substantial constitutional challenge.

Moreover, the general approach that the bill employs is itself constitutionally suspect. Unlike the regulation at issue in Rust, H.R. 1003 does not attempt to identify a particular program, or group of programs, in which a funding restriction would serve the government's legitimate interests in ensuring program integrity or facilitating the effective communication of a governmental message. It would instead impose a broad and undifferentiated viewpoint-based restriction on all uses of federal funds. As a result of the unusually broad and indiscriminate nature of the proposed funding restriction, the bill does not appear to be designed to serve the legitimate governmental interests identified in Rust. Thus, the bill is vulnerable to arguments that it reflects an "ideologically driven attempt[] to suppress a particular point of view [which would be] presumptively unconstitutional in funding, as in other contexts." Rosenberger, 115 S.Ct. at 2517) (internal quotations omitted). We therefore recommend that this provision be deleted from the bill.

Thank you for your consideration of this matter. Please do not hesitate to call upon us if we may be of additional assistance in connection with this or any other matter. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to the presentation of this report.

Sincerely



Andrew Fois
Assistant Attorney General

cc: The Honorable Tom Daschle
Minority Leader

PETER McCLOSKEY LEIBOLD
General Counsel



THE CATHOLIC HEALTH ASSOCIATION
OF THE UNITED STATES

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Assisted Suicide File

February 6, 1998

THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

President William J. Clinton
The White House
Washington, DC 20500

Dear Mr. President:

On behalf of more than 1,200 Catholic-sponsored facilities and organizations nationwide that make up the membership of the Catholic Health Association of the United States (CHA), I write with regard to the critical issues surrounding the protection of life and the provision of pain relief for those nearing the end of life.

CHA

I am writing specifically to urge you to: 1) support the Drug Enforcement Agency's (DEA) recent legal interpretation of the Controlled Substances Act regarding physician-assisted suicide; 2) encourage you to issue enforcement guidelines to the DEA urging it to be sensitive to the legitimate concern that overly aggressive or misguided enforcement could have a chilling effect on pain relief for persons at the end of life; and 3) appoint a task force to make concrete recommendations on how to reduce legal and regulatory barriers to *appropriate* pain relief for dying persons.

First, CHA strongly supports DEA's declaration that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a legitimate medical purpose." The religious beliefs and values upon which both CHA and its member hospitals and long-term care facilities are founded compel us to reject assisted suicide. More generally, this practice is radically inconsistent with proper regard for the dignity of human life and irreconcilably incompatible with the appropriate ends of medicine.

The DEA's legal interpretation is completely consistent with your support for the Assisted Suicide Funding Restriction Act passed last year. In that legislation, you supported the proposition that no federal funds, programs, or health facilities should be used to further assisted suicide. Thus, from the federal government's perspective, assisting in a suicide is not a legitimate medical practice. Consistency demands that you support the legal interpretation provided by the administrator of the DEA.

Second, your support for a consistent legal interpretation does not mean that you cannot take ameliorative steps with regard to enforcement. CHA is acutely aware that the DEA's correct, legal interpretation, if not carefully implemented, may *unintentionally* have a chilling effect on physicians who prescribe, dispense, and administer appropriate and effective amounts of

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morphine and other opioids in treating pain as death approaches. Certainly, a physician would have reason for serious concern if the DEA routinely second-guesses his or her dosages to a dying person to determine if they violate the Controlled Substances Act. In a recent study, the Institute of Medicine (IOM) found that physicians have significant apprehension about legal sanctions related to addiction and anti-addiction regulations.

Therefore, when announcing your support for DEA's interpretation, CHA urges you to issue an enforcement directive to the agency concerning your expectations with regard to its agents' enforcement of the law. Specifically, the DEA must be aware of, and sensitive to, the impact that its investigation may have on the dispensing of needed pain relief medication to dying persons. The DEA should be aware that it is *not* a violation of the Controlled Substances Act to dispense controlled substances for the legitimate medical purpose of relieving pain, even if they may indirectly shorten the person's life. This essential distinction is codified in the Assisted Suicide Funding Restriction Act itself and was affirmed by the U.S. Supreme Court when it upheld laws prohibiting assisted suicide last June.

The DEA should initiate investigations or enforcement actions only when their agents have credible and substantive allegations that health care providers have established a pattern or practice of prescribing or dispensing controlled substances to persons for the purpose of helping them to take their lives. It is not, nor should it be, a DEA priority to expend significant resources second-guessing the opinions of health care providers about the controlled substances needed to adequately and appropriately relieve the pain of dying persons.

Third, CHA asks that you form a federal/state advisory task force to make concrete recommendations to you and to the 50 governors on how to reduce legislative and regulatory barriers to pain relief. A 1997 Institute of Medicine Study, *Approaching Death: Improving Care at the End of Life*, states the concern succinctly:

Outdated and scientifically flawed drug-prescribing laws, regulations, and interpretations by state medical boards continue to frustrate and intimidate physicians who wish to relieve their patient's pain. Addiction to opioids appropriately prescribed to relieve pain and other symptoms is virtually non-existent, whereas underuse of these medications is a well-documented problem (pp 5&6).

Specifically, the IOM identifies, among others, triplicate prescription laws, limits on the number of medication dosages that may be prescribed at one time, medical board policies, and state anti-addiction laws as barriers to effective pain relief.

President William J. Clinton

Page 3

CHA recognizes the critical need to address illegal drug use and diversion. Yet, as the IOM points out, there is little evidence that the prescription of opioids in the care of dying persons contributes in any meaningful way to illegal drug use and drug diversion problems. It is both counterintuitive and counterproductive if drug control laws tragically result in the increasing reluctance of physicians and other health professionals to treat dying persons by seeking to alleviate their pain. Dying persons should not be held hostage by regulations that, while rightly motivated, can cause great suffering and distress for them and their families.

CHA and its member facilities and organizations are committed to provide dying persons and their families both competent and compassionate care. Toward that end several Catholic health systems and CHA have joined together in a collaborative effort, *Supportive Care of the Dying: A Coalition for Compassionate Care*. One specific goal of this project is to ensure that adequate and effective pain management is available to every person living with life-threatening illness so that they may live well even while dying.

Mr. President, concrete recommendations for reform by a federal/state task force on these issues will allow you to suggest legitimate steps to improve pain relief for dying persons. In this way, you can continue your consistent support for the principle that assisting in a suicide is not a legitimate medical purpose and, at the same time, suggest appropriate and necessary public policy mechanisms to improve pain relief for dying persons.

In conclusion, CHA urges you to remain consistent on the federal government's treatment of assisted suicide while exploring all available and legitimate methods for improving pain relief for those in the last stages of life.

With personal best wishes, I am

Sincerely,



Rev. Michael D. Place, STD
President

cc: Attorney General Janet Reno

March 23, 1997

TO: Chris Jennings, Special Assistant to the President for Health Policy Development and Elena Kagan, Deputy Assistant to the President for Domestic Policy

FROM: Peter M. Leibold

RE: Legislative Idea Related to Assisted Suicide and Revocation Proceedings under the Controlled Substances Act

Assisted Suicide (7/1)
Peter sent this memo to you yesterday but then got in trouble b/c CHA doesn't want you to think this is their only solution so you can say you have been official told it is not.

CHA supports the concept of making the dispensing of controlled substances with the intent to aid in suicide grounds for revocation of a federal license to dispense controlled substances. However, CHA is sensitive to the argument that clarifying this revocation authority may have the unintended effect of deterring needed pain relief for dying patients. For that reason, we propose the following concept to address this tension:

Specifications for "Medical Review Board on Pain Relief"

- Under 21 U.S.C. § 824(a), a registration to dispense controlled substances may be suspended or revoked by the Attorney General upon a finding that a registrant has committed such acts as would render the registration inconsistent with the public interest.
- One way to structure the underlying legislation is to simply state that the dispensing of controlled substances with the intent to aid in a suicide is inconsistent with the public interest as that term is used in the Controlled Substances Act. This should not be construed, however, to make adequate pain relief, even if the effect of that pain relief is to increase the likelihood of death, grounds for revoking a license to dispense controlled substances, provided that the intent is not to aid in a suicide.
- Under 21 U.S.C. § 824(c), prior to revoking or denying a registration, the Attorney General serves upon an applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause requires the applicant or registrant to appear before the Attorney General at a certain time and place. This proceeding is not in lieu of a criminal prosecution for dispensing controlled substances illegally.
- In order not to discourage needed pain relief, which may involve the use of controlled substances, any legislation to make assisting in suicide grounds for revoking a license to dispense controlled substances should establish a "Medical Review Board on Pain Relief."
- The Attorney General or the Secretary of HHS, in consultation with the American Medical Association, the Supportive Care of the Dying Project, the American Academy of Hospice and Palliative Care Medicine, the National Hospice Organization, and the American Geriatrics Society, should establish a 20 or 30 member physician board, 1/3rd of which are

— SB

experts in palliative care medicine. A physician who has been served a "show cause" order by the Attorney General would have an automatic right to appeal to a three-physician panel made up of members of the Medical Review Board on Pain Relief, prior to the proceeding before the Attorney General.

