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SENATE

{ REPORT
106-299

THE PAIN RELIEF PROMOTION ACT

MAY 23, 2000.—Ordered to be printed

Mr. HATCH, from the Committee on the Judiciary,
submitted the following

REPORT

together with

MINORITY VIEWS

[To accompany H.R. 2260]

The Committee on the Judiciary, to which was referred the bill (H.R. 2260) amending the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes, having considered the same, reports favorably thereon, with an amendment in the nature of a substitute, and recommends that the bill, as amended, do pass.

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I. TEXT OF H.R. 2260

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pain Relief Promotion Act of 2000".

SEC. 2. FINDINGS.

Congress finds that—

- (1) in the first decade of the new millennium there should be a new emphasis on pain management and palliative care;
- (2) the use of certain narcotics and other drugs or substances with a potential for abuse is strictly regulated under the Controlled Substances Act;
- (3) the dispensing and distribution of certain controlled substances by properly registered practitioners for legitimate medical purposes are permitted under the Controlled Substances Act and implementing regulations;
- (4) the dispensing or distribution of certain controlled substances for the purpose of relieving pain and discomfort even if it increases the risk of death is a legitimate medical purpose and is permissible under the Controlled Substances Act;
- (5) inadequate treatment of pain, especially for chronic diseases and conditions, irreversible diseases such as cancer, and end-of-life care, is a serious public health problem affecting hundreds of thousands of patients every year; physicians should not hesitate to dispense or distribute controlled substances when medically indicated for these conditions; and
- (6) for the reasons set forth in section 101 of the Controlled Substances Act (21 U.S.C. 801), the dispensing and distribution of controlled substances for any purpose affect interstate commerce.

TITLE I—PROMOTING PAIN MANAGEMENT AND PALLIATIVE CARE

SEC. 101. ACTIVITIES OF AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.

Part A of title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end the following:

“SEC. 903. PROGRAM FOR PAIN MANAGEMENT AND PALLIATIVE CARE RESEARCH AND QUALITY.

“(a) IN GENERAL.—Subject to subsections (e) and (f) of section 902, the Director shall carry out a program to accomplish the following:

- “(1) Promote and advance scientific understanding of pain management and palliative care.
- “(2) Collect and disseminate protocols and evidence-based practices regarding pain management and palliative care, with priority given to pain management for terminally ill patients, and make such information available to public and private health care programs and providers, health professions schools, and hospices, and to the general public.

“(b) DEFINITION.—In this section, the term ‘pain management and palliative care’ means—

- “(1) the active, total care of patients whose disease or medical condition is not responsive to curative treatment or whose prognosis is limited due to progressive, far-advanced disease; and
- “(2) the evaluation, diagnosis, treatment, and management of primary and secondary pain, whether acute, chronic, persistent, intractable, or associated with the end of life;

the purpose of which is to diagnose and alleviate pain and other distressing signs and symptoms and to enhance the quality of life, not to hasten or postpone death.”.

SEC. 102. ACTIVITIES OF HEALTH RESOURCES AND SERVICES ADMINISTRATION.

(a) IN GENERAL.—Part D of title VII of the Public Health Service Act (42 U.S.C. 294 et seq.) is amended—

- (1) by redesignating sections 754 through 757 as sections 755 through 758, respectively; and
- (2) by inserting after section 753 the following:

“SEC. 754. PROGRAM FOR EDUCATION AND TRAINING IN PAIN MANAGEMENT AND PALLIATIVE CARE.

“(a) IN GENERAL.—The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality, may award grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain management and palliative care.

“(b) PRIORITY.—In making awards under subsection (a), the Secretary shall give priority to awards for the implementation of programs under such subsection.

“(c) CERTAIN TOPICS.—An award may be made under subsection (a) only if the applicant for the award agrees that the program to be carried out with the award will include information and education on—

“(1) means for diagnosing and alleviating pain and other distressing signs and symptoms of patients, especially terminally ill patients, including the medically appropriate use of controlled substances;

“(2) applicable laws on controlled substances, including laws permitting health care professionals to dispense or administer controlled substances as needed to relieve pain even in cases where such efforts may unintentionally increase the risk of death; and

“(3) recent findings, developments, and improvements in the provision of pain management and palliative care.

“(d) PROGRAM SITES.—Education and training under subsection (a) may be provided at or through health professions schools, residency training programs and other graduate programs in the health professions, entities that provide continuing medical education, hospices, and such other programs or sites as the Secretary determines to be appropriate.

“(e) EVALUATION OF PROGRAMS.—The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the effect of such programs on knowledge and practice regarding pain management and palliative care.

“(f) PEER REVIEW GROUPS.—In carrying out section 799(f) with respect to this section, the Secretary shall ensure that the membership of each peer review group involved includes individuals with expertise and experience in pain management and palliative care for the population of patients whose needs are to be served by the program.

“(g) DEFINITION.—In this section, the term ‘pain management and palliative care’ means—

“(1) the active, total care of patients whose disease or medical condition is not responsive to curative treatment or whose prognosis is limited due to progressive, far-advanced disease; and

“(2) the evaluation, diagnosis, treatment, and management of primary and secondary pain, whether acute, chronic, persistent, intractable, or associated with the end of life;

the purpose of which is to diagnose and alleviate pain and other distressing signs and symptoms and to enhance the quality of life, not to hasten or postpone death.”.

(b) AUTHORIZATION OF APPROPRIATIONS; ALLOCATION.—

(1) IN GENERAL.—Section 758 of the Public Health Service Act (as redesignated by subsection (a)(1) of this section) is amended, in subsection (b)(1)(C), by striking “sections 753, 754, and 755” and inserting “sections 753, 754, 755, and 756”.

(2) AMOUNT.—With respect to section 758 of the Public Health Service Act (as redesignated by subsection (a)(1) of this section), the dollar amount specified in subsection (b)(1)(C) of such section is deemed to be increased by \$5,000,000.

SEC. 103. DECADE OF PAIN CONTROL AND RESEARCH.

The calendar decade beginning January 1, 2001, is designated as the “Decade of Pain Control and Research”.

SEC. 104. EFFECTIVE DATE.

The amendments made by this title shall take effect on the date of enactment of this Act.

TITLE II—USE OF CONTROLLED SUBSTANCES CONSISTENT WITH THE CONTROLLED SUB- STANCES ACT

SEC. 201. REINFORCING EXISTING STANDARD FOR LEGITIMATE USE OF CONTROLLED SUB- STANCES.

(a) IN GENERAL.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

“(i)(1) For purposes of this Act and any regulations to implement this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death. Nothing in this section authorizes inten-

tionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death.

“(2)(A) Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia.

“(B) Paragraph (2) applies only to conduct occurring after the date of enactment of this subsection.

“(3) Nothing in this subsection shall be construed to alter the roles of the Federal and State governments in regulating the practice of medicine. Regardless of whether the Attorney General determines pursuant to this section that the registration of a practitioner is inconsistent with the public interest, it remains solely within the discretion of State authorities to determine whether action should be taken with respect to the State professional license of the practitioner or State prescribing privileges.

“(4) Nothing in the Pain Relief Promotion Act of 2000 (including the amendments made by such Act) shall be construed—

“(A) to modify the Federal requirements that a controlled substance be dispensed only for a legitimate medical purpose pursuant to paragraph (1); or

“(B) to provide the Attorney General with the authority to issue national standards for pain management and palliative care clinical practice, research, or quality;

except that the Attorney General may take such other actions as may be necessary to enforce this Act.”.

(b) PAIN RELIEF.—Section 304(c) of the Controlled Substances Act (21 U.S.C. 824(c)) is amended—

(1) by striking “(c) Before” and inserting the following:

“(c) PROCEDURES.—

“(1) ORDER TO SHOW CAUSE.—Before”; and

(2) by adding at the end the following:

“(2) BURDEN OF PROOF.—At any proceeding under paragraph (1), where the order to show cause is based on the alleged intentions of the applicant or registrant to cause or assist in causing death, and the practitioner claims a defense under paragraph (1) of section 303(i), the Attorney General shall have the burden of proving, by clear and convincing evidence, that the practitioner’s intent was to dispense, distribute, or administer a controlled substance for the purpose of causing death or assisting another person in causing death. In meeting such burden, it shall not be sufficient to prove that the applicant or registrant knew that the use of controlled substance may increase the risk of death.”.

SEC. 202. EDUCATION AND TRAINING PROGRAMS.

Section 502(a) of the Controlled Substances Act (21 U.S.C. 872(a)) is amended—

(1) by striking “and” at the end of paragraph (5);

(2) by striking the period at the end of paragraph (6) and inserting “; and”; and

(3) by adding at the end the following:

“(7) educational and training programs for Federal, State, and local personnel, incorporating recommendations, subject to the provisions of subsections (e) and (f) of section 902 of the Public Health Service Act, by the Secretary of Health and Human Services, on the means by which investigation and enforcement actions by law enforcement personnel may better accommodate the necessary and legitimate use of controlled substances in pain management and palliative care.

Nothing in this subsection shall be construed to alter the roles of the Federal and State governments in regulating the practice of medicine.”.

SEC. 203. FUNDING AUTHORITY.

Notwithstanding any other provision of law, the operation of the diversion control fee account program of the Drug Enforcement Administration shall be construed to include carrying out section 303(i) of the Controlled Substances Act (21 U.S.C. 823(i)), as added by this Act, and subsections (a)(4) and (c)(2) of section 304 of the Controlled Substances Act (21 U.S.C. 824), as amended by this Act.

SEC. 204. EFFECTIVE DATE.

The amendments made by this title shall take effect on the date of enactment of this Act.

II. PURPOSE AND SUMMARY

The purpose of the Pain Relief Promotion Act is to promote pain research and management and palliative care and to make clear that medications subject to the Controlled Substances Act (“CSA”) may not be lawfully used to assist in suicide or to perform euthanasia. In the 105th Congress, the Judiciary Committee favorably reported the Lethal Drug Abuse Prevention Act, S. 2151 (Report 105–372); this legislation and similar goals to the substitute language to H.R. 2260 that the Committee now adopts.

In enacting the Controlled Substances Act of 1970, the Congress firmly established the principle that certain types of drug substances were subject to national regulation. The statute recognizes that “[m]any of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American public.”¹ However, the law also was mindful of the fact that illicit traffic use of controlled substances has “* * * a substantial and detrimental effect on the health and general welfare of the American people.”² Further, the CSA finds that “[f]ederal control of the interstate incidents in traffic in controlled substances is essential to the effective control of the interstate incidents in the United States.”³

H.R. 2260, as adopted by the Judiciary Committee, advances the two historical goals of the CSA of promoting the public health by making necessary medications available to patients and protecting the public safety by curbing illicit diversion of these substances. H.R. 2260 explicitly adopts a safe harbor that makes clear that physicians and other health care professionals acting to alleviate pain or discomfort in the usual course of medical practice are protected under the CSA, even if such use of a controlled substance may increase the risk of death. The legislation also makes clear that the diversion of controlled substances for the purpose of causing death or assisting another person in causing death is not permitted under the CSA.

Inadequate treatment of pain is a serious public health problem affecting hundreds of thousands of patients a year. Perhaps “the biggest obstacle” to adequate treatment of pain, however, is “ignorance”: Few medical schools or residency programs require training in pain management, and many rank-and-file physicals are unaware of modern advances in palliative care.⁴

Highlighting the need for improved care, and posing its own obstacle to such improvement, is the drive by some for acceptance of assisted suicide as a “quick fix” supplanting the more difficult but more responsible task of caring for terminally ill patients’ real needs. As the National Hospice Organization has warned, “the acceptance of assisted suicide as a way to deal with terminal illness would undercut further efforts to increase the public’s awareness of hospice as a life-affirming option.”⁵

¹ 21 U.S.C. 801(1).

² 21 U.S.C. 801(2).

³ 21 U.S.C. 801(6).

⁴ S. Brownlee and J. Schrof, “The Quality of Mercy,” U.S. News and World Report, vol. 122, No. 10 (Mar. 17, 1997): p. 56.

⁵ Brief for Amicus National Hospice Organization at 18, *Vacco v. Quill*, 521 U.S. 793 (1997) and *Washington v. Glucksberg*, 521 U.S. 702 (1997).

H.R. 2260 addresses this problem in several ways. In addition to definitively establishing that the use of controlled substances to alleviate pain or discomfort in the usual course of professional practice is authorized and encouraged under Federal law, in order to promote better pain management, H.R. 2260 authorizes a \$5,000,000 program under which the Secretary of Health and Human Services may award grants to health professions schools, hospices and other sites to develop and implement palliative care education and training. Third, it authorizes the Agency for Healthcare Research and Quality in the Department of Health and Human Services to collect and disseminate protocols for palliative care, while making clear that neither the Department nor the Attorney General are authorized to mandate national standards of clinical practice in this area.

The legislation reinforces the widely held view that under existing law the purpose of causing death or assisting another person in causing death is not a legitimate use of controlled substances and is not consistent with public health and safety. In order to encourage medical practitioners to prescribe, dispense, distribute and administer controlled substances as medically appropriate in order to relieve pain and discomfort, the bill makes it more difficult to revoke doctors' registrations to prescribe controlled substances by raising the required standard of proof from the current preponderance of the evidence standard to the more difficult to satisfy clear and convincing evidence standard.

It is also important to note that the bill would designate this decade as the "Decade of Pain Control and Research." This will result in focusing greater attention among scientists and practitioners into pain management and research. Further, the law charges the Attorney General to carry out educational training programs for law enforcement personnel in how better to accommodate health professionals' legitimate use of controlled substances for pain management.

In summary, this legislation is premised on the principle that the Controlled Substances Act contemplates use of controlled substances to alleviate pain and suffering and that this purpose cannot be turned on its head—and turned against a central teaching of the Hippocratic Oath—First, do no harm—by allowing controlled substances to be intentionally used as agents of death.

Under the Pain Relief Promotion Act, as amended, Congress finds that Federal law regarding controlled substances allows dispensing and distributing controlled substances only by properly registered practitioners for legitimate medical purposes. The bill finds that the dispensing and distribution of controlled substances, acts which affect interstate commerce, are not legitimate medical purposes when used to assist in a suicide or euthanasia. At the same time, the measure recognizes the key role that controlled substances can play in the legitimate medical use of relieving pain and discomfort.

III. BACKGROUND AND NEED FOR THE LEGISLATION

A number of recent events have sparked a national debate over the intertwined legal and ethical issues surrounding end-of-life care, especially the provision of adequate pain relief and palliative care

and physician-assisted suicide. These include: the involvement of Jack Kevorkian in a lengthy series of assisted suicides before being finally convicted of homicide after giving a lethal injection to a man with severe disabilities in a videotape aired on national television; two, recent Supreme Court cases on assisted suicide, *Vacco v. Quill*⁶ and *Washington v. Glucksberg*;⁷ enactment of Oregon's Measure 16 (the "Death with Dignity Act");⁸ Presidential signature of the Assisted Suicide Funding Restriction Act of 1997 (Public Law 105-12)⁹; and the Senate Judiciary Committee's favorable action on S. 2151 in the 10th Congress.

On November 8, 1994, Oregon became the only jurisdiction in the United States authorizing physician-assisted suicide as a matter of State law when the State's voters approved Ballot Measure 16 by a slight margin of 51 percent to 49 percent.¹⁰ On November 27, 1994, however, a lawsuit was filed against the measure alleging its unconstitutionality on equal protection and due process grounds that prevented it from going into immediate effect.¹¹ On August 3, 1995, a Federal district court held the law unconstitutional as a violation of the 14th amendment's equal protection clause.¹² The State of Oregon appealed the decision, and on February 27, 1997, the ninth circuit overturned the lower court's decision without reaching the merits, instead ruling that the plaintiffs lacked standing.¹³ On October 27, 1997, the ninth circuit accordingly lifted the injunction against the act, which thus officially went for the repeal of the act by a margin of 60 percent to 40 percent. However, on November 5, 1997, the Federal Drug Enforcement Administration issued a ruling that regardless of the change in Oregon's State law, under the Federal Controlled Substances Act federally controlled drugs could not legally be prescribed or administered to assist suicide, either in Oregon or any other State. (After the ruling was later reversed by Attorney General Reno, as described in detail below, all of the drugs officially reported as having been used to assist in the death of patients under Oregon's Death with Dignity Act were federally controlled substances.¹⁴) Meanwhile, on June 26, 1997, the U.S. Supreme Court reversed two circuit courts of appeal

⁶ 521 U.S. 793 (1997).

⁷ 521 U.S. 702 (1997).

⁸ Or. Rev. Stat. § 127.800-127.995

⁹ The Assisted Suicide Funding Restriction Act of 1997, 111 Stat. 23, Apr. 30, 1997.

¹⁰ See Spencer Heinz, "Assisted Suicide: Advocates Weigh In," *Oregonian*, Dec. 9, 1994, at A1. The Death With Dignity Act authorizes terminally ill Oregon residents, those who are determined to have fewer than 6 months to live, to obtain a lethal prescription. In other circumstances, Or. Rev. Stat. § 163.125 continues to apply: "Criminal homicide constitutes manslaughter in the second degree when * * * [a] person *intentionally* causes or aids another person to commit suicide." (Emphasis added.)

¹¹ Federal District Court Judge Michael Hogan agreed with the opponents and issued a temporary restraining order against implementation of the act on the day before it was to go into effect, pending a full hearing of their claims. On December 27, 1994, Judge Hogan placed his temporary restraining with a preliminary injunction, further delaying implementation of the act. *Lee v. Lee Oegon*, 891 F. Supp. 1429, 1431 (D. Or. 1995).

¹² *Lee v. Oregon*, 891 F. Supp. 1429, 1431 (D. Or. 1995).

¹³ 107 F. 3rd 1382 (9th Cir. 1997). On May 16, 1997, a petition for writ of certiorari was filed with the U.S. Supreme Court, and the Court denied the petition on October 14, 1997. 522 U.S. 927 (1997).

¹⁴ A Sullivan et al., "Legalized Physician-Assisted Suicide in Oregon—The Second Year," *New England Journal of Medicine*, vol. 342, no. 8 (Feb. 24, 2000); p. 598, 599; A. Chin et al., "Legalized Physician-Assisted Suicide in Oregon—The First Year's Experience," *New England Journal of Medicine*, vol. 340, no. 7 (Feb. 18, 1999), p. 577, 578 (of 21 lethal prescriptions, 20 were for 9g of secobarbital or pentobarbital; one was for (26 of the 27 patients were given 9g or more of secobarbital; one received 6 g of phenobarbital).

rulings that had struck down the laws of New York and Washington preventing assisting suicide; the Nations highest court concluded that the laws prohibiting assisting suicide do not violate the U.S. Constitution. The Solicitor General of the United States filed briefs as amicus curiae opposing the overturning of the State laws in each case. In his brief in the *Glucksberg* case, the Solicitor General emphasized that there is a clear ethical and legal distinction between pain control that unintentionally hastens death and the prescribing of lethal drugs with the intent to cause death:

[T]he ethical standards of the medical community have long permitted physicians to prescribe medication in sufficient doses to relieve pain, even when the necessary dose will hasten death. * * * So long as the physician's intent is to relieve pain, and not to cause death, such treatment does not violate the ethical standards of the medical community.¹⁵

The Supreme Court concurred with this distinction, noting, “Just as a State may prohibit assisting suicide while permitting patients to refuse unwanted lifesaving treatment, it may permit palliative care related to that refusal, which may have the foreseen but unintended ‘double effect’ of hastening the patient’s death. See New York task force. *When Death is Sought*, supra, n. 6, at 163 (‘It is widely recognized that the provision of pain medication is ethically and professionally acceptable even when the treatment may hasten the patient’s death, if the medication is intended to alleviate pain and severe discomfort, not to cause death’).”¹⁶

The Solicitor General also noted that “no Federal law * * * either authorizes or accommodates physician assisted suicide.”¹⁷

¹⁵ Brief for the United States as Amicus Curiae Supporting Petitioners at 17–18, *Washington v. Glucksberg*, 521 U.S. 702 (1997).

¹⁶ *Vacco v. Quill*, 521 U.S. 793, 808 n. 11 (1997).

¹⁷ Solicitor General’s Amicus Brief at 2, *Glucksberg*. Relevant portions of the *Glucksberg* brief are as follows: Health facilities controlled by the Federal Government “do not permit physicians to assist patients in committing suicide by providing lethal dosages of medication.” Id. at 1; “Overriding State interests justify the State’s decision to ban physicians from prescribing lethal medication.” Id. at 9; “There is an important and common-sense distinction between withdrawing artificial supports so that a disease will progress to its inevitable end, and providing chemicals to be used to kill someone.” Id.; “Once a State decides to create an exception to its prohibition against assisted suicide, there is no obvious stopping point.” Id. at 10; “One special source of concern is that terminally ill persons who contemplate suicide often suffer from undiagnosed depression and inadequately treated pain * * *. In most cases, once appropriate treatment is provided, the desire for suicide abates.” Id. at 19; “Any exception to the ban on assisted suicide therefore runs a very significant risk that persons with treatable depression and pain will be allowed to commit suicide. A State has an overriding interest in avoiding that risk and in protecting persons who would want to remain alive if provided with the appropriate treatment.” Id. at 20; “Another area of concern is that terminally ill patients are often extremely vulnerable and susceptible to influence by physicians, family members, and others on whom they depend for support * * *. The point is not that physicians or family members will attempt to coerce persons into committing suicide, although there may be some cases of that. The real dangers are much more subtle and extremely difficult to monitor and address.” Id.; “Another difficulty with permitting doctors to prescribe lethal drugs for terminally ill patients is that illnesses can be misdiagnosed as terminal * * *. If the State were to create an exception to its ban on assisted suicide for terminally ill adults, such a misdiagnosis could have tragic consequences * * *. The State has an overwhelmingly strong interest in preventing such tragedies from occurring.” Id. at 22; In the Netherlands, which allowed assisted suicide with safeguards, “a recent study shows that those procedural safeguards have not worked.” Id. at 23; “[T]here is a very significant distinction between removing artificial supports—and thereby allowing the underlying disease to progress to its inevitable end—and providing chemicals to kill someone. In one case, the cause of death can reasonably be viewed as the underlying disease; in the other, the cause of death can only be viewed as the lethal medication.” Id. at 24; Similarly, after reviewing various Federal policies that forbid physician-assisted suicide in Veteran’s Administration hospitals, military hospitals, the National Institutes of Health, and the Indian Health Service, the Solicitor General’s amicus brief in *Vacco v. Quill* stated: “No Federal law authorizes or

In upholding laws preventing assisting suicide, the Supreme Court described the legitimacy of the governmental interests at stake:

Those who attempt suicide—terminally ill or not—often suffer from depression or other mental disorders. See New York Task Force 13–22, 126–128 (more than 95 percent of those who commit suicide had a major psychiatric illness at the time of death; among the terminally ill, uncontrolled pain is a “risk factor” because it contributes to depression): * * * Research indicates * * * that many people who request physician-assisted suicide withdraw that request if their depression and pain are treated. H. Hendin, “Seduced by Death: Doctors, Patients and the Dutch Cure”, 24–25 (1997) (suicidal, terminally ill patients “usually respond well to treatment for depressive illness and pain medication and are then grateful to be alive”) * * *

* * * * *
 [T]he State has an interest in protecting vulnerable groups—including the poor, the elderly, and disabled persons—from abuse, neglect, and mistakes. * * * [T]he New York Task Force warned that “[l]egalizing physician-assisted suicide would pose profound risks to many individuals who are ill and vulnerable. * * * The risk of harm is greatest for the many individuals in our society whose autonomy and well-being are already compromised by poverty, lack of access to good medical care, advanced age, or membership in a stigmatized social group.” New York Task Force 120, see “Compassion in Dying,” 49 F.3d, at 593 (“[A]n insidious bias against the handicapped—again coupled with a cost-saving mentality—makes them especially in need of Washington’s statutory protection”). If physician-assisted suicide were permitted, many might resort to it to spare their families the substantial financial burden of end-of-life health-care costs.

The State’s interest here goes beyond protecting the vulnerable from coercion; it extends to protecting disabled and terminally ill people from prejudice, negative and inaccurate stereotypes, and “societal indifference.” 49 F.3d, at 592. The State’s assisted-suicide ban reflects and reinforces its policy that the lives of terminally ill, disabled, and elderly people must be no less valued than the lives of the young and healthy, and that a seriously disabled person’s suicidal impulses should be interpreted and treated the same way as anyone else’s.¹⁸

Members of the Court also expressed concern that legal acceptance of assisted suicide could erode society’s willingness to expand pain management and other aspects of palliative care for dying patients. As Justice Breyer noted during oral argument, the Netherlands, which permits assisted suicide, had been found by a select

encourages physician assisted suicide.” Brief for the United States as Amicus Curiae Supporting Petitioners at 2, *Vacco*.

¹⁸ *Glucksberg*, 521 U.S. at 730, 731–32.

committee of the British House of Lords to contain only three palliative care centers, compared with 185 in Great Britain where assisted suicide is forbidden.¹⁹

While litigation was still pending challenging Oregon's law authorizing assisted suicide, on the one hand, and the laws of Washington and New York prohibiting it, on the other hand, Congress debated the issue of whether the Federal Government would facilitate euthanasia and assisting suicide should it become legal. On April 30, 1997, after the bill had passed the House by a vote of 398-16 and the Senate by a vote of 99-0, President William J. Clinton signed the Assisted Suicide Funding Restriction Act of 1997.²⁰ The law prohibits the use of Federal funds to cause a patient's death. It also effectively prohibits the practice of assisted suicide in Federal health facilities, removes it from the scope of "rights" under State laws of which patients must be informed under the Federal Patient Self-Determination Act, and forbids Federal subsidies to health programs or benefit packages which include assisted suicide.

Of central importance to the law was the intent-based distinction it made between the provision of services for the purpose of alleviating pain even then they may increase the risk of death and their provision for the purpose of causing death. 42 U.S.C. 14402(b)(4) provided that nothing in the Act

shall be construed to apply to or to affect any limitation relating to * * * the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.²¹

It is noteworthy that this intent-based distinction in existing law governs not only Federal funding, but also the provision of medical treatment

(1) by or in a health care facility owned or operated by the Federal Government, or

(2) by any physician or other individual employed by the Federal Government to provide health care services within the scope of the physician's or individual's employment * * *.²²

¹⁹Oral Arguments in *Vacco v. Quill*, reprinted in 12 issues in "Law & Medicine," 417, 437 (spring 1997).

²⁰Public Law 105-12, April 30, 1997, 111 Stat. 23, largely codified at 42 U.S.C. 14401 to 14408.

²¹In its letter endorsing the Assisted Suicide Funding Restriction Act of 1997, the American Medical Association emphasized the positive role of this provision:

The AMA is particularly pleased to note that your bill acknowledges—in its "Rules of Construction" section—the appropriate role for physicians and other caregivers in end-of-life patient care.* * * Most important * * * is the Rule of Construction which recognizes the medical principle of "secondary effect," that is, the provision of adequate palliative treatment, even though the palliative agent may also foreseeably hasten death. This provision assures patients and physicians alike that legislation opposing assisted suicide will not chill appropriate palliative and end-of-life care.

Letter from P. John Seward, M.D., executive vice president, American Medical Association, to Senator John Ashcroft 1 (Feb. 12, 1997).

²²42 U.S.C. 14402(c).

President Clinton lauded the bill, saying it “will allow the Federal Government to speak with a clear voice in opposing these practices,” and warning that “to endorse assisted suicide would set us on a disturbing and perhaps dangerous path.”²³

In this act Congress also recognized the need to promote pain management and palliative care in part as a bulwark against desperate resort to assisted suicide. The act urged priority attention to this field in grant programs managed by the Department of Health and Human Services, and commissioned the Government Accounting Office to conduct a study of medical school training in palliative care. The disappointing findings of that study have highlighted the need for a more focused commitment to professional training in palliative care, like that found in the present legislation.