- The three-member panel of the Board, chaired by a palliative care expert, would hear arguments of the physician as to why her dispensing of controlled substances was for the purpose of relieving pain and not assisting in suicide. Any finding of this Board would be admissible in the revocation proceeding before the Attorney General authorized under § 824(c). In addition, if a panel of the Medical Review Board on Pain Relief found that a physician did not violate the Act because the dispensing of a controlled substance was for pain relief and not assisted suicide, one could provide the physician with immunity from federal criminal prosecution for the unlawful dispensing of controlled substances resulting from the dispensing of the controlled substances at issue. This further protection for a physician would undoubtedly raise controversy as invasive of the Attorney General's discretion to initiate criminal proceedings. Yet, it may be warranted as a mechanism to prevent the deterrence of needed pain relief. Of course, immunity from federal prosecution would not hinder a state prosecutor from initiating state criminal proceedings for assisting in suicide.

LEGISLATIVE HISTORY OF FEDERAL DRUG LAW SUPPORTS AUTHORITY TO ACT AGAINST PHYSICIAN-ASSISTED SUICIDE

The Controlled Substances Act of 1970 was amended in 1984 to strengthen the Drug Enforcement Administration's ability to prevent diversion of federally regulated prescription drugs for illicit purposes. The amendments were approved by the U.S. Senate 91-to-1 on February 2, 1984 as part of a Comprehensive Crime Control Act (S. 1762). Almost identical language was approved by the House 392-to-1 as a free-standing "Dangerous Drug Diversion Control Act of 1984" (H.R. 5656) on September 18, 1984. The House and Senate versions were reconciled and ultimately approved as part of H.J. Res. 648, a continuing resolution which became law on October 12, 1984 (P.L. 98-473).

This legislative background helps answer some questions raised about the federal government's authority to apply this federal law against physicians who prescribe controlled substances to assist suicides:

Was the federal law directed primarily against street drugs like heroin and cocaine?

No, the 1984 amendments were directed specifically against the misuse or "diversion" of federally regulated prescription drugs which have a legitimate medical use. The prime House sponsor said these had become a more serious problem in some ways than street drugs but had "failed to get the societal or the enforcement attention that it deserves" (Rep. Hughes, Cong. Record, 9/18/84, H9679).

Was the law directed against physicians?

Yes, though not exclusively. "The bill gives to DEA greater latitude to suspend or revoke the registration of a practitioner who dispenses drugs in a manner that threatens the public health and safety" (Id.). As the chairman of the House Commerce Subcommittee on Health and the Environment said at the subcommittee hearing on this bill: "Today's pusher is not always a back alley salesman. He or she may well be a highly educated health professional" (Rep. Waxman, Hearing of July 31, 1984, Hearing Record No. 98-168, p. 365). There were also provisions directed at manufacturers and pharmacists.

Was the law directed against addiction, or against the use of drugs to cause death?

The chief concern cited was their potential to cause physical harm and death. Sponsors cited a government study indicating that "prescription drugs are responsible for close to 70 percent of the *deaths* and injuries due to drug abuse" (Rep. Hughes, Cong. Record, 9/18/84, H9679). The chairman of the Health subcommittee in the House agreed: "Drugs legally manufactured for use in medicine are responsible for a substantial majority of *drug-related deaths* and injuries" (Rep. Waxman, Hearing Record No. 98-168, op. cit., p. 365) One sponsor used the example of an

opiate widely used as a pain-killer, saying: "Because these pills have an even greater potential for *physical injury and danger*, they involve more than half of the hospital entries for illegal use and *overdose* of drugs" (Rep. Sawyer, Cong. Record, 9/18/84, H9680).

Was the law designed to defer to states' judgments on the proper medical use of drugs?

On the contrary: It was designed to give the DEA more independent authority to revoke a physician's registration in cases where a state *refused* to intervene. The 1984 amendments authorized the DEA to revoke a physician's registration if it deems that registration to be "inconsistent with the public interest" (in cases where, for example, revoking registration will serve "public health and safety"). As Rep. Charles Rangel said in support of the amendments: "Under current law, the DEA must register physicians, pharmacies, or other practitioners if they are authorized to dispense drugs by the law of the State in which they practice.... The public interest standard added by H.R. 5656 will provide greater flexibility to deny or revoke registrations in the most egregious cases" (Cong. Record, 9/18/84, H9682). (When a law is enacted to prevent prescription drugs from being used for lethal overdoses, there is nothing more egregious than a physician who *intentionally* dispenses drugs for such overdoses.) Prime Senate sponsor Strom Thurmond spoke similarly, saying that this provision "expands the standards for practitioner registration beyond the current exclusive reliance upon authorization by the practitioner's own jurisdiction" (Cong. Record, 2/2/84, S758). Sponsors said giving such flexibility to the federal government was necessary because states often did not respond adequately to these abuses: "State policing of these activities, as well as peer review within the profession, have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate" (Rep. Fish, Cong. Record, 9/18/84, H9680). At a hearing before the House Commerce Subcommittee on Health and the Environment, the DEA called the expanded federal authority to revoke practitioner registration "one of the most important sections of the bill," not only because states were often ill-equipped to enforce their own drug laws but also because "many controlled drug violations involving prescription drugs *are not felonies under state law* and therefore cannot be used in a DEA revocation action" under then-existing law (Testimony of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration, Hearing Record No. 98-168, p. 404). Congress's view was that while the states are the first line of defense against misuse of prescription drugs, the federal government must enforce its own objective standard as to what constitutes such misuse -- and it must have the authority to enforce that standard when a state cannot or will not do so.

In light of this history, it cannot be maintained that the Controlled Substances Act as it exists today was directed only against professional drug traffickers rather than physicians, or only against addiction rather than lethal drug overdoses, or only against physicians who violate state laws. Independent federal authority to enforce federal drug standards was intended to apply to "Schedule II" prescription drugs like barbiturates or morphine as much as to "Schedule I" drugs like marijuana or cocaine -- most especially when such drugs are being used to cause death.

3/10/98

Legal Issues

The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.

Cruzan v. Director, Missouri Department of Health, 497 US 261, 278 (1990)

A seriously ill or dying patient whose wishes are not honored may feel a captive of the machinery required for life-sustaining measures or other medical interventions.

Justice Sandra Day O'Connor, concurring opinion in *Cruzan*, 497 US at 28

The roles of judges, legislators, and administrative officials in influencing care at the end of life vary from the dramatic to the commonplace. On the dramatic end of the continuum are the court cases about the legality of physician-assisted suicide, which were argued before the U.S. Supreme Court as this report was being drafted. In contrast, the right of people to refuse unwanted life-sustaining and other treatments—once the subject of highly charged court cases—is now commonly accepted and enforced (if not always perfectly).

Documenting the impact of statutes, regulations, case law, and administrative actions on clinicians, patients, families, and others can be difficult. In addition, the applicability of various statutes and judicial precedents to specific patient circumstances is quite often a matter of dispute and speculation rather than straightforward matching of law to facts. Nonetheless, in the committee's view, the legal issues discussed here raise concerns either about their possible effects on compassionate and effective care for those approaching death or about the unrealistic expectations they may create or both.

This chapter considers laws relating to prescription of opioids, informed consent and advance directives, and assisted suicide. Among those with clinical, administrative, or similar involvement in end-of-life care, much of the debate about issues such as prescription regulation or informed consent is practical. For example, how can prescription laws be modified so that they do not discourage effective pain management but still respond to legitimate concerns about misuse of controlled substances? For some issues, most notably assisted suicide and euthanasia, ethical concerns may dominate legal discussions, but practical issues also arise as described later in this chapter. The focus here is primarily on how laws may affect the quality of care for dying patients.

Although the impact of malpractice litigation on medical practice is a complex and disputed question, it is discussed only briefly because the committee did not view the prospect of malpractice litigation as likely to have a significant impact on end-of-life care specifically. The committee, however, recognized concerns that physicians may engage in defensive medicine (e.g., ordering extra tests, prescribing unnecessary medications, performing hopeless CPR) because they fear being sued for a bad outcome that plaintiffs might attempt to attribute to lack of a test or procedure. Similarly, decisions might sometimes be influenced by the fear of being sued for not following a family's wishes, even if those wishes were contrary to the doctor's clinical judgment and the patient's own wishes. The committee did not find evidence that physicians were concerned about liability for failure to intervene to relieve pain or other symptoms.

In any case, many of the steps proposed in this report would tackle problems of undertreatment, overtreatment, or mistreatment of dying patients in ways that should reduce the potential for litigation and physician uncertainties and fears about being sued. At the practitioner level, these steps include changing clinicians' attitudes, knowledge, and practices so that they communicate more effectively with patients and families, engage patients and families in a process of goal setting and decisionmaking that increases trust and minimizes misunderstanding, and properly assess and treat pain and other symptoms. At the system level, they include strategies for measuring, monitoring, and improving care that seek to identify and respond to the preferences, experiences, and feelings of patients and families. If, however, these strategies fail to correct the deficits identified in Chapter 3 and if patients come to understand that the standards of care (e.g., practice guidelines) call for efforts to relieve symptoms, then litigation stemming from inattention to symptom management might become more likely—but not necessarily productive. The primary injured plaintiff would, in the case of a dying patient, likely have died, and although a family could claim injury and testify about the decedent's suffering, damages would be hard to establish. In addition, the status of practice guidelines in the courts

is still evolving. Overall, the committee was doubtful that malpractice litigation could be relied upon as an instrument to improve care at the end of life.

PRESCRIPTION LAWS AND BARRIERS TO PAIN RELIEF

All patients who suffer pain—not just the dying—deserve relief through treatments that are known to be effective for most pain. Indeed, early treatment of pain as a part of a continuum of good care for those who are seriously ill may be the best approach to minimizing pain at the end of life. Other parts of this report document deficiencies in pain management and gaps in scientific knowledge. This section examines how effective pain management may be compromised by prescription drug laws that are intended to minimize drug addiction and diversion of drugs from legal to illegal sources. (Relief of dyspnea may also be affected by these laws, although this has not been the subject of much attention.) Because these laws both arise from and interact with the misperceptions and attitudes of physicians, medical boards, lawmakers, patients, and the public, reform needs to go beyond revisions in written policies to affect knowledge and values.

Anti-Diversion Policies

The Problem of Diversion and Regulatory Responses

Diversion occurs when persons with legal access to controlled substances distribute them or use them for illegal purposes or when people fraudulently obtain drugs from legal sources (Cooper et al., 1992; Cooper et al., 1993).¹ Pain relief medication, for example, might be prescribed to phony patients and then sold on the streets. Alternatively, people might forge prescriptions or misrepresent their symptoms to secure prescriptions. Newspaper articles and television news reports periodically expose the problems of diverted opioids and clinician addiction. No reliable studies document the extent of opioid diversion specifically or compare it to other illegal sources (e.g., illegal imports and domestic production). A 1990 household survey estimated that 4 percent of the population over the age of 12 had used prescription analgesics, stimulants, tranquilizers, or sedatives at least once for nonmedical reasons in the preceding year, and almost 1.5 percent were currently using them (NIDA, 1991). A California estimate puts the

¹Theft and other forms of illegal access are also problems but are less susceptible to control through anti-diversion regulations.

dollar value of diverted controlled substances during the mid-1980s at somewhere between \$500 million and \$1 billion (Marcus, 1996).

Legal and regulatory policies intended to prevent diversion include triplicate prescriptions and limits on the number of medication dosages that may be prescribed at any one time. These policies are burdensome and appear to deter legitimate prescribing of opioids (see, e.g., Cooper et al., 1992; IOM, 1995a, 1996d; Joranson, 1995a). Triplicate prescription programs require the prescribing physician to complete detailed, multiple-copy prescription forms. The forms themselves are often difficult to obtain and, if incorrectly filled out, must be completed again by the physician. The triplicate forms also become available to the state medical board, which may choose to pursue disciplinary measures on the basis of such information. Electronic forms and monitoring systems would ease the burden on physicians as well as allow easier monitoring but such systems have not been widely adopted or rigorously evaluated nor have appropriate norms to guide such oversight been developed and tested.

Some states have laws limiting the dosages a physician may prescribe to one patient at any given time. These laws force patients who suffer pain that requires frequent medication to request and renew prescriptions repeatedly. This not only inconveniences both patients and physicians but may subject patients to possible interruptions in pain management if something disrupts the timely requests and responses. Such problems are a special concern for patients who are not in a medical facility but are at home or in a care facility without an on-site physician.

The committee recognizes the problems created by illegal drug use and drug diversion and the need for law enforcement responses. It, however, knows of no evidence, anecdote, or other reason to believe that the prescription of opioids in the care of dying patients contributes in any meaningful way to drug diversion problems.

Effects on Care at the End of Life

The effect of anti-diversion policies on their intended targets is unclear. They do, however, appear to affect the rate of prescriptions and perhaps increase the use of less effective or even harmful medications (Cooper et al., 1993; Joranson and Gilson, 1994a, b; IOM, 1995a, 1996d). One study reported that when Texas introduced a multiple-copy prescription program, prescriptions for opioids to control pain were halved (Sigler et al., 1984). It is not known whether this dramatic drop resulted from declines in inappropriate prescribing and diversion or whether physicians and pharmacists became reluctant to prescribe appropriate medications. Nonetheless, the magnitude of the change makes it reasonable to expect that the regulation had some impact on patient care (Von Roenn et al., 1993; Wastila and

Bishop, 1996). Surveys of physicians—discussed further below—suggest that anti-diversion and anti-addiction policies combined with social antipathy toward real or imagined addiction discourages effective, appropriate, and legal pain prevention and management.

Options for Improvement

How can laws be constructed and interpreted in ways that minimize drug diversion without obstructing effective medical management of pain? Options include (1) replacing triplicate forms with electronic reporting of prescriptions and (2) allowing standing prescriptions for outpatients (to be monitored by home health care professionals or pharmacists). In addition to reducing regulatory barriers to effective pain prescribing practices, states could require that pain experts or palliative care specialists be represented on state medical boards to help inform board policies and interpretations. Information collected from triplicate or electronic prescriptions might also be analyzed to identify questionable prescribing practices, which could be used to guide education of physicians and pharmacists about effective and appropriate use of opioids. Another IOM committee has already recommended additional research on the effects of controlled substance regulations on patient care and scientific research (IOM, 1996d).

Anti-Addiction Policies

The creation of new addictions is a separate issue from the diversion of drugs to the black market. A collection of social forces joins with legal restrictions to create a general antipathy toward drug use that flows into the area of medical practice and undermines effective pain management. Even the terminology muddies the waters when chronic use of opioids, which produces physical dependence, is sometimes equated with addiction. For example, California law defines addicts as “habitual users,” which might include patients with chronic pain who regularly and appropriately take opioids necessary to manage their pain (Marcus, 1996).

States have addressed the perceived problem of medically induced drug addiction through varied combinations of laws, regulations, and medical board disciplinary policies. Because the committee concluded that policies often reflect inadequate understanding of the mechanisms of pain and addiction, these mechanisms will be described before the policies are considered.

Mechanisms of Pain and Addiction

Efforts to devise reasonable anti-addiction policies are complicated by

ignorance and confusion about the biological and psychological mechanisms of pain management and addiction (Bruera et al., 1987; WHO, 1990; Nestler et al., 1993; Von Roenn et al., 1993; Portenoy et al., 1994; Buchan and Tolle, 1995; Joranson, 1995a; Portenoy, 1996). Research indicates that addiction in patients appropriately receiving opioids for pain is very small, ranging from roughly 1 in 1,000 to less than 1 in 10,000 (Porter and Jick, 1980; Angell, 1982; Jaffe, 1985; Rinaldi et al., 1988; Portenoy and Payne, 1992; Portenoy, 1996).

The committee concluded that drug tolerance and physical dependence should be more uniformly and clearly distinguished from addiction. *Tolerance* occurs when a constant dose of a drug produces declining effects or when a higher dose is needed to maintain an effect. *Physical dependence* on opioids is characterized by a withdrawal effect following discontinuation of a drug. Such dependence is a common effect in chronic pain management, but it is not restricted to opioids. Other agents such as beta-blockers, caffeine, and corticosteroids also produce physical dependence. Further, clinical evidence suggests that patients receiving opioids can be easily withdrawn from them in favor of an alternative, effective pain control mechanism if that is clinically indicated. Typical practice is to reduce the dose by fractions, stopping administration of opioids altogether after a week or so (Doyle et al., 1993). This practice may not be relevant, however, for dying patients.

Neither physical dependence nor tolerance should be equated with addiction or substance abuse. Portenoy and Kanner (1996) proposed that "addiction is a psychological and behavioral syndrome characterized by (1) the loss of control over drug use, (2) compulsive drug use, and (3) continued use despite harm" (p. 257). This is consistent with a definition proposed by the American Medical Association: "the compulsive use of a substance resulting in physical, psychological, or social harm to the user and continued use despite that harm" (Rinaldi et al., 1988, p. 556). The federal Controlled Substances Act defines an addict as someone who habitually uses an opioid in ways that endanger public health or safety (AHCPR, 1994a).

Unfortunately, the general term *substance dependence* is often used as a synonym for addiction, perhaps because the latter is more stigmatizing. For example, the American Psychiatric Association sets out criteria for dependence rather than addiction in its *Diagnostic and Statistical Manual of Mental Disorders* (4th ed., 1995). Despite a disclaimer that the scheme focuses on "maladaptive" substance use, the discussion of substance dependence may nonetheless mislead (p. 181). A later disclaimer about distinguishing legitimate medical purposes from opioid dependence is not specific, given that, as described below, many seem to be confused about what is legitimate. The committee is particularly concerned about misinterpreta-

tion of criteria related to tolerance, withdrawal, and overuse. Tolerance and withdrawal are, in general, clinically acceptable (although not necessarily invariable or desirable) consequences of effective use of opioids to manage pain, and "overuse" as defined above may be difficult to distinguish from increasing use due to uncontrolled pain, which may result from increasing pathology, tolerance, or other sources (Weissman and Haddox, 1989). Similarly, some behaviors suggestive of addiction may be confused with those resulting from inadequately managed pain or anxiety about the reliability of pain management.