“The availability of continuing medical education courses that focus on palliative care issues for terminally or chronically ill people appears limited,” the GAO found.²⁴ The American Medical Association’s database of over 2,000 accredited continuing medical education activities found that few specifically addressed palliative care. A recent MedPAC report on end of life care stated: “Much knowledge of effective palliative care exists, but it has been infrequently taught to health care professionals and infrequently put into practice.”²⁵

This lack of medical education and public focus comes at great detriment to patients. As stated in the GAO report: “People suffering from terminal or chronic illnesses or from disabilities are considered especially vulnerable to suicide because their need or desire for palliative- or comfort-care may not be adequately met in a health system that focuses on curative care.”²⁶

Shortly after the effective date of the Assisted Suicide Funding Restriction Act, on July 25, 1997, the Chairmen of the Senate and House Judiciary Committees, Senator Orrin Hatch and Representative Henry Hyde, wrote a joint letter to Drug Enforcement Administrator Thomas Constantine inquiring whether delivering, distributing, dispensing, prescribing, filling a prescription, or administering a controlled substance in the deliberate assistance of a suicide would violate the Controlled Substances Act, regardless of whether assisting suicide were to become legal as a matter of State law.

As noted in the July, 1997, letter to Mr. Constantine, under existing regulations (21 CFR 1306.04), a controlled substance must be used “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”

A panoply of national and State medical associations have condemned the practice of assisting suicide, both in testimony to the Congress and in briefs accompanying the *Vacco* and *Washington*

²³ Statement by President William Jefferson Clinton upon signing H.R. 1003, 33 weekly comp. Pres. Doc. 617 (May 5, 1997).

²⁴ U.S. General Accounting Office, “Suicide Prevention: Efforts to Increase Research and Education in Palliative Care” (Washington, DC: GPO, 1998), GAO/HEHS-98-128, p. 11.

²⁵ Medicare Payment Advisory Commission, “Report to the Congress: Selected Medicare Issues” (Washington, DC: GPO, 1998), p. 120.

²⁶ GAO, “Suicide Prevention,” p. 1.

cases. Even before enactment of the Assisted Suicide Funding Restriction Act of 1997, the Health Care Financing Administration had determined that physician-assisted suicide is not “reasonable and necessary” to the diagnosis or treatment of disease and injury, and therefore is not reimbursable under Medicare.²⁷

In response to the letter of Chairman Hatch and Hyde, the Drug Enforcement Administration undertook a serious review of professional organizations’ views, case law, legal briefs, law review articles, and State laws related to assisted suicide.

Based on that study, in a November 5, 1997, response, DEA Administrator Constantine advised the Members of Congress that “we are persuaded 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’” “As a result,” Administrator Constantine found, “the activities you described in your letter to us would be, in our opinion, a violation of the CSA.”

Several months later, the two Chairmen received a letter from Attorney General Janet Reno dated June 5, 1998. This letter had the effect of upholding the DEA position with respect to the use of controlled substances for assisting suicide or euthanasia in any State which has not authorized the practice as a matter of State law, and even within Oregon to the extent assisting suicide remains illegal (for example, for a person who is not predicted to die within 6 months). She wrote, “Adverse action under the CSA may well be warranted * * * 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.”²⁸

However, the Attorney General’s letter overruled the DEA’s determination that federally controlled substances could not be used to assist suicides when such assistance is permitted as a matter of Oregon State law. “[A]dverse action against a physician who has assisted in a suicide in full compliance with the Oregon act would not be authorized by the CSA,” she wrote.

The Attorney General’s opinion and the need for legislation to reverse it can best be evaluated in the context of the history and structure of the Controlled Substance Act.

The Controlled Substances Act of 1970 (CSA) provides a uniform national standard for the control of potentially dangerous drugs, and a system of enforcement and penalties that is, in important respects, independent of State law. The CSA prohibits any distribu-

²⁷ Letter of May 1, 1996, from Debbie I. Chang, Director of the Office of Legislative and Intergovernmental Affairs, Health Care Financing Administration.

²⁸ More recently, a letter from the DEA has confirmed this position. “H.R. 2260 does not alter the long-standing federal requirement that controlled substances be dispensed only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The bill simply makes clear that, in determining whether a registration is consistent with the public interest, the Attorney General (and DEA, by designation), ‘shall give no force and effect to State law authorizing assisted suicide or euthanasia.’ *Since Oregon is the only State with a law permitting assisted suicide, DEA’s authority to take administrative action in every other state would not be changed by H.R. 2260.*” Letter from Donnie R. Marshall, Acting Administrator, Drug Enforcement Administration (Apr. 5, 2000), p. 2 (emphasis added).

tion of controlled substances unless the distribution is authorized pursuant to a statutory exception.²⁹

One such exception is distribution pursuant to registration by the Attorney General under 21 U.S.C. 823. Physician and pharmacists may apply to The Drug Enforcement Administration (DEA) for a Federal license to prescribe and administer controlled substances, called a DEA registration. The primary role of DEA with respect to pharmaceutical controlled substances is to prevent, detect, and investigate their diversion from legitimate uses while ensuring their availability for legitimate medical use.³⁰

While physicians receive their licenses to practice medicine from State medical boards, they receive this separate registration to prescribe controlled substances directly from the DEA.³¹ Prescriptions for these potentially dangerous drugs must be written using DEA registration numbers.

The CSA was amended in 1984 to strengthen the DEA's ability to prevent diversion of federally regulated prescriptions drugs for illicit purposes.³² The chief concern cited as justification for the 1984 amendments was the potential of controlled substances to cause physical harm and death when used for something other than a legitimate medical purpose. According to Representative Hughes, the chief House sponsor of the measure, "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."³³

The 1984 amendments were designed to give the DEA more independent authority to revoke a physician's registration in cases where a State was unable or unwilling to intervene.³⁴

²⁹According to 21 U.S.C. 841, it is "unlawful for any person [to] knowingly or intentionally * * * distribute, or dispense * * * a controlled substance" * * * "[e]xcept as authorized by this subchapter [Control and Enforcement, 801 904]."

³⁰All DEA policies, procedures, and investigative programs with respect to this issue are guided by the underlying principle stated in the Code of Federal Regulations which links the validity of any prescription for a controlled substance to the requirement that it be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04.

³¹As Congress declared in 1984 when it last revised this part of the CSA. Registration of a physician under the Controlled Substances Act is a matter entirely separate from a physician's State license to practice medicine. Therefore, revocation of registration only precludes a physician from dispensing substances controlled under the Controlled Substances Act and does not preclude his dispensing other prescription drugs or his continued practice of medicine. S. Rep. No. 98-225, at 267 (1983), reprinted in 1984 U.S.C.A.N. 3182, 3449 n. 40.

³²The 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 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 (Public Law No. 98-473, Stat. 1987).

³³130 Cong. Rec. 25849 (1984). Representative Hughes also cited a Government study indicating that "prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse." Id. at 25849.

³⁴Representative Hamilton Fish, another sponsor of the amendments, 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." Id. at 25849.

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. Dangerous Drug Diversion Control Act of 1984: Hearing on H.R. 5656 before the Subcommittee on Health and the Environment of the House Committee on Energy and Com-

21 M.S.C. 823 of the GSA sets forth requirements for controlled substances registrations and section 824 sets forth grounds for revocation. Physicians who abuse their registrations and prescribe controlled substances for nonmedical purposes are subject to license revocation under section 824 and to potential criminal prosecution under section 841.³⁵

Section 823 provides that the Attorney General may deny an application for registration “if such registration would be inconsistent with the public interest”³⁶ as determined by consideration of several factors.³⁷

Two of the factors listed under 823 that are relevant to assisted suicide are: compliance with State law relating to controlled substances (21 U.S.C. 823(f)(4)), and the public health and safety (21 U.S.C. 823(f)(5)). Most States specifically prohibit assisted suicide; no State has authorized assisted suicide except Oregon.³⁸

Public health and safety has been invoked as a separate ground for revoking the registrations of physicians who prescribe drugs

merce, 98th Cong. 404 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration).

³⁵In practice, a criminal proceeding is almost never initiated. Instead, an administrative penalty is applied (simply revoking or suspending the physician’s special Federal privilege to handle controlled substances), and this effectively prevents further illicit use. Typically, the DEA does not initiate action at all until after the State has acted against a registrant.

³⁶As Representative 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.

130 Cong. Rec. 25,852 (1984).

³⁷21 U.S.C. 824(a)(4) provides that one of the grounds for revocation is the commission of “such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.”

³⁸Currently, 44 States prohibit assisted suicide, either through statutes or common law. Thirty-eight States prohibit assisted suicide through statutes: Alaska: (Ak. Stat. § 11.41.120 [1998]); Arizona: (Az. Rev. Stat. Ann., § 13–1103(A)(3) [West Supp. 1998–1999]); Arkansas: (Ark. Code Ann., § 5–10–104(a)(2) [Michie 1993], § 5–10–106 [Supp. 1999]); California: (CA Penal Code, § 401 [West 1999]); Colorado: (CO Rev. Stat. Ann., § 18–3–104(1)(b) [West 1999]); Connecticut: (CT Gen. Stat. Ann., § 53a–56(a)(2) [West 1994]); Delaware: (DE Code Ann., title 11 § 645 [Michie 1995]); Florida: (FL Stat. Ann., § 782.08 [West 1992]); Georgia: (GA Code Ann., § 16–5–5(b) [Michie 1998]), Hawaii: (HI Rev. Stat., § 707–702(1)(b) [Michie 1999]); Illinois: (IL Comp. Stat., ch. 720, § 5/12–31(a)(2) [Smith-Hurd Supp. 1999]); Indiana: (IN Stat. Ann., § 35–42–1–2.5 [Burns 1998]); Iowa: (IA Code Ann., § 707A.2 [West Supp. 1999]); Kansas: (KS Stat. Ann., § 21–3406 [Supp. 1999]); Kentucky: (Ken. Stat. Ann., § 216.302 [Michie 1998]); Louisiana: (La. Rev. Stat. Ann. § 14: 32.12 [West 1997]); Maine: (Me. Rev. Stat. Ann., tit. 17–A § 204 [West 1983]); Maryland: (Assisted Suicide—Prohibition Act, ch. 700, 1999 Laws of Maryland); Michigan: (Mich. Comp. Laws Ann., § 750.329a [Supp. 1999]); Minnesota: (Minn. Stat. Ann., § 609.215 [Supp. 1999]); Mississippi: (Miss. Code Ann., § 97–3–49 [1994]); Missouri: (Mo. Ann. Stat., 565.023(1)(2) [1999]); Montana: (Mont. Code Ann., § 45–5–105 [1999]); Nebraska: (Neb. Rev. Stat. Ann., § 28–307 [Michie 1995]); New Hampshire: (N.H. Rev. Stat. Ann. § 630:4 [1996]); New Jersey: (N.J. Stat. Ann. § 2C: 11–6 [West 1995]); New Mexico: (N.M. Stat. Ann., § 30–2–4 [Michie 1994]); New York: (N.Y. Penal Law, §§ 120.30, 125.15(3) [West 1998]); North Dakota: (N.D. Cent. Code, § 12.1–16–04 [Michie 1997]); Oklahoma: (Okla. Stat. Ann., §§ 813, 814, 815 [West 1983], §§ 3141.1 to 3141.8 [West Supp. 1999]); Pennsylvania: (Penn. Cons. Stat. Ann., tit. 18 § 2505(b) [West 1998]); Rhode Island: (R.I. Gen. Laws, §§ 11–60–1 through 11–60–5 [West Supp. 1998]); South Carolina: (S.C. Code of Laws § 16–3–1090 [West Supp. 1998]); South Dakota: (S.D. Codified Laws § 22–16–37 [Michie 1998]); Tennessee: (Tenn. Code Ann., § 39–13–216 [Michie 1997]); Texas: (Tex. Penal Code Ann., § 22.08 [West 1994]); Virginia: (Va. Code Ann., § 8.01–622.1 [Michie Supp. 1999]); Washington: (Wash. Rev. Code Ann., § 9A.36.060 [West 1988]); Wisconsin: (Wis. Stat. Ann., § 940.12 [West 1996]); Six States prevent assisting suicide through application of the common law of crimes: Alabama, Idaho, Massachusetts, Nevada, Vermont, and West Virginia. Issue Brief, Health Policy Tracking Service, National Conference of State Legislatures, (Sept. 17, 1999) (Maria Rothoner and Elizabeth Kaiser). It is also arguable that Ohio prohibits assisting suicide under the common law. *Blackburn v. State*, 23 Ohio St. 146 (1872). It is also noteworthy that in circumstances other than those covered by the Oregon Death with Dignity Act, Oregon prohibits assisting suicide by statute. Or. Rev. Stat. § 163.125 provides, “Criminal Homicide constitutes manslaughter in the second degree when * * * [a] person intentionally causes or aids another person to commit suicide.”

used in lethal overdoses.³⁹ In some cases, the physicians were found to have been negligently involved in suicides or attempted suicides.⁴⁰

Each of these cases was theoretically a candidate for criminal prosecution under section 841, but, apparently, no Federal criminal prosecution followed. Even where physicians were previously convicted of manslaughter under State law for negligent and reckless involvement in a suicide or other lethal overdose, the separate Federal standard of “public health and safety” was the basis upon which the registration was revoked and, in one case, reinstatement repeatedly denied.⁴¹

This background indicates that H.R. 2260 does not expand Federal authority to act against misuse of controlled substances in 49 States, and that its application in Oregon is fully consistent with current understanding of the relationship between State and Federal authority under the CSA.

IV. SECTION-BY-SECTION ANALYSIS

Following is a section-by-section analysis of the Chairman’s substitute as ordered reported by the Committee on April 27, 2000:

³⁹ See, e.g., “Denial of Registration of Dr. Samuel Fertig,” 49 Fed. Reg. 6577 (Feb. 22, 1984) (denied a registration for prescribing massive quantities of controlled substances to several young people who used them in lethal overdoses, despite fact that State license had been restored, on grounds that he “was responsible, directly or indirectly, for the deaths of several young people”); “Revocation of Registration of Dr. Murray Walker,” 55 Fed. Reg. 5306 (Feb. 14, 1990) (registration revoked for prescribing Percodan for nonmedical purposes to several people, one of whom died of an overdose, the DEA stating, “Substances are controlled because they are potentially dangerous and therefore should be handled with extreme care. Respondent has failed to exercise such care and, as a result, has ignored his duties as a health care professional to protect the public health and safety from the illicit use of these drugs.”). See 21 U.S.C. 824(c) for the procedure for such a suspension or revocation, and 21 U.S.C. 824(d) for the authority to “suspend any registration simultaneously with the institution of proceedings under this section, in cases where [the Attorney General] finds that there is an imminent danger to the public health or safety.”

⁴⁰ See, e.g., “Denial of registration of Dr. Pompeyo Q. Braga Bonado,” 55 Fed. Reg. 37579 (Sept. 12 1990). Here, the DNA found that granting a registration to this physician would be “clearly contrary to the public interest.” *id.* at 37580. The physician had prescribed controlled substances to several individuals “for no legitimate medical purpose,” including to one man addicted to Percocet who was hospitalized after a suicide attempt. “As a health care professional and DEA registrant,” the DEA stated, “Respondent bears a heavy responsibility to ensure that the controlled substances he prescribes are not abused.” *id.* at 37580.

⁴¹ In the case of “Revocation of Registration of Hugh Schade, M.D.,” 60 Fed. Reg. 56354 (Nov. 8, 1995), Dr. Schade gave potentially lethal amounts of Darvocet to a depressed patient who used them to commit suicide. Giving these drugs to a patient in this mental state, said one expert witness, was “like handing him a loaded gun.” While Dr. Schade was also convicted of negligent homicide under State law because of this case, his DEA application was denied not on the basis that he had violated a State law, but on the separate basis that his conduct objectively threatened “public health and safety”.

In the case of “Revocation Registration of David W. Bradway, M.D.,” 48 Fed. Reg. 49937 (Oct. 28, 1983), the physician’s registration was revoked after conviction under State law on various counts, most notably “one count of manslaughter by unlawfully distributing controlled substances in such a grossly negligent [and] reckless manner as to cause the death of an individual” *Id.* at 49937. Years later, after allegedly rehabilitating and resuming medical practice, the physician applied for a new DEA registration; citing the fact that “a death was directly attributable to Respondent’s misuse of his DEA Certificate of Registration,” the DEA denied the application, stating:

It is the position of the DEA that a Certificate of Registration to handle controlled substances is a privilege, not a right, and it should only be granted to doctors who have demonstrated high standards of ethical conduct and who are completely trustworthy in handling dangerous controlled substances which, as can be seen in this case, can have a devastating impact on individuals who abuse them.

54 Fed. Reg. at 53384. In 1992 he again applied for a DEA registration, but due to “the egregious nature of Respondent’s past conduct,” the DNA ruled in 1994 (15 years after the patient’s death) that “the registration of the Respondent is still not in the public interest”. *Id.* at 6299.

Section 1. Short title

Entitles the act the “Pain Relief Promotion Act of 2000.”

Section 2. Findings

Makes a series of findings about the importance of emphasizing pain management and palliative care in the first decade of the new millennium, the regulation of drugs with a potential for abuse under the Controlled Substances Act, the use of such drugs by practitioners for legitimate medical purposes, especially the purpose of relieving pain and discomfort even if it increases the risk of death, the need for improved treatment of pain, and the fact that dispensing and distributing such drugs affects interstate commerce.

TITLE I

Section 101. Activities of Agency for healthcare research and quality

This section amends the Public Health Services Act by authorizing a program responsibility for the Agency for Healthcare Research and Quality in the Department of Health and Human Services to promote and advance scientific understanding of palliative care. The Agency is directed to collect and disseminate protocols and evidence-based practices for pain management and palliative care with priority for terminally ill patients.

The section is specifically made subject to subsections (e) and (f) of section 902 of the Public Health Service Act [42 U.S.C. 299a(e) and (f)],⁴² added by the Healthcare Research and Quality Act of 1999, Public Law 106–129, which prevent the mandating of national standards of clinical practice.

This section has a definition of pain management and palliative care which is a modified version of the World Health Organization’s definition of palliative care.

Section 102. Activities of Health Resources and Services Administration

This section amends the Public Health Services Act by authorizing a program for education and training in pain management and palliative care in the Health Resources and Services Administration of the Department of Health and Human Services. This section allows the Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality to award grants, cooperative agreements and contracts to health professions schools, hospices, and other public and private entities to develop and implement pain management and palliative care education and training programs for health care professions.

This section requires the applicant for the award to include three educational informational components in the program: (1) the pro-

⁴²The provisions of subsections (e) and (f) of Section 902 of the Public Health Service act state:

(e) Disclaimer.—The Agency shall not mandate national standards of clinical practice or quality health care standards. Recommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.

(f) Rule of Construction.—Nothing in this section shall be construed to imply that the Agency’s role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, health care delivery systems, and individual preferences.

gram must have a component that addresses a means for diagnosing and alleviating pain and other distressing signs and symptoms of patients, especially in terminally ill patients, including the use of controlled substances; (2) the program must provide information and education on the applicable laws on controlled substances, including those permitting dispensing or administering them to relieve pain even in cases where such efforts may unintentionally increase the risk of death, and (3) the information and education must provide recent findings and developments in the improvement of pain management and palliative care. Health professions schools, residency training programs, continuing education, graduate programs in the health professions, hospices, and other sites as determined by the Secretary will be used as program sites.

This section also requires the Secretary to evaluate the programs directly or through grants or contracts and mandates that the Secretary include individuals with expertise and experience in pain management and palliative care for the population of patients whose needs are to be served in each peer review group involved in the selection of the grantees.

Five million dollars annually are authorized to carry out these program.

Section 103. Decade of pain control and research

This section designates the decade beginning January 1, 2001, as the “Decade of Pain Control and Research.”

Section 104. Effective date

This section makes title I effective on the date of enactment.

Section 201: Reinforcing existing standard for legitimate use controlled substances

This section amends the Controlled Substances Act to establish that physicians and other licensed health care professionals holding DEA registrations are authorized to dispense, distribute, or administer controlled substances for the legitimate medical purpose of alleviating a patient’s pain or discomfort in the usual course of professional practice even if the use of these drugs may increase the risk of death.⁴³ Essentially, this provision makes clear that these exists a “safe harbor” for those who dispense controlled substances for pain relief and palliative care, even if such treatment increases

⁴³ Because the language of H.R. 2260 applies only to dispensing, distributing, or administering controlled substances, it can only apply to schedule II, III, IV, or V drugs. Schedule I drugs, such as marijuana (21 CFR 1308.11(d)(19)), may not be dispensed for any reason but may be used only for approved research. 21 U.S.C. 823(f) provides, “The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered: * * * (5) such other factors as may be relevant to and consistent with the public health and safety.” By contrast, the only provision authorizing registration of practitioners with respect to schedule I controlled substances is for research: “Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine qualifications and competency of each practitioner requesting registration.” *Id.* Thus, a physician’s or pharmacist’s registration to dispense controlled substances under 21 U.S.C. 823 does not apply to or authorize dispensing marijuana since it is a schedule I controlled substance.

a patient's risk of death. The Department of Justice (DOJ) has taken the position that the Pain Relief Act "would eliminate any ambiguity about the legality of using controlled substances to alleviate the pain and suffering of the terminally ill by reducing any perceived threat of administrative and criminal sanctions in this context."⁴⁴

Without creating any new Federal standard, this section also ensures that the new safe harbor is not construed to change the proper interpretation of current law that the administration, dispensing, or distribution of a controlled substance for the purpose of assisting a suicide⁴⁵ is not authorized by the Controlled Substances Act. Individuals covered by the CSA would not be subject to any new liability under the statute—with the exception of those who would attempt in the future to rely on the Oregon Act as a defense to alleged violations of the CSA.

This section further provides that the Attorney General in implementing the Controlled Substances Act shall not give force or effect to any State law permitting assisted suicide or euthanasia. This effectively overturns the June 5, 1998, ruling of the Attorney General insofar as that ruling concluded "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 [or the law of any other state that might authorize assisting suicide or euthanasia]."⁴⁶

This section provides that the provisions of the bill are effective only upon enactment with no retroactive effect. This means that the Oregon statute will serve as a defense for any actions taken in compliance under the Oregon law prior to the enactment of H.R. 2260, if enacted.

This section further provides that nothing in it shall be construed to alter the roles of the Federal and State governments in regulating the practice of medicine, affirming that regardless of whether a practitioner's DEA registration is deemed inconsistent with the public interest, the status of the practitioner's State professional license and State prescribing privileges remain solely within the discretion of State authorities.

This section also provides that nothing in the act is to be construed to modify Federal requirements that a controlled substance may be dispensed only for a legitimate medical purpose nor to authorize the Attorney General to issue national standards for pain management and palliative care clinical practice, research, or qual-

⁴⁴Letter from Robert Raben, Assistant Attorney General, Department of Justice, to Hon. Henry Hyde, Oct. 19, 1999.

⁴⁵"Webster's Third New International Dictionary Unabridged" (Merriam-Webster, 1986) defines "suicide" in relevant part as "the act or an instance of taking one's own life voluntarily and intentionally; self-destruction." It defines "euthanasia" in relevant part as "the act or practice of painlessly putting to death persons suffering from incurable conditions or diseases." By "assisted suicide," the bill describes provision of means to another person with the intent of enabling or assisting that person to kill himself or herself (as by ingesting a lethal overdose). By "euthanasia" the bill more generally describes the use of active means by one person to cause the death of another person (as by lethal injection) because, as a result of illness, injury, or disability, either the person is deemed to be dying or suffering or the person is considered to be a "burden" on family, community or society. It should be emphasized that euthanasia can occur whether or not the person who is killed consents to be killed. Cf. H.R. Rep. No. 46 Pt. I, 105th Cong., 1st sess. 11 (1997) (Assisted Suicide Funding Restriction Act of 1997).

⁴⁶Letter from Attorney General Janet Reno to Hon. Henry Hyde (June 5, 1998) p. 3.

ity, except that the Attorney General may take such other actions as may be necessary to enforce the act.

This section provides that in any proceeding to revoke or suspend a DEA registration based on alleged intent to cause or assist in causing death in which the practitioner claims to have been dispensing, distributing, or administering controlled substances to alleviate pain or discomfort in the usual course of professional practice, the burden rests with the Attorney General to prove by clear and convincing evidence that the practitioner's intent was to cause or assist in causing the death.

Section 202: Education and training programs

This section directs educational and research training programs for law enforcement to include means by which they may better accommodate the necessary and legitimate use of controlled substances in pain management and palliative care.

This section clarifies that, because the activities under this legislation are consistent with the Drug Enforcement Administration's registration activities under current law, agency activities pursuant to this bill are to be reimbursed under the diversion control fee account.

Section 204. Effective date

This section establishes that the effective date of the act is that of its enactment.

V. LEGISLATIVE HISTORY AND VOTE OF THE COMMITTEE

H.R. 2260, the "Pain Relief Promotion Act of 1999" was received in the Senate on October 28, 1999, after being passed in the House. On November 19, 1999, it was read twice and referred to the Committee on the Judiciary. A companion measure, S. 1272, had been introduced by Senators Nickles and Lieberman on June 23, 1999, and was referred to the Committee on Health, Education, Labor, and Pensions, which held hearings on October 13, 1999. It currently has 43 sponsors and cosponsors.⁴⁷ No further action has been taken on S. 1272.

In the House of Representatives, H.R. 2260 had been introduced on June 17, 1999, by Judiciary Committee Chairman Henry Hyde and Representative Bart Stupak. The Judiciary Committee's Subcommittee on the Constitution approved the bill, without amendment, by a voice vote on July 20, 1999. The full Committee ordered it reported on September 14, 1999. On October 13, 1999, the Commerce Committee proceeded to the immediate consideration of H.R. 2260 and ordered it reported to the House, amended, by a voice vote. The House of Representatives voted to pass H.R. 2260 on October 27, 1999, by a vote of 271 to 156.

On April 25, 2000, the Judiciary Committee held a hearing to examine issues associated with the legislation, including its effect on the provision of palliative care to terminally ill patients and its

⁴⁷S. 1272 is currently sponsored by Senators Nickles, Lieberman, Abraham, Allard, Bayh, Bennett, Bond, Breaux, Brownback, Bunning, Burns, Cochran, Coverdell, Craig, Crapo, DeWine, Dodd, Domenici, Enzi, Fitzgerald, Frist, Grams, Grassley, Gregg, Hagel, Helms, Hutchinson, Inhofe, Kyl, Landrieu, Lott, Lugar, Mack, McConnell, Moynihan, Murkowski, Santorum, Sessions, Shelby, R. Smith, Thomas, Thurmond, and Voinovich.

interrelationship with State law. The Committee heard testimony from two panels of witnesses, including Members of Congress and public advocates expert in end-of-life care issues.

In the first panel, Senator Don Nickles of Oklahoma testified that the purposes of the bill are two-fold: To promote aggressive pain management and to clarify Federal law on the use of controlled substances. To advance pain management, the bill establishes that the relief of pain and discomfort is a "legitimate medical purpose," even if the large doses used in treating pain may increase the risk of death. It also provides Federal support for training and research in the areas of pain management and palliative care. To clarify the use of federally controlled drugs, H.R. 2260 states that their use to deliberately cause death or assist in causing death is not a legitimate medical purpose. Therefore, for purposes of the Controlled Substances Act of 1970, the Attorney General "shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia."