Regulatory Responses

Responses to the problem of addiction take several forms including some of those already identified in the discussion of drug diversion. Federal and state laws and regulations attempt to control the prescribing behavior of physicians, nurses, and pharmacists by criminalizing certain activities. In addition to legislatures and courts, state medical boards set policies that, although not having the official force of law, may be just as powerful in their effect. These policies dictate the standards by which physicians may be professionally disciplined. Laws and medical board policies are also intertwined, in that legislatures may place legal limitations on the extent of a medical board's powers.

Medical Board Policies. State medical boards may establish guidelines on pain-prescribing practices that constitute official statements of board policy. Such guidelines describe acceptable medical practice and notify health care practitioners of professional boundaries. Violating them may lead to disciplinary action. The sometimes restrictive perspective of state boards could interfere with the treatment of pain. In 1987, for instance, the Washington State Medical Disciplinary Board stated that it did "not recognize repeated prescribing of controlled drugs as appropriate therapy for chronic pain" (cited in Joranson, 1995a, pp. 2-3).

Several state medical boards have issued guidelines that deal with the use of opioids to treat intractable pain.² In California, the nursing and pharmacy boards have also created guidelines addressing the same issue (Joranson, 1995b). These guidelines are intended not only to instruct phy-

²State medical boards that have issued guidelines regarding the use of controlled substances to treat pain (along with the year in which the guidelines were first issued) include: Utah (1987), Minnesota (1988), Massachusetts (1989), Arizona (1990), Georgia (1991), Oregon (1991), Alaska (1993), Texas (1993), Wyoming (1993), Alabama (1994), California (1994), Idaho (1995), Colorado (1996), Florida (1996), Maryland (1996), Montana (1996), North Carolina (1996), and Washington (1996) (Joranson, 1997).

sicians and other caregivers on the proper use of opioids in pain management but also to reduce physicians' fear of attracting board discipline for such use. Another way for state medical boards to improve pain control might be for the boards to educate the physicians within their states about how to comply with laws, regulations, and board-set standards. Information collected from triplicate prescription forms could be used in this educational effort.

Some state boards, however, continue to require that physicians avoid the potential for addiction and that they justify the continued prescribing of opioids (Joranson, 1995b). A survey of state medical board members conducted in 1991 showed that most would discourage the use of opioids to relieve chronic, noncancer pain; a third of them said they would investigate such a prescription as a potential violation of the law (Joranson et al., 1992). There is still, it seems, an inappropriate sense of distrust on the part of the medical boards, which this committee believes has developed, in part, on the basis of misperceptions discussed above about the nature and consequences of dependence and addiction.

Laws and Regulations. In 1974, the federal government, through the Federal Intractable Pain Regulation, clarified the federal law that prohibits physicians from prescribing opioids to detoxify or maintain an opioid addiction (Code of Federal Regulations, Title 21 Part 1300). The regulation states that the prohibitive regulations are "not intended to impose any limitation on a physician . . . to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable effort" (21 Code of Federal Regulations, Title 21 Sec. 1306.7[c]). The policies of the Drug Enforcement Administration are similarly explicit.

Even when antiaddiction laws exempt those with intractable pain, the protections generally do not extend to those already addicted (Joranson, 1995a). When these people become patients suffering intractable pain, physicians are not free to prescribe opioids to relieve their suffering. This problem becomes especially acute in the AIDS wards of many urban hospitals.

At the state level, a number of prescribing laws include provisions that could interfere with effective medical use of opioids. For example, in New Jersey, regulations call on physicians "periodically to either cease the medication or taper down the dosage . . . to reduce the addiction propensity for the patient" (Joranson, 1995a).

In 1988, the Commonwealth of Virginia passed the first state law addressing the need to treat pain in terminally ill cancer patients (Joranson, 1995a). The legislation—despite its positive provisions—also illustrated the misperceptions surrounding the treatment of pain. It allowed physicians to

prescribe heroin to their terminally ill patients even though heroin is not legally available under federal law and has no significant advantages over other available opioids (Joranson, 1995a).

Texas was the first state to pass an Intractable Pain Treatment Act, in 1989. California followed suit in 1990 and Florida in 1994 (Joranson, 1995a).³

Some state pain treatment laws, (e.g., Colorado and Washington) recognize the benefits of pain control and allow physicians to prescribe controlled substances but do not address concerns about inappropriate discipline by medical boards. The Texas and California acts do address this problem by prohibiting medical board discipline of physicians who follow the provisions within the laws. Both acts also define intractable pain (following the model of the Federal Intractable Pain Regulation⁴), authorize physicians to prescribe controlled substances to treat intractable pain, and prohibit health care facilities within the states from limiting such prescriptions. California's act requires an evaluation of the patient by a specialist.

Effects on Care at the End of Life

Surveys suggest that physician apprehension about addiction and anti-addiction regulations is widespread (Cleeland et al., 1986; Portenoy, 1990; Weissman, Joranson et al., 1991; Hill, 1993; Von Roenn et al., 1993). Such apprehension is not limited to physicians within the United States. In a survey of all the governments in the world conducted by the International Narcotics Control Board (within the United Nations International Drug Control Program), 47 percent of responding governments cited health care provider reluctance due to concerns about legal sanctions as an impediment to medical use of opioids (Joranson and Colleau, 1996).

The frequency of punitive action against physicians for apparently legitimate prescribing practices is unknown, but the committee heard many

³States with intractable pain treatment policies (along with the year in which the policy was instituted) include Virginia (1988), Texas (1989), California (1990), Colorado (1992), Washington (1993), Florida (1994), Missouri (1995), Nevada (1995), Oregon (1995), and Wisconsin (1996) (Joranson, 1997).

⁴Both statutes define intractable pain as "a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain" (Code of Federal Regulations [1988] Title 21 Sec. 1306.07[c]).

anecdotes about threatening statements by medical disciplinary boards and about physicians who find the scrutiny and requirements sufficiently burdensome that they choose not to prescribe medications needed to manage pain effectively. In addition, the earlier discussion of regulations to limit drug diversion indicate that these policies may discourage the appropriate medical use of opioids and may discourage research to develop better medications.

Options for Improvement

More states could pass carefully drawn pain treatment laws. The American Medical Association (AMA) recently adopted a resolution to create a model state law, based on the Texas and California acts (AMA, 1996a). By protecting physicians from disciplinary actions, the AMA hopes to "provide patients with the security and knowledge that intractable pain resulting from terminal illness need not persist in a chronic, unrelieved manner" (AMA, 1996a, p. 4).

Although such laws constitute an important step to promote effective pain management for patients, they may not go far enough or may imply clinical clarity that does not exist. By making positive statements about the benefit of opioid use in the control of pain, legislators hope to reduce the fear of arbitrary medical board discipline. Yet they do not, in all cases, mark a clear area of medical practice in which physicians feel free to manage their patients' pain. The more specific laws, for example those that set out detailed prescription practices, may actually afford physicians less leeway in the practice of medicine. Additionally, by carving out an area of pain treatment that is immune from medical board discipline, there may be an implication that other forms of pain treatment should be subject to disciplinary review.

Even the strongest intractable pain law is still limited by the term *intractable*. Many cases are ambiguous, and physicians may believe that they must delay opioid treatment until pain is far enough along to be called intractable. An additional problem arises when state laws define addiction without regard to pain management. As noted earlier, California defines addicts as "habitual users," which might include patients taking opioids for chronic pain. Such confusing definitions once again expose physicians to the threat of medical board discipline.

Finally, the legal affirmations in these laws of the importance of pain control do not, in themselves, correct practice patterns or improve physician training. Laws could, however, encourage patients to expect diligence in pain relief, including use of generally effective medications. Medical boards could consider disciplining physicians who fail to apply proven methods of pain control.

Overall, the committee is encouraged by recent actions to revise drug prescribing. It urges continued review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies, physician attitudes and practices, patients, and illegal or harmful drug use.

INFORMED CONSENT AND ADVANCE CARE PLANNING

A series of legal decisions over the past three decades has affirmed the right of people to refuse unwanted medical treatments (President's Commission, 1982; Faden et al., 1986; Appelbaum et al., 1987). As stated in an important 1960 California Supreme Court case, "Anglo-American law starts with the premise of thoroughgoing self-determination," which includes the right of individuals to refuse medical treatments (*Natanson v. Kline*, 1960). This legal reasoning reinforced a shift in emphasis in medical ethics from a dominant paternalism (i.e., action in the best interest of patients as judged by physicians) toward autonomy (i.e., patients' right to choose the course they prefer) (Childress, 1982).

One means for recognizing patient autonomy in decisionmaking is informed consent, which means that patients voluntarily accept (or refuse) a medical intervention after disclosure of its expected benefits and risks and discussion of the alternatives. For dying patients who are unconscious or in such distress that they cannot reasonably communicate their wishes when a treatment decision needs to be made, the legal concept of informed consent may have limited application.

In response, the concept of *advance care planning* was devised to allow people (whether or not they are "active patients") to specify how they want to be treated should serious illness or injury leave them without the capacity to make decisions or communicate (see, e.g., President's Commission, 1982; AARP, 1986; Emanuel and Emanuel, 1989; Annas, 1991; Burt, 1994). Documents used in advance care planning, called advance directives, take several forms, including surrogate decisionmaking arrangements and what are popularly called "living wills." For purposes of this report, advance directives refer particularly to statements intended to be legally binding.⁵

As discussed in Chapter 3, advance care planning is a broader, less legally focused concept than that of advance directives. It encompasses not

⁵Guardianship involves the court appointment of a decisionmaker in cases where the patient is, for some reason, incompetent to make decisions for him or herself. A guardian is usually appointed for reasons other than health care, such as financial management. State guardianship laws vary on the power of a guardian to consent to or refuse medical treatments. The committee here limits its discussion to decisionmakers appointed by patients themselves.

only preparation of legal documents but also discussions with family members and physicians about what the future may hold for people with serious illnesses, how patients and families want their beliefs and preferences to guide decisions (including decisions should sudden and unexpected critical medical problems arise), and what steps could alleviate concerns related to finances, family matters, spiritual questions, and other issues that trouble seriously ill or dying patients and their families. Impediments to advance planning and the implementation of written directives may be less a matter of law than of ordinary inertia or unwillingness to consider unpleasant matters. The rest of this section discusses resuscitation orders, living wills, designation of surrogates, and the Patient Self-Determination Act of 1991.

Do Not Resuscitate Orders

Do not resuscitate orders or DNRs are orders placed by a physician with a patient's or surrogate's consent into the patient's treatment chart. As discussed in Chapter 2, it is not unusual for severely ill patients, who may be dying from any of a variety of diseases, to suffer cardiac or respiratory arrests. The normal action when this occurs is called a "code."⁶ DNRs, or "no-codes," inform hospital staff or other caregivers that, in the event of such an episode, no attempts at revival should be made. Even when attempted, success rates of cardiopulmonary resuscitation are often low, especially for elderly patients (Murphy et al., 1989). For that reason, DNRs are sometimes called DNARs or "Do Not Attempt to Resuscitate" orders.

Because DNRs are physicians' orders, they come out of the clinical rather than the legal tradition. They thus have more in common with orders for medication or lab tests than they do with such legal documents as living wills or durable powers of attorney. Additionally, many hospitals had DNR options in place before they were required to do so by law. DNRs might, however, have some legal significance, if courts take them into account when determining whether a patient's preferences have been followed. Also, because the decision by the physician to place the DNR in the chart should be made in consultation with the patient and should reflect a patient's decision to forego certain forms of life-prolonging treatment, DNRs share with living wills and durable powers of attorney a role in the process of advance care planning.

⁶Caregivers attempt, through the insertion of breathing tubes and a pump, or by electric shock to the heart, to revive the patient. These attempts may stabilize the patient or may result in actual damage, leaving the patient alive but in a worse condition than before the code.

Living Wills

As of 1990, 40 states and the District of Columbia allowed adults to create what is popularly called a "living will" (Strauss et al., 1990). These statutes vary in their particulars, but they generally envision that individuals may make legally binding arrangements to the effect that they shall not be sustained by medical treatment that artificially prolongs the dying process if they are in a terminal condition and can no longer make decisions.

The statutes include several safeguards against abuse. Most include a requirement that the two witnesses to the signing of the document be neither related to the patient nor involved in his or her treatment or financial support. Also, the determinations that the patient fits the statutory definition of terminal and is unable to make decisions sometimes must be made by at least two physicians. A mentally competent individual is always entitled to revoke his or her advance directive. The statutes vary on whether nutrition and hydration are considered "artificially life-sustaining" treatments. Some statutes explicitly exempt nutrition and hydration from the care a patient may choose to refuse, others give the signer the option to explicitly include them, while a third group is silent on the matter (Strauss et al., 1990).

Skeptics of living wills argue that these documents, which may be standard forms approved by the legislature of some states, provide little practical guidance in real life clinical situations, which often involve many more factors or contingencies than anticipated by standard forms (see, e.g., Brett, 1991; Lynn, 1991). Indeed, by leading patients to believe that the signing of a living will means that their preferences for an end-of-life treatment plan have been made clear, these documents could even discourage active and ongoing discussions among patients, their families, and health care professionals. In contrast, a document designating a surrogate decisionmaker could encourage such communication.

Designation of Surrogate Decisionmakers

Adults

Another legal option for advance care planning involves the designation of a surrogate to act on one's behalf in the event one becomes incompetent to make decisions about medical care. State statutes (or, in some cases, sections within the living will statutes) vary in the amount of authority a person can assign to a surrogate. For example, in California, the patient's agent, who is assigned durable power of attorney⁷ for health care

⁷"Durable" power of attorney differs from general power of attorney in that it does not expire when the designator loses the competence to make decisions. This is integral to health

may make all health care decisions that the patient could make for himself or herself, had he or she the capacity (California Civil Code Sec. 2500). The attorney-in-fact's duty is to follow the wishes of the power's grantor, but specific instructions need not be included in the document. In contrast, Nevada and Rhode Island that require statutory forms be used (Nevada Chapter 449 Secs. 2-8; Rhode Island Sec. 23-4.10-1). Grantors of the power of attorney choose options on the form, instructing their agents when to consent to or refuse life-sustaining treatments.

In one sense, although the statutes that provide for standard forms and checked options seem more specific, they may still lead to ambiguities of definition and decision. For example, when an agent is instructed to refuse treatment when that treatment's burdens outweigh the expected benefits, it remains up to the agent (with the help of the health caregivers and others involved) to make the determination. In fact, under the broader powers available under California's statute, the grantor and the agent may be more likely to sit down together and discuss the grantor's wishes, rather than have the grantor check a box and leave it at that.

Other states place even more limits on the powers of the agent. In New York, power of attorney may not be used to delegate medical decision-making authority, only to communicate the wishes of the grantor (Strauss et al., 1990). This inflexible provision restricts people's ability to plan ahead and may prevent humane care at the end of life.⁸

Children

Decisions regarding dying children involve special considerations (Lantos and Miles, 1989; Strain, 1994; AAP, 1995; Fleischman, 1996). Although specific state laws vary, those below a certain age are legally unable to agree to or refuse medical treatment, and so others must make decisions for them. Even so, the best interests of these patients often oblige caregivers to discuss the situation with the children in ways appropriate for their developmental level and physical condition. This discussion may go beyond the sharing of information to ask children what they want for themselves (see discussion in Chapter 3). Problems arise when those with the power to consent to treatment for children disagree with each other or with clinicians. For health care providers, parental decisionmaking may also be complicated by spousal disagreement or evidence of child abuse.

care decisionmaking, as it is exactly at the time of a patient's incompetence that the designated attorney-in-fact's role begins.

⁸The Conference of Commissioners on Uniform State Laws has recently proposed a Uniform Act on surrogate decisionmaking.

Parents' decisionmaking discretion is not absolute, and pediatricians view themselves as having a professional obligation to look after the best interest of their patients (AAP, 1995). In some cases, their conclusions may conflict with those of the patients' families. Some of the most difficult cases arise from parents' demands for what clinicians regard as "futile" or "inhuman" care. The possibilities for resolving conflict include sensitive conversations between the child's physician and the parents; involvement by social workers, ethicists, pastoral counsellors, or others trained in working with grief-stricken families; mediation by a hospital ethics committee; or recourse to the legal system. The latter is widely viewed as a last resort because of the burden it places on families, the stress it creates for clinicians, and the potential for negative publicity for families and institutions.

The Patient Self-Determination Act

The Patient Self-Determination Act (PSDA) was enacted by Congress in 1990 and went into effect in December 1991 (White and Fletcher, 1991; GAO, 1995b). The PSDA requires health care institutions that receive Medicare or Medicaid funds to provide written information to adult patients about state laws regarding advance directives. It also requires those institutions, among other things, to note any advance directive in a patient's file, not to discriminate between patients on the basis of whether they have an advance directive, and to educate staff and community about the availability of advance directives.

The purpose of the PSDA was to encourage greater awareness and use of advance directives so that situations of ambiguity, as illustrated by the Nancy Cruzan case, might be avoided. In that 1990 case, the United States Supreme Court recognized a competent patient's right to refuse life-sustaining treatment, but left it to the lower courts to determine whether testimony of Nancy Cruzan's previously expressed oral wishes was persuasive. In *Cruzan v. Director, Missouri Health Department*, Justice Sandra Day O'Connor suggested in a concurring opinion that written advance directives could dispel such ambiguity. That year, Congress passed the PSDA.

The law, however, appears to have had modest effects (Teno, Lynn et al., 1994; Morrison et al., 1994; Emanuel, 1995a; see also Chapter 3). There are no national studies on the rates of persons completing advance directives, but studies of discrete populations (e.g., nursing home residents or hospital patients) conducted both before and after passage of the PSDA show rates between 5 percent and 29 percent (GAO, 1995b; Yates and Glick, 1995). The SUPPORT investigators found a small increase of seriously ill patients having an advance directive since the PSDA went into effect (from one in five to one in four), but this increase did not translate

into higher rates of documented resuscitation discussions or DNR orders for patients who seemed to want them (Teno, Lynn, Wenger et al., 1997).