Also on panel one, Senator Ron Wyden of Oregon testified against H.R. 2260. He said that he opposes assisted suicide, but does not believe that he has the authority to apply his personal convictions as a substitute for the judgment made by Oregon voters. Senator Wyden strongly expressed the view that the Oregon law, twice the subject of favorable statewide popular votes, ought not to be thwarted by the application of H.R. 2260. Senator Wyden expressed other concerns with the bill, including his belief that it would tie the hands of doctors who treat patients in severe pain, including the terminally ill. He argued that the bill could cause doctors to underprescribe medication and leave patients in intractable pain.

As the final witness in the first panel, Senator Gordon Smith of Oregon explained that he believes assisted suicide is an issue of conscience. He outlined his own experience with the law as an Oregon State Senator and a member of the State senate's Health Care and bioethics Committee, as well as his experiences as a lay bishop visiting the sick, the elderly and the dying. He expressed his concern that acceptance of assisting suicide will lead to pressures on vulnerable people to feel they have a duty to die if they are an economic burden to their families and society. He stated that while a majority of Oregon voters supports the State's law on assisted suicide, he would follow his own conscience and his best judgment on sound public policy and vote for the legislation.

The second panel of witnesses consisted of experts who deal with end-of-life issues and physician-assisted suicide. The first witness in this panel, Dr. Eric Chevlen, is the director of palliative care at St. Elizabeth hospital in Ohio and medical director of two hospices. Dr. Chevlen expressed his support of H.R. 2260. He believes it will improve the ability of doctors to relieve suffering, which is a legitimate medical purpose, while he believes that assisted suicide is not. Dr. Chevlen maintained that H.R. 2260 restores the uniform application of the Controlled Substances Act to all 50 states and does not usurp the rights of the States.

Dr. Arthur Caplan, a nationally recognized expert in the field of bioethics; Dr. Caplan directs the Center for Bioethics at the University of Pennsylvania; he is Trustee Professor at the University

of Pennsylvania. Dr. Caplan voiced opposition to the legislation because of his concern that it could hinder doctors in aggressively treating pain. Dr. Chaplan believes that decisions about pain control and treatment of the dying should be kept, as much as possible, in the hands of health care professionals, not legal authorities.

The third witness was Rabbi J. David Bleich, professor of law at the Benjamin Cardozo School of Law, professor of Talmud and director of the graduate program in jurisprudence and family law at the Rabbi Isaac Elchanan Theological Seminary, as well as Herbert and Florence Tenzer Professor of Jewish Law and Ethics at Yeshiva University. He spoke at the request of the Union of Orthodox Jewish Congregations of America. Rabbi Bleich testified that the effect of H.R. 2260 is solely to remove the Federal imprimatur for assisted suicide, a practice he described as morally repugnant to the majority of our populace and offensive to the traditions of our country. He also stated his belief that H.R. 2260 encourages palliative care above and beyond current law, while paying full deference to the physician's judgment in managing pain.

The fourth witness, Dr. Kathleen Foley, is a Professor of neurology, neuroscience and clinical pharmacology at the Cornell University Medical College, as well as the attending neurologist in the Pain and Palliative Care Service at Memorial Sloan-Kettering Cancer Center. She opposed H.R. 2260 because she believes it expands the authority of the Controlled Substances Act, does not provide sufficient funding to have any real impact on pain management, and may lead doctors to undertreat patients with pain because of concern for regulatory oversight.

The fifth and final witness, Dr. Walter Hunter, associate national medical director of VistaCare Hospice, testified in support of the legislation, stating that this bill will not interfere with his ability, as a hospice physician, to deliver palliative care. In fact, argued Dr. Hunter, the Chairman's substitute for H.R. 2260 recognizes legitimate palliative care and protects physicians who practice it, while prohibiting the deliberate killing of a patient. He said the legislation would make an important first step in committing the Federal Government to optimum palliative care for all patients who need it.

The bill was considered by the full committee in an executive session on April 27, 2000. Chairman Hatch offered a substitute amendment which was agreed to by a recorded roll call vote 10 yeas to 8 nays, as follows:

YEAS	NAYS
Thurmond	Leahy
Grassley	Kennedy
Kyl	Kohl
DeWine	Feinstein
Ashcroft	Feingold
Abraham	Torricelli
Sessions	Schumer
Smith	Specter
Biden	
Hatch	

VI. EXPLANATION OF LEGISLATION AND COMMITTEE VIEWS

A. PROMOTING BETTER PAIN MANAGEMENT AND PALLIATIVE CARE

In written testimony submitted to the Committee, the Pain Care Coalition (representing the American Academy of Pain Medicine, the American Headache Society, and the American Pain Society) summarized current problems in assuring that pain is adequately treated:

Pain is a major public health problem in this country. It affects people of all ages and at every stage of life. It is generally recognized that throughout the nation, and regardless of age, setting, or health status, severe pain is often under-treated or mistreated, if not overlooked entirely. *Nine out of ten* Americans experience some sort of pain on a regular basis—monthly or more often. *Fifty million* Americans are partially or totally disabled by pain, and *45 percent* of all Americans seek care for persistent pain at some point in their lives. Pain imposes a tremendous burden on these individuals and their families.

* * * Recent studies of end-of-life care in hospitals, of the elderly in nursing homes, and of the general public in Michigan all reach the same conclusion: many, many people endure unnecessary suffering due to inadequate pain care.

As one palliative care expert has written:

In a society at the brink of accepting physician-assisted suicide, medical schools still do not adequately teach pain management and care for the dying. * * * [T]he University of Wisconsin Medical School published a study of U.S. cancer centers which documented that 42 percent of cancer patients in pain were not prescribed appropriate pain medication. In another study, 86 percent of the surveyed American oncologists believe that most patients with cancer pain are undermedicated. Even today, many doctors—and too many dying patients—needlessly fear addiction. Similarly, patients may fear side effects of medications more than pain. Moreover, it is documented that patients tend to underreport pain to avoid becoming “a complainer” or to prevent distracting the doctor from “more important matters.” The net consequence of these factors is needless suffering, but each one of these obstacles to assuring comfort among the nation’s dying is surmountable.

* * * Comfort at the end of life is medically possible. Once comfort is assured, the experience of dying can become a rich, meaningful time of life for the dying person and his or her family, a time marked by a sense of rightness and peace. This is true even for those who once considered suicide because of “intractable” pain or other uncontrolled symptoms. We must insist, immediately, that medical schools and training programs—including NCI’s designated cancer centers—teach care for the dying. This

single change could improve current and future care immediately.⁴⁸

The problem is not that modern medicine is incapable of controlling pain, but that too many clinicians are inadequately trained in the most up-to-date techniques. In a survey of 1,177 physicians who had treated a total of more than 70,000 patients with cancer in the previous six months, 76 percent cited lack of knowledge as a barrier to their ability to control pain.⁴⁹

In title I, the bill amends the Public Health Service Act to authorize programs within the Department of Health and Human Services to develop and advance the scientific understanding of palliative care and for education and training in palliative care. These programs take two principal forms.

First, subject to provisions ensuring that it does not mandate national clinical standards, the Agency for Healthcare Research and Quality is to collect and disseminate protocols and evidence-based practices regarding pain management and palliative care. The objective of this program is not for the Agency itself to draft or develop such protocols and practice guidelines, but rather to foster widespread knowledge of those already developed or to be developed by other sources, such as medical specialty organizations. Based on a survey of senior medical directors from Blue Cross Blue Shield insurance plans across the country, a study by Diane Hoffman recently concluded that “insurers have a hard time identifying good pain-relief providers. Before we can make improvements in this area, we need more evidence-based treatment guidelines, preferably from randomized clinical trials, better use of the guidelines we do have, and the development of more meaningful standards.”⁵⁰ Hoffman concluded that widespread dissemination and acceptance of such guidelines is needed to obtain adequate and appropriate coverage of pain relief treatments by private insurers. “[U]ntil then, it is rough on insurers to take the lead in providing coverage.”

Second, title I provides for the awarding of grants, cooperative agreements, and contracts by the HHS Health Resources and Services Administration to health professions schools, hospices, and other public and private entities to develop and implement palliative care education and training programs for health care professionals in palliative care. The decision to award these programs will be made by peer review groups, each of which must include one or more individuals with expertise and experience in palliative care for the population to be served by the program.

As Dr. Hunter testified,

As a physician, I am ashamed to admit that the vast majority of our nation’s medical schools and residency programs have simply failed to make medical ethics, pain and

⁴⁸ Ira Byock, M.D. (Hospice Medical Director of Partners in Home Care, Missoula, Montana), “Caring for the Dying: We Must Confront the Issues,” “Choices,” vol. 4, no. 2 (summer 1995): p. 5.

⁴⁹ U. von Roenn et al., “Physician attitudes and practice in cancer pain management,” “Ann. Intern. Med.,” vol. 119 (1993): pp. 121–26.

⁵⁰ Charles Marwick, “New Advocates of Adequate Treatment Say Have No Fear of Pain or of Prosecution,” “Journal of the American Medical Association,” vol. 281, no. 5 (Feb. 3, 1999): p. 406.

symptom management priorities in their curricula. This information, however, is absolutely essential for physicians to properly provide excellent care for patients. * * * This legislation provides for much needed education in the professional community. We at VistaCare applaud this bill for its commitment of monies for the advancement of understanding of palliative care and for the education of health care professionals in the principles and practice of palliative care. This commitment of time and money to these educational efforts will send a very clear message that the United States Congress has taken up the cause of providing competent, compassionate, and comprehensive palliative care for our citizens who face life-threatening illness.

B. ASSISTING SUICIDE AND EUTHANASIA

By a margin of 64 percent to 31 percent, Americans say that Federal law should not allow the use of federally controlled drugs for the purpose of assisted suicide and euthanasia.⁵¹ The dangers posed by federal facilitation of legalized assisted suicide were dramatically stated by Oregon Senator Gordon Smith in his moving testimony to the committee:⁵²

To [allow federally controlled substances to be used in physician assisted suicide] * * * would have consequences over time unimaginable now-consequences outlined by Derek Humphry, an Oregonian and one of the most vocal and visible advocates of assisted suicide, in his 1998 book *Freedom to Die*.

The final chapter of Mr. Humphrey's book is entitled "The Unspoken Argument." Why it is unspoken? Because it is so awful. Let me quote from page 313 of Mr. Humphry's book, where he reveals the true reason why he believes assisted suicide's time has come:

"* * * one must look at the realities of the increasing cost of health care in an aging society, because in the final analysis, economics, not the quest for broadened individual liberties or increased autonomy, will drive assisted suicide to the plateau of acceptable practice."

Then he asks this chilling question:

⁵¹ Wirthlin Worldwide national telephone poll June 10, 1999. 3.1 percent margin of error at the 95 percent confidence level. The question wording was as follows:

As you may or may not know, the use of narcotics and other dangerous drugs is generally prohibited by federal law except when a doctor prescribes them for a "legitimate medical purpose." Should the federal law allow use of these federally controlled drugs for the purpose of assisted suicide and euthanasia?

31 percent Yes.

64 percent No.

5 percent Don't Know/Refused.

⁵² It is noteworthy that neither Senator WYDEN in his testimony before the Committee nor any member of the Committee has attempted to argue for or defend the legalization of assisting suicide as a matter of public policy, nor (apart from raising federalism issues dealt with below) to argue that the Federal Government should facilitate assisting suicide or euthanasia as a positive public policy.

“Is there, in fact, a duty to die—a responsibility within the family unit—that should remain voluntary but expected nevertheless?”

Mr. Humphry answers yes, but I believe we must answer his vision of Orwellian ugliness with a resounding no. I will not be party to building such a society or justifying such a culture of death. In such a culture, we should never wonder why children do not value life when adults write laws that do not value it either.

The right to kill oneself is a private one. It is a right that can be exercised in nearly anyone’s medicine cabinet. But it is dangerous to make doctors and the state complicit in killing, even though consensual. In an age of medical rationing and for profit HMO’s, there is a terrible ethical and financial conflict of interest. And the federal government should see it and stay away from it. Where Mr. Humphry sees a duty to die, I see a duty to resolve the shortcomings of our medical budgets rationally and honestly without sacrificing the most vulnerable in our society—the elderly and the disabled.

Among the most comprehensive and careful modern examinations of this issue was one undertaken in 1994 by the New York State Task Force on Life and the Law, appointed by New York’s Governor Mario Cuomo.⁵³ Its 23 members, drawn from the fields of medicine, law, and ethics, differed on whether assisting suicide could in theory be ethically appropriate, but the task force was unanimous in concluding “that legalizing it would pose serious and insurmountable risks of mistake and abuse that would greatly outweigh any benefit that might be achieved. These risks center on the likelihood that many individuals would request suicide assistance because of improper medical care, unrecognized lack of decisionmaking capacity, or coercion, not because of a voluntary, settled commitment to die.”⁵⁴

In 1997, the task force issued a supplement to its report that briefly summarized in 10 points “the primary risks associated with legalization”⁵⁵:

- *Undiagnosed or untreated mental illness.* Many individuals who contemplate suicide—including those who are terminally ill—suffer from treatable mental disorders, most commonly clinical depression. Yet, physicians routinely fail to diagnose and treat these disorders, particularly among patients at the end of life. As such, if assisted suicide is legalized, many requests based on mental illness are likely to be granted, even though they do not reflect a competent, settled decision to die.

- *Improperly managed physical symptoms.* Requests for assisted suicide are also highly correlated with unrelieved pain and other discomfort associated with physical illness. Despite significant ad-

⁵³The New York State Task Force on Life and the Law, “When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context” New York: The New York State Task Force on Life and the Law, 1994).

⁵⁴The New York State Task Force on Life and the Law, “When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context Supplement to Report April 1997” (New York: The New York State Task Force on Life and the Law, 1997), p. 4. <http://www.health.state.ny.us/nysdoh/taskfcsought.pdf>

⁵⁵Id. at 4–5.

vances in palliative care, the pain and discomfort that accompanies many physical illnesses are often grossly undertreated in current clinical practice. If assisted suicide is legalized, physicians are likely to grant requests for assisted suicide from patients in pain before all available options to relieve the patient's pain have thoroughly been explored.

- *Insufficient attention to the suffering and fears of dying patients.* For some individuals with terminal or incurable diseases, suicide may appear to be the only solution to profound existential suffering, feelings of abandonment, or fears about the process of dying. While the provision of psychological, spiritual, and social supports—particularly, comprehensive hospice services—can often address these concerns, many individuals do not receive these interventions. If physician-assisted suicide is legalized, many individuals are likely to seek the option because their suffering and fears have not adequately been addressed.

- *Vulnerability of socially marginalized groups.* No matter how carefully any guidelines for physician-assisted suicide are framed, the practice will be implemented through the prism of social inequality and bias that characterizes the delivery of services in all segments of our society, including health care. The practices will pose the greatest risks to those who are poor, elderly, isolated, members of a minority group, or who lack access to good medical care.

- *Devaluation of the lives of the disabled.* A physician's reaction to a patient's request for suicide assistance is likely to depend heavily on the physician's perception of the patient's quality of life. Physicians, like the rest of society, may often devalue the quality of life individuals with disabilities, and may therefore be particularly inclined to grant requests for suicide assistance from disabled patients.

- *Sense of obligation.* The legalization of assisted suicide would itself send a message that suicide is a socially acceptable response to terminal or incurable disease. Some patients are likely to feel pressured to take this option, particularly those who feel obligated to relieve their loved ones of the burden of care. Those patients who do not want to commit suicide may feel obligated to justify their decision to continue living.

- *Patient deference to physician recommendations.* Physicians typically make recommendations about treatment options, and patients generally do what physicians recommend. Once a physician states or implies that assisted suicide would be "medically appropriate," some patients will feel that they have few, if any, alternatives but to accept the recommendation.

- *Increasing financial incentives to limit care.* Physician-assisted suicide is far less expensive than palliative and supportive care at the end of life. As medical care shifts to a system of capitation, financial incentives to limit treatment may influence the way that the option of physician-assisted suicide is presented to patients, as well as the range of alternatives patients are able to obtain.

- *Arbitrariness of proposed limits.* Once society authorizes physician-assisted suicide for competent, terminally ill patients experiencing unbelievable suffering, it will be difficult, if not impossible, to contain the option to such a limited group. Individuals who are

not competent, who are not terminally ill, or who cannot self-administer lethal drugs will also seek the option of physician-assisted death, and no principled basis will exist to deny them this right.

- *Impossibility of developing effective regulation.* The clinical safeguards that have been proposed to prevent abuse and errors are unlikely to be realized in everyday medical practice. Moreover, the private nature of these decisions would undermine efforts to monitor physicians' behavior to prevent mistake and abuse.

The data so far publicly available about the operation of Oregon's assisted suicide law does not inspire confidence that the dangers detailed by the New York Task Force on Life and the Law are being avoided in that State.

On February 17, 1999, the Oregon Health Division released a report detailing the first full year under Oregon's physician-assisted suicide law. A report on the second year was released on February 23, 2000.⁵⁶ Forty-three physician-assisted suicides were reported for the 2 years, all of them involving the use of federally controlled substances. According to family members surveyed for the second report, in 47 percent of the cases patients were influenced to undergo assisted suicide by "concern about being a burden on others."⁵⁷

The report also revealed that a predominant motivation was fear of future disability. The two reasons most frequently cited were "concern about loss of control of bodily functions" (68 percent) and "loss of autonomy" (63 percent)⁵⁸ This is consistent with the first year's report, which noted that those whose suicides were assisted at the time of death were less disabled than a control group of patients who did not commit suicide. Disability rights activists frequently point out that nondisabled people can have a distorted and negative view of the quality of life with a disability, and that newly disabled people go through an adjustment period before realizing this.⁵⁹ Tragically, those whose fear of disability led to their deaths in Oregon will never have that opportunity.⁶⁰

The reports are lacking in several respects. They do not provide independent objectively verified information about the extent to which physicians have complied with the law, but instead, rely heavily on physician self-reporting. This deficiency in objective re-

⁵⁶ Amy Sullivan et al., "Legalized Physician-Assisted Suicide in Oregon—The Second Year," *New England Journal of Medicine*, vol. 342, no. 8 (Feb. 24, 2000): p. 598. <http://www.ohd.hr.state.or.us/chs/pas/ar-index.htm>

⁵⁷ Id. at 601.

⁵⁸ Id.

⁵⁹ In one study, the duration of disability was positively related with acceptance of disability in persons with spinal cord injury-related paralysis. Severity of disability was of no importance in accepting life with a disability. F. Woodrich J.B. Patterson, "Variables Related to Acceptance of Disability in Persons With Spinal Cord Injuries," *Journal of Rehabilitation*, vol. 49, no. 3 (June, July, Aug. 1983) pp. 26–30. 86 percent of spinal cord injured high-level quadriplegics rated their quality of life as average or better than average, while only 17 percent of their emergency room doctors, nurses, and technicians thought that if they acquired quadriplegia they would have a quality of life average or better than average. K.A. Gerhart et al. "Quality of Life Following Spinal Cord Injury: Knowledge and Attitudes of Emergency Care Providers," *Annals of Emergency Medicine*, vol. 23, no. 4 (Apr. 1994): pp. 807–812.

⁶⁰ Disability rights groups that have taken a position opposing the legalization of assisting suicide include American Disabled for Attendant Programs, Disability Rights Education and Defense Fund, Justice for All, National Council on Disability, National Council on Independent Living, National Spinal Cord Injury Association, Not Dead Yet, TASH, World Association of Persons with Disabilities, and World Institute on Disability. In the words of Not Dead Yet, "[A]ssisted suicide cannot be legalized so long as people with disabilities face prejudice, discrimination, and pressure to 'get out of the way.'" Not Dead Yet, "The Pain Relief Promotion Act of 1999," Nov. 12, 1999.

porting is exacerbated by the fact that the law itself is governed by a “good faith” standard that protects physicians from civil, professional, and criminal liability so long as they believe “in good faith” that they have complied with the guidelines.⁶¹

The reports make no serious effort to uncover the extent of covert assisted suicide,⁶² and the law’s confidentiality requirements⁶³ and its provision barring notification of family members without a patient’s express consent⁶⁴ make it very unlikely that abuses will be discovered.⁶⁵ Significantly, the reports fail to provide thorough information on the mental state of the patients. Under the Oregon law, physicians are to assist suicides only in cases where a patient is expected to die in 6 months,⁶⁶ yet physicians generally concede, and the professional literature confirms, that such predictions of life expectancy are unreliable.⁶⁷

In addition, physicians are to assist suicides only in cases where a patient is not suffering from “a psychiatric or psychological disorder, or depression causing impaired judgment.”⁶⁸ Most physicians are ill-equipped to detect depression in their patients at all, much less to determine what level of clinical depression is sufficient to cause “impaired judgment.”⁶⁹

Certain omissions call into question the comprehensiveness of the Oregon reports. For example, they fail to mention that it appears that the first publicly reported case of assisted suicide in the

⁶¹Or. Rev. Stat. § 127.885 (1997). An Oregon physician generally acknowledged to have performed active euthanasia without his patient’s consent (still a homicide under Oregon law) was declared “unprosecutable” by State officials because of the climate created by the Oregon law permitting assisted suicide. See Doctor won’t be prosecuted, *The Bulletin* (Bend, OR), Dec. 11, 1997, at 7.

⁶²Upon releasing the first report, the Oregon Health Division distributed a memorandum to State employees stating that any employee who reveals that a physician-assisted death has occurred in his or her county “will immediately be terminated.” Death with Dignity Memorandum from Sharon Rice, Manager Registration Unit, Center for Health Statistics of the Oregon Health Division, to County Vital Records Registrars and Deputies (Dec. 12, 1997), reprinted in “Confidentiality of Death Certificates,” 14, *Issues in Law & Med.* 333, 334 (1998).

⁶³Or. Rev. Stat. § 127.865 (1997).

⁶⁴Or. Rev. Stat. § 127.835 (1997).

⁶⁵Another factor worthy of note is that, during the first year of the assisted suicide law’s operation, the Oregon Health Plan placed barriers to the funding of antidepressants (Jeanette Hamby, “The Enemy Within: State Bureaucratic Rules Threaten the Spirit of Oregon Health Plan’s Founding Principles,” *Oregonian*, Jan. 21, 1998), restricted the availability of mental health services (Joe Rojas-Burke, “Survey Gives Oregon Health Plan High Marks,” *Oregonian*, Feb. 3, 1999, at B15), and restricted pain medication for poor and disabled patients (Diane Gianelli, “Suicide Opponents Rip Oregon Medicaid Pain Control Policy,” *American Medical News*, Sept. 28, 1998). By contrast, Oregon fully funds assisted suicide. See Pain Relief Promotion Act of 1999, hearing on H.R. 2260 before the Subcommittee on the Constitution of the House Committee on the Judiciary, 106th Cong. (June 24, 1999) (statement of N. Gregory Hamilton, M.D., president of Physicians for Compassionate Care) <<<http://www.house.gov/judiciary/hami0624.htm>>> [hereinafter cited as Hamilton testimony]. Some private Health Maintenance Organizations have placed caps on in-home palliative care while fully funding assisted suicide. *Id.*

⁶⁶Or. Rev. Stat. §§ 127.800, 127.805 (1997).

⁶⁷Joanne Lynn et al., “Defining the ‘Terminally Ill’: Insights from SUPPORT,” 35, *Duquesne Law Review*, 311 (1996); Eric Chevlen, “The Limits of Prognostication,” 35, *Duquesne Law Review*, 337 (1996); Robert A. Pearlman, “Inaccurate Predictions of Life expectancy,” *Archives of Internal Medicine*, vol. 148, no. 12 (Dec. 1988): pp. 2537–38.

⁶⁸Or. Rev. Stat. 127.825 (1997).

⁶⁹Lethal Drug Abuse Prevention Act: Hearing on H.R. 4006 before the Subcommittee on the Constitution of the House Committee on the Judiciary, 105th Cong., 2d sess. (July 14, 1998) (oral statement of Dr. Herbert Hendin). See also, The New York State Task Force on Life and the Law, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* (New York: The New York State Task Force on Life and the Law, 1994): p. 1268. <http://www.health.state.ny.us/nysdoh/provider/death.htm>. The chief author of the Oregon law has written somewhat chillingly that “depression in itself does not rule out the physician’s assistance” under the act. See Cheryl K. Smith, “Safeguards for Physician-assisted Suicide: The Oregon Death with Dignity Act,” in “Death, Dying and the Law,” ed. Sheila McLean (Brookfield, Vt.: Dartmouth, 1996): p. 75.

State involved an out-of-State woman who was found to be depressed by one doctor she consulted. Within 3 weeks of contacting Compassion in Dying and moving to Oregon, she was dead by lethal overdose. Significantly, while two doctors had rendered opinions against the assisted suicide, including a physician who believed the woman was suffering from clinical depression, these opinions were not included in the report.⁷⁰ Two opposing conclusions, at opposite extremes, have been articulated about the Pain Relief Promotion Act: that if enacted it will override State law so as to prohibit all instances of assisting suicide, and that it will have no effect on their number. The Committee believes that neither extreme is correct.

The Pain Relief Promotion Act does not nullify or pre-empt Oregon's statute legalizing certain cases of assisting suicide. It simply prevents the Federal Government's facilitation of assisting suicide by refusing to authorize the use of federally controlled substances to assist suicide, regardless of whether such assistance is legal or illegal as a matter of State law. The same would be true with respect to any statute that a state might in the future enact permitting assisting suicide or euthanasia as a matter of State law. Killing of patients by means other than the use of federally controlled substances is not prohibited by the Pain Relief Promotion Act.

At the same time, the Committee believes that just as Federal facilitation of assisting suicide is likely to increase its incidence, refusal of the Federal Government to facilitate it is likely to decrease that incidence. In particular, refusal to authorize the use of federally controlled drugs to put patients to death is likely to help prevent the institutionalization of induced death as a standard part of medical practice. A study published in the April 23, 1998, "New England Journal of Medicine," showed that while 36 percent of doctors would be willing to write lethal prescriptions if assisting suicide were legal, only 11 percent are willing to do so while it is against the law.⁷¹ Currently, while 18.3 percent of doctors have been asked to assist suicide with a lethal prescription, only 3.3 percent have done so. This suggests that legal limits are effectively deterring over two-thirds of doctors who otherwise might assist suicide.

C. FEDERALISM

Both Senator Wyden in his testimony before the Committee and members of the Committee who oppose the bill have argued that it usurps the power of States to enact legislation, a power which is reserved under the 10th amendment to the Constitution.

The Controlled Substances Act (CSA) was enacted almost 30 years ago as a measure to ensure strict, national regulation of drugs which have a serious potential for abuse. Given the devastating national problem of illicit drug use, the Controlled Substances Act itself found that, "The illegal importation, manufacture, distribution, and possession for improper use of controlled substances have a substantial and detrimental effect on the health

⁷⁰ See Herbert Hendin et al., "Physician-Assisted Suicide: Reflections on Oregon's First Case," 14 issues in "Law & Med." 243 (1998).

⁷¹ Diane Meier et al., "A National Survey of Physician-Assisted Suicide and Euthanasia in the United States," "New England Journal of Medicine," vol. 338, no. 17 (Apr. 23, 1998): p. 1193.

and general welfare of the American people.” It is almost inconceivable that it could seriously be contended that the Controlled Substances Act is beyond the constitutional authority of Congress,⁷² nor does the Committee believe that many Members of Congress would favor its repeal so as to eliminate any national regulation of narcotics and other dangerous drugs. Given the national and indeed the international nature of the drug problem, it is difficult to see how a 50-State, crazy quilt approach to the regulation of controlled substances could adequately protect the health of the American public.