Although it requires health care organizations to provide information, the PSDA does not specify the content of that information. Often, patients are informed of their rights regarding advance directives during admission to a hospital or long-term care facility. The information is provided on a piece of paper, one of many that crosses the table during this usually stressful time. Other problems with implementation of the PSDA exist. One study found problems in the accessibility of previously completed advance directives during subsequent hospitalizations (Morrison et al., 1995). Another study found that, of the patient charts that indicated the existence of an advance directive, only 57.5 percent actually contained a copy of the directive (Yates and Glick, 1995). The study also revealed that a mere 32 percent of medical institutions covered by the law had done any community education on advance directives. The lack of involvement of physicians, especially primary doctors, also contributes to the tendency of patients to overlook the information offered.

The committee, while recognizing the value of advance directives, questions the urgency of intensive efforts to universalize their use. In this area of decisionmaking at the end of life, the law's favorite product—the legally binding document—may sometimes stand in the way of, rather than ease, the process, especially if these documents are naively viewed as ultimate solutions to the difficulties of decisionmaking. Rather, the documents known as advance directives should be seen as a set of tools useful in the ongoing process of advance care planning. Methods must be developed for encouraging continuing conversation among patients, their families, and the health professionals involved in their care. Less legalistic ways to approach planning and decisionmaking at the end of life were discussed in Chapter 3.

PHYSICIAN-ASSISTED SUICIDE

"Physician-assisted suicide" refers to a practice by which physicians provide, but do not directly administer, the means for a patient voluntarily to hasten his or her own death. This typically is done by prescribing lethal doses of medication that the patient then ingests. "Euthanasia," in contrast, is a practice by which the means of hastening death are administered directly by the physician, for example, when a doctor injects a patient with a lethal medication.

Controversies about assisted suicide have received recent widespread attention as a result of two lawsuits challenging the constitutionality of New York and Washington laws that prohibit physician-assisted suicide. The U.S. Supreme Court heard arguments on the cases (*Vacco v. Quill*, No.

95-1858 and *State of Washington v. Glucksberg*, No. 96-110) in early 1997.⁹ The litigation followed popular referenda in California and Washington in 1990 and 1991 in which proposals to legalize physician-assisted suicide were defeated. In 1992, however, Oregon voters approved a similar proposal. Oregon thus became the first jurisdiction in the United States to provide formal legal recognition of the practice of physician-assisted suicide, although court challenges delayed implementation of the law and legislative reconsideration was being discussed as this report was completed.

The committee agreed that it would not take a position on the legality or morality of assisted suicide, but it did examine some of the issues that might arise if the Supreme Court ultimately ruled either that a terminally ill person who is mentally competent and voluntarily chooses suicide has a constitutional right to self-administer lethal drugs received with the assistance of a physician or that it was constitutionally permissible for individual states, such as Oregon to permit the practice. Many of these issues were explored in friend-of-the-court briefs filed with the Court.¹⁰

Although proposals to legalize physician-assisted suicide typically include various safeguards or restrictions to protect patients and physicians, these provisions involve a number of ambiguities that might make them impossible or impractical to implement. For example, as noted earlier in this report, the status of being "terminally ill" has not been satisfactorily defined conceptually or in application because no boundary prognosis correlates precisely with an important clinical change and none can reliably be supported by data (Lynn et al., 1996). Subjective definitions of illness can be criticized as being so variable as to seem capricious. Already, several hospices have been challenged over terminal illness identifications, prognoses of survival, and small percentages of patients who survive for more than six months (see Chapter 6). In the case of care that is widely viewed as beneficial, the acceptance of some prognostic errors for a large population of patients is reasonable. It is harder to be so sanguine about such errors when the issue is assistance in suicide.

⁹On June 30, 1997 (after the initial release of this report), the Supreme Court ruled that there is no general constitutional right to physician assistance in suicide. Some of the justices, however, wrote statements that suggested that a narrowly defined right might be upheld in specific circumstances.

¹⁰See, for example, the briefs filed by the American Geriatrics Society, the American Medical Association, the American Nurses Association, the American Psychiatric Association et al., the Project on Death in America, and Ronald Dworkin, Thomas Nagel; Robert Nozick, John Rawls, Thomas Scanlon and Judith Jarvis Thomson. The latter was reprinted in *The New York Review of Books*, March 27, 1997, pp. 41-47. Several briefs are available at www.soros.org/death/brieftxt.html.

The criterion of voluntariness also presents problems in determining patient status and articulating boundaries (e.g., what constitutes undue influence by another party). Further, the question can be raised whether serious socioeconomic disadvantage nullifies voluntariness. If a desirable treatment would bankrupt a patient's family and, therefore, a patient chooses suicide, should a physician be authorized to assist? The dilemma between complicity with societal inequalities (by allowing assisted suicides) and magnification of them (by refusing assistance in suicides) is not readily resolvable.

Similarly, requiring that patients be mentally competent raises questions about what standards will be used, what threshold will be set, how fluctuating capacities will be handled, and what will be done about directions in advance. If competence requires very good mental functioning, then few persons known to be near death may qualify. If, however, one cannot direct suicide in advance of becoming incompetent, then people may consider preemptive suicide far in advance of death.

Proposals typically require that self-administered prescription drugs be authorized by a physician. If many physicians consider themselves ethically or otherwise precluded from doing so, pressure for more involvement of nonphysicians is likely to arise and, perhaps, to require new safeguards.

In sum, the proposed restrictions and intended safeguards in initiatives to legalize physician-assisted suicide are problematic: difficult to define, uncertain in implementation, or vulnerable to unanticipated and unwanted consequences for those they propose to protect. Resolving uncertainties would likely be a difficult process for clinicians, and the courts almost certainly would be involved in further challenges to the implementation of assisted-suicide laws.

Other questions can be posed concerning autonomy—an individual's right to exercise free choice regarding his or her life. This is the core principle that is advanced in favor of physician-assisted suicide. The committee agrees that this principle is a centrally important value. It also believes that the current serious deficiencies in the provision of care to dying people—deficiencies highlighted throughout this report—themselves compromise the autonomy principle by depriving individuals of many choices that should, and realistically can, be made available to them. As discussed in Chapter 5, substantial numbers of dying people today suffer from avoidable pain and other symptoms, and many of the arguments for physician-assisted suicide reflect fear of pain. Offering these patients just two options—either physician assistance for hastened death or continued life with untreated pain—is a highly constricted choice that undermines the principle of autonomy. Truly autonomous choice would allow for adequate relief of pain and other distressing symptoms, adequate psychological support from properly trained health care professionals, and adequate financial and per-

sonal service support for home care in preference to impersonal hospital or nursing home settings.

If, one way or another, Oregon proceeds, the committee believes that its implementation of legal physician-assisted suicide should be carefully and intensively monitored. One key objective would be to learn whether legal safeguards are truly effective. A second objective would be to determine whether general deficiencies in the care of dying people influence individual choices for physician-assisted suicide and whether legalization stimulates correction of deficiencies. If the Oregon law is implemented, advantage should be taken of the opportunity to develop a more adequate factual basis for evaluating the competing claims for and against legal recognition of physician-assisted suicide.

Individual committee members had varied views about the morality, legality, and administrability of assisted suicide. The group fully agreed, however, that the current deficiencies in the provision of care for dying people are so extensive that they may provide inappropriate incentives for people to choose hastened death if that option is made available to them without accompanying remedial measures to improve their care. The nation should not need the prod of assisted suicide to drive it to act in behalf of the dying, although this committee, realistically, believes that media coverage of the assisted suicide cases has put the issues before the public and the professions in a very attention-getting fashion.

CONCLUSION

Reliable, excellent care at the end of life is an objective that should be supported, not impeded, by public policy. Unfortunately, some laws, regulations, and policies of public/private regulatory bodies may obstruct good care, either by their specific provisions or by the fear and misunderstanding they create. Drug-prescribing laws stand out in this regard and, in the view of the committee, warrant revisions to minimize discouragement of effective pain management. Other laws and regulations reflect an overly optimistic view of the effectiveness of laws and legal documents in clarifying how people wish to be treated when dying. Legal documents have a role to play but should not deflect attention from the more significant and complex process of advance care planning as considered in Chapter 3.

Deficiencies in care of the dying were recognized well before recent assisted suicide referenda, legislative activities, and court challenges. Nonetheless, much of the recent attention to deficiencies in end-of-life care arose only when the issue of assisted suicide came before the Supreme Court. Even if assisted suicide becomes legal, both society and the professions should feel confident that no one who chooses suicide does so because care systems are deficient in meeting their needs.

Assisted Suicide File

Dear Mr. Chairman:

This is in response to your request concerning the question whether the Department of Justice, through the Drug Enforcement Administration ("DEA"), may invoke the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971, to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances. The issue has arisen in the context of Oregon's "Death with Dignity Act," Oreg. Rev. Stat. §§ 127.800-127.995, which permits physicians to assist competent, terminally ill patients in ending their lives in compliance with certain detailed procedures. The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

The Oregon Act was approved by Oregon voters on November 8, 1994, and went into effect on October 27, 1997. The Act provides for a detailed procedure by which a mentally competent, terminally ill patient may request to end his or her life "in a humane and dignified manner." O.R.S. § 127.805. The procedure requires, for example, that the patient's competence and the voluntariness of the request be documented in writing and confirmed by two witnesses, see id. § 127.810(1), that the patient's illness and competence and the voluntariness of the request be confirmed by a second physician, see id. § 127.820, and that the physician and patient observe certain waiting periods, see id. §§ 127.840, 127.850. Once a request has been properly documented and the requisite waiting periods have expired, the patient's attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance.