As Senator Nickles testified before the Committee:

Under present Federal law, the Controlled Substances Act, these federally-controlled substances can only be prescribed for a “legitimate medical purpose” in the usual course of professional practice, to promote public health and safety. A lethal overdose, otherwise known as assisted suicide, has never been considered a legitimate medical purpose and certainly does not promote public health and safety.

* * * When Oregon passed a state law to allow physician assisted suicide, it had that right. But it did not have the right to change or amend an existing federal law. If Oregon were to legalize the use of heroin for any purposes that wouldn’t change the federal law prohibiting its use. The Controlled Substances Act is a federal law governing all 50 states, not 49.

⁷²Congress has made the following findings with respect to the effect of traffic in controlled substances on interstate commerce in 21 U.S.C. § 801 (3)–(6):

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce immediately before their distribution, and

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

Section 2(6) of the Pain Relief Promotion Act finds that “for the reasons set forth in section 101 of the Controlled Substances Act (21 U.S.C. 801), the dispensing and distribution of controlled substances for any purpose affect interstate commerce.”

Every Federal circuit court of appeal that has considered the issue—and almost all have—has upheld the constitutionality of the Controlled Substances Act as a valid exercise of Congressional power to regulate interstate commerce. *United States v. Edwards*, 98 F.3rd 1364, 1369 (D.C. Cir. 1996); *United States v. Lerebours*, 87 F.3rd 582, 584–85 (1st Cir. 1996); *Procyet v. United States*, 101 F.3rd 11, 13–14 (2d Cir. 1996); *United States v. Leshuk*, 65 F.3d 1105, 1112 (4th Cir. 1995); *United States v. Clark*, 67 F.3rd 1154 (5th Cir. 1995), cert. denied, 116 S. Ct. 1432 (1996); *United States v. Tucker*, 90 F.3rd 1135, 1139–41 (6th Cir. 1996); *United States v. Rogers*, 89 F.3rd 1326, 1338 (7th Cir. 1996); *United States v. Bell*, 90 F.3rd 318, 321 (8th Cir. 1996); *United States v. Bramble*, 103 F.3rd 1475, 1479–80 (9th Cir. 1996); *United States v. Wacker*, 72 F.3rd 1453, 1475 (10th Cir. 1995), cert. denied, 117 S. Ct. 136 (1996); *United States v. Jackson*, 111 F.3rd 101, 102 (11th Cir. 1997).

Given the structure of the Controlled Substances Act and its implementing regulations, the Federal Government must either treat assisting suicide and euthanasia as forms of legitimate medical practice, or as an unauthorized misuse of controlled substances. It would hardly be consistent to concede that Congress has the constitutional authority to enact a Controlled Substances Act to prevent potent drugs from being used for other than legitimate medical purposes, yet to maintain that Congress may not constitutionally set boundaries for what may count as a legitimate medical purpose.⁷³

The Committee is convinced that it is both constitutional and good public policy for Congress to ensure that federally controlled substances are not used to effectuate the ultimate harm of deliberately inflicting death.⁷⁴

D. INTENT AS A BASIS FOR DISTINGUISHING BETWEEN THE USE OF CONTROLLED SUBSTANCES TO ALLEVIATE PAIN AND TO ASSIST SUICIDE

Following the substantial changes to address medical concerns incorporated in the Chairman's substitute adopted by the Committee, remaining charges that the Pain Relief Promotion Act could adversely impact pain control center on objections to the intent standard.⁷⁵ As articulated by Oregon Senator Ron Wyden in his testimony before the Committee, the criticism is this:

⁷³That setting such boundaries is integral to the Controlled Substances Act is implicit in the provisions of 21 U.S.C. 801a. In that section Congress finds and declares that the Comprehensive Drug Abuse Prevention and Control Act of 1970 (which amended the Controlled Substances Act) is the means employed by the United States to fulfill its treaty obligations under the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971. In subsection (3), Congress finds that this ensures that nothing in the Convention "will interfere with ethical medical practice in this country as determined by the Secretary of Health and Human Services on the basis of a consensus of the views of the American medical and scientific community." It is noteworthy that the measure of what constitutes ethical medical practice is not left by this subsection solely to the varying interpretations of the several States, but rather is deemed to arise from the consensus of the American medical and scientific community. It was an analysis of precisely that consensus that lead Drug Enforcement Administrator Constantine to make the original determination that assisting suicide and euthanasia are not legitimate medical purposes in the course of professional practice for the purposes of the Controlled Substances Act, a determination the Committee considers to be documentably accurate.

⁷⁴In *Washington v. Glucksberg*, 521 U.S. 702, 735 (1997), the Court wrote, "Throughout the nation, Americans are engaged in an earnest and profound debate about the morality, legality and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." This passage is sometimes cited for the position that States may constitutionally choose, if they wish, to legalize physician-assisted suicide.

Clearly, however, this was not the Court's own view. Neither in the quoted passage nor elsewhere in its opinion did the Court assign this issue to state as opposed to Federal jurisdiction. In reviewing the Nation's longstanding tradition against assisting suicide, it cited Federal enactments such as the Assisted Suicide Funding Restriction Act of 1997 alongside State laws. Illustrating the Government's interest in protecting terminally ill patients, the Court favorably cited an earlier decision upholding the Federal Food and Drug Administration's authority "to protect the terminally ill, no less than other patients," from life-endangering drugs. *Id.* at 729, quoting *United States v. Rutherford*, 442 U.S. 544, 558 (1979).

Indeed, the Court explicitly left open the question of whether State laws like Oregon's authorizing assisting suicide in certain circumstances might themselves be unconstitutional. Oregon's law selectively permitting assisted suicide for certain patients had been found by one Federal district court to violate equal protection; that ruling was not before the Supreme Court. See *Lee v. Oregon*, 891 F.Supp. 1429 (D. Or. 1995), *vacated on other grounds*, 107 F.3d 1382 (9th Cir. 1997), cert. denied, 118 S. Ct. 328 (1997). As Chief Justice Rehnquist said in his majority opinion in *Glucksberg*: "*Lee*, of course, is not before us * * * and we offer no opinion as to the validity of the *Lee* court's reasoning." *Glucksberg*, 521 U.S. at 709-710 n. 7. To this day no appellate court in the country has ruled on the constitutionality of a law like Oregon's.

⁷⁵The intent distinction is found in Section 201(a)(1):

For purposes of this Act and any regulations to implement this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is con-

Continued

Your bill would authorize local, state, and Federal law enforcement officials, with no expertise and scant training in health care, to dissect a physician's intent with respect to prescribing pain relief medications. * * * [T]he effect would be * * * physicians' fear of being investigated by law enforcement and losing their ability to practice medicine will result in less aggressive pain management for countless patients.

Yet the intent distinction whose negative effects on pain relief are thus predicted is in fact now part of Federal law, the Assisted Suicide Funding Restriction Act, which was enacted in 1997, after having passed the Senate without a dissenting vote.⁷⁶ Moreover, an intent standard is currently incorporated in the law of Senator Wyden's State of Oregon, as it is in most States, including many States represented by members of the Judiciary Committee.⁷⁷

As Dr. Eric Chevlen, director of Palliative Care at the Cancer Care Center of St. Elizabeth Medical Center in Youngstown, Ohio, testified, there is empirical evidence of the effect of an intent-based standard, similar to that in the Pain Relief Promotion Act, on the willingness of physicians to prescribe pain-killing drugs.⁷⁸ During the 1990's, the six States of Iowa, Kansas, Louisiana, Rhode Island, Virginia, and Tennessee all adopted statutes strikingly similar in wording to the promotion of the Pain Relief Promotion Act protecting doctors who provide pain relief even at the risk of death while preventing intentionally causing death.⁷⁹ The following

sistent with public health and safety, even if the use of such a substance may increase the risk of death. Nothing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death.

⁷⁶ See supra nn. 11 and accompanying text. As pointed out there, the intent standard in the Assisted Suicide Funding Restriction Act (ASFRA) governs not only Federal funding, but also the provision of medical treatment in Federal health care facilities and by physicians and other health care professionals employed by the Federal Government. The Committee is unaware of any evidence that the provision of pain relief in Federal facilities or by federally employed physicians has been chilled by ASFRA. Indeed, Veterans Administration hospitals implemented widely praised improvements in palliative care after passage of the act. S. Beckwith, "VA Makes Better End-of-Life Care a Top Priority," "Last Acts Newsletter," Summer 1998 at 6.

⁷⁷ In circumstances other than those of terminally ill individuals, Or. Rev. Stat. § 163.125 continues to apply: "Criminal homicide constitutes manslaughter in the second degree when * * * [a] person *intentionally* causes or aids another person to commit suicide." (Emphasis added.)

Similarly, California Penal Code section 401 (West 1998) punishes any doctor (or other person) who "*deliberately* aids, or advises, or encourages another to commit suicide." (Emphasis added.) New Jersey Statutes Annotated sec. 2C: 11-6 (West 1999) punishes anyone who "*purposely* causes or aids another person to commit suicide." (Emphasis added.) New York Penal Law sec. 125.15 (McKinney 1999) punishes anyone who "*intentionally* causes or aids another person to commit suicide." (Emphasis added.) Wisconsin Statutes Annotated sec. 940.12 (1997-98) punishes anyone who "*with intent* that another take his or her own life assists such person to commit suicide." (Emphasis added.)

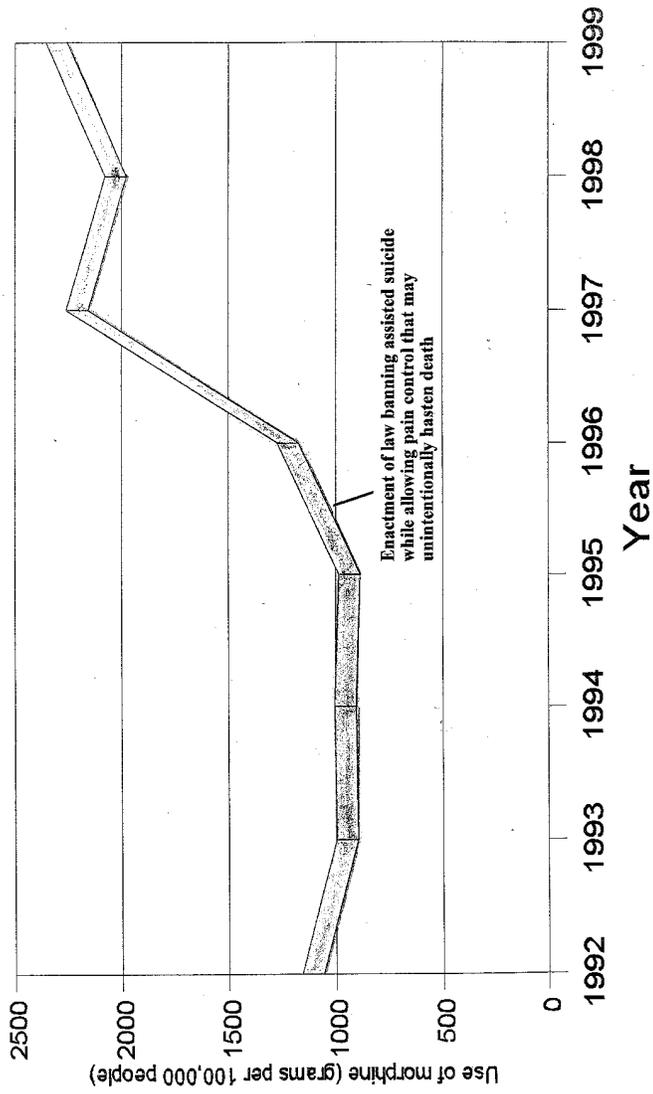
⁷⁸ As explained in more detail in the following two subsections of this report, since the DEA automatically has the authority now to investigate cases where controlled substances have been used to violate State law, it has authority now to investigate whether these drugs were used "intentionally" to assist a suicide. The only new legal effect of the Pain Relief Promotion Act in almost every State is to provide clearer protection against a *broader* application of the law when practitioners are seeking to control pain.

⁷⁹ The relevant provisions are as follows: Iowa Code § 707A.3.1. (Adopted 1996.) ("A licensed health care professional who administers, prescribes, or dispenses medications or who performs or prescribes procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate section 707A.2 unless the medications or procedures are intentionally or knowingly administered, prescribed, or dispensed with the primary intention of causing death."); Kan. Stat. Ann. § 60-4403(a) (Adopted 1998.) ("A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate K.S.A. 21-3406 and amendments thereto unless the medications or procedures are knowingly administered, prescribed or dispensed with the intent to cause death."); La. Rev. Stat. Ann. § 14:32.12 (Adopted 1995). ("The

charts, derived from DEA data, demonstrate that per capita morphine use went up, not down, after enactment of all of these laws:

provisions of this Section shall not apply to any licensed physician or other authorized licensed health care professional who * * * [p]rescribes, dispenses, or administers any medication, treatment, or procedure if the intent is to relieve the patient's pain or suffering and not to cause death."); R.I. Gen. Laws § 11-60-4(A) ("A licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate the provision of this chapter unless the medications or procedures are knowingly administered, prescribed, or dispensed to cause death."); Va. Code Ann. § 8.01-622.1 (E). ("This section shall not apply to a licensed health care provider who (i) administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort and without intent to cause death, even if the medication or procedure may hasten or increase the risk of death. * * * This section shall not apply to any person who properly administers a legally prescribed medication without intent to cause death, even if the medication may hasten or increase the risk of death."); and Tenn. Code Ann. § 39-13-216(b)(2) (Adopted 1993.) ("It is not an offense under this section to: * * * [p]rescribe, dispense, or administer medications or perform medical procedures calculated or intended to relieve another person's pain or discomfort (but not calculated or intended to cause death), even if the medications or medical procedures may hasten or increase the risk of death * * *").

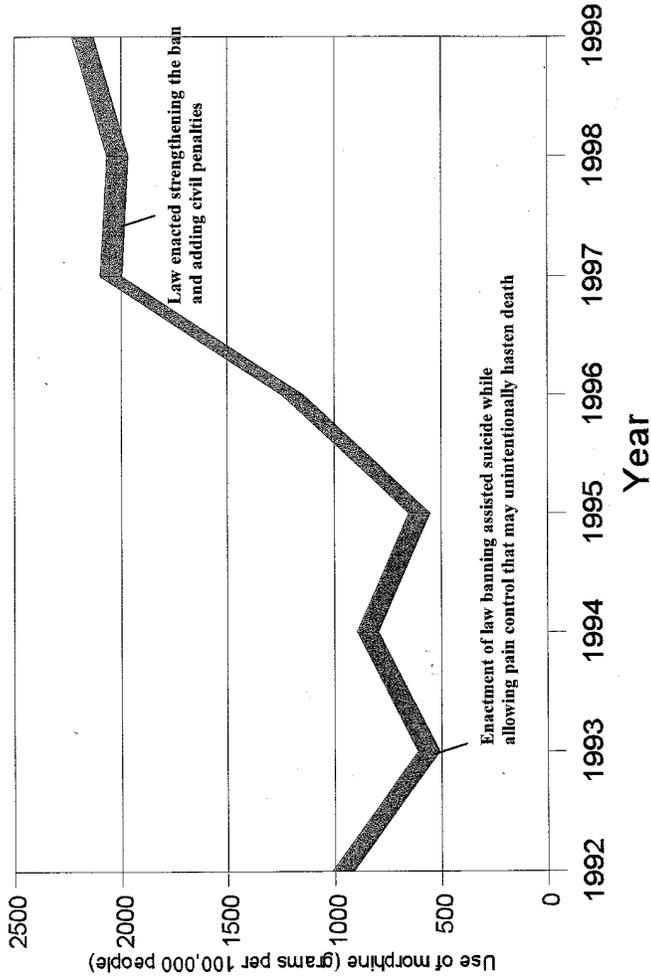
Use of Pain Control Drugs Rises When States Ban Assisted Suicide IOWA



(Source of morphine data: Drug Enforcement Administration)

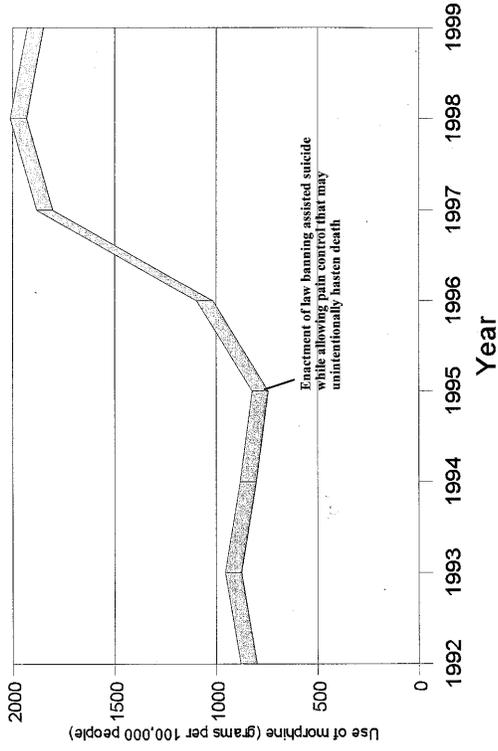
Use of Pain Control Drugs Rises When States Ban Assisted Suicide

KANSAS



(Source of morphine data: Drug Enforcement Administration)

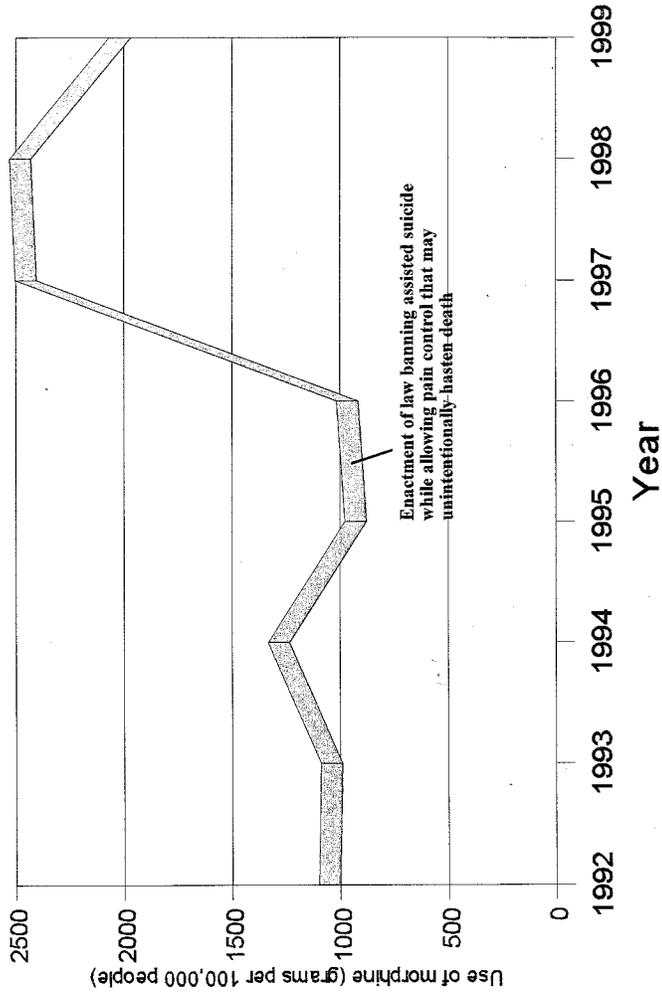
Use of Pain Control Drugs Rises When States Ban Assisted Suicide
LOUISIANA



(Source of morphine data: Drug Enforcement Administration)

Use of Pain Control Drugs Rises When States Ban Assisted Suicide

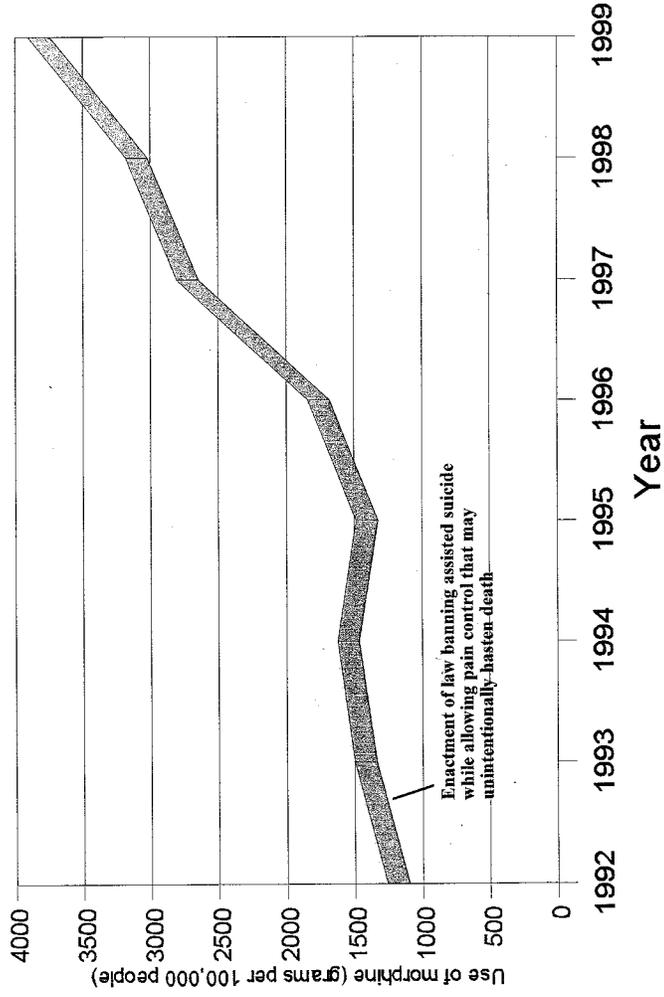
RHODE ISLAND



(Source of morphine data: Drug Enforcement Administration)

Use of Pain Control Drugs Rises When States Ban Assisted Suicide

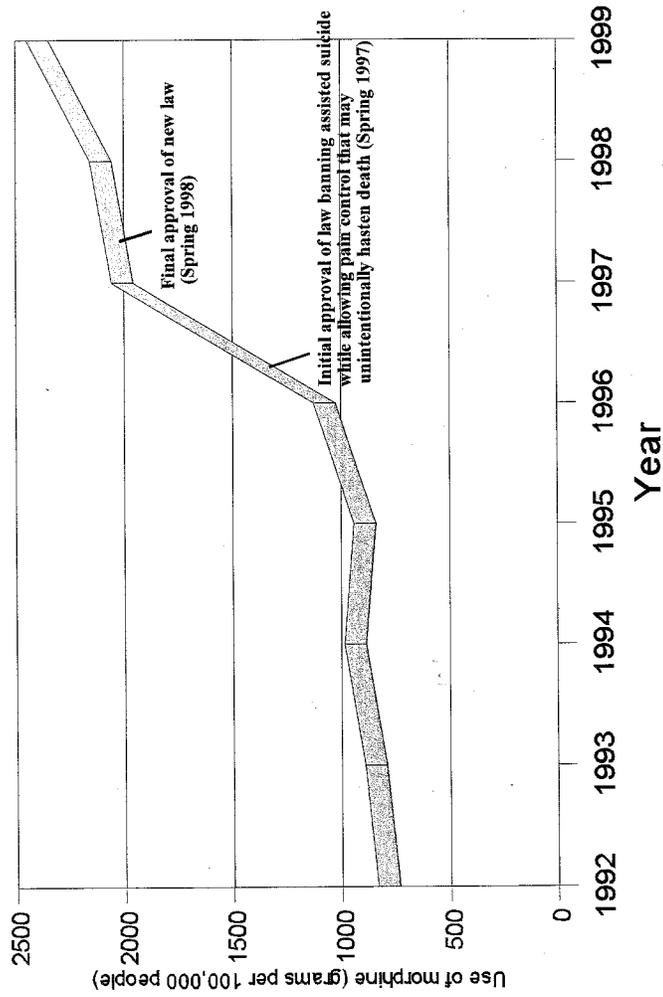
TENNESSEE



(Source of morphine data: Drug Enforcement Administration)

Use of Pain Control Drugs Rises When States Ban Assisted Suicide

VIRGINIA



(Source of morphine data: Drug Enforcement Administration)

While she testified in opposition to the Pain Relief Promotion Act, Dr. Kathleen M. Foley, attending neurologist in the Pain & Palliative Care Service at Memorial Sloan-Kettering Cancer Center and Professor of neurology, neuroscience and clinical pharmacology at the Cornell University Medical College, summarized significant evidence that in modern medicine providing effective pain relief does *not* entail an increased risk of death:

Pain and palliative care experts have defined clear distinctions between pain management and palliative care, and physician assisted suicide. Yet, it has been the advocates for physician assisted suicide who have used the argument that opioids, such as morphine, kill and to try to relate these practices. Yet, there is a preponderance of evidence that demonstrates that the proper use of opioids in patients with chronic pain, as well as in patients at the end of life, does not hasten their death. There is accumulating data to suggest that the proper use of opioids may in fact prolong their lives.

Studies by Dr. Brescia at Calvary Hospital in New York City show that there is no correlation between the dose of opioids a patient receives in the last weeks of life and the timing of their death. Studies of dying patients who were being withdrawn from respiratory support demonstrate that those patients who received morphine lived longer than those who did not receive morphine. Studies recently published from a series of British hospices show no difference in the time to death between those patients who were sedated to control their symptoms as compared to those patients who were not sedated. Finally, the doses of opioids that are often used to treat patients at the end of life are highly variable. The great majority of dying patients are receiving doses in a range equivalent to what you or I might receive as part of postoperative pain management and these doses are safe and effective.

The New York State Task Force on Life and the Law has made a similar point:

While high doses of morphine can depress respiration when administered to patients who have not developed tolerance to the drug, physicians who treat patients with morphine for the relief of pain increase the dose gradually, so that tolerance can develop. * * * The claim that the use of morphine at properly titrated levels “hastens” patients’ deaths, based on the effects of high doses of morphine on patients who have not developed tolerance, is entirely unfounded. It represents one of the many myths about the consequences of using narcotics in the clinical setting.
* * * 80

⁸⁰The New York State Task Force on Life and the Law, “When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context Supplement to Report April 1997” (New York: The New York State Task Force on Life and the Law, 1997), p. 17. <http://www.health.state.ny.us/nysdoh/taskfce/sought.pdf>

If physicians do not need to increase the risk of death in order to provide the most effective pain relief available, even the theoretical possibility that preventing the use of controlled substances with intent to cause death will “chill” the provision of effective pain relief of course vanishes. However, although rare, there are circumstances in which providing effective pain relief may indeed increase the risk of death.⁸¹

Therefore, the Pain Relief Promotion Act introduces into the Controlled Substances Act a “safe harbor” for physicians to protect them in any eventuality in which such an increased risk of death may be associated with the use of controlled substances to alleviate pain or discomfort. While existing DEA guidelines recognize and encourage the use of federally controlled substances for the treatment of pain,⁸² they do not mention or specifically protect the provision of a controlled substance to alleviate pain or discomfort “*even if the use of such a substance may increase the risk of death.*” This new protection, in the words of the American Medical Association,

⁸¹Dr. Walter R. Hunter, associate national medical director, VistaCare Hospice, Indianapolis, IN, testified concerning such an instance from his own experience:

As an example of the work I am called to do daily, let me describe a case of a young AIDS patient I cared for a few years ago. On a Monday morning the hospice for whom I worked received a phone call from his family that he was having difficulty breathing. His nurse and I made a house call. When we entered the room we could hear his labored and most respirations across the room. His respiratory rate was 44 and he was unconscious. We immediately set to work. I gave him 40 mg of Lasix (furosemide) intravenously. There was no effect. I then gave him 10 mg of morphine intravenously. There was no effect after several minutes. I repeated the dose of 10 mg of morphine and waited several minutes. Again, there was no effect. I gave 5 mg of morphine. There was still no effect. I then gave 5 mg of Valium (diazepam) in an attempt to sedate him and ease the work of breathing. There was no effect. I repeated the Valium dose and there was still no effect. I gave 5 mg of morphine, waited, saw no effect and gave another, 10 mg of morphine. After a few minutes, his respirations decreased to about 20. This was a reasonable goal. However, instead of stabilizing at 20, they continued to diminish and he stopped breathing several minutes later.