Prior to the Oregon Act's taking effect last year, you wrote to DEA Administrator Thomas Constantine seeking the DEA's view as to whether delivering, distributing, dispensing, prescribing, or administering a controlled substance with the intent of assisting in a suicide would violate the CSA notwithstanding a state law such as the Oregon Act. In response, Administrator Constantine explained that "physician-assisted suicide would be a new and different application of the CSA," and that the determination whether to pursue adverse action under the CSA would first require "a medico-legal investigation" involving "state and local law enforcement agencies and prosecutors." He also stated, however, that "the activities that you described in your letter to us would be, in our opinion, a violation of the CSA." Subsequently, many other Members of Congress have sent letters urging that I support the DEA's conclusions and enforce federal laws and regulations accordingly. I have received other correspondence supporting a contrary conclusion.

The Department has conducted a thorough and careful review of the issue of whether the CSA authorizes adverse action against a physician who prescribes a controlled substance to assist in a suicide in compliance with Oregon law.

The CSA is a complex regulatory scheme that controls the authorized distribution of scheduled drugs. Physicians, for example, are authorized to prescribe and distribute scheduled drugs only pursuant to their registration with the DEA, and the unauthorized distribution of drugs is generally subject to criminal and administrative action. The relevant provisions of the CSA provide criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice," 21 U.S.C. § 802(21), see id. § 841(b), and provide for revocation of the DEA drug registrations of physicians who have engaged either in such criminal conduct or in other "conduct which may threaten the public health and safety," id. § 823(f). Because these terms are not further defined by the statute, we must look to the purpose of the CSA to understand their scope.

The CSA was intended to keep legally available controlled substances within lawful channels of distribution and use. See S. Rep. No. 91-613, at 3 (1969). It sought to prevent both the trafficking in these substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress intended to prevent was that deriving from the drug's "stimulant, depressant, or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f).

There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regulating the practice of medicine that involves legally available drugs (except for certain specific regulations dealing with the treatment of addicts, see 42 U.S.C. § 257a; 21 C.F.R. § 291.505).

Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," Washington v. Glucksberg, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances. If Congress had assigned DEA this role under the CSA, it would ultimately be DEA's task to determine whether assistance in the commission of a suicide, in compliance with a state law specifically permitting and regulating such assistance, nevertheless falls outside the legitimate practice of medicine and is inconsistent with the public interest. These questions, however, are not susceptible of scientific or factual resolution, but rather are fundamental

questions of morality and public policy. Such a mission falls well beyond the purpose of the CSA.

The state of Oregon has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures. Under these circumstances, we have concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law. We emphasize that our conclusion is limited to these particular circumstances. Adverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so. However, the federal government's pursuit of adverse actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA.

Finally, notwithstanding our interpretation of the CSA as it applies to the Oregon Act, it is important to underscore that the President continues to maintain his longstanding position against assisted suicide and any Federal support for that procedure. This position was recently codified when he signed the Assisted Suicide Funding Restriction Act last year. While states ordinarily have primary responsibility for regulating physicians, the President and the Administration nonetheless remain open to working with you and other interested members of Congress on this complex but extremely important issue.

Sincerely,

Janet Reno

cc: Ranking Minority Member

TALKING POINTS FOR CALL TO SENATOR WYDEN

- I am calling concerning the physician-assisted suicide issue. We have reviewed the issue thoroughly and we have concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon's "Death with Dignity Act" would not be authorized by the Controlled Substances Act.
- We have concluded that the Controlled Substances Act does not displace the states as the primary regulators of the medical profession and cannot be used to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice.
- Even more fundamentally, we have concluded that the Controlled Substances Act does not assign DEA the role of resolving the profound debate about the morality, legality, and practicality of physician-assisted suicide, simply because that procedure involves the use of controlled substances.
- I want to emphasize that our conclusion is limited to the particular circumstances of the state of Oregon, which has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures. Adverse action under the Controlled Substances Act may well be warranted in other circumstances. [If asked: For example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so.]
- [If asked whether we would support legislation giving this authority to DEA or some other agency:] While states ordinarily have primary responsibility for regulating physicians, the President and the Administration nonetheless remain open to working with you and other interested members of Congress on this complex issue.¹
- Later this morning, we will be sending you a letter detailing our analysis of this issue.
- Thank you for your patience as the Department conducted the thorough review that this issue deserved.

¹ As background, you should know that the White House wants to remain flexible at present on this question and on the question of which agency, if any, would be appropriate to get such authority.

MEMORANDUM

TO: Jonathan Schwartz

June 4, 1998

FR: Chris Jennings

RE: Outstanding Qs & As vis a vis assisted suicide

cc: Gregory King, Gary Grindler, and Joe Graupensterger

Thank you for the Justice Department's solid work on the assisted suicide issue. We greatly appreciate it. The following are a few questions that we will use to answer policy questions that may arise after the release of the Department's decision:

Q. Does the Administration support legislation that criminalize, or penalize in any other way, through Federal statute actions taken by health care professionals that hasten the death of terminally ill people?

A. The President has a longstanding position against assisted suicide or any Federal support for this practice. This position was codified as he enacted into law the Assisted Suicide Funding Restriction Act just last year. Although he recognizes that states traditionally regulate medical practice, he is open to reviewing legislation that may emerge from Capitol Hill on this subject.

Q. Does that mean that he supports or opposes a legislative intervention in this area?

A. It means he recognizes there is great interest on both sides of this issue on Capitol Hill and he is open to reviewing any initiative that addresses this important matter. It also means that this issue is one that should be carefully considered on the specific details and merits of any such legislation -- not on the basis of a general concept of the desirability (or lack thereof) of a legislative intervention.

Q. What about simply giving the DEA the authority that Senator Hatch and Congressman Hyde seem to appear to desire the agency to have to penalize physicians for prescribing medications that hasten death?

A. Again, it would be premature to comment on any legislation until and unless we have seen and carefully reviewed it.

Q. Some health groups, such as the AMA, are very concerned that legislation in this area may further exacerbate the problem of under prescribing pain relief medications for the terminally ill. They cite an Institute of Medicine (IoM) study that concludes this is a chronic and extremely serious problem. Does the Administration share their concern?

A. The President is extremely concerned about the documented problem of under-medicating terminally ill people. Terminally ill Americans frequently experience great pain and, to the extent possible, should be relieved of it through appropriate medical intervention. It is his hope that discussions around the issue of assisted suicide will not further exacerbate this problem. He hopes to work with the Department of Health and Human Services and the medical community to better inform physicians and other health professionals about the problems associated with under-medicating.

OREGON ASSISTED SUICIDE Q&As

- Q. What is the result of the Department's review of the Oregon Assisted Suicide, or "Death with Dignity" Act?
- A. After a thorough review, the Department has concluded that the Controlled Substances Act does not authorize any adverse action against a physician who has assisted in a suicide in full compliance with the Oregon's assisted suicide law.
- Q. Doesn't the Controlled Substances Act give the federal government the power to regulate the prescription by doctors of potentially lethal drugs?
- A. The states are the primary regulators of the medical profession. The Controlled Substances Act ordinarily should not be used to override a state's determination as to what constitutes a legitimate medical practice in the absence of a federal law specifically prohibiting that practice.
- Q. Isn't the decision about whether the prescription of drugs for the purposes of assisting a suicide one that should be made by the DEA?
- A. No. We have concluded that the Controlled Substances Act does not assign DEA the role of resolving the profound debate about the morality, legality, and practicality of physician-assisted suicide, simply because that procedure involves the use of controlled substances.
- Q. Does this decision legalize assisted suicide throughout the United States?
- A. No. Our conclusion is limited to the particular circumstances of the state of Oregon, which has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures. Adverse action under the Controlled Substances Act may well be warranted in other circumstances.
- Q. If a physician assists in a suicide in a state that has not authorized the practice under any conditions, could the federal government intervene?
- A. Action may well be warranted in such a situation.
- Q. What if a physician fails to comply with state procedures in prescribing drugs to assist in a suicide?
- A. Again, action may well be warranted.

Q. Why did it take so long to reach this conclusion?

A. There are many complex issues involved and an appropriate amount of time was taken for a full review?

Q. Does the DEA agree with this decision?

A. Yes.

Q. Did the White House review this decision?

A. While the White House has examined the policy issues surrounding assisted suicide, they did not participate in our legal review.

Q. Is that unusual?

A. No, the White House office regularly looks at the policy implications of legal decisions of major importance.

Q. Was this decision influenced by pressure from Capitol Hill?

A. No, the decision was based on a careful and thorough review of the state and federal statutes that apply in this area.

Q. Do you think the DEA should be given statutory authority to intervene in this area?

A. Not necessarily. Because of the complex moral, legal and practical issues involved -- issues normally reserved to the states -- that issue needs to be carefully examined before we can reach a determination.

Q. Will you be sending legislation to the Hill on this subject?

A. We don't anticipate sending legislation at this time, however, we will be happy to work with members of Congress to determine if further actions are necessary.