* * * * *

I knew that there was a slight risk of lethal side effects to the medications. But I knew that I might have to risk them, tolerate them in part or in totality if I were to attempt to ease his breathing easier. Had I intended the side effect of cessation of breathing. I did not intend for him to die, but I did intend to make his breathing. I would not have given incremental doses of medicine over time and observed his clinical response with each dose. I would have given a very large dose all at once to stop the breathing.

* * * * *

* * * In short, the Principle of Double Effect guided me through the decision making process and the actions I performed in this case. Chairman’s Substitute for H.R. 2260 recognizes what I did in this case as legitimate palliative care, does not view my actions as assisting a suicide or committing euthanasia, and therefore protects me from prosecution for committing those acts.

⁸²In March 1990 the DEA published guidelines which stated “Controlled substances have legitimate clinical usefulness and the prescriber should not hesitate to consider prescribing them when they are indicated for the comfort and well-being of patients.” “Guidelines for Prescribers of Control Substances: A Joint Statement of the Drug Enforcement Administration and the DEA/Practitioners Working Committee” Physician’s Manual, Drug Enforcement Administration,” rev. Mar. 1990, p. 24. The DEA has also stated:

Controlled substances and, in particular narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or chronic disorder. These drugs have a legitimate clinical use and the physician should not hesitate to prescribe, dispense, or administer them when they are indicated for a legitimate medical purpose. It is the position of the Drug Enforcement Administration that these controlled substances should be prescribed, dispensed, or administered when there is a legitimate medical need.

Id., p. 21.

“is a vital element in creating a legal environment in which physicians may administer appropriate pain care for patients.”⁸³

E. THE EFFECT OF TITLE II ON STATES OTHER THAN OREGON

At present, under the same June 5, 1998, ruling by Attorney General Janet Reno that allowed the use of federally controlled drugs to assist suicides which comply with Oregon State law, the Drug Enforcement Administration (DEA) may nevertheless revoke the registration of any doctor or other registrant who uses federally controlled substances to assist suicide “in a state that has not authorized the practice under any conditions.”⁸⁴ Thus, in 49 States the bill does not increase the DEA’s existing authority at all. Therefore, in all States other than Oregon, the bill will in no way increase DEA authority to investigate or revoke the registrations of health care personnel.

It will, in fact, limit such DEA authority in two significant ways.

First, as noted in the preceding subsection, it will introduce an explicit “safe harbor” for physicians and other registrants when federally controlled substances are used to alleviate pain or discomfort *even when this may increase the risk of death*.

Second, it will increase the burden of proof the DEA must meet when seeking to suspend or revoke a registration based on an intent to cause or assist in causing death whenever the registrant claims that she or he was acting to alleviate pain or discomfort in the usual course of professional practice. That burden will be raised from the current preponderance of the evidence standard common to such administrative proceedings to “clear and convincing evidence,” the highest standard to the civil law (the standard required, for example, for involuntary commitment to a mental health facility).

In the words of Chairman Hatch at the Committee’s hearing on this bill,

[T]o address the concerns of health care providers, the substitute bill that I will offer during the Committee’s markup of H.R. 2260 contains a provision that is neither in the House bill nor the Senate companion bill. The new provision, modeled on the legislation reported out of this Committee during the 105th Congress, establishes the higher clear and convincing evidentiary standard for DEA administrative hearing involving allegations of assisted suicide or euthanasia. I know DOJ and DEA oppose this higher standard. However, when we completed our markup in 1998, I pledged to the members of this Committee—to Senators Leahy and Feinstein—that I would continue to work to see whether we could develop a broader a broader consensus on this bill. I believe it is proper for Congress to make a strong statement about the need for state-of-the-art pain management and palliative care and to restore the original intent of our drugs laws relative to assisted suicide.

⁸³ Letter from Dr. E. Ratcliffe Anderson, executive vice president, American Medical Association, to Chairman Orrin Hatch (Apr. 6, 2000), p. 1.

⁸⁴ See supra n. 14 and accompanying text.

Therefore, in all these States the only effect of the bill will be to reduce, and not increase, any conceivable “chilling effect” on pain medication prescription that may exist under the current Controlled Substances Act.⁸⁵

F. THE EFFECT OF TITLE II IN OREGON

Oregon is the only State that has enacted legislation authorizing physicians to assist suicides, and therefore is the only State in which the DEA, under the June 1998 ruling of the Attorney General, currently cannot revoke or suspend registrations in such instances. Hence, it is the only State in which this legislation can even arguably be said to expand DEA authority over current practice under the Attorney General’s highly debateable view of the current statutory situation. However, this expanded authority should not and will not lead to *any* increased DEA scrutiny of Oregon physicians’ pain relief prescribing practices. Instead, reports and records required by the Oregon Death with Dignity Act will unmistakably demonstrate whether federally controlled substances have been intentionally dispensed to assist suicide as authorized by Oregon State law.

Under section 127.865(b) of the Oregon Revised Statutes, “The [Oregon Health] Division shall require any health care provider upon dispensing medication pursuant to ORS 127.800 to 127.897 to file a copy of the dispensing record with the division.” Thus, in order to comply with the Oregon Death with Dignity Act and escape criminal liability that would otherwise exist under Oregon law for assisting a suicide,⁸⁶ a physician must file a form listing the precise drugs used to assist a suicide with State authorities.

The Drug Enforcement Administration has authority to subpoena these dispensing records from the State authorities. Under section 876 of the CSA, “[i]n any investigation * * * with respect to controlled substances, the Attorney General may * * * require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation.”

The DEA therefore has the authority to obtain copies of any relevant reports filed with the Oregon authorities.⁸⁷ These provide identification of each physician who has provided lethal drugs to a

⁸⁵The DEA has stated:

Even if H.R. 2260 were enacted, it is not feasible that DEA would devote its limited resources to investigate an allegation that a practitioner assisted suicide unless either (i) the practitioner made a clear admission that s/he dispensed controlled substances with the specific intent to assist suicide or (ii) competent state or local authorities concluded—based on sufficient evidence provided to DEA—that the practitioner dispensed controlled substances with the specific intent to assist suicide.

Memorandum from Ken Ronald, DEA Congressional Affairs, Mar. 28, 2000.

⁸⁶Whenever anyone assists suicide in a manner that does not comply with the Oregon Death with Dignity Act, Or. Rev. Stat. § 163.125 continues to apply: “Criminals homicide constitutes manslaughter in the second degree when * * * [a] person intentionally causes or aids another person to commit suicide.” Under Attorney General Reno’s ruling, such unauthorized assisted suicides can prompt adverse action by the DEA as well.

⁸⁷Oregon authorities have been quoted as indicating they would refuse to furnish the DEA with such reports. “Oregon says data on suicide protected,” *The Oregonian*, Nov. 27, 1999. The Committee notes that under the supremacy clause of article VI, cl. 2 of the U.S. Constitution, they would not legally have this option. It provides, “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof * * * shall be the supreme Law of the Land; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”

patient for the purpose of assisting suicide as permitted by Oregon law, and will identify the substances used.

This information will indicate unequivocally whether a federally controlled substance had been prescribed to assist suicide in violation of Federal law.⁸⁸ If so, this would be sufficient in itself—without need for further investigation—to provide adequate evidence for the suspension or revocation of the physician’s registration to distribute controlled substances in accordance with 21 U.S.C. 824(a)(4).⁸⁹

The DEA would have the same authority to obtain such documents in any other State in which assistance of suicide should become legal and in which reports of such assistance must be made, as a matter of State law, to State authorities.

Therefore, the DEA may identify all cases in which federally controlled substances have been used to assist suicide in Oregon in compliance with Oregon law⁹⁰ simply by obtaining reports from the Oregon Health Division without ever having to review patient medical records or otherwise investigate physicians. Thus, physicians in Oregon who prescribe controlled substances for pain relief will have no reason to fear investigation of their use of controlled substances for pain, and should not, therefore, be deterred in any way from prescribing pain relief.

G. PREVENTING FEDERALLY IMPOSED CLINICAL STANDARDS AND PROTECTING THE AUTHORITY OF STATES TO REGULATE MEDICINE

The substitute proposed by Chairman Hatch and adopted by the Committee substantially rewrites the House-passed legislation to ensure that it provides the Federal Government no authority to mandate standards of clinical practice and that it protects the authority of the States to regulate medical practice.⁹¹

The substitute now includes a provision stating: “Nothing in the Pain Relief Promotion Act of 2000 (including the amendments

⁸⁸It is the intent of the Committee that the DEA maintain confidentiality of the information so obtained to the full extent compatible with enforcement of the Controlled Substances Act.

⁸⁹The situation would then fall within one of the limited circumstances in which the DEA states it would in practice be in a position to act against a practitioner’s registration for assisting suicide, namely when “the practitioner made a clear admission that s/he dispensed controlled substances with the specific intent to assist a suicide.” See supra n. 68.

See 21 U.S.C. 824(c) for the procedure for such a suspension or revocation, and 21 U.S.C. 824(d) for the authority to “suspend any registration simultaneously with the institution of proceedings under this section, in cases where [the Attorney General] finds that there is an imminent danger to the public health or safety.”

⁹⁰Anyone who assists a suicide in Oregon but fails to provide Oregon authorities the required report is in violation of Oregon law. Under the Attorney General’s June 1998 ruling, of course, registration under the CSA is currently subject to revocation “where a physician fails to comply with state procedures in [assisting suicide].” Thus, a physician who assists suicide without making the reports required by Oregon law is equally subject to registration revocation under current law and under the Pain Relief Promotion Act.

⁹¹After opposing the Lethal Drug Abuse Prevention Act in 1998, the American Medical Association, the National Hospice Organization, and other medical groups endorsed its substantially reworked successor, the Pain Relief Promotion Act, in 1999. In December 1999 the AMA House of Delegates adopted a resolution calling for changes in the bill to deal with a perceived concern that under it the Federal Government might be authorized to “establish federal protocols and/or regulations for pain management and palliative care”. After detailed negotiations by Chairman Hatch and sponsor Senator Don Nickles with representatives for the AMA, the Pain Care Coalition, and other medical groups, a substitute was crafted to address this concern. This substitute, unlike the House-passed legislation, has now been endorsed by the Pain Care Coalition, which is comprised of the American Academy of Pain Medicine, the American Headache Society, and the American Pain Society. The AMA wrote to Chairman Hatch that “The language of the Substitute * * * fully satisfies the concerns expressed by our House of Delegates.” Letter from Dr. E. Ratcliffe Anderson, executive vice president, American Medical Association, to Chairman Orrin Hatch (Apr. 6, 2000), p. 2.

made by such Act) shall be construed * * * to provide the Attorney General with the authority to issue national standards for pain management an palliative care clinical practice, research, or quality * * * .” Section 201(a)(4)(B).

In order to ensure that the Department of Health and Human Services does not use the bill as the basis to promulgate mandatory national clinical standards for pain management or palliative care, the provision in the bill providing for the collection and dissemination of protocols and evidence-based practices for pain management and palliative care (section 903[a] being added to the Public Health Service Act by section 101 of the bill) has been made specifically subject to provisions in the recently passed Healthcare Research and Quality Act of 1999, Public Law 106–129, that provide that the relevant “Agency shall not mandate national standards of clinical practice or quality health care standards. Recommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer” and state “Nothing in this section shall be construed to imply that the Agency’s role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, health care delivery systems, and individual preferences.”⁹²

The bill’s provision for training DEA and other law enforcement personnel has been substantially reworked. The training is now to be focused on how “investigation and enforcement actions by law enforcement personnel may better accommodate the necessary and legitimate use of controlled substances in pain management and palliative care.” This replaces language in the original bill which had been seen as suggesting that law enforcement personnel might themselves be “trained” in how to make determinations about what is or is not appropriate pain management and palliative care.

In addition, to clarify that the bill does not generally pre-empt State laws or standards relating to the practice of medicine, a provision has been added as section 201(a)(i)(3) stating, “Nothing in this subsection shall be construed to alter the roles of the Federal and State governments in regulating the practice of medicine. Regardless of whether the Attorney General determines pursuant to this section that a practitioner’s registration is inconsistent with the public interest, it remains solely within the discretion of State authorities to determine whether action should be taken with respect to the State professional license of the practitioner or State prescribing privileges.”

⁹²Public Health Service Act, § 902(e) and (f) [42 U.S.C. 299a(e) and (f)].

VII. COST ESTIMATE

U.S. CONGRESS,
 CONGRESSIONAL BUDGET OFFICE,
 Washington, DC, May 9, 2000.

Hon. ORRIN G. HATCH,
 Chairman, Committee on the Judiciary, U.S. Senate, Washington,
 DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2260, the Pain Relief Promotion Act of 2000.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Mark Grabowicz (for effects on spending by the Department of Justice), who can be reached at 226-2860; Cynthia S. Dudzinski (for costs to the Health Resources and Services Administration), who can be reached at 226-9010; Christopher J. Topoleski (for costs to the Agency for Health Care Research and Quality), who can be reached at 226-9010; Shelley Finlayson (for the state and local impact), who can be reached at 225-3220; and John Harris (for the private-sector impact), who can be reached at 226-2618.

Sincerely,

BARRY B. ANDERSON
 (For Dan L. Crippen, Director).

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

H.R. 2260—Pain Relief Promotion Act of 2000

Summary: H.R. 2260 would increase an existing authorization of appropriations to the Health Resources and Services Administration (HRSA) for the purpose of making grants to public and private entities to educate and train health care professionals in palliative care. The act also would direct the Agency for Health Care Research and Quality (AHRQ) to develop a program to improve palliative care, and would prohibit the use of controlled substances for assisted suicide or euthanasia, regardless of any state law authorizing such activity.

Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 2260 would result in additional discretionary spending of about \$25 million over the 2000-2005 period. Enacting this legislation could affect direct spending and receipts, so pay-as-you-go procedures would apply; however, CBO estimates that the amounts involved would be less than \$500,000 a year.

H.R. 2260 contains both an intergovernmental and a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the act would result in no costs to state, local, or tribal governments, so the threshold established in UMRA (\$55 million in 2000, adjusted annually for inflation) would not be exceeded. CBO also estimates that the costs of the private-sector mandate would fall below the threshold established in UMRA (\$109 million in 2000, adjusted annually for inflation).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2260 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

CHANGES IN SPENDING SUBJECT TO APPROPRIATION ¹

	By fiscal year, in millions of dollars—					
	2000	2001	2002	2003	2004	2005
Estimated Authorization Level	7	7	7	2	2	2
Estimated Outlays	2	6	7	5	3	2

¹The bill could also affect direct spending and receipts, but CBO estimates any additional costs and receipts would be less than \$500,000 annually.

Basis of estimate: For the purposes of this estimate, CBO assumes that the legislation will be enacted during fiscal year 2000, that the necessary amounts will be provided each year, and that outlays will follow historical spending rates for these activities.

Spending subject to appropriation

The estimated change in spending subject to appropriation has two components: (1) an increase in the existing authorization of HRSA grants for education and training of health care professionals, and (2) a new AHRQ research program aimed at improving the quality of care for terminally ill patients.

The existing HRSA grant program received an appropriation of \$23 million for fiscal year 2000. This program is part of a larger HRSA activity which has a current authorization of such sums as necessary through fiscal year 2002. H.R. 2260 would increase the existing target level of \$23 million a year (within that “such sums” authorization) by \$5 million. The agency would use the additional funds to award grants to public and private entities to develop, implement, and evaluate education and training programs in palliative care.

H.R. 2260 would direct AHRQ to develop a research program to improve palliative care, mainly through the collection and dissemination of guidelines for providing such care. CBO estimates that implementing this provision would cost about \$1 million in fiscal year 2000 and \$2 million annually thereafter, assuming the appropriation of the necessary amounts. (The agency received an appropriation of \$111.4 million for 2000.)

Direct spending and revenues

Violations of the act’s provisions regarding the use of controlled substances to assist in suicide could face revocation of their license to prescribe controlled substances. Upon revocation of an individual’s license, the Drug Enforcement Administration could seize any such substances in their possession. Thus, enacting H.R. 2260 could lead to the seizure of more assets and their forfeiture to the United States, but we estimate that any such increase would be less than \$500,000 annually in value. Proceeds from the sale of any such assets would be deposited as revenues into the Assets Forfeiture Fund of the Department of Justice and spent from that fund, generally in the same year. Thus, the changes in direct spending from the Assets Forfeiture Fund would match any increase in revenues to that fund.

Violators of the act's provisions also could be subject to criminal fines, so the federal government might collect additional fines if H.R. 2260 is enacted. Collections of such fines are recorded in the budget as governmental receipts (revenues), which are deposited in the Crime Victims Fund and spent in subsequent years. CBO expects that any additional receipts and direct spending would be negligible.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. Enacting H.R. 2260 could affect both direct spending and receipts, but CBO estimates that any such effects would be less than \$500,000 a year.

Estimated impact on state, local, and tribal governments: H.R. 2260 contains an intergovernmental mandate as defined in UMRA, but CBO estimates that complying with the mandate would impose no costs on state, local, or tribal governments, and thus would not exceed the threshold established in that act (\$55 million in 2000, adjusted annually for inflation).

In October 1997, an Oregon law that legalized doctor-assisted suicide for terminally ill patients went into effect. Since that time, the interaction of the Controlled Substances Act with that state law has been controversial. As it currently stands, under both Oregon and federal law, it is acceptable for doctors in Oregon to use federally controlled substances for the purposes set forth in state law. H.R. 2260 would direct the Attorney General to give no force and effect to such a state law when determining whether the federal registration of a doctor under the Controlled Substances Act is consistent with the public interest. This would be a preemption of the Oregon "Death with Dignity Act" because it would limit the options available to doctors acting under that state law. Because the state would not be required to take any action, the preemption would have not no cost. The act also would authorize \$5 million for education and training in palliative care for health care professionals, many of whom are employed by state and local facilities.

Estimated impact on the private sector: H.R. 2260 would create a new private-sector mandate for physicians registered to prescribe or administer federally controlled substances by prohibiting the use of such substances in physician-assisted suicides. Under current law, medical practitioners who are licensed by the state must also register with the U.S. Attorney General through the Drug Enforcement Administration if they intend to dispense or prescribe controlled substances. The act would amend the Controlled Substances Act to require the Drug Enforcement Administration to treat the use of controlled substances for physician-assisted suicide as a violation of the act without regard for state law permitting the practice. Doctors who violate the prohibition would have to give up their stocks of controlled substances and would no longer be permitted to use controlled substances in their medical practice. The prohibition would affect doctors in Oregon, which is the only state that permits physician-assisted suicide. CBO estimates that the direct costs associated with the mandate would fall below the threshold in UMRA (\$109 million in 2000, adjusted annually for inflation).

Previous CBO estimate: On September 24, 1999, CBO transmitted a cost estimate for H.R. 2260, as ordered reported by the House Committee on the Judiciary on September 14, 1999. On October 18, 1999, CBO transmitted a cost estimate for H.R. 2260, as ordered reported by the House Committee on Commerce on October 13, 1999. The three versions of the legislation are similar and the cost estimates are nearly identical.

Estimate prepared by: Federal Costs: DOJ—Mark Grabowicz; HRSA—Cynthia S. Dudzinski; AHRQ—Christopher J. Topoleski. Impact on State, Local, and Tribal Governments; Shellby Finlayson. Impact on the Private Sector: John Harris.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VIII. REGULATORY IMPACT STATEMENT

In compliance with paragraph 11(b)(1), rule XXVI of the Standing Rules of the Senate, the Committee, after due consideration, concludes that H.R. 2260 will not have significant regulatory impact.

IX. MINORITY VIEWS OF SENATORS LEAHY, KENNEDY,
KOHL, AND FEINSTEIN

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I. INTRODUCTION

We strongly oppose the Hatch substitute to H.R. 2260, the Pain Relief Promotion Act of 2000 (PRPA).¹ Although we—like the majority—are troubled by physician-assisted suicide, we see this legislation as unprecedented, unnecessary, and harmful.

¹For convenience, we will refer to the Hatch substitute as PRPA.

It is unprecedented because it would effectively establish the first preemptive Federal standard of care for the medical profession in the United States—seriously undermining well-established principles of federalism.

It is unnecessary because it would needlessly encroach on State medical boards' traditional regulatory role in policing doctors' actions, a role they have been performing well for more than a century.

And it is harmful because it would have a chilling effect on medical care givers, indirectly causing further suffering in thousands of terminally ill patients and leading to an *increase* in the number of suicides.

Over thirty established National and State-based medical organizations share our concerns.²

II. BACKGROUND

Most States have debated physician-assisted suicide and decided to prohibit its practice. Thus far, one state—Oregon—has passed a law permitting the practice. The issue continues to arise and voters in at least one other State will go to the polls in the upcoming elections to decide whether to legalize physician-assisted suicide.

Following its long-standing tradition of public referenda, Oregon has held two public referenda votes on the issue of physician-assisted suicide. Oregon voters first passed the Oregon Death With Dignity Act by public referendum on November 8, 1994, with 51 percent of the vote. The State legislature then decided to return the law for an additional public referendum in which voters were asked

²These include:

American Academy of Family Physicians
 American Academy of Hospice and Palliative Medicine
 American Academy of Pharmaceutical Physicians
 American Geriatrics Society
 American Nurses Association
 American Pain Foundation
 American Pharmaceutical Association
 American Society for Action on Pain
 American Society of Health-System Pharmacists
 American Society of Pain Management Nurses
 College on Problems of Drug Dependence
 Hospice and Palliative Nurses Association
 National Foundation for the Treatment of Pain
 Oncology Nursing Society
 Society of General Internal Medicine
 Triumph over Pain Foundation
 California Medical Association
 Massachusetts Medical Society
 North Carolina Medical Society
 Oregon Medical Association
 Rhode Island Medical Association
 San Francisco Medical Society
 Indiana State Hospice and Palliative Care Association
 Hospice Federation of Massachusetts
 Kansas Association of Hospices
 Maine Hospice Council
 Maine Consortium of Palliative Care and Hospice
 Missouri Hospice and Palliative Care Association
 New Hampshire State Hospice Organization
 New Jersey Hospice and Palliative Care Organization
 New York State Hospice Organization
 Oregon Hospice Association

Other organizations with concerns about PRPA include the Hospice of the Carolinas, Americans for Better Care of the Dying, and the North Carolina Board of Pharmacy.

if they wanted to maintain the law. On November 4, 1997, Oregon's voters voted to keep the law by 60 percent of the vote.

The Death With Dignity Act provides for a comprehensive and detailed procedure by which a mentally competent terminally ill patient may request assistance to end his or her life "in a humane and dignified manner."³ Under the Oregon law, the physician is required to provide extensive documentation, including that the patient has made three separate requests for assistance in ending his or her life. One of these requests must be in writing and witnessed by two individuals who are not family members. The process must also include documentation that this is a voluntary request. A second opinion must confirm that the patient is a capable adult with a terminal illness and that the patient has less than six months to live. The patient and physician must also enter into a discussion about alternatives to physician-assisted suicide. Should the patient decide that he wants to engage in physician-assisted suicide, he must administer the lethal dose himself.

In the first 2 years of its existence, 42 terminally ill Oregonians took their lives under the State statute. Thirty of the 42 had terminal cancer. During this period, a total of about 60,000 Oregonians have died, about 14,000 from cancer. Patients taking lethal drugs under the Oregon law account for only a minute percentage of these deaths. Last year, patients taking lethal medications under the law accounted for $\frac{9}{100}$ of one percent of deaths in Oregon and $\frac{39}{100}$ of one percent of cancer deaths in Oregon; the previous year, it was $\frac{6}{100}$ of one percent of deaths and $\frac{20}{100}$ of one percent of cancer deaths.⁴ A recent survey of Oregon physicians shows that many patients who request physician-assisted suicide choose—after appropriate medical, social, or spiritual intervention—not to take their lives.⁵

A. PRPA WOULD OVERRIDE THE DEPARTMENT OF JUSTICE'S WELL-REASONED POSITION ON THE ROLE OF FEDERAL DRUG ENFORCEMENT

In July 1997, and again in October 1997, Senator Hatch and Representative Hyde, writing on behalf of the Senate and House Judiciary Committees respectively, asked then Drug Enforcement Administration (DEA) Administrator Thomas Constantine whether prescribing or dispensing a controlled substance with the "deliberate intent of assisting a suicide" would violate the Controlled Substances Act (CSA).

In a letter dated November 5, 1997, Mr. Constantine responded that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not fall under any current definition of a 'legitimate medical purpose'" and such activity would violate the CSA. Thus, 1 day after the second successful Oregon assisted suicide referendum, the DEA declared it had authority to prosecute physicians in Oregon who prescribed drugs at the request of a terminally ill patient in compliance with State law.

³Or. Rev. Stat. 127.800 et seq.

⁴A. D. Sullivan, et al., Legalized Physician-Assisted Suicide in Oregon—The Second Year, *New England Journal of Medicine*, vol. 342, no. 8, at 598–604 (2000).

⁵L. Ganzini, et al., Physicians' Experiences with the Oregon Death With Dignity Act, *New England Journal of Medicine*, vol. 342, no. 8, at 557–563 (2000).

On June 5, 1998, Attorney General Reno issued a letter on the Oregon referendum. In this letter, after a thorough review of relevant authority, General Reno rejected the DEA's position, concluding that a healthcare provider who assisted with a suicide in full compliance with the Oregon referendum did *not* violate the CSA. First, she determined that the CSA "was intended to keep legally available controlled substances within lawful channels of distribution and use" by seeking "to prevent both the trafficking in these substances for unauthorized purposes and drug abuse." Then she found that Congress did not intend the CSA 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. * * *"

General Reno also noted that giving the DEA the mission of determining whether a doctor who assists a suicide in compliance with State law has gone beyond the legitimate practice of medicine or acted against the public interest would go far beyond the scope of the CSA because it would put the agency in the position of resolving fundamental questions of morality and public policy. Finally, she reiterated that the President continues to oppose assisted suicide and Federal support for it. Numerous National and State medical organizations, including the American Medical Association, concurred with the Attorney General's letter.⁶

If enacted, PRPA would override the Department of Justice's position regarding the purpose of the CSA and the role of the DEA. For the first time, a federal statute will empower an agency—one established to go after drug abusers and traffickers—to regulate and investigate doctors, pharmacists, and other healthcare providers regarding their use of controlled substances for the purposes of pain relief.

B. THE MANY MODIFICATIONS MADE TO PRPA HAVE ONLY MADE IT WORSE

PRPA has been through numerous incarnations. Each time, supporters have restructured PRPA and added boilerplate language about pain relief, palliative care, or federalism to try to placate the bill's many critics. However, these frequent alterations have not changed the substance of the bill and done little but raise the suspicion that supporters want to conceal their true intention: to overrule Oregon's physician-assisted suicide law. Revealingly, for example, the majority views dismiss pain relief promotion in 2½ pages and then spend more than 26 pages arguing about assisted suicide.

Most recently, Senator Hatch has offered a substitute amendment to PRPA. Unfortunately, changes offered by that substitute are mostly symbolic. For example, the substitute adds nonbinding findings about the importance of pain management and palliative

⁶See, e.g., "Statement of the American Medical Association to the Committee" on Health, Education, Labor, and Pensions Committee, U.S. Senate, Oct. 13, 1999 ("The AMA concurred with the Attorney General's June 5, 1998 opinion that provided that neither the language of the CSA nor its legislative history supported the Act's application to physicians in compliance with state law.').

care, declares a Decade of Pain Control and Research, and puts the provisions supposedly promoting palliative care *before*—rather than after—the provisions overruling Oregon law.

These modifications do nothing to improve the bill. Worse, if they have any effect at all, it would be to hurt the 50 million Americans in chronic pain and the millions of terminally ill Americans who all too often face excruciating agony before they die. Former Harvard Law School Dean James Vorenberg and other experts crisply summarize the majority's changes as follows: "Senator Hatch's substitute bill doubles the size of the original H.R. 2260 by adding to it some hastily put together jurisdictional and procedural provisions that exacerbate the bill's potential for frightening physicians into undertreating pain."⁷ These experts also note, "[W]e have concluded that the substitut[e] represents, if anything, a greater threat than the original to the effort to improve delivery of palliative care to patients who presently suffer unrelieved pain."⁸

The first change offered by the Hatch substitute is some superfluous language intended to camouflage the legislation's attack on our system of federalism: "Nothing in this subsection shall be construed to alter the roles of the Federal and State governments in regulating the practice of medicine."⁹

To suggest that this provision has any meaning is laughable. The whole point of the subsection—and indeed of the bill itself—is to overrule the people of Oregon's decision to allow a limited form of physician-assisted suicide. Currently, State governments may permit or forbid physician-assisted suicide as they see fit; under the bill, the Federal Government would usurp this decision from the States and effectively ban almost all physician-assisted suicide. Hence, the bill is intended to and would alter the roles of Federal and State governments in regulating the practice of medicine.

In addition, the added language is merely a rule of construction. Rules of construction exist so that, if any ambiguity inheres in a statute, a court knows how to interpret that ambiguity. But PRPA's effect on Oregon law is not ambiguous. The Hatch substitute would clearly nullify Oregon's physician-assisted suicide law and greatly interfere with statutes passed by other States concerning pain management and palliative care. Moreover, if this bill had been enacted several years ago, when it was first proposed, every single doctor or pharmacist in Oregon who subsequently assisted a suicide would have faced the loss of his or her DEA registration, a mandatory *minimum* 20-year jail term, and a possible \$1,000,000 plus fine.¹⁰ In fact, healthcare providers who participated in several assisted suicides in concert with other persons, could have even faced the death penalty.¹¹ The purpose of the Hatch substitute, of course, is to give Oregon doctors the Hobson's choice of practicing medicine in compliance with State law or facing draconian federal sanctions. Hence, PRPA would not preserve the roles of the Federal and State

⁷ Letter from Harvard Law School Professor James Vorenberg, Boston College Law School Professor Charles H. Baron, and former Assistant Attorney General of the Massachusetts Board of Registration in Medicine Garrick F. Cole to Senator Edward Kennedy, dated Apr. 10, 2000, at 1.

⁸ *Id.*

⁹ Sec. 201(a).

¹⁰ 21 U.S.C. 841.

¹¹ 21 U.S.C. 848.

governments with regard to regulating the practice of medicine; it would reverse them.

It makes a mockery of the legislative process to pass a bill that clearly preempts State law and then contains a sentence suggesting that, if a court finds any ambiguity, the statute should be construed as not preempting State law. It is equally misleading to add a clause—as PRPA also does—providing that the bill’s physician-assisted suicide ban “applies only to conduct occurring after the date of enactment of this subsection” and then claim that this provision would protect healthcare providers who have participated lawfully under Oregon’s law. First, the Constitution’s Ex Post Facto Clause would already shield these healthcare providers from criminal punishment.¹² Second, regardless of PRPA, investigators can easily examine documents in Oregon naming physicians, family members, and others who may have provided advice for a physician-assisted suicide and use the information they glean to target those individuals for future scrutiny.

Other language added by the Hatch substitute is similarly meaningless. For example, the Hatch substitute adds the following:

Regardless of whether the Attorney General determines pursuant to this section that the registration of a practitioner is inconsistent with the public interest, it remains solely within the discretion of State authorities to determine whether action should be taken with respect to State professional license of the practitioner or State prescribing privileges.¹³

This language is irrelevant because if the DEA revokes a doctor’s registration, the doctor’s career is effectively over, regardless of what the State may or may not do (and of course, given PRPA, State authorities are likely to follow the DEA).¹⁴ Moreover, even if the DEA decides not to revoke the doctor’s registration, the agency’s investigation might irreparably damage his or her career. And, regardless of what the DEA does, the state medical board could still sanction him or her, since under PRPA “it remains solely within the discretion of State authorities” to regulate the state’s doctors.¹⁵

The Hatch substitute also adds that nothing in PRPA shall be construed “to provide the Attorney General with the authority to issue national standards for pain management and palliative care clinical practice, research, or quality.”¹⁶ However, PRPA itself imposes such a national standard—or rather substandard—so this second rule of construction is also irrelevant. In short, the bill would give the DEA a statutory license to second-guess every doc-

¹² See, e.g., *Collins v. Youngblood*, 487 U.S. 37, 41–43 (1990).

¹³ Sec. 201(a).

¹⁴ In every State, a doctor must hold a “current DEA registration” to be able to prescribe controlled substances. If the Federal Government finds a doctor in violation of PRPA, the doctor will almost certainly lose his or her DEA registration, which will in turn eliminate his or her right under State law to prescribe a controlled substance. Loss of DEA registration makes it difficult—if not impossible—for a doctor to practice medicine, regardless of whether the State revokes the doctor’s license to practice or takes other action against the doctor. See, e.g., *Sokoloff v. Saxbe*, 501 F.2d 571 (2d Cir. 1974) (finding that revoking doctor’s DEA registration seriously affects doctor’s capacity to practice medicine).

¹⁵ Sec. 201(a). Under the quoted PRPA language, a physician or pharmacist could go to jail for violating the CSA but still not lose his or her State medical or pharmacy license.

¹⁶ Sec. 201(a).

tor's administration of pain medication or palliative care to determine if the doctor is acting with a "legitimate medical purpose."

Moreover, what PRPA appears to take away from the Attorney General it returns with the following clause: "except that the Attorney General may take such other actions as may be necessary to enforce this Act."¹⁷ This open-ended language not only contradicts the second rule of construction but also appears to confer broad authority on the Attorney General to regulate the practice of medicine within a State's borders. Finally, the standard of medical care developed through law enforcement training programs the Hatch substitute also authorizes would become the de facto standard.¹⁸ Law enforcement—not doctors, pharmacists, or nurses—would determine what is proper medical care.

The Hatch substitute then states:

For the purposes of this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death.¹⁹

This "double effect"²⁰ language adds nothing to the bill; alleviating pain or discomfort in this way is "a prerogative doctors have always had."²¹ Not only does it confer no enforceable rights on doctors but it already exists as an "administrative guideline."²² As Dr. Eric Chevlen, one the supporters of PRPA, conceded, "[E]very day of my practice since I left medical school, I have been practicing under that law because that has been the law since the CSA was established. * * *"²³

Finally, supporters of the Hatch substitute trumpet the fact that they now require the Attorney General to prove by "clear and convincing" evidence that a doctor intended to assist a suicide rather than by a mere "preponderance" of evidence.²⁴ They suggest that this would reduce the chilling effect PRPA would have on healthcare providers. However, the Supreme Court has suggested that the difference between "preponderance" and "clear and convincing" is unclear and that how these two standards of proof affect decisionmaking may well be "unknowable."²⁵ Moreover, Dean Vorenberg and other experts point out that:

Whatever difference the higher level of proof might make in other circumstances, it is likely to make very little difference in this context. When we are speaking of physi-

¹⁷ Id.

¹⁸ Sec. 202.

¹⁹ Sec. 201(a).

²⁰ Rooted in 13th century Catholic theological teachings, the doctrine of "double effect" holds that an effect that would be morally wrong if it were caused intentionally is permissible if it was unintended—even if it was foreseeable. This principle has guided physicians for centuries: doctors are free to prescribe powerful drugs to relieve pain, even if these drugs run the risk of hastening the patient's death.

²¹ Care for the Dying Congressional Mischief, *New England Journal of Medicine*, vol. 341, no. 25, at 1923–24.

²² Testimony of Eric Chevlen before the Senate Committee on the Judiciary, July 31, 1998, at 79, line 6–17.

²³ Id. at 79, lines 14–16.

²⁴ 24 Sec. 201(b).

²⁵ *Addington v. Texas*, 441 U.S. 418, 424–25 (1979).

cians' intentions, we are dealing with an internal mental event that will not, in the ordinary case, be amenable to any sort of objective proof. Although, in the end, the Attorney General may have no easier time proving what went on in a physician's mind than a physician would have disproving it, the fact that H.R. 2260 makes every physician vulnerable to investigation and prosecution whenever he prescribes controlled substances to a dying patient will undoubtedly have a chilling effect on his willingness to effectively treat pain.²⁶

This chilling effect would possibly result in tens of thousands of patients dying without adequate pain or palliative care, and even subject doctors to civil liability for undertreating patients.

III. PRPA SERIOUSLY VIOLATES BASIC PRINCIPLES OF FEDERALISM

PRPA seriously violates the basic tenets of federalism. Medical practice has always been regulated by the States under their traditional police powers. This bill attempts to upset the time-tested and constitutionally enshrined division of power between the Federal Government and the States in order to target a single law in a single State.

Currently, physician-assisted suicide is illegal in 45 States (36 by statute; nine under common law).²⁷ In one State, Oregon, the citizens have twice approved by referendum physician-assisted suicide under very limited and highly regulated circumstances.²⁸ Moreover, at least 20 States have established commissions or task forces to examine end-of-life care issues, including physician-assisted suicide.²⁹ And voters in at least one State will be voting soon on whether to legalize physician-assisted suicide. Clearly, the States have made—and are continuing to make—a concerted effort to address the issue of physician-assisted suicide intelligently and thoroughly. PRPA would not enhance the regulation of physician-assisted suicide. On the contrary, it is extremely harmful to the States' ongoing efforts in this area.

In fact, PRPA's attempt to usurp the rights of Oregon's citizens to deal with the issue of physician-assisted suicide is entirely indefensible. When asked about PRPA, one Oregon resident—who twice voted *against* legalizing physician-assisted suicide—said:

Why are they doing this? The people in Oregon had a vote. I may not agree with it, but is Congress really saying that our vote doesn't count, it doesn't matter? That's just wrong.³⁰

²⁶Letter from Harvard Law School Prof. James Vorenberg, Boston College Law School Prof. Charles H. Baron, and former Assistant Attorney General of the Massachusetts Board of Registration in Medicine Garrick F. Cole to Senator Edward Kennedy, dated Apr. 10, 2000, at 2.

²⁷D. Merrit, et al. of the National Conference of State Legislatures, and J. Lynn, et al. of the Center to Improve the Care of the Dying, The George Washington University, State Initiatives in End-of-Life Care: Policy Guide for State Legislators, National Conference of State Legislatures, at 40 (1998) (the "End-of-Life Care: Policy Guide"). The four States which do not have a criminal statute or common law banning physician-assisted suicide are North Carolina, Ohio, Utah and Wyoming.

²⁸Or. Rev. Stat. §§ 127.800–127.995.

²⁹End-of-Life Care: Policy Guide, at 3.

³⁰Sam Howe Verhovek, "Oregon Chafes at Measure to Stop Assisted Suicide," The New York Times, Oct. 29, 1999, at A1.

Moreover, it is certainly ironic that the Republican Senators in the majority, who often promote themselves as members of the party of States' rights, would choose to overrule a law just because they are uncomfortable with it. Indeed, President Reagan's Solicitor General, Charles Fried, has pointed out that "[i]f principles of federalism—to which I'd bet many of those voting for this bill fervently swear allegiance—mean anything, this issue is none of Congress' business."³¹

Although the majority argues that PRPA is designed to mend a "50-state, crazy quilt approach to the regulation of controlled substances,"³² it is readily apparent that PRPA was drafted and is being moved forward not in an effort to deal with controlled substances, but rather in a direct attempt to limit starkly the scope of the Oregon referendum and physician-assisted suicide in that State. The "problem" that this bill aims to solve is simply that the voters of Oregon have decided to permit physician-assisted suicide in their State. Indeed, Thomas Marzen, general counsel for the National Legal Center for the Medically Dependent and Disabled and an originator of PRPA, has admitted that "paralyzing Oregon's law has always been the goal."³³ Marzen also stated that the strategy behind PRPA works—because doctors are very reluctant to go up against the DEA and the Controlled Substances Act—that is, PRPA is effective because it intimidates doctors and chills their discretion in treating patients.³⁴

A. PRPA CONTRADICTS THE VIEWS OF ALL NINE SUPREME COURT JUSTICES

The majority cites two 1997 Supreme Court cases on assisted suicide—*Washington v. Glucksberg*³⁵ and *Vacco v. Quill*³⁶—as support.³⁷ Unfortunately for the majority though, the justices *unanimously* ruled in these cases that the States, not the Federal Government, should determine how best to address the issue of physician-assisted suicide.³⁸

In *Glucksberg*, for example, the Supreme Court refused to strike down a State assisted-suicide ban under Federal constitutional due process principles, concluding that "the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues. * * * Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue as it should in a democratic society."³⁹

³¹ Charles Fried, "Leave the Personal to the States," *The New York Times*, Oct. 29, 1999, at A35.

³² Majority Views at ____.

³³ *The Oregonian*, Sept. 8, 1999, at A8.

³⁴ *Id.*

³⁵ 521 U.S. 702 (1997).

³⁶ 521 U.S. 793 (1997).

³⁷ The majority also points to the enactment of the "Assisted Suicide Prevention Act," P.L. 105-12, which outlawed the use of Federal funds for the practice of physician-assisted suicide. But the existence of a Federal statute forbidding *Federal money* to be used for physician-assisted suicide says nothing about whether the Federal Government can or should forbid *States* from permitting (let alone funding) this practice.

³⁸ The Supreme Court's denial of *certiorari* in a case that challenged the Oregon referendum—*Lee v. Oregon*, 107 F.3d 1382 (9th Cir.), *cert. denied*, 522 U.S. 927 (1997)—further demonstrates the Court's belief that the issue of assisted suicide is best left to the States.

³⁹ *Glucksberg*, 521 U.S. at 719, 735.

Other justices concurred in this point. Justice Souter noted that “facts necessary to resolve the controversy * * * are more readily subject to discovery through legislative factfinding and experimentation. It is assumed in this case, and must be, that a * * * State [may] bar aid to any but a knowing and responsible person intending suicide. How, and how far, a State should act in that interest are judgments for the State.* * *⁴⁰ He further stated that there is good reason to suppose that there will be additional “experimentation” by the States in this area and such experimentation is “highly desirable.”⁴¹ Justices O’Connor, Ginsburg, and Breyer stated, “As the Court recognizes, States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. In such circumstances, the challenging task of crafting appropriate procedures for safeguarding * * * liberty interests is entrusted to the laboratory of the States.”⁴² Justice Stevens noted that “[t]he Court ends its opinion with the important observation that our holding today is fully consistent with a continuation of the vigorous debate about the morality, legality, and practicality of physician-assisted suicide.”⁴³

Indeed, this was exactly the result called for in an *amici curiae* brief filed by a large number of States. This brief, written by then Alabama Attorney General Jeff Sessions and other attorneys general, argued that

[s]tatutes in a majority of States * * * recognize an individual’s right to refuse unwanted medical treatment and, at the same time, reject any affirmative act to end life. Whether that balance should be abandoned and the line redrawn to permit an individual to commit suicide without state interference, and then redrawn yet again to permit assisted suicide, is a matter appropriately left for the people to decide, through their duly elected representatives or by initiative ballot. The principles of federalism embodied in our Constitution require no less.⁴⁴

PRPA would stop in its tracks the very experimentation the Supreme Court found so important. Not only would referenda and state legislatures be shut down on this issue but State courts as well. For example, in the absence of a Federal law to the contrary, State supreme courts would normally be free to disregard *Glucksberg* and recognize a State constitutional right to assisted suicide. Indeed, several State supreme courts had found in their State constitutions a right to die without unwanted medical intervention more than a decade before the U.S. Supreme Court followed suit with regard to the Federal Constitution.⁴⁵ However, if PRPA passes, no State supreme court in the country could meaningfully recognize such a right. Under PRPA, the DEA—not to

⁴⁰Id. at 787.

⁴¹Id. at 788–89.

⁴²Id. at 737 (citations and internal quotation marks omitted).

⁴³Id.

⁴⁴Brief Amici Curiae of the States of California, et al., *Washington v. Glucksberg*, Nov. 8, 1996.

⁴⁵See, e.g., *Cruzan v. Director, MDH*, 497 U.S. 261 (1990); *In re Quinlan*, 348 A.2d 801 (N.J. 1975); *Superintendent of Belchertown State School v. Saikewicz*, 370 N.E.2d 417 (Mass. 1977).

mention Federal, State, and local prosecutors—would be free to ignore such a State constitutional interpretation.

PRPA would not only choke off States’ “serious, thoughtful examinations” about physician-assisted suicide,⁴⁶ it would also discourage the administration of strong medicine to terminally ill patients. Thus, ironically enough, PRPA would perhaps invite the Supreme Court to find a constitutional right to physician-assisted suicide. Indeed, a number of justices left open the possibility of finding a right to assisted suicide under such circumstances. Justice Breyer noted, for instance, that if there were a law preventing the administration of drugs as needed to avoid pain at the end of life, then—as Justice O’Connor suggests, the Court might have to revisit its conclusions in these cases.”⁴⁷ And Justice Souter stated that “While I do not decide for all time that respondents’ claim should not be recognized, I acknowledge the legislative institutional competence as the better one to deal with that claim at this time.”⁴⁸ PRPA could lead to its sponsors’ worst nightmare: a right to physician-assisted suicide that they could topple only by amending the Constitution.

In addition, the Supreme Court’s assisted suicide opinions have made clear that barriers to the availability of proper palliative care must be eliminated.⁴⁹ In fact, the Court has,

conclude[d] that the double-effect doctrine provides a rational and constitutional basis for States to allow narcotics given in high dosages for pain relief in terminally ill patients, while prohibiting assisted suicide. Thus the majority opinion delineates an acceptable justification for aggressive palliative care * * * The concurring justices go further suggesting that the State is obligated to permit physicians to provide adequate pain relief at the end of life, even if such care leads to unconsciousness or hastens death.⁵⁰

The Supreme Court has also given its imprimatur to the use of sedatives and analgesics when life-sustaining treatment is being withheld or withdrawn as well as to the practice of terminal sedation.⁵¹

Therefore, for all the above reasons, PRPA contradicts the Supreme Court’s rulings in this area and flies in the face of settled jurisprudence.

⁴⁶ *Glucksberg*, 521 U.S. at 719.

⁴⁷ *Id.* at 792.

⁴⁸ *Id.* at 789.

⁴⁹ R. A. Burt, “The Supreme Court Speaks—Not Assisted Suicide but a Constitutional Right to Palliative Care,” *New England Journal of Medicine*, vol. 337, at 1234–1236 (1997).

⁵⁰ A. Lapers and B. Lo, “The Supreme Court Addresses Physician-Assisted Suicide: Can its Rulings Improve Palliative Care?,” *Archives of Family Medicine*, vol. 8, at 200–205 (1999).

⁵¹ Thus, it is troubling that the majority loosely throws around the word “euthanasia” defined in a way that includes these approved end-of-life medical practices. See Majority Views, at n. 45. This is certainly not the Supreme Court’s definition of the term nor ours.

The majority also makes the timeworn argument that supporters of Oregon’s physician-assisted suicide law really want to legalize euthanasia, and quote some of Derek Humphry’s 1998 book “Freedom to Die” as “proof.” However, Humphry advocates a kind of assisted suicide illegal in Oregon, not physician-assisted suicide as practiced in the State. See D. Humphry and M. Clement, “Freedom to Die,” at 313–34 (1998). Moreover, there is no evidence that Oregon voters share Humphry’s support of euthanasia.

B. PRPA WOULD EVISCERATE THE STATES' WELL-ESTABLISHED POWER
TO REGULATE MEDICAL PRACTICES

The majority claims that PRPA would not usurp the police power of the States to regulate medical practices, and that it is not designed to negate Oregon's Death With Dignity Act. It is clear, however, that these are precisely the two things the bill would accomplish. In fact, this poorly written, poorly thought-out statute would wreak havoc on States' traditional police authority to regulate their own doctors—an authority they have enjoyed for more than 200 years. And for what? To tell the voters of Oregon that they cannot pass a law that has resulted in a couple of dozen assisted suicides each year by terminally ill patients.

First, although the DEA has the authority to regulate how doctors and pharmacists use and dispense controlled substances, this regulatory power does not appear to include the ability to directly investigate doctors and pharmacists who have allegedly engaged in physician-assisted suicide. In the Attorney General's June 5, 1998 letter, the Department of Justice clearly limited its views to the situation in Oregon. By indicating that the DEA could not investigate doctors in Oregon, where physician-assisted suicide is permissible under certain limited circumstances, we do not believe the Department meant to imply that the DEA *could* investigate in other States. In our opinion, this letter did not resolve this issue. The States have traditionally regulated medical practice and all 50 States have their own medical review boards, which are the proper forum to investigate such matters.

This bill would add an unnecessary new layer of review of medical and pharmacy practice regarding pain management by providing the DEA with the power to investigate doctors and pharmacists independent from any criminal or medical board proceedings. In our view, the DEA is not qualified to handle investigations into allegation of the misuse of pain management drugs. When asked during a Committee hearing whether the DEA can discern between an appropriate dosage of drugs and one intended to kill, then DEA Administrator Constantine testified that:

[T]hose types of evidentiary bases that you would have to use would have to come from somebody in the medical community. * * * So you really would need an expert medical opinion to be able to say that the administration of that level and amount of drugs to that individual caused the death.⁵²

And DEA Acting Administrator Donnie Marshall recently reiterated that the agency lacks the "expertise" to determine whether physicians are appropriately prescribing pain medications.⁵³ As then Principal Deputy Associate Attorney General Joseph N. Onek testified, PRPA "will embroil the DEA in decisions about the use

⁵²Testimony of Thomas Constantine before the Senate Committee on the Judiciary, July 31, 1998, at 55, lines 5–13.

⁵³Letter from Donnie R. Marshall to Senator Orrin G. Hatch, dated Apr. 5, 2000.

of pain medication for terminally ill patients which it is poorly equipped to make.”⁵⁴

In addition, PRPA changes the fundamental balance that was struck in the Controlled Substances Act to create separate Federal and State domains with regard to controlled substances. The CSA is a law enforcement statute aimed at preventing drug abuse, diversion, and trafficking; that is why it is administered by the Attorney General—the Nation’s chief law enforcement officer. However, as David Joranson, director of the University of Wisconsin Pain and Policy Studies Group and leading expert on the CSA, has testified, Congress certainly did not draft CSA with the intention of giving the Attorney General plenary authority over every aspect of Federal drug law enforcement. Specifically, Congress recognized that the Attorney General would have no real role in three areas: “(1) the medical and scientific decisions necessary to administer the CSA, (2) * * * the medical uses of drugs, and (3) * * * the role of State laws, especially those regulating medical practice.”⁵⁵ Yet PRPA licenses the Attorney General to invade all three of these areas, all domains that the CSA carefully reserved to the States.

PRPA is unquestionably at war with the clear legislative intent behind the CSA. For example, in discussing the requirement of registration for doctors, pharmacies, and hospitals, the House Committee that crafted the CSA reported that those “engaged in the distribution chain would be required to be registered, but registration *would be as a matter of right where the individual or firm is engaged in activities involving these drugs that are permitted by State law.*”⁵⁶ And, in spite of the majority’s suggestion otherwise, the 1984 amendment by which Congress added a requirement that the Attorney General determine that registration was “in the public interest” is not to the contrary.⁵⁷ This change was made simply to prevent “improper diversion” of controlled substances to people for whom they were not prescribed—such diversion risked fueling “drug abuse.”⁵⁸

The American public overwhelmingly agrees that the States should regulate assisted suicide. The results of a national opinion survey released in July 1998 show that:

- 72 percent of the respondents oppose Federal legislation prohibiting doctors from prescribing medication that a terminally ill patient could take to end his or her own life.⁵⁹
- 76 percent of the respondents agree that “[i]t is not appropriate for Congress to get involved in regulating legal drugs prescribed by doctors to their patients.”⁶⁰

Despite the majority’s statements to the contrary, PRPA was obviously drafted to override Oregon’s Death With Dignity Act. It is

⁵⁴ Testimony of Joseph Onek before the Senate Committee on the Judiciary, July 31, 1998 at 28, lines 14–19.

⁵⁵ Testimony of David E. Joranson before Senate Committee on Health, Education, Labor, and Pensions, October 13, 1999, at 2–3.

⁵⁶ H.R. 91–1444 (Sept. 10, 1970) (emphasis added).

⁵⁷ See 21 U.S.C. 823, 824.

⁵⁸ H.R. 98–0030, at 266–67 (Sept. 17, 1984); *Humphreys v. DEA*, 96 F.3d 658, 661 (3d Cir. 1996).

⁵⁹ *Id.*

⁶⁰ GLS Research, National Voter Research Findings, “Attitudes Regarding the Terminally Ill” (July 1998).

hardly a coincidence that until Oregon decided to permit physician-assisted suicide, Congress never considered any action to “clarify” the CSA’s stance on the use of controlled substances for assisted suicide, even though physician-assisted suicides were occurring illegally around the country. Worse, PRPA nullifies the States’ long-established authority to regulate medical practices within their own borders.

C. PRPA WOULD UNDERMINE AND EFFECTIVELY NULLIFY MANY INNOVATIVE STATE LAWS AND PROGRAMS THAT HAVE NOTHING TO DO WITH PHYSICIAN-ASSISTED SUICIDE

What is particularly unfortunate about PRPA is that it not only usurps the States’ traditional role in managing medical practices, but that it would undermine and even nullify innovative State efforts to deal with medical issues such as physician-assisted suicide and pain management. PRPA would run roughshod over countless licensure acts, pain statutes, and other medical and pharmacy laws and regulations, muting and distorting their effect.

A number of States, for example, have passed laws directing doctors to alleviate their patients’ pain. In 1988, Virginia passed the first state law addressing the need to treat pain in terminally ill cancer patients. Several States—starting with Texas in 1989, California in 1990, and Florida in 1994—have passed intractable pain treatment acts. Other States, starting again with California in 1997, have passed pain patients’ bills of rights. PRPA would undercut these laws by threatening every healthcare provider aggressively treating pain with draconian penalties, including loss of DEA registration and/or a minimum 20 years in jail. This would lead to more patient pain and suffering.

PRPA would preempt other kinds of State laws as well. A number of States have passed innovative, sometimes unique laws to deal with the crisis of poor palliative care and pain management.⁶¹ PRPA would render these laws irrelevant.

Congress should pass legislation to reinforce and enhance State efforts to deal with the public health crisis of poor management, not bills undercutting and nullifying such efforts.