Q. How is this situation different than the one in California where the federal government says the use of marijuana for medical patients violates federal law?

A. Marijuana is a Schedule I controlled substance that cannot be prescribed by physicians under any circumstances. Physicians are not barred from prescribing the drugs that are at issue in Oregon.

Q. Does this mean that other states can act to legalize assisted suicide?

A. The states are the primary regulators of the medical profession.

Q. If California were to designate marijuana as a prescription drug, would doctors there be able to prescribe it for patients?

A. No, marijuana is a Schedule I controlled substance that cannot be prescribed under any circumstances. States are not empowered to reschedule drugs under the Controlled Substances Act.



Office of the Attorney General
Washington, D. C. 20530

June 5, 1998

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is in response to your request concerning the question whether the Department of Justice, through the Drug Enforcement Administration ("DEA"), may invoke the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971, to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances. The issue has arisen in the context of Oregon's "Death with Dignity Act," *Oreg. Rev. Stat.* §§ 127.800-127.995, which permits physicians to assist competent, terminally ill patients in ending their lives in compliance with certain detailed procedures. The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

The Oregon Act was approved by Oregon voters on November 8, 1994, and went into effect on October 27, 1997. The Act provides for a detailed procedure by which a mentally competent, terminally ill patient may request to end his or her life "in a humane and dignified manner." *O.R.S.* § 127.805. The procedure requires, for example, that the patient's competence and the voluntariness of the request be documented in writing and confirmed by two witnesses, *see id.* § 127.810(1), that the patient's illness and competence and the voluntariness of the request be confirmed by a second physician, *see id.* § 127.820, and that the physician and patient observe certain waiting periods, *see id.* §§ 127.840, 127.850. Once a request has been properly documented and the requisite waiting periods have expired, the patient's attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance.

The Honorable Orrin G. Hatch

Page 2

Prior to the Oregon Act's taking effect last year, you wrote to DEA Administrator Thomas Constantine seeking the DEA's view as to whether delivering, distributing, dispensing, prescribing, or administering a controlled substance with the intent of assisting in a suicide would violate the CSA notwithstanding a state law such as the Oregon Act. In response, Administrator Constantine explained that "physician-assisted suicide would be a new and different application of the CSA," and that the determination whether to pursue adverse action under the CSA would first require "a medico-legal investigation" involving "state and local law enforcement agencies and prosecutors." He also stated, however, that "the activities that you described in your letter to us would be, in our opinion, a violation of the CSA." Subsequently, many other Members of Congress have sent letters urging that I support the DEA's conclusions and enforce federal laws and regulations accordingly. I have received other correspondence supporting a contrary conclusion.

The Department has conducted a thorough and careful review of the issue of whether the CSA authorizes adverse action against a physician who prescribes a controlled substance to assist in a suicide in compliance with Oregon law.

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The CSA was intended to keep legally available controlled substances within lawful channels of distribution and use. See S. Rep. No. 91-613, at 3 (1969). It sought to prevent both the trafficking in these substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress intended to prevent was that deriving from the drug's "stimulant, depressant, or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f).

The Honorable Orrin G. Hatch
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There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regulating the practice of medicine that involves legally available drugs (except for certain specific regulations dealing with the treatment of addicts, see 42 U.S.C. § 257a; 21 C.F.R. § 291.505).

Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," Washington v. Glucksberg, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances. If Congress had assigned DEA this role under the CSA, it would ultimately be DEA's task to determine whether assistance in the commission of a suicide, in compliance with a state law specifically permitting and regulating such assistance, nevertheless falls outside the legitimate practice of medicine and is inconsistent with the public interest. These questions, however, are not susceptible of scientific or factual resolution, but rather are fundamental questions of morality and public policy. Such a mission falls well beyond the purpose of the CSA.

The state of Oregon has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures. Under these circumstances, we have concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law. We emphasize that our conclusion is limited to these particular circumstances. Adverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so. However, the federal government's pursuit of adverse actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA.

Finally, notwithstanding our interpretation of the CSA as it applies to the Oregon Act, it is important to underscore that the President continues to maintain his longstanding position against assisted suicide and any Federal support for that procedure. This position was recently codified when he signed the Assisted Suicide Funding Restriction Act last year. While states

The Honorable Orrin G. Hatch
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ordinarily have primary responsibility for regulating physicians, the President and the Administration nonetheless remain open to working with you and other interested members of Congress on this complex but extremely important issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Janet Reno".

Janet Reno

cc: The Honorable Patrick J. Leahy, Jr.
Ranking Minority Member



Office of the Attorney General
Washington, D. C. 20530

June 5, 1998

The Honorable Henry J. Hyde
Chairman
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request concerning the question whether the Department of Justice, through the Drug Enforcement Administration ("DEA"), may invoke the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971, to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances. The issue has arisen in the context of Oregon's "Death with Dignity Act," Oreg. Rev. Stat. §§ 127.800-127.995, which permits physicians to assist competent, terminally ill patients in ending their lives in compliance with certain detailed procedures. The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

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The Honorable Henry J. Hyde
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Prior to the Oregon Act's taking effect last year, you wrote to DEA Administrator Thomas Constantine seeking the DEA's view as to whether delivering, distributing, dispensing, prescribing, or administering a controlled substance with the intent of assisting in a suicide would violate the CSA notwithstanding a state law such as the Oregon Act. In response, Administrator Constantine explained that "physician-assisted suicide would be a new and different application of the CSA," and that the determination whether to pursue adverse action under the CSA would first require "a medico-legal investigation" involving "state and local law enforcement agencies and prosecutors." He also stated, however, that "the activities that you described in your letter to us would be, in our opinion, a violation of the CSA." Subsequently, many other Members of Congress have sent letters urging that I support the DEA's conclusions and enforce federal laws and regulations accordingly. I have received other correspondence supporting a contrary conclusion.

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The Honorable Henry J. Hyde
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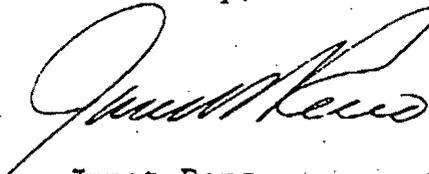
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The Honorable Henry J. Hyde
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Sincerely,



Janet Reno

cc: The Honorable John Conyers, Jr.
Ranking Minority Member

He called
Jon Schwatz's
office. They are the
only ones w/copies
and they can't
release it until
they get a confir-
mation to release it

It should
be available
later today.
Otherwise, no one
~~has~~ has a
copy. |

5/20/81
514-2003/ Full:
U.S. DEPARTMENT OF JUSTICE
AG's
Gary Grindler 514-2003
Joe Graupeneter
JONATHAN D. SCHWARTZ - L 80
ASSOCIATE DEPUTY ATTORNEY GENERAL
305-2643 514 3451



OFFICE OF THE DEPUTY ATTORNEY GENERAL
950 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20530
PHONE (202) 305-8060
FAX (202) 514-9368

LETTER #2 (resolving statutory authority question,
but not addressing policy)

DRAFT

Dear Congressman Hyde:

This is in response to your letter urging the Department of Justice, through the Drug Enforcement Administration ("DEA"), to invoke the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971 (1994), to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances. The issue has arisen in the context of Oregon's "Death with Dignity Act," Oreg. Rev. Stat. §§ 127.800-127.995, which permits physicians to assist competent, terminally ill patients in ending their lives in compliance with certain detailed procedures. The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

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There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regulating the practice of medicine that involves legally available drugs (except for certain specific regulations dealing with the treatment of addicts, *see* 42 U.S.C. § 257a; 21 C.F.R. § 291.505).

Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," *Washington v. Glucksberg*, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances. If Congress had assigned DEA this role under the CSA, it would ultimately be DEA's task to determine whether assistance in the commission of a suicide, in compliance with a state law specifically permitting and regulating such assistance, nevertheless falls outside the

legitimate practice of medicine and is inconsistent with the public interest. These questions, however, are not susceptible of scientific or factual resolution, but rather are fundamental questions of morality and public policy. Such a mission falls well beyond the purpose of the CSA.

The state of Oregon has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures. Under these circumstances, we have concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law. We emphasize that our conclusion is limited to these particular circumstances. Adverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so. However, the pursuit of such adverse action against a physician in Oregon who has fully complied with that state's Death with Dignity Act would go beyond anything Congress intended in crafting the CSA.

Sincerely,

Janet Reno

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Finally, it is ~~important to~~ to show it is ~~important~~
to involve the President ~~longstanding~~ ^{will demand} ~~is~~ ^{and} ~~discharge~~ with
~~support~~ ~~of~~ assisted suicide, ~~the law~~ ~~is~~ ~~to~~ ~~be~~

He illustrated his ~~point~~ ^{point} when he cited the
side law last year, ~~which the President will~~ ^{as you know, this new law...}
~~that he~~ ~~did~~

While the President understands the ~~states~~ ^{states have} ~~constitutionally~~
ground/~~oversight~~ ^{oversight} the practice of medicine, he remains
open to the ~~possibility~~ ^{possibility} that Federal legislation might
have ~~been~~ ~~the~~