IV. MANY IN THE MEDICAL COMMUNITY AGREE THAT PRPA WOULD BE HARMFUL

This bill will result in a step backwards in the treatment of pain; physicians will be hesitant to prescribe and pharmacists will be hesitant to dispense sufficient doses of controlled substances due to

⁶¹Just in the past few years, for example, California has enacted a host of creative statutes intended to improve the lives of the sick and dying. These include laws that:

- Add pain management and end-of-life care to the continuing education curricula of doctors, surgeons, and nurses;
- Eliminate the need for a triplicate prescription for Schedule II drugs for terminal patients;
- Institute an electronic monitoring system pilot program at the Board of Pharmacy;
- Establish an expedited system for HMO approval for pain medication for terminally ill patients;
- Revise California Medical Board disciplinary processes for doctors who treat their patients’ pain;
- Require that all health care facilities assess pain as a fifth vital sign and require that the information be charted; and
- Mandate that medical school curricula include coursework in end-of-life care and pain management.

a fear of unwarranted investigations, possible revocations of their Federal registrations, aggressive criminal prosecutions, and even long jail terms. As the *New England Journal of Medicine*—probably the world’s preeminent medical publication—has stated in an editorial against PRPA:

The bill’s effect would be felt more by terminally ill patients who do not wish physician-assisted suicide than by those who do, since there are so many more of them. Many terminally ill patients require extremely high doses of controlled substances for adequate relief of symptoms. Doctors, faced with the possibility of long prison sentences if their intentions are misread, may be reluctant to prescribe or administer such doses. Treatment of pain in the terminally ill is already notoriously inadequate, largely because our society’s preoccupation with drug abuse seeps into the medical arena. Many doctors are concerned about the scrutiny they invite when they prescribe or administer controlled substances, and they are hypersensitive to ‘drug-seeking behavior’ in patients. Patients, as well as doctors, often have exaggerated fears of addiction and the side effects of narcotics. Congress would make this bad situation worse.⁶²

In short, PRPA would make physicians and pharmacists far less likely to prescribe and dispense the most effective pain management drugs, thus needlessly causing patients to suffer from otherwise treatable pain and encouraging them to consider suicide as a way to end their torment.

A. PRPA WOULD DISCOURAGE EFFECTIVE PAIN MANAGEMENT AND PALLIATIVE CARE

Unrelieved pain is a public health crisis in the United States. Fifty percent of patients experience moderate to severe pain at least half the time in their last days of life.⁶³ Opioids are the major class of analgesics used in the management of moderate to severe pain because of their effectiveness, the ease of establishing an appropriate dose, and favorable risk to benefit ratio.⁶⁴ Opioids, however, are also classified as a controlled substance under the CSA.

The DEA, therefore, would be newly empowered to interfere in the physician-patient and/or pharmacist-patient relationship to determine why the physician or pharmacist is prescribing or dispensing (or perhaps overprescribing or overdispensing) this medication. And prosecutors would be newly authorized to follow up on these investigations and bring charges against any healthcare provider who prescribes or dispenses a controlled substance to a patient who later dies. In fact, if PRPA passes, prosecutors could pursue charges against healthcare providers in Oregon and other States even if those providers only *attempt* to assist a patient’s sui-

⁶²“Care for the Dying—Congressional Mischief,” *New England Journal of Medicine*, vol. 341, no. 25, at 1923–24.

⁶³“The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment,” *The Journal of the American Medical Association*, Vol. 274, at 1591–98 (1995).

⁶⁴The Cancer Pain Management Panel. *Clinical Management of Cancer Pain. Practice Guideline No. 9 Agency for Health Care Policy and Research, U.S. Department of Health and Human Services*, at 49–60 (1994).

cide.⁶⁵ This could easily happen where, for instance, a doctor prescribes a lethal medication and the terminally ill person subsequently opts not to commit assisted suicide.

Worse, because the Controlled Substances Act was written as a law to prevent drug abuse, diversion, and trafficking, it contains broad language regarding those who might be considered a conspirator or aider and a better of a drug-related crime.⁶⁶ By lumping health care providers who aggressively treat pain together with drug abusers and drug traffickers, PRPA throws a wide regulatory net over the medical community. Federal law enforcement officers could not only investigate and charge physicians and pharmacists but also nurses, orderlies, hospital directors, medical board members, and others. Only a test case would really be able to define the scope of this extraordinarily broad statute.

Therefore, PRPA would inevitably lead to physicians and pharmacists not prescribing or dispensing or perhaps underprescribing opioids in an effort to escape unnecessary bureaucracy and potentially harmful investigations.⁶⁷

Some of the most distinguished doctors, pharmacists, ethicists, and scientists in the country have testified before Congress about this problem, including Kathleen M. Foley, Attending Neurologist in the Pain and Palliative Care Service at Memorial Sloan-Kettering Cancer Center and Professor of Neurology at Cornell University; Arthur L. Caplan, Ph.D., Director of the Center for Bioethics and Trustee Professor at the University of Pennsylvania; Scott Fishman, M.D., Chief of the Division of Pain Medicine at the University of California at Davis and author of "The War on Pain;" Joseph J. Fins, M.D., F.A.C.P., Associate Professor of Medicine at Cornell University; David Orentlicher, M.D., J.D., Professor of Law and Co-Director of the Center for Law and Health at the Indiana University School of Law-Indianapolis; David E. Joranson, Senior Scientist and Director of the Pain and Policy Studies Group at the University of Wisconsin Comprehensive Cancer Center at Madison; and Calvin H. Knowlton, R.Ph., M.Div., Ph.D., Past President of the American Pharmaceutical Association. Numerous others wrote in to express similar views.

As Dr. Fins put it, for example, PRPA would "have the *de facto* effect of criminalizing the use of opioids at the end of life. This would be a tragedy for dying patients and their families who would have to watch them suffer. As a physician, it seems inappropriate to me that medical practice should be dictated by the fear of a regulatory agency and not by professional and scientific norms."⁶⁸ Dr. Caplan testified similarly:

⁶⁵ See, e.g., 21 U.S.C. 846.

⁶⁶ *Id.*

⁶⁷ Experts have pointed out that the CSA itself contains impediments to effective pain management. A New York State Commission of Health report, for example, details a number of these obstacles and makes numerous recommendations about how to remove them. These recommendations include definitional changes, the partial filing of Schedule II prescriptions, and broadening the existing law under which controlled substances may lawfully be prescribed and dispensed to habitual users but still be used to treat nonmalignant acute and chronic pain.

If the majority had truly wanted to improve pain management, it could have implemented some of these recommendations. However, other than putting into statute what DEA regulations already provide concerning the use of controlled substances for pain, this legislation does nothing to address any concerns raised about the CSA's effect on pain treatment.

⁶⁸ Testimony of Joseph J. Fins, M.D., F.A.C.P. before the Senate Committee on Health, Education, Labor, and Pensions, Oct. 13, 1999.

It is well known from many previous studies that physicians cite legal concerns as one of the main reasons for their unwillingness to use narcotics and other agents to control pain aggressively. * * * I believe that this legislation will scare many doctors and nurses and administrators into inaction in the face of pain. * * * Studies consistently indicate that physicians are unduly influenced by regulatory considerations in their use of opioids and other drugs. * * * If the goal of the PRPA is to encourage pain control it is hard to see how the introduction of more liability and greater prosecutorial authority will achieve this end.⁶⁹

Dr. Fishman echoed these views:

The possibility of having one's actions misinterpreted with extremely harsh consequences will almost certainly make most physicians think twice before ordering a strong narcotic pain reliever, and many will unfortunately opt to ignore the patients' pain. * * * It is ironic that the "Hatch substitute," which seeks to prevent physician-assisted suicide, will ultimately impair one of the truly effective counters to physician-assisted suicide, which is swift and effective pain medicine. Thus, the "Hatch substitute" will neither bring about what it seeks to accomplish, nor prevent what it seeks to block.⁷⁰

Patients weighed in, too. Kimberly A. Kynsi, for example, wrote to make sure that Congress knew how much she would suffer if PRPA passes. As she explained:

I am a chronic pain sufferer. I have lived with this pain my whole life, (I am 45 years old), and it will be with me until I die. I finally received help in dealing with this pain 4½ years ago. I now have an almost normal life. I can enjoy my family and get out of the house to enjoy the world. Before I got help with opiates I was ready to give up on life. I was screaming and crying nearly 24 hours a day.

My concern with H.R. 2260 is that someone other than my doctor will dictate how much opiates I can receive. As it is, I now take more than twice what is "standard" for my body weight. It took me 40 years to find out what it felt like not to be in pain. This bill will frighten doctors away from prescribing the necessary medications for people like me, chronic pain sufferers. I have a difficult enough time getting refills when my doctor is on vacation. This bill will make it impossible.⁷¹

Besides this evidence, there are numerous reports and studies concluding that overly bureaucratic regulation of pain management drugs discourages effective palliative care. The Institute of Medi-

⁶⁹Testimony of Arthur L. Caplan, Ph.D., before the Senate Committee on Judiciary, Apr. 25, 2000, at 3-5.

⁷⁰Written Testimony of Scott Fishman, M.D., before the Senate Committee on Judiciary, Apr. 20, 2000, at 1-2.

⁷¹Letter from Kimberly A. Kynsi to Senator Dianne Feinstein, dated Apr. 6, 2000.

cine (IOM), for example, recently published an exhaustive report pointing out that “[n]umerous studies indicate that dying patients and patients with advanced illnesses experience considerable amounts of pain and other physical and psychological symptoms.”⁷² Many studies also demonstrate that one of the primary barriers to treating that pain adequately has been government regulation. For example:

- In a survey of controlled substance laws in 38 countries, the World Health Organization found that “[t]he proliferation of national laws and/or administrative measures regulating the prescription and distribution of opioid drugs necessary for cancer pain relief has hindered access by patients to these drugs.”⁷³

- A nationwide study of cancer physicians demonstrated a “reluctance to prescribe” opioids due to concern about “excessive regulations.” These excessive regulations were viewed as barriers to effective cancer pain management. Doctors’ concerns were greatest in States with triplicate prescription programs.⁷⁴

- In California, 69 percent of physicians surveyed stated that the risk of disciplinary action made them more reluctant to use opioids in pain management with 1/3 reporting that their patients may be suffering from neglected, treatable pain.⁷⁵

- A survey completed by the New York Ad Hoc Committee on Pain Management for the New York State Health Commissioner found that physicians may be concerned that aggressive pain management using controlled substances could be misconstrued as inappropriate and/or excessive prescribing and could lead to a professional misconduct or other administrative proceedings.⁷⁶

- Seventy-one percent of physicians surveyed in New York State reported that they do not prescribe effective medication for cancer pain, if such prescriptions require them to use a special State-monitored prescription form for controlled substances even when the medication is legal and medically indicated for the patient.⁷⁷

- A study of 13,625 elderly cancer patients living in Medicare/Medicaid certified nursing homes found 26 percent of residents with daily pain received no medication for pain. Daily pain is prevalent among nursing home residents with cancer; that pain is often left untreated, especially in African-American and older patients;⁷⁸ and

- An article states that one-quarter of medical licensing and disciplinary board members surveyed were unaware that prescribing opioids for an extended period for cancer patients was both legal and acceptable medical practice.⁷⁹

⁷²M. J. Field, and C. K. Cassel, eds., with the Institute of Medicine, “Approaching Death: Approving Care at the End of Life” 128 (1997).

⁷³World Health Organization, “Cancer Pain Relief,” at 28 (1986).

⁷⁴J. Von Roenn, et. al., “Results of Physicians’ Attitudes toward Cancer Pain Management Survey,” Proceedings of the American Society of Clinical Oncology, Vol. 109, p. 326 (1991).

⁷⁵F. J. Skelly, “Fear of Sanctions Limits Prescribing of Pain Drugs,” American Medical News, at 19 (Aug. 15, 1994).

⁷⁶New York State Public Health Council, Report to the Commissioner of Health, “Breaking Down the Barriers to Effective Pain Management: Recommendations to Improve the Assessment and Treatment of Pain in New York State” at 10 (1998).

⁷⁷Id. at 11, App. F.

⁷⁸R. Bernabei, et al., “Pain Management in Elderly Patients with Cancer,” Journal of the American Medical Association, vol. 279, at 1877–1882 (1998).

⁷⁹D.E. Joranson, “Federal and State Regulation of Opioids,” Journal of Pain and Symptom Management, vol. 5, at S12–23 (1990).

These studies point to the need for less regulation, and demonstrate that current restrictions already result in massive undertreatment of pain and neglect of suffering. Here are some real-life examples of that undertreatment and its consequences, examples which are sure to multiply if PRPA becomes the law of the land:

- E.B., a 54-year-old man, underwent successful surgery for bladder cancer. After the surgery, he complained of severe pelvic pain. E.B. was given limited amount of Percodan, but this only partially relieved his pain. His family physician was afraid to increase the dose. E.B. went to pain clinics in Dallas and ended up in Lubbock, TX. He was given hypogastric nerve blocks without relief. According to his daughter, E.B. asked for pain medication to enable him to drive back to Kansas, but the pain clinic refused. Upon arriving home, E.B. took Tylenol, but without any relief. He then wrote a brief note, saying that he could no longer live with his pain, went to the garage, shut the door, and started the car. E.B. died of carbon monoxide poisoning. Even more tragically, the exhaust fumes seeped into an upstairs bedroom, killing E.B.'s 18-year-old daughter.⁸⁰

- A 78-year-old man (E.H.) was denied adequate pain relief medicine on consecutive visits to the emergency room for severe pain resulting from an acute medical condition. In desperation, E.H. shot himself through the head, and his wife—who would have had to return to a nursing home upon his death—followed suit and shot herself in the heart.⁸¹

- An 80-year-old woman was diagnosed with spinal stenosis. After being denied pain medication for the extreme discomfort that she was experiencing relating to this disorder, the elderly woman jumped from a window in her senior citizen center, plummeting 20 stories to her death.⁸²

- A 29-year-old athlete (T.T.) committed suicide due to agonizing pain that she was experiencing due to a particular medical disorder. T.T.'s physician, a specialist in the field of this disorder, had been reluctantly prescribing medication that adequately controlled her pain. However, the physician became so uncomfortable prescribing the medicine that one day he refused to grant her an early refill. In several emotional suicide notes, T.T. related her adamant disgust with the already disgraceful and difficult procedure associated with procuring adequate pain medication from doctors. Because she could not cope with the excruciating pain that she was suffering from without the relief of pain medicine, T.T. killed herself.⁸³

- A patient was suffering from severe chronic daily headaches and was put on pain medication for relief. The doctor then decided that he could no longer continue to prescribe the medication to her. As a result, the patient had a severe migraine and experienced nausea and vomiting for several days. In an attempt to control the pain that she was experiencing, she overdosed on aspirin and acetaminophen, and died in the hospital soon after.⁸⁴

⁸⁰ Letter from Harvey L. Rose, M.D. to Senator Dianne Feinstein, dated Apr. 3, 2000.

⁸¹ Id.

⁸² Id.

⁸³ Id.

⁸⁴ Id.

- A 78-year-old woman (S.N.) was suffering serious pain in her neck and shoulders due to previous disc surgeries. S.N.'s doctors had been unwilling to give her enough pain medication and repeatedly called her a drug addict because of her requests for additional pain relief medicine. S.N. attempted suicide four times through various means including wrist slashing, medication overdoses, and electrocution in her bathtub. She was then sent to a psychiatric hospital and a clinic for drug addicts before she became the patient of another doctor. That doctor was willing to prescribe adequate pain medication, and as a result S.N. continued to live (without the desire to attempt suicide) in a senior center until her death 2 years later from natural causes.⁸⁵

- A patient was suffering from early prostate cancer with mild pain, but was very concerned with how his pain would be managed by doctors as his condition became steadily worse. Several weeks after his first consultation with another doctor, the patient killed himself out of fear that he would not be given adequate pain medication.⁸⁶

- A cardiologist was caring for a patient with heart disease and colon cancer. The cardiologist was so wary of prescribing any pain medication for the patient's significant abdominal pain, that he asked another doctor to write the prescription for him. If that doctor had not been willing to step in for the cardiologist and prescribe the medication, and had not actively encouraged the cardiologist to continue administering the medication, the patient would have died an agonizingly painful death. Additionally, that second doctor reports that he has witnessed patients suffer for weeks, or even months with pain from advanced stages of cancer when doctors have been unwilling to prescribe pain relief medication.⁸⁷

- A Dateline NBC segment has described the ordeal of William Bergman. Mr. Bergman was suffering from terminal lung cancer. Doctors refused to prescribe adequate pain control and as a result he died in agony. The California Medical Board ruled that the doctors had undertreated Mr. Bergman's pain, but refused to take action against the doctors.⁸⁸

- A patient (J.D.) with "unremitting, sharp, burning, throbbing" pain from cancer was not given adequate pain relief medication. As a result, J.D. had unnecessarily agonizing difficulty sleeping, breathing, and even sitting in a chair. Despite the fact that J.D.'s wife was a physician who strongly advocated for pain relief to relieve his condition, he was still unable to receive adequate medication due to the reluctance of doctors to prescribe pain relief medicine.⁸⁹

The majority claims that PRPA would help solve the problems demonstrated by these cases. But that is simply false. In fact, PRPA would cause additional suffering in tens of thousands of terminally ill patients or patients with chronic pain, and it would

⁸⁵ Id.

⁸⁶ E-mail from Scott Fishman, M.D., chief of the Division of Pain Medicine, University of California at Davis, to Senator Dianne Feinstein, dated Apr. 4, 2000.

⁸⁷ Letter from Robert V. Brody, M.D., San Francisco General Hospital, to Senator Dianne Feinstein.

⁸⁸ See Sheryl Gay Stolberg, "Doctors Walk Fine Line in Giving Painkillers to Dying Patients", San Diego Union-Tribune, Oct. 21, 1998, at E5.

⁸⁹ Letter from Karen C. Douglas, M.D. to Senator Dianne Feinstein, dated Apr. 5, 2000.

drive many of these individuals to suicide. PRPA not only fails to address the underlying need that may cause some patients to seek physician-assisted suicide, it *exacerbates* that need. Thus, the bill would have the perverse effect of increasing the demand for assisted suicide.

As PRPA reduces the number of physicians who are willing to prescribe the most effective pain relieving medications (controlled substances such as narcotics and opioid analgesics), the number of suffering patients and the amount of each's pain will steadily grow. Many of these patients—unable to handle the severity of their pain—will desperately turn to the “final exit” of assisted suicide, an outcome we wish to avoid at all costs.

Moreover, PRPA would not even do what it really intends: stop physician-assisted suicide in Oregon. A physician in Oregon (or any other State) could still assist a suicide by prescribing a noncontrolled substance, an over-the-counter drug, or common chemicals such as carbon monoxide or potassium (which Jack Kevorkian used)—though, of course, this is not the intent of the Oregon law.

B. PRPA WOULD NOT ADDRESS THE NEEDS OF TERMINALLY ILL AMERICANS OR THOSE SUFFERING FROM CHRONIC PAIN

Despite the claim made by the bill's title that it would promote pain relief, this legislation does virtually nothing to address the needs of the 50 million Americans who are in chronic pain or the needs of the 2.4 million Americans who die each year.

As discussed above, the Institute of Medicine recently completed one of the most wide-ranging and detailed studies ever done on end-of-life care. To undertake the study, the IOM appointed a 12-member committee of experts in medical and nursing care for chronically and severely ill patients, ethics, quality of care, health policy, health services research, law, economics, social services, and related fields. This committee met with numerous groups, researchers, and others and surveyed the relevant literature. The committee settled on seven recommendations for “the achievement of a compassionate care system that dying people and those close to them can rely on for respectful and effective care.”⁹⁰ However, in

⁹⁰The seven IOM recommendations are:

(1) People with advanced, potentially fatal illnesses and those close to them should be able to expect and receive reliable, skillful, and supportive care.

(2) Physicians, nurses, social workers, and other health professionals must commit themselves to improving care for dying patients and to using existing knowledge effectively to prevent and relieve pain and other symptoms.

(3) Because many problems in care stem from system problems, policymakers, consumer groups, and purchasers of health care should work with health care practitioners, organizations, and researchers to:

- Strengthen methods for measuring the quality of life and other outcomes of care for dying patients and those close to them;
- Develop better tools and strategies for improving the quality of care and holding healthcare organizations accountable for care at the end of life;
- Revise mechanisms for financing care so that they encourage rather than impede good end-of-life care and sustain rather than frustrate coordinated systems of excellent care; and
- Reform drug prescription laws, burdensome regulation, and State medical board policies and practices that impede effective use of opioids to relieve pain and suffering.

(4) Educators and other healthcare professionals should initiate changes in undergraduate, graduate, and continuing education to ensure that practitioners have relevant attitudes, knowledge, and skills to care well for dying patients.

(5) Palliative care should become, if not a medical speciality, at least a defined area of expertise, education, and research.

spite of this work, as Dr. Kathleen Foley of Memorial Sloan-Kettering Cancer Center testified, PRPA does not even begin to address a single one of these recommendations.⁹¹ Worse, the legislation actually defies the recommendations. Rather than work to reform “burdensome regulations * * * that impede effective use of opioids to relieve pain and suffering” (recommendation 3), for example, PRPA imposes just such a regulation, one of breathtaking preemptive sweep.

True, PRPA does authorize \$5 million in grants for education and training. But there is less here than meets the eye. The money is for less than 2 years and the Health Resources Services Administration (HRSA) already has the authority to fund this kind of training. In addition, as the Congressional Budget Office recently noted, the existing HRSA grant program has already received an appropriation of \$23 million for fiscal year 2000.⁹²

The \$5 million in additional money is rather paltry compared to the billions this Nation spends each year on end-of-life care and less than what some private foundations disburse in a single year on medical education and training grants. In fact, the Robert Wood Johnson Foundation alone spent over \$80 million in the past 5 years on training for palliative care and pain management. Moreover, a General Accounting Office review of how HRSA used funds set aside for suicide prevention projects—as required under the 1997 Federal ban against funding of assisted suicide—found *HRSA had not placed a high priority on spending this money and had not even spent all the money available*. Nothing in PRPA would address this problem. As Dr. Foley testified, “[T]he Bill provides insufficient funding to have any “real” impact on pain and palliative care education and training.”⁹³

At bottom, this meager authorization seems far more related to public relations than public health. It is simply not a serious commitment of resources to this huge problem.

C. PRPA WOULD REPLACE STATE MEDICAL BOARDS WITH FEDERAL DRUG ENFORCEMENT AGENTS AS GOVERNORS OF PAIN MANAGEMENT PRACTICES

Since they were established more than a century ago, State medical boards have evolved into sophisticated regulatory agencies dedicated to protecting the public from unacceptable practitioners. All States have medical licensing boards that oversee the practice of medicine, including physicians’ prescribing patterns. The current system of medical licensure has worked well in protecting the public health. This system is also the most appropriate and most effective forum for regulating pain management practices.

(6) The Nation’s research establishment should define and implement priorities for strengthening the knowledge base for end-of-life care.

(7) A continuing public discussion is essential to develop a better understanding of the modern experience of dying, the options available to patients and families, and the obligations of communities to those approaching death.

See M.J. Field, and C.K. Cassel, eds., with the Institute of Medicine, *Approaching Death: Approving Care at the End of Life* 7–13 (1997).

⁹¹ Testimony of Kathleen Foley, M.D., before the Senate Committee on the Judiciary, July 31, 1998 at 28, lines 15–17.

⁹² Congressional Budget Office Cost Estimate, H.R. 2260, at 2 (May 9, 2000).

⁹³ Testimony of Kathleen Foley, M.D., before the Senate Committee on the Judiciary, Apr. 25, 2000, at 1.

PRPA would establish a new and burdensome oversight mechanism whereby the DEA would have prospective authority to deny DEA registration based on the DEA's interpretation of the healthcare provider's intent. Any DEA investigation on the issue of a provider's intent—which is *always* an issue when a controlled substance is given to a patient—would be quite intrusive because the DEA would have the virtually impossible task of discerning “why” a physician prescribed the drug he or she did and “why” the particular amount of that drug was prescribed. As many healthcare providers have pointed out and as was discussed in the Department of Justice's testimony before the Committee, most terminally ill patients already have an ample supply of controlled substances on hand to use in any suicide effort. The DEA, therefore, would not be able to make an objective determination based upon the drug and dosage the patient had on hand. Rather, the DEA would be forced to determine the *intent behind every prescription or combination of prescriptions*. This cannot be done without an intrusive investigation that pries both into the practice of the physician and pharmacist involved, and the lives of the family and friends of the deceased. PRPA would make the question of a physician's intent in treating a patient crucial and, as the Department of Justice stated,

the issue of intent would not necessarily be resolved simply by asking physicians about their intent. To establish intent, the DEA might also need to investigate the details of the physician's prescribing practices and of the physician's relationship with the patient and the patient's family.⁹⁴

In addition, the issue of a physician's intent is not always clear. Research and experience indicate that when physicians and nurses take action that may hasten death, they invariably have many intentions.⁹⁵ For example, one study revealed that when doctors ordered controlled substances to be administered to patients who were dying and who were to have life-sustaining treatment withheld or withdrawn, those physicians typically had more than three different intentions behind their orders and 36 percent of the physicians had as one of their intentions hastening death. Similarly, nurses who administered the medications had on average almost three intentions, and 39 percent of them said that one of their intentions was to hasten death.⁹⁶

As these figures indicate, the issue of “intent” is especially complicated in the case of treating terminally ill patients. Many doctors subscribe to the principle of “double effect,” under which it is perfectly ethical for a doctor to administer medicine to a patient even if it is foreseeable that that medicine will hasten the patient's death. Indeed, “there is evidence that a significant number of physicians support the practice of hastening death in particular situa-

⁹⁴ Letter of L. Anthony Sutin, Acting Assistant Attorney General, to Senator Orrin G. Hatch, dated Sept. 16, 1998.

⁹⁵ T.E. Quill, *The Ambiguity of Clinical Intentions*, *New England Journal of Medicine*, vol. 329, at 1039–1040 (1993).

⁹⁶ W. Wilson, et al., “Ordering and Administration of Sedatives and Analgesics During the Withholding and Withdrawal of Life Support from Critically Ill Patients,” *Journal of the American Medical Association*, vol. 267, at 949–953 (1992).

tions.” *Glucksberg*, 521 U.S. at 749 n.12 (Stevens, J., concurring) (citing relevant literature).

Moreover, this enhanced role for the DEA conflicts with the mission of medical licensure boards, which, unlike the DEA, have long held the role of assuring appropriate delivery of medical care. If enacted, this legislation would replace the well-established system of peer review and regulation at the State level with an untested, superfluous, and intrusive Federal enforcement mechanism. According to the Federation of State Medical Boards (FSMB), in cases where the inappropriate prescribing of controlled substances is determined, State medical boards already require a physician to surrender his or her DEA certificate as part of the disciplinary action taken and to notify the DEA of such action. In fact, surrendering a DEA certificate may be only one of the conditions a medical board imposes on a physician. If the physician fails to comply with all the terms of the disciplinary action, the board may then revoke his or her medical license.

Under the current system, all licensed physicians are subject to peer review. Hospitals, other healthcare organizations and insurance companies are asked to provide licensing boards with any information about adverse actions they have taken against individual physicians. These reports are reviewed by the State boards and, if necessary, disciplinary action is taken. In addition, a majority of State boards require all licensees to continue their medical education in order to maintain licensure. These processes are designed to help identify those individuals who should no longer be engaged in the practice of medicine and to ensure that physicians maintain their level of medical knowledge and clinical abilities.

In some States, licensure boards are taking steps to educate physicians on the proper use of pain medication for patients nearing the end of life. Recently, the FSMB published “Proposed Model Guidelines for the Use of Controlled Substances” in the treatment of pain. The federation is recommending all States adopt these model guidelines as a way to educate and reassure physicians that they can safely use controlled substances to treat pain.

Clearly, the boards have taken a comprehensive approach to the governing and advising of physicians and pharmacists on the practice of pain management. There is no reason to strip them of their responsibility or to pile on layers of unnecessary Federal bureaucracy.

D. PRPA WOULD INTERFERE WITH THE GOALS OF HOSPICE AND COMFORT CARE

In 1997, 3200 hospices cared for nearly 500,000 terminally ill patients in the United States. Hospices provide comprehensive and compassionate care by addressing the physical, psychological, social and spiritual needs of dying patients and their families. One of the main goals of hospice care is to treat patients’ pain aggressively through a variety of means, including the use of controlled substances. These include the use of morphine and other opioids so patients can maintain the highest quality of life during their remaining days.

Hospice care use has increased significantly in Oregon as a result of the physician-assisted suicide debate and the legal require-

ment that physicians and their patients discuss options other than physician-assisted suicide. This increase demonstrates the public's need for information concerning alternatives to physician-assisted suicide and the overall need for improvements in end-of-life care. Oregon is also the only State to have disciplined a physician for the *under-use* of pain medication and has consistently been in the top ten States for per capita morphine use.

PRPA neither addresses the public's need for information concerning alternatives to physician-assisted suicide nor promotes improvements in end-of-life care that might make a terminally ill individual seek other options. Palliative care and pain management are both evolving fields that should be left to medical professionals, not law enforcement, to provide care for the dying without excessive government intrusion. PRPA does not address these serious concerns, and in the opinion of numerous physicians, pharmacists, hospice providers, nurses, and pain patients, it will only exacerbate the problems of pain management and hinder the ongoing evolution of the fields of palliative care and pain management.

V. THE MAJORITY'S OTHER ARGUMENTS ARE ALSO INCORRECT

A. PRPA WOULD DO NOTHING TO LESSEN THE DEMAND FOR PHYSICIAN-ASSISTED SUICIDE

The majority contends that PRPA would discourage physician-assisted suicide. Nothing could be further from the truth.

Forty-seven bioethicists with differing views about physician-assisted suicide wrote members of the Judiciary Committee that:

H.R. 2260 will not eliminate physician-assisted suicide. Every study that has been conducted in this country reveals its occurrence, in every part of the country where such research has been undertaken, underground and in completely uncontrolled conditions. This bill will simply drive the practice further underground into more disguised and more unprotected conditions.⁹⁷

And supporters of PRPA agree. Rabbi Bleich—who has written two law review articles on the subject—not only testified that PRPA “will not have the effect of reducing the incidence of physician-assisted suicide,”⁹⁸ but even *noted* that “I doubt very much * * * that the passage of the bill will prevent as much as a single suicide.”⁹⁹ Supporters of PRPA have focused so intently on Oregon—the one State that, so far, has dissented from the majority view on physician-assisted suicide—that they have blinded themselves to the fact that physician-assisted suicide is a *national* problem and a tragic symptom of a healthcare system that is failing some of our most vulnerable citizens.

If we truly want to end the practice of physician-assisted suicide everywhere, we need a far more complete and complex response than this bill provides.

⁹⁷ Letter from Alan Meisel, J.D., Director of the Center for Bioethics and Health Law, University of Pittsburgh, and 46 other bioethicists to Senator Arlen Specter, dated Apr. 24, 2000, at 2–3 (footnote listing research studies omitted).

⁹⁸ Testimony of Rabbi J. David Bleich before the Senate Committee on the Judiciary, Apr. 25, 2000, at 51, lines 8–12.

⁹⁹ *Id.*, at 77, lines 12–17.

For starters, we need to do much more to educate people on end-of-life care. For example, a study published in the *Journal of the American Medical Association* found that of the 50 best selling general and specialty medical textbooks, less than ¼ contained helpful of end-of-life information.¹⁰⁰ Moreover, recent polls reveal that nine out of ten Americans would want the kind of care that hospice provides but that many who respond do not know what services hospices offer.¹⁰¹ Last, a recent study published reviewing the Oregon experience found that when physicians did find an intervention appropriate for the patient, including pain management, the request for physician-assisted suicide receded.¹⁰²

B. PRPA WOULD FURTHER EXPAND THE DEA'S AUTHORITY OVER THE PRACTICE OF MEDICINE

The majority repeatedly states that PRPA would only expand the DEA's authority over the practice of medicine in one State: Oregon. That is incorrect.

The DEA's current mission is to determine the "appropriate use" of drugs only as part of an effort to prevent diversion and illegal drug trafficking. Yet, the majority wants the DEA to now get involved in defining the medical uses of drugs.

The CSA was passed to prevent and control drug abuse—to interrupt the flow of illicit drugs to the street. It was never intended to empower the DEA to make a medical determination of what is a reasonable and necessary use of drugs for patient care, at least beyond the narrow band of cases involving illegal drug diversion or trafficking.

C. PRPA IS NOT NECESSARY TO ENSURE THE UNIFORM APPLICATION OF THE CONTROLLED SUBSTANCES ACT

The majority claims that this legislation is necessary to avoid the creation of 50 different State policies regarding the Controlled Substances Act. The CSA classifies drugs as to their dependence and medical use and is directed to prevent diversion and illegal drug trafficking. No evidence has been brought forward to show that States are revising the schedules included in the CSA.

If the proponents really want uniform usage of drugs in the practice of medicine, then the Federal Government would have to preempt State medical and pharmacy laws. Such an effort would run counter to the long established way in which States, not the Federal Government, have regulated medicine and pharmacy practices.

D. PRPA WOULD HAVE A CHILLING EFFECT ON THE USE OF MORPHINE AND OTHER LEGAL DRUGS TO MANAGE PAIN

Proponents of this legislation point to States in which morphine use increased after similar legislation passed and try to argue that this shows that passage of PRPA would not have a chilling effect

¹⁰⁰M. Rabow, et al., "End-of Life Care Content in 50 Textbooks from Multiple Specialties," *Journal of the American Medical Association*, vol. 283, at 771-78.

¹⁰¹See, e.g., Judy Talbert, "Expansion of Hospice Benefits Needed," *Pittsburgh Post-Gazette*, June 1, 1999, at F10.

¹⁰²L. Ganzini, et al., "Physicians' Experiences with the Oregon Death With Dignity Act," *New England Journal of Medicine*, vol. 342, no. 8, at 557-563 (2000).

on pain management. However, as shown in the discussion in part IV and as demonstrated in the letters and other documents filed by the many State medical societies opposing PRPA, the legislation *would* have a chilling effect on the use of morphine and other legal drugs to manage pain. Moreover, the proponents' argument is simply wrong on its face.

First, proponents ignore the fact that some of the top-ranked States for pre capita morphine use have no comparable statutes to PRPA—including Nevada (fourth ranked) and Vermont (fifth ranked). See Figures 1 and 2. And Oregon itself, PRPA's sponsors' target, ranked second in per capita morphine use.

Second, proponents fail to recognize that the *national* average for morphine use increased during the periods they cite. The fact is that morphine use increased in *most* States during this period, not just in a few States with PRPA-type laws.

Third, proponents carefully omit reference to States where passage of PRPA-type legislation was followed by a *decrease* in the use of morphine or an increase *less* than the national average. For example, Oklahoma passed a law similar to PRPA in 1998, a year when Oklahoma was ranked 30th in the country for the use of morphine. A year later, Oklahoma had dropped to 34th in the Nation—even though morphine use increased nationally during this period. See Figure 3. Similarly, while there has been an increase in morphine use in Iowa since that State passed a PRPA-type law in 1996, this increase has been *less* than the national average. See Figure 4. And the same can be said for Louisiana, which passed a law similar to Iowa's in 1995. See Figure 5.

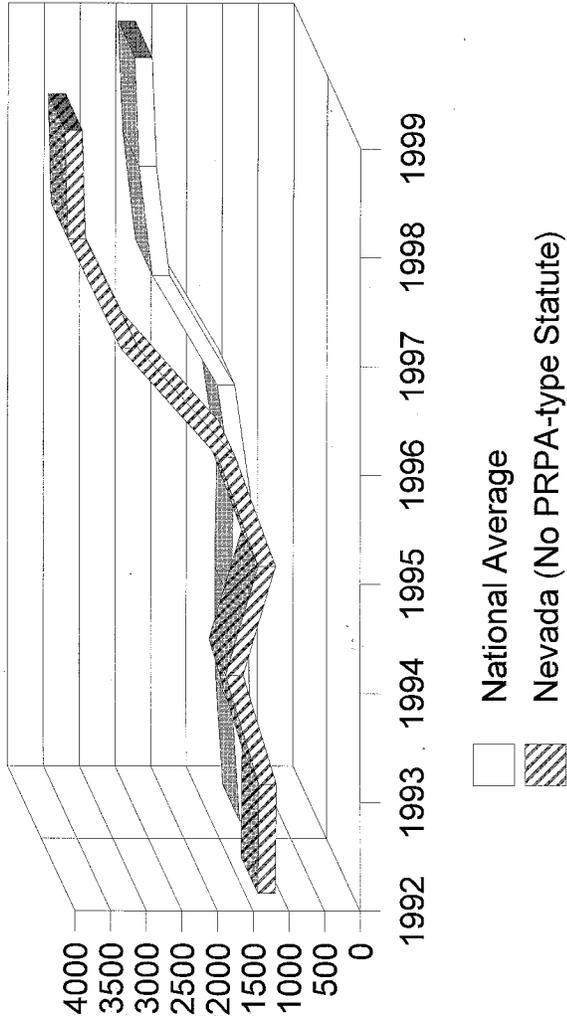
Fourth, the morphine-use statistics proponents cite do not specify *who* is receiving the drug. We do not know if the numbers reflect morphine receipt by post-operative pain patients, chronic pain patients, and/or dying patients. To know whether a State PRPA-type law really had a chilling effect on prescription of morphine, we would need to know if such severe regulation caused doctors to be more unwilling to prescribe morphine to patients facing imminent death.

And the answer to that question is an unqualified yes. As discussed above, numerous surveys of doctors have shown that they are often unwilling to give morphine to dying patients because of regulatory fears.

DEA regulations published in 1974 already make clear the policy that controlled substances should be used for pain. Simply changing the statute will not solve the well-documented health crisis patients in pain face today.

Figure 1

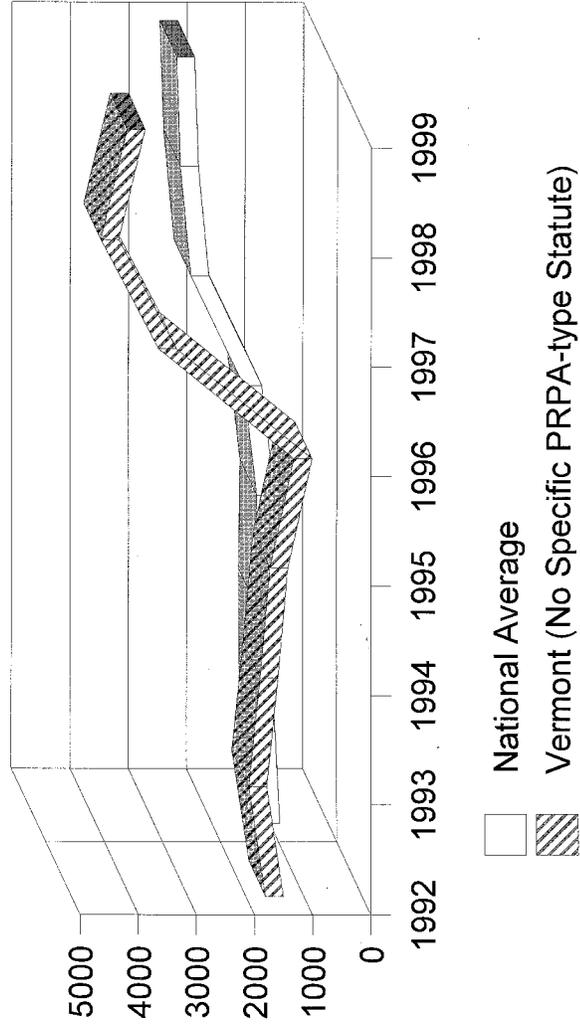
Nevada Morphine Use



Source: Drug Enforcement Agency

Vermont Morphine Use

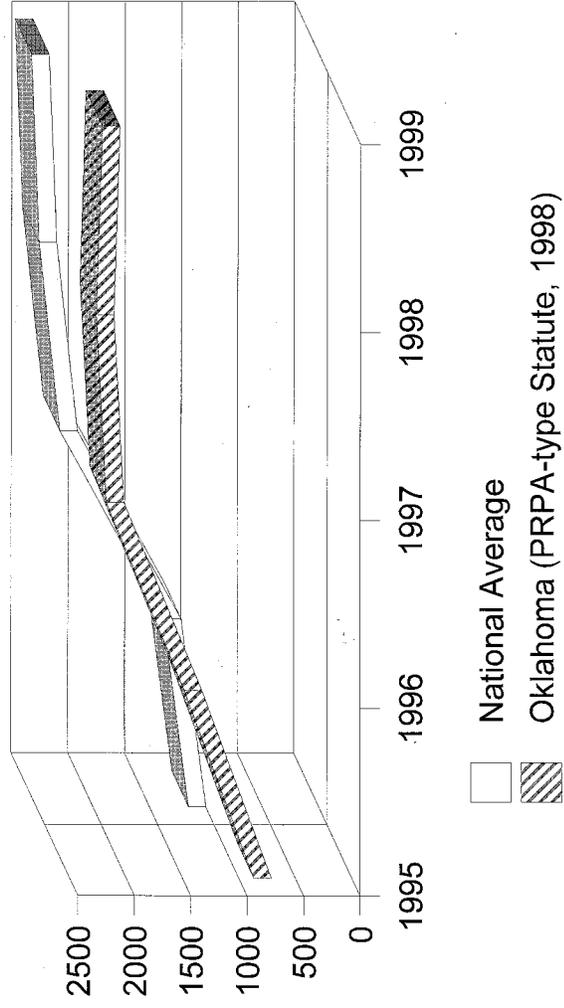
Figure 2



Source: Drug Enforcement Agency

Figure 3

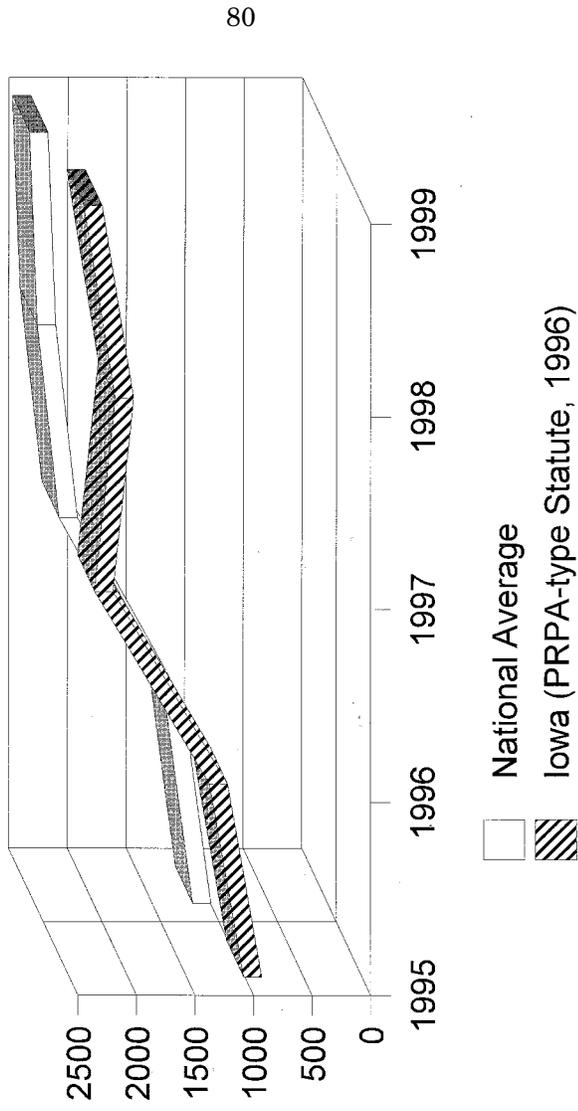
Oklahoma Morphine Use



Source: Drug Enforcement Agency

Figure 4

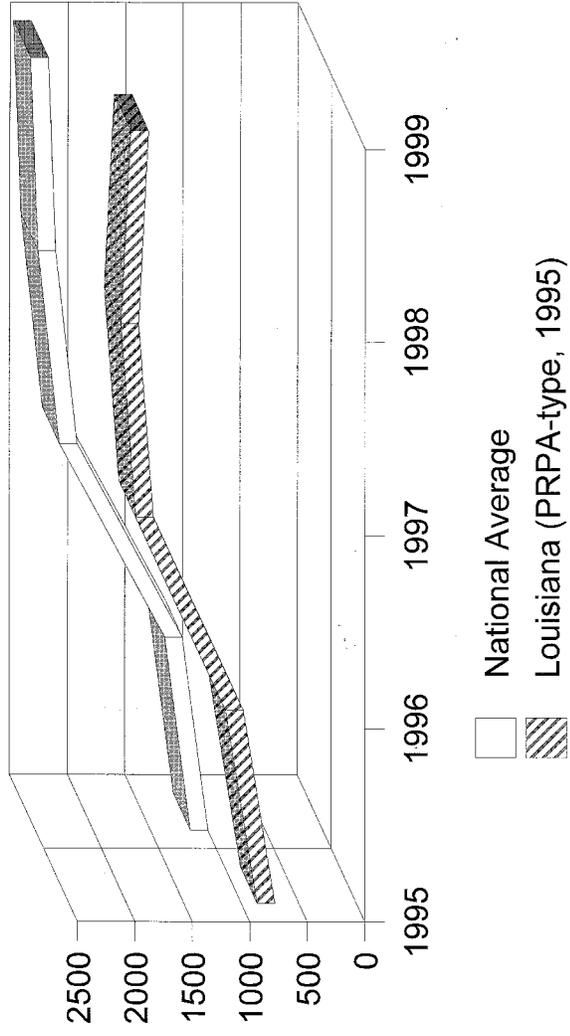
Iowa Morphine Use



Source: Drug Enforcement Agency

Louisiana Morphine Use

Figure 5



Source: Drug Enforcement Agency

VI. CONCLUSION

Physician assisted-suicide is a disturbing practice that we all seek to eliminate. We would prefer that no person ever be put in the situation where he or she is suffering so much pain, that he or she chooses self-inflicted death over the agony being endured. The reality, however, is that physician-assisted suicide does exist and PRPA does not address the reasons why individuals ask their physicians for help in dying.

Indeed, the majority, under the guise of amending the CSA, has attempted to substitute its judgment for those of the States, especially that of Oregon. The result of this misguided effort is a bill that would discourage appropriate, palliative care and may actually increase the demand for physician-assisted suicide.

If the majority really wishes to reduce physician-assisted suicide, it should address the root causes of the practice. Patients do not commit assisted suicide because their physicians have the power to prescribe controlled substances for pain relief. On the contrary, for the most part, patients commit suicide because they are suffering from chronic pain and/or depression, because they fear being a burden on their loved ones, or because they do not have access to palliative or hospice care. This bill does nothing to address these far reaching and complex problems. In fact, PRPA just makes them worse.

Ironically, proponents of PRPA invoke the Hippocratic maxim “first, do no harm” as a justification for the bill. Instead, it is Congress that should invoke that principle here with regard to itself—and reject this unprecedented, unnecessary, and harmful legislation.

PATRICK LEAHY.
TED KENNEDY.
HERB KOHL.
DIANNE FEINSTEIN.

X. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 625, as reported, are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

REGISTRATION REQUIREMENTS

SEC. 303. [823] (a) The Attorney General * * *

* * * * *

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 102(39)(A)(iv). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

* * * * *

(5) such other factors as are relevant to and consistent with the public health and safety.

(i)(1) For purposes of this Act and any regulations to implement this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death. Nothing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death.

(2)(A) Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest

under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia.

(B) Paragraph (2) applies only to conduct occurring after the date of enactment of this subsection.

(3) Nothing in this subsection shall be construed to alter the roles of the Federal and State governments in regulating the practice of medicine. Regardless of whether the Attorney General determines pursuant to this section that the registration of a practitioner is inconsistent with the public interest, it remains solely within the discretion of State authorities to determine whether action should be taken with respect to the State professional license of the practitioner or State prescribing privileges.

(4) Nothing in the Pain Relief Promotion Act of 2000 (including the amendments made by such Act) shall be construed—

(A) to modify the Federal requirements that a controlled substance be dispensed only for a legitimate medical purpose pursuant to paragraph (1); or

(B) to provide the Attorney General with the authority to issue national standards for pain management and palliative care clinical practice, research, or quality;

except that the Attorney General may take such other actions as may be necessary to enforce this Act.

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. [824] (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

* * * * *

[(c) Before] (c) PROCEDURES.—

(1) ORDER TO SHOW CAUSE.—Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5 of the United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecution or other proceedings under this title or any other law of the United States.

(2) BURDEN OF PROOF.—At any proceeding under paragraph (1), where the order to show cause is based on the alleged intentions of the applicant or registrant to cause or assist in causing death, and the practitioner claims a defense under paragraph (1) of section 303(i), the Attorney General shall have the burden of proving, by clear and convincing evidence, that the practitioner's intent was to dispense, distribute, or administer a con-

trolled substance for the purpose of causing death or assisting another person in causing death. In meeting such burden, it shall not be sufficient to prove that the applicant or registrant knew that the use of controlled substance may increase the risk of death.

* * * * *

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

* * * * *

EDUCATION AND RESEARCH PROGRAMS OF THE ATTORNEY GENERAL

SEC. 502. [872] (a) The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this title. Such programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, and Federal personnel;

* * * * *

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into the illegal channels; [and]

(6) studies or special projects to develop information necessary to carry out his functions under section 201 of this title[.]; and

(7) *educational and training programs for Federal, State, and local personnel, incorporating recommendations, subject to the provisions of subsections (e) and (f) of section 902 of the Public Health Service Act, by the Secretary of Health and Human Services, on the means by which investigation and enforcement actions by law enforcement personnel may better accommodate the necessary and legitimate by of controlled substances in pain management and palliative care.*

Nothing in this subsection shall be construed to alter the roles of the Federal and State governments in regulating the practice of medicine.

* * * * *

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE VII—HEALTH PROFESSIONS EDUCATION

* * * * *

PART D—INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES

* * * * *

SEC. 753. [294C] EDUCATION AND TRAINING RELATING TO GERIATRICS.

(a) GERIATRIC EDUCATION CENTERS.—

(1) IN GENERAL.—The Secretary shall award grants or contracts under this section to entities described in paragraphs (1), (3), or (4) of section 799B, and section 853(2), for the establishment or operation of geriatric education centers.

* * * * *

(c) GERIATRIC FACILITY FELLOWSHIPS.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to provide Geriatric Academic Career Awards to eligible individuals to promote the career development of such individuals as academic geriatricians.

* * * * *

(5) SERVICE REQUIREMENT.—An individual who receives an Award under this subsection shall provide training in clinical geriatrics, including the training of interdisciplinary teams of health care professionals. The provision of such training shall constitute at least 75 percent of the obligations of such individual under the Award.

SEC. 754. PROGRAM FOR EDUCATION AND TRAINING IN PAIN MANAGEMENT AND PALLIATIVE CARE.

(a) IN GENERAL.—*The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality, may award grants cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain management and palliative care.*

(b) PRIORITY.—*In making awards under subsection (a), the Secretary shall give priority to awards for the implementation of programs under such subsection.*

(c) CERTAIN TOPICS.—*An award may be made under subsection (a) only if the applicant for the award agrees that the program to be carried out with the award will include information and education on—*

(1) *means for diagnosing and alleviating pain and other distressing signs and symptoms of patients, especially terminally ill patients, including the medically appropriate use of controlled substances;*

(2) *applicable laws on controlled substances, including laws permitting health care professionals to dispense or administer controlled substances as needed to relieve pain even in cases where such efforts may unintentionally increase the risk of death; and*

(3) *recent findings, developments, and improvements in the provision of pain management and palliative care.*

(d) PROGRAM SITES.—*Education and training under subsection (a) may be provided at or through health professions schools, residency training programs and other graduate programs in the health professions, entities that provide continuing medical education, hospices, and such other programs or sites as the Secretary determines to be appropriate.*

(e) *EVALUATION OF PROGRAMS.*—The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the effect of such programs on knowledge and practice regarding pain management and palliative care.

(f) *PEER REVIEW GROUPS.*—In carrying out section 799(f) with respect to this section, the Secretary shall ensure that the membership of each peer review group involved includes individuals with expertise and experience in pain management and palliative care for the population of patients whose needs are to be served by the program.

(g) *DEFINITION.*—In this section, the term “pain management and palliative care” means—

(1) the active, total care of patients whose disease or medical condition is not responsive to curative treatment or whose prognosis is limited due to progressive, far-advanced disease; and

(2) the evaluation, diagnosis, treatment, and management of primary and secondary pain, whether acute, chronic, persistent, intractable, or associated with the end of life;

the purpose of which is to diagnose and alleviate pain and other distressing signs and symptoms and to enhance the quality of life, not to hasten or postpone death.

SEC. [754] 755. [294d] QUENTIN N. BURDICK PROGRAM FOR RURAL INTERDISCIPLINARY TRAINING.

(a) *GRANTS.*—The Secretary may make grants or contracts under this section to help entities fund authorized activities under an application approved under subsection (c).

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SEC. [755] 756. [294e] ALLIED HEALTH AND OTHER DISCIPLINES.

(a) *IN GENERAL.*—The Secretary may make grants or contracts under this section to help entities fund activities of the type described in subsection (b).

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SEC. [756] 757. [294f] ADVISORY COMMITTEE ON INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES.

(a) *ESTABLISHMENT.*—The Secretary shall establish an advisory committee to be known as the Advisory Committee on Interdisciplinary, Community-Based Linkages (in this section referred to as the “Advisory Committee”).

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SEC. [757] 758. [294g] AUTHORIZATION OF APPROPRIATIONS.

(a) *IN GENERAL.*—There are authorized to be appropriated to carry out this part, \$55,600,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(b) *ALLOCATION.*—

(1) *IN GENERAL.*—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall make available—

(A) not less than \$28,587,000 for awards of grants and contracts under section 751;

* * * * *

(C) not less than \$22,631,000 for awards of grants and contracts under [sections 753, 754, and 755] sections 753, 754, 755, and 756.

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HEALTHCARE RESEARCH AND QUALITY ACT OF 1999

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TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

PART A—ESTABLISHMENT AND GENERAL DUTIES

SEC. 901. MISSION AND DUTIES.

(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality, which shall be headed by a director appointed by the Secretary. The Secretary shall carry out this title acting through the Director.

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SEC. 902. GENERAL AUTHORITIES.

(a) IN GENERAL.—In carrying out section 901(b), the Director shall conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to—

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(g) ANNUAL REPORT.—Beginning with fiscal year 2003, the Director shall annually submit to the Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations.

SEC. 903. PROGRAM FOR PAIN MANAGEMENT AND PALLIATIVE CARE RESEARCH AND QUALITY.

(a) IN GENERAL.—Subject to subsections (e) and (f) of section 902, the Director shall carry out a program to accomplish the following:

- (1) Promote and advance scientific understanding of pain management and palliative care.
- (2) Collect and disseminate protocols and evidence-based practices regarding pain management and palliative care, with priority given to pain management for terminally ill patients, and make such information available to public and private health care programs and providers, health professions schools, and hospices, and to the general public.

(b) DEFINITION.—In this section, the term “pain management and palliative care” means—

- (1) the active, total care of patients whose disease or medical condition is not responsive to curative treatment or whose prognosis is limited due to progressive, far-advanced disease; and

(2) the evaluation, diagnosis, treatment, and management of primary and secondary pain, whether acute, chronic, persistent, intractable, or associated with the end of life; the purpose of which is to diagnose and alleviate pain and other distressing signs and symptoms and to enhance the quality of life, not to hasten or postpone death.

